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IMPACT ASSESSMENT REPORT

Accompanying the documents

Proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products (recast)
and
Proposal for a Regulation of the European Parliament and of the Council on the supplementary protection certificate for plant protection products (recast)
and
Proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for medicinal products, and amending Regulation (EU) 2017/1001, Regulation (EC) No 1901/2006 as well as Regulation (EU) No 608/2013
and
Proposal for a Regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for plant protection products

{COM(2023) 221 final} - {SEC(2023) 172 final} - {SWD(2023) 117 final} -
{SWD(2023) 119 final}

Glossary

Term/Acronym	*Meaning/Definition*
Basic patent	(legal definition of Art. 1(c) of the SPC regulations) a patent which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate
Biosimilar (product)	a biological medicine highly similar to another already approved biological medicine (i.e. the reference medicine)
BoA	Board of Appeal of the newly proposed examination authority
CJEU	Court of Justice of the European Union.
EA	The examination authority - the newly proposed authority that would be in charge of the examination of SPC applications
EBE	European Biopharmaceutical Enterprises
EEA	European Economic Area
EFPIA	European Federation of Pharmaceutical Industries and Associations
EFSA	European Food Safety Authority
EMA	European Medicines Agency
Enhanced cooperation area	The group of EU Member States that are part in the enhanced cooperation regarding unitary patent protection and that have ratified the UPC Agreement
EPO	European Patent Office
EUIPO	European Union Intellectual Property Office
FDA	U.S. Food and Drug Administration
Follow-on manufacturer	Firm producing generics and/or biosimilar products
Follow-on product	Generic and/or biosimilar products
FTE	Full time equivalent – a unit of measure obtained by comparing an employee's average number of hours worked to the average number of hours of a full-time worker
Generic (product)	a medicine or plant protection product that is developed to be the same as the original product that has already been authorised
HERA	European Health Emergency Preparedness and Response Authority
IFAH-Europe	International Federation for Animal Health
INN	International Non-proprietary Names
IP	Intellectual property
MA	Marketing authorisation
MPI	Max Planck Institute for Innovation and Competition
NACE	Statistical classification of economic activities in the European Community; NACE is the acronym for *Nomenclature statistique des activités économiques dans la Communauté européenne*

NPO	National patent office(s)
Originator or innovator	Company that was first to develop and produce a specific medicine
PPP	Plant protection product
PTR	Patent term restoration
RDP	Regulatory data protection
R&D	Research and development
SME	Small or medium-sized enterprise(s), as defined in Commission Recommendation 2003/361 and its subsequent amendments
SPC	Supplementary protection certificate
SPC evaluation	European Commission, Commission Staff Working Document, Evaluation of the Regulation (EC) No 469/2009 of the European Parliament and of the Council concerning the supplementary protection certificate for medicinal products, and Regulation (EC) No 1610/96 of the European Parliament and of the Council concerning the creation of a supplementary protection certificate for plant protection products
SPC manufacturing waiver	Regulation (EU) 2019/933 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products - allows to start early export to non-EU countries or prepare pre-launch stockpiling in the EU
SPC Regulations	Regulations (EC) 469/2009 and 1610/96
TRIPS	Agreement of the World Trade Organization (WTO) on *Trade-Related Aspects of Intellectual Property Rights*
UP-MS	Member States of the unitary patent area – countries participating in the unitary patent system, i.e. having ratified the UPC Agreement (17 Member States, tentatively, at the time where the unitary patent system will be launched).
UPC	Unified Patent Court
UPC Agreement or UPCA	Agreement on a Unified Patent Court
WHO	World Health Organization
WIPO	World Intellectual Property Organization

Country codes used in the text:

AL- Albania
AT - Austria
AU - Australia
BE - Belgium
BG - Bulgaria
DE - Germany
DK - Denmark
CH - Switzerland
CN – China
CY - Cyprus
CZ - Czechia
EE – Estonia
FI - Finland
FR- France
EL - Greece
HR - Croatia
HU - Hungary
IE - Ireland
IT - Italy
JP – Japan
KR - South Korea
LV - Latvia
LT - Lithuania
LU - Luxembourg
MC - Monaco
MK - North Macedonia
MT - Malta
NL – Netherlands, the
NO –Norway
PL - Poland
PT - Portugal
RO - Romania
RS - Serbia
SK - Slovakia
SI – Slovenia
ES - Spain
SE - Sweden
SM – San Marino
TR – Turkey
UK - United Kingdom, the
US – United States of America, the

1. INTRODUCTION: POLITICAL AND LEGAL CONTEXT

Supplementary protection certificates (SPCs) are *sui generis* intellectual property (IP) rights that extend by up to five years[1] the 20-year term of patents related to medicinal or plant protection products (PPP). They aim to offset the loss of effective patent protection due to the compulsory and lengthy testing required in the EU for the regulatory marketing authorisation of these products. The relevant EU legislation is Regulations (EC) 469/2009 and 1610/96, on SPCs for medicinal and plant protection products respectively. Between 25 and 81 SPC applications were filed annually per Member State and more than 26 000 national SPCs have been granted since 1993[2]. The average duration of the SPC protection is estimated at 3.5 years[3].

The Commission's Intellectual Property Action Plan[4] of November 2020, building on the SPC evaluation[5], highlighted the need to tackle the remaining fragmentation of the EU's IP system, which leads to complex and costly procedures. The plan noted that, for medicinal products and PPPs, protection through SPCs is only available at national level. At the same time, there is a single procedure for granting European patents, as well as a single set of rules for obtaining marketing authorisations. In the same vein, the Pharmaceutical Strategy for Europe[6] emphasised the importance of investments in R&D to provide for innovative medicines while stressing that the differences across Member States in the implementation of IP regimes, especially for SPCs, lead to duplications and inefficiencies, affecting the competitiveness of the pharmaceutical industry. Both the Council[7] and the European Parliament[8] have called on the Commission to fix these deficiencies.

Of particular importance for this Impact Assessment is the unitary patent system, expected to enter into force in June 2023. It will allow for a single patent covering all participating Member States in a unitary manner[9]. However, but for the policy initiative in question, there would not be a corresponding unitary SPC to accompany (extend) it in a unitary manner.

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[1] An additional 6-month period of protection is available, subject to specific conditions, for medicinal products for use in the paediatric population, as defined by Regulation (EC) 1901/2006.
[2] Data for 1993–2014 from Mejer, M. (2017) 25 years of SPC Protection for Medicinal Products in Europe: Insights and challenges, European Commission, DG GROW, p. 6. Data for 2015–2021 as in Figure 17 in Annex 5A.
[3] Copenhagen Economics, Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe, Publications Office of the European Union, Luxembourg, 2018.
[4] European Commission, Commission communication – Making the most of the EU's innovative potential: An intellectual property action plan to support the EU's recovery and resilience, COM(2020)760 final , 2020 (https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52020DC0760).
[5] European Commission, Evaluation of EU Regulations 469/2009 and 1610/96 on supplementary protection certificates for medicinal and plant protection products, SWD(2020) 292 final (https://ec.europa.eu/docsroom/documents/43847).
[6] European Commission, Commission communication – Pharmaceutical Strategy for Europe, COM(2020)761 final, 2020 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0761).
[7] Council of the European Union, Intellectual property policy and the revision of the industrial designs system in the Union, Council conclusions (10 November 2020), 12339/20 (https://www.consilium.europa.eu/media/46671/st-12750-2020-init.pdf).
[8] European Parliament Committee on Legal Affairs, Report on an intellectual property action plan to support the EU's recovery and resilience, 2021/2007(INI) (https://www.europarl.europa.eu/doceo/document/A-9-2021-0284_EN.html).
[9] The unitary patent (UP) is a legal title that will provide uniform protection across all participating countries on a one-stop-shop basis. At the time of writing this impact assessment, 17 Member States ere

The COVID-19 pandemic has underlined the importance of having a strong and balanced IP system to provide the necessary incentives to develop new treatments and vaccines to be accessible to patients. It has also further highlighted the need of transparent and easily accessible information on the status of IP rights, including SPCs, to facilitate potential collaborations, licensing and freedom-to-operate analyses[10]. Patents and SPCs are key to support the EU in its efforts to build a European Health Union and other related initiatives such as the new European Health Emergency Preparedness and Response Authority (HERA)[11], EU FAB[12] and the Pharmaceutical Strategy for Europe.

All these combined are behind the Commission's efforts to simplify the EU SPC system, as well as improve its transparency and efficiency, including the possible creation of a unitary supplementary protection certificate to complement the unitary patent. This initiative was announced in the Commission Work Programme for 2022 (initiative number 16 under Annex II REFIT initiatives)[13].

This initiative runs in parallel with other ongoing Commission efforts in the field of health, with by far broader scope, and which aim at fostering innovation and availability of medicines. These may include introducing conditionality to the period of regulatory data/market protection for medicines[14] or revision of the current legislation on medicines for rare diseases and for paediatric use[15].

2. PROBLEM DEFINITION

2.1. Market context – pharmaceutical and agrochemical industries

The pharmaceutical industry (part of the EU Health ecosystem[16]) is of key importance for the EU's economy. Pharmaceuticals and other medical non-durable goods accounted for around one sixth of total current health expenditure in EU-27 in 2021[17]. This estimate excludes expenditure on

expected to participate in the UP system. For updates and more information, see: https://ec.europa.eu/growth/industry/strategy/intellectual-property/patent-protection-eu/unitary-patent_en.

[10] Discussions in this regard have been taken to the World Intellectual Property Organisation (WIPO), where national/regional patent offices were invited to share information on their collaborations with publicly accessible databases of patent status information concerning medicines and vaccines, such as MedsPaL. See: WIPO, Standing Committee on the Law of Patents, 32nd session, SCP/32/7, 2020.

[11] European Commission, Commission Communication – HERA Incubator: Anticipating together the threat of COVID-19 variants, COM/2021/78, 2021.

[12] European Commission, 'Questions and answers : HERA incubator – Anticipating together the threat of COVID-19 variants', 2021 (https://ec.europa.eu/commission/presscorner/detail/en/qanda_21_642).

[13] European Commission, Annexes to Commission communication – Commission work programme 2022, COM(2021) 645 final, 2021, p. 9 (https://eur-lex.europa.eu/resource.html?uri=cellar%3A9fb5131e-30e9-11ec-bd8e-01aa75ed71a1.0001.02/DOC_2&format=PDF#page=9).

[14] Data protection is a period of protection during which pre-clinical and clinical data and data from clinical trials handed in to the authorities by one company cannot be referenced by another company in their regulatory filings. For more explanations, see: Annex 5A.

[15] European Commission, Revision of the EU general pharmaceuticals legislation, Inception impact assessment, 2021 (https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12963-Revision-of-the-EU-general-pharmaceuticals-legislation_en); and European Commission, Revision of the EU legislation on medicines for children and rare diseases, Inception impact assessment, 2020 (https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12767-Medicines-for-children-rare-diseases-updated-rules_en).

[16] European Commission, Commission communication – A new industrial strategy for Europe, COM(2020)102, 2020.

[17] OECD (2022), 'Pharmaceutical spending', indicator, doi: 10.1787/998febf6-en (accessed on 18.8.22).

pharmaceuticals consumed in hospitals and other health care settings, which typically accounts for 20% on top of retail spending[18].

There are around 4 000 enterprises manufacturing basic pharmaceutical products and pharmaceutical preparations[19] in EU-27 that generate turnover of EUR 334 billion yearly and employ 626 thousand staff[20]. Firms active in the sector range from multinational firms to SMEs concentrating on certain niche markets. Producers can be divided into i) the developers of new pharmaceutical products (the originators); and ii) the follow-on manufacturers that develop biosimilar[21] or generic medicines[22] (once the IP and regulatory data protection have expired for the original medicines). Nonetheless, there are many cases where large pharmaceutical groups are active in both market segments. The generic and biosimilar industries association reports that its members employ 190 000 direct employees in over 400 manufacturing and R&D sites in Europe, and invest up to 17% of its turnover in R&D[23].

The broadly understood European health industries spent roughly EUR 36.6 billion on innovation in 2020 and recorded R&D intensity[24] of around 12.1%, which was more than in any other industry[25]. In this regard, the role of SMEs in pharmaceutical innovation is significant, for example in such critical areas as the global preclinical antibacterial pipeline[26].

The innovative agrochemical industry is part of the EU agri-food ecosystem. As in the pharmaceutical sector, two strategic groups of producers may be distinguished: firms manufacturing new products based on their own R&D and producers of generic ('follow-on') pesticides. There are over 544 enterprises active in this sector[27] in the EU that altogether employed 27 600 persons and generated turnover of EUR 12.7 billion[28]. The annual industry expenditure on crop protection R&D worldwide more than doubled from USD 3.06 billion to USD 6.71 billion between 1995 and 2012[29]. A study

[18] OECD (2021), Health at a Glance 2021: OECD indicators, OECD Publishing, Paris, https://doi.org/10.1787/ae3016b9-en, p. 236.
[19] Defined as division 21 of NACE Rev.2. – a very broad definition which in addition to medicinal active substances, includes also for example tests or diagnostic preparations, impregnated bandages, etc.
[20] Eurostat, Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E), sbs_na_ind_r2 (last update: 18.5.22, extracted on: 5.06.22).
[21] A biosimilar is a biological medicine highly similar to another already approved biological medicine (i.e. the reference medicine). Source: European Medicines Agency, 'Biosimilar medicines: Overview', 2021 (https://www.ema.europa.eu/en/human-regulatory/overview/biosimilar-medicines-overview).
[22] A generic medicine is a medicine that is developed to be the same as a medicine that has already been authorised. Source: European Medicines Agency, 'Generic medicine', 2021 (https://www.ema.europa.eu/en/glossary/generic-medicine).
[23] Medicines for Europe, Communications Toolkit: Generic medicines group, 2016 (https://medicinesforeurope.com/docs/20160518%20-%20Comms-Kit-Generic-Medicines.pdf). It should be noted that these numbers are not directly related to SPC as such.
[24] For an enterprise, R & D intensity is the ratio of a firm's R & D investment to its revenue (the percentage of revenue that is reinvested in R & D). Source: Eurostat, 'Glossary: R & D intensity', 2022 (https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Glossary:R_%26_D_intensity).
[25] European Commission, The 2021 EU Industrial R & D Investment Scoreboard, JRC/DG RTD, p. 12.
[26] See: Annex 6.
[27] Defined as NACE Rev.2: 20.2 Manufacture of pesticides and other agrochemical products.
[28] Eurostat, Annual detailed enterprise statistics for industry (NACE Rev. 2, B-E), sbs_na_ind_r2 (last update: 18.5.22, extracted on: 5.6.22).
29Phillips McDougal, R&D trends for chemical crop protection products and the position of the European Market, ECPA, 2013.

conducted in 2018 stated that around 7%-10% of the sector's revenue was devoted to research and development annually over the last 50 years[30].

The pharmaceutical and agrochemical sectors are global and highly competitive (see: Section 2.5.1). Finally, it is important to note that the pharmaceutical and agrochemical markets are among the most regulated, as placing products on the market requires complex and lengthy authorisations to ensure safe usage (see: Annex 5A).

2.2. SPC rules, market size and applications for SPC protection

An SPC takes effect at the end of the term of a basic patent (20 years), and is granted for a term equal to the period which elapsed between the date on which the application for the basic patent was filed and the date of the first authorisation to place the product on the market in the EU (which often takes more than 10 years of development), reduced by five years. The term of an SPC cannot exceed 5 years. An additional 6-month extension of the SPC can be requested if a paediatric investigation plan has been concluded for the protected medicinal product[31].

SPC protection is available only for new patented active ingredients ("products"), while medicines based on new formulations (e.g. involving additional ingredients) or new uses of known products are usually not entitled to SPC protection. IPRs, including SPCs, run in parallel with the regulatory data protection[32] provided by the EU pharmaceutical legislation for medicinal products[33].

Some products may not be eligible for SPC protection at all (if the marketing authorisation was granted quickly[34]), some may enjoy SPC protection having the full duration (5-year, or 5 ½ years with paediatric extension). The average duration of an SPC for medicinal products in the EU amounts to 3.5 years[35].

The benefits of an SPC for its holder[36] are significant. Since an SPC '*confer*[s] *the same rights as conferred by the basic patent*'[37], the monopoly resulting from the basic (reference) patent is extended and enables its holder to prevent competitors from exploiting the invention (manufacturing the product, offering it for sale, storing it, etc.) in those Member States in which an SPC has been granted[38].

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[30] Phillips McDougal, Evolution of the Crop Protection Industry since 1960, Phillips McDougall AgriService, 2018, p. 3.

[31] See: Article 13 of Regulation (EC) 469/2009 and Article 36 of Regulation (EC) No 1901/2006.

[32] Includes: data exclusivity (8 years), market protection (10 years) and market exclusivity for orphan medicinal products (additional 2 years). See: Annex 5A for more details.

[33] In certain cases the regulatory protection period extends beyond the term of a possible SPC, which implies that the latter would not be the decisive factor regarding generics entry.

[34] No later than 5 years after the filing of the patent application (cf. Article 13(1) of Regulation 469/2009).

[35] Copenhagen Economics, Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe, Publications Office of the European Union, Luxembourg, 2018.

[36] The SPC holder usually also holds the reference patent, although other situations are possible – for instance where the patentee licenses the patent and the licensee invests in the clinical trials and obtains the marketing authorisation and the SPC.

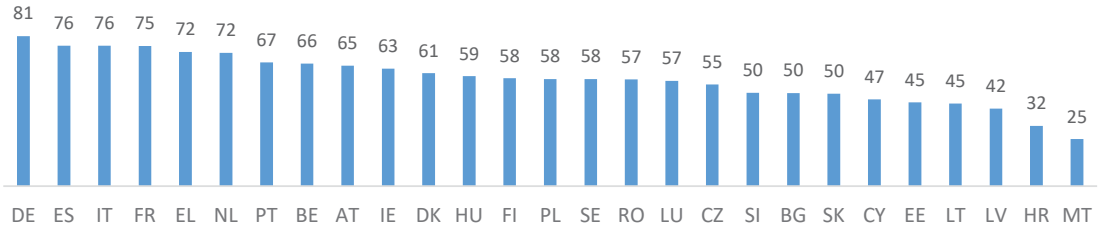
[37] Cf. Article 5 of Regulation 469/2009 – subject to the SPC manufacturing waiver introduced by Regulation 933/2019 – and of Regulation 1610/96.

[38] Some further limitations may still apply to the patent rights, such as the Bolar exemption, which is also relevant to the SPC protection (i.e. it allows to conduct the testing required to obtain regulatory approval for

Market size and applications for SPC protection

In the period 2014-2021 there were between 25 and 81 SPC applications filed annually with respective national patent offices of the individual EU Member States. The highest number of applications was filed in Germany (81 on average per year), followed by Italy and Spain (76) and France (75). SPCs were less frequently applied for in smaller jurisdictions, such as Croatia (32) and Malta (25). The total number of SPC applications filed in all Member States increased from about 500 applications in 1993 (in then EU-12) to a total of 1 459 SPC applications filed in the EU-27 in 2021[39].

Figure 1: Number of SPC applications filed – yearly average by country in 2014-2021



Source: "Current trends in activity at the NPOs and at the EPO", Administrative Council of the EPO (documents: CA/36/19, CA/31/18, CA/13/17, CA/9/16) and "Exchange of information on current trends in activity at the NPOs and at the EPO", May 2022. Note: data missing for the following countries – 2014: BE, SE, 2015: SE.

During 2014-2021 the European Commission[40] issued 88 central marketing authorisations on average per year[41]. An SPC can be requested within six months after receiving such authorisation[42]. With up to 81 SPCs registered annually in Member States, and given that marketing authorisations of new active ingredients via national route are negligible[43], we can assume that nearly all new medicines benefit from SPC protection in at least one country (estimated at 86% by an earlier study[44]).

In terms of global composition, EU firms accounted for around one third of SPCs applied for in the largest (German) patent office in 2010-2021[45] whereas up to 19% of all SPC holders were SMEs[46] –

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the generic/biosimilar during the patent/SPC protection period of the reference medicine). In addition, Regulation (EU) 2019/933 introduced two distinct limitations to the SPC protection in the form of a manufacturing waiver (allowing, during the SPC protection, generic and biosimilar companies' production in the EU for export-only purposes to non-EU countries that do not provide for equivalent SPC protection) and a 6-month stockpiling waiver (allowing, during the last 6 months of SPC protection, generic and biosimilar companies' production in the EU for storing purposes and entry in the EU market as of the date of expiry of the SPC).

[39] European Patent Office, Exchange of information on current trends in activity at the NPOs and at the EPO, 2022 (https://www.epo.org/about-us/governance/documentation/ac-documents.html).

[40] Companies apply for marketing authorisations at EMA, which concludes on the safety, quality and efficacy of the medicines. Marketing authorisations are granted by the European Commission.

[41]The number includes marketing authorisations for human, veterinarian and plant protection products. The marketing authorisations issued to follow-on producers are excluded (see: Annex 5A).

[42] Article 7(1) of the SPC regulations.

[43] Max Planck Institute for Innovation and Competition, Study on the Options for a Unified SPC System in Europe, 2022, pp.71–72.

[44] Kyle, M., Economic Analysis of Supplementary Protection Certificates in Europe, MINES ParisTech (CERNA), PSL Research University and CEPR, 2017, pp. 18–19.

[45] Based on SPC data from German NPO covering years 2010–2021; the remaining shares of applications were: US – 39 %, CH – 12 %, JP – 8 %, UK – 5 % and 4 % from other countries (see: Annex 5A).

[46] After matching the German NPO data on SPC with the Orbis database, 8 % of SPC holders were classified by Orbis as small or medium-sized companies and did not belong to any corporate group. Another

such data can be a good proxy for the EU market as whole, given that SPCs are predominantly sought in the EU largest economy. The estimates based on German data are also aligned with the SMEs share among the holders of EU-centralised marketing authorisation, as in 2010-2012 they accounted for around 13% of all firms[47]. Nonetheless, SPCs are predominantly held by companies belonging to large corporate groups, with 16 of them holding half of all SPCs granted[48]. Universities or research institutes held roughly 7% of all SPC issued in DE in the period under scrutiny[49].

Additionally, SPCs are granted in an increasing number of Member States for a given product. Since their first entry into force in the 1990s up to 2014, SPCs were applied for in 20 countries on average[50]. In value terms, SPC protection increases the turnover generated from a given medicine, by around 13% over the period of 12.5 years from market launch of a medicine, which translates into around EUR 37 billion[51] total gain across the Single Market. Finally, nearly eight times more SPCs are applied for and granted for medicinal products than for PPPs[52].

Different types of protections available

SPCs and patents are not the only forms of protection available for pharmaceutical products or PPPs. Besides intellectual property rights, the regulations establishing the conditions under which medicines (or plant protection products) can be marketed offer data protection (exclusivity) based on the initial marketing authorisations. In case of medicinal products, a 10-year market protection is also foreseen. Once certain conditions are fulfilled[53], such rights will result from the marketing authorisations (MA) and are referred to as regulatory data protection (RDP). Although marketing authorisations and SPCs have some features in common, they are distinct and separate, and have different policy objectives.

First, they differ in their effect. Patents and SPCs allow their holders to prevent third parties from performing activities infringing these rights. On the contrary, market protection is the period of time within which a generic or biosimilar cannot be placed on the market, even if a marketing authorisation has already been granted. Data exclusivity concerns a period of time within which another application (e.g. from a generics maker) cannot rely on data (such as results of clinical trials) already submitted in support of the originator's own marketing authorisation. Second, they pursue different objectives. SPCs protect patented medicines (or plant protection products) so as to incentivise innovation, i.e. the development of new products, by compensating for the years of

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11 % of SPC holders were not matched – as the Orbis database has better coverage with regards to large companies, it is more probable that the unmatched companies are SMEs (see: Annex 4).

[47] Lincker, H., Ziogas, C., Carr, M., Porta, N. and Eichler, H.-G., 'Where do new medicines originate from in the EU?', Nature Reviews Drug Discovery, Macmillan Publishers Limited, 2014, pp. 92–93.

[48] See: Annex 5A for more details on the most frequent global ultimate owners of companies holding SPCs.

[49] Based on the same dataset as above (i.e. extracted from the German NPO).

[50] Mejer, M., 25 years of SPC protection for medicinal products in Europe: Insights and challenges, European Commission, DG GROW, 2017, p. 7.

[51] Based on a sample of 232 active pharmaceutical ingredients. Source: European Commission, Evaluation of EU Regulations 469/2009 and 1610/96 on supplementary protection certificates for medicinal and plant protection products, SWD(2020) 292 final, p. 38 (https://ec.europa.eu/docsroom/documents/43847).

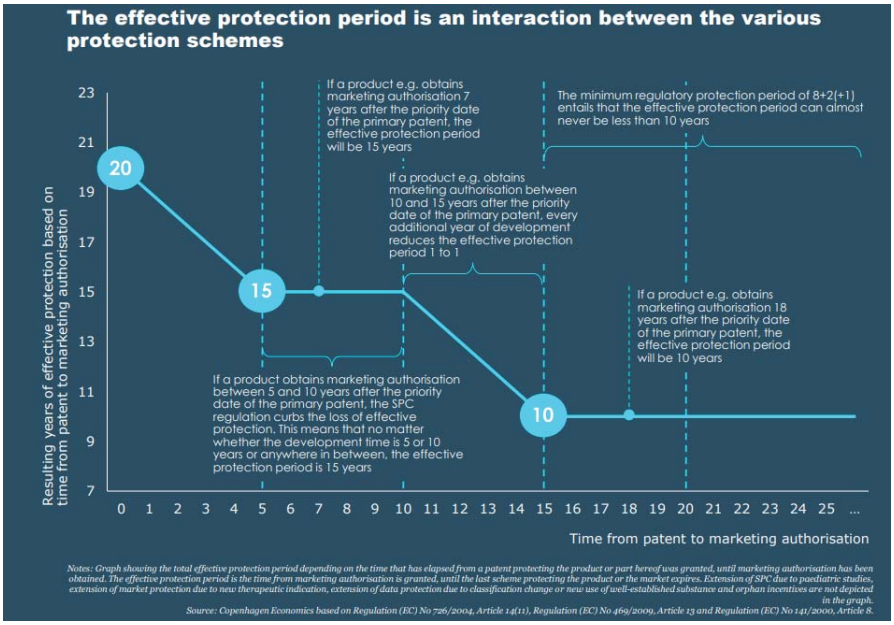
[52] Based on replies from BE, DK, FR, DE, NL, PT and RO to questions Q20 and Q21 of the Allensbach survey conducted under the 2018 Study on the legal aspects of SPCs in Europe by the Max Planck Institute for Innovation and Competition.

[53] Concerning for example significant pre-clinical tests or clinical trials related to authorisation of a new active substance or new therapeutic indication for a well-established substance, provided that significant pre-clinical or clinical studies were carried out in relation to the new indication.

effective patent protection lost due to the regulatory authorisation procedures. On the other hand, RDPs intend to offer protection to the investment-intensive data generated for the regulatory authorities in order to demonstrate quality, safety and efficacy of a pharmaceutical product, ignoring such aspects as novelty or inventive steps, which characterise patents.

The interactions between the two are presented in Figure 2, below – the figure assumes a basic scenario in which there was no paediatric extension of the SPC. It may be noted that the starting points of both protections are different: patent protection starts from the filing of the patent application, SPC protection starts from the expiry of the patent, while RDPs are triggered by the marketing authorisation.

Figure 2: The effective protection period for medicinal products



Source: Copenhagen Economics, Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe, European Commission, Directorate General for Internal Market, Industry, Entrepreneurship and SMEs, 2018, p.42.

As shown in the previous figure, the effective protection for medicinal products depends on the development time and the duration of clinical trials, calculated from the patent filing date (the horizontal axis). If this "delay" from patent filing to marketing authorisation is shorter than five years, then the last protection to expire would be the patent, as no SPC will be granted[54]. If that delay is longer than 5 years, then the SPC steps in to allow for additional IP protection (i.e. 15 years in total – the vertical axis), until the delay reaches 10 years. Subsequently, if the delay took between 10 and 15 years, the SPC protection would gradually decrease until the total protection time reaches 10 years (i.e. 5 years "left" from the patent and 5 years from the SPC). Finally, in cases where the delay lasted longer than 15 years, the RDP (8 years of data protection and 2 additional years of market protection) would be that last protection to expire. More details about the regulatory context of the current SPC rules, patent systems and marketing authorisations in the EU are provided in Annex 5B.

[54] See: to this extent Article 13 of Regulation (EC) 469/2009.

2.3. What are the problems?

This impact assessment draws from the evaluation[55] of current SPC rules, which indicated a number of problems impacting the efficiency and effectiveness of the rules currently in force. The fact that SPCs are administered and managed at national level creates significant red tape and entails extra costs for businesses, which is especially challenging for SMEs. It also emerged that national procedures have resulted in different approaches and outcomes (nearly a quarter of SPC procedures concluded with contradictory outcomes[56]), undermining legal certainty and thus the proper functioning of the Single Market.

In addition, national granting procedures, including transparency obligations, generate costs and administrative challenges for national administrations (especially for those with limited administrative capacity). Some national administrations do not make full use of digital solutions, and there is no EU-wide SPC database. This hampers innovation and the availability of new medicines and PPPs, as well as access to affordable generic products, due to the uncertainty faced by generics manufacturers.

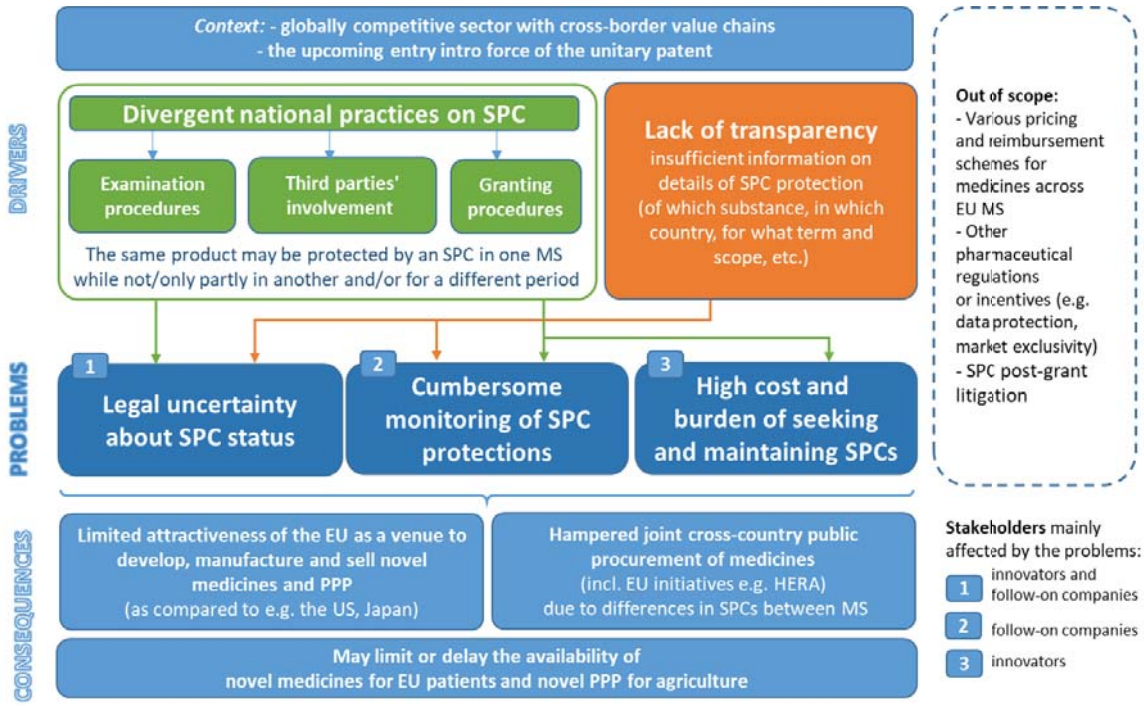
The findings from the SPC evaluation have been completed by more recent research carried out for this impact assessment. The key problems that have been identified in this context are: 1. Legal uncertainty about SPC status; 2. Cumbersome monitoring of SPCs; and 3. High cost and burden of seeking and maintaining SPC protection in the EU. Problem 3 mainly concerns the originators, Problem 2 is typical for the follow-on manufacturers (and to some extent other originators as well), while Problem 1 is common to both groups.

These problems are caused by divergent national practices for application and grant of SPC as well as insufficient and patchy information on the SPC status in each EU country. They should be seen in a general context of pharmaceutical and PPP sector acting globally and with increasingly cross-border value chains. Additionally, the currently fragmented SPC system will stand at odds with the upcoming launch of the unitary patent. While pharmaceutical and PPP companies will have a one-stop-shop to obtain a unitary patent to cover all the countries participating in the unitary patent system, they will still need to apply separately in each Member State to extend their patent protection by an SPC. Quoting one Member State from the Commission expert Group on Industrial Property Policy: "*In the case of supplementary protection certificates based on unitary patents, it is obvious that a uniform system for the grant of unitary protection certificates is required.*"

[55] DG GROW, Evaluation of EU Regulations 469/2009 and 1610/96 on supplementary protection certificates for medicinal and plant protection products, SWD(2020) 292 final (https://ec.europa.eu/docsroom/documents/43847).

[56] Based on sample research around 26 % of SPC were granted in one Member State, but rejected or withdrawn in another. Source: Mejer, M., 25 years of SPC protection for medicinal products in Europe: Insights and challenges, European Commission, DG GROW, 2017, p. 13.

Figure 3: Problem tree – current settings of the SPC system in the EU



Note: problems are numbered, as this is how they are sometimes referred to in the following sections of the impact assessment.

2.3.1. Legal uncertainty and cumbersome monitoring of SPC protection

Although common eligibility criteria are defined in the SPC Regulations (notably Articles 2 and 3)[57], around one in four SPC applications covering the same product resulted in divergent decisions in Member States[58] (in respect of 740 products approved between 2004 and 2014 and referring to the same basic patent). Some Member States grant SPCs for a certain product while equivalent applications are refused in others, or granted with a different scope. This was corroborated by the public consultation results: fragmentation causes legal uncertainty because decisions on granting protection can conflict across Member States concerning the national SPCs of the same product.

Divergent national SPC decisions stand in contrast to the simplicity and unitary nature of the upcoming unitary patents[59]. SPC users might be forced to rely on the current system of nationally granted SPCs to extend their unitary patents, not benefitting from certainty about maintaining the same scope of protection in the Member States where the unitary patent took effect. Moreover, 11 (out of 71) originators responding to the Commission public consultation cast doubts on the

[57] Article 3: '(a) the product is protected by a basic patent in force; (b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate; (c) the product has not already been the subject of a certificate; (d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.'

[58] Mejer, M., 25 years of SPC protection for medicinal products in Europe: Insights and challenges, European Commission, DG GROW, 2017, p. 13.

[59] Once the Unified Patent Court becomes operational, it will be able to handle litigation relating to SPCs as well, provided that these SPCs are based on a European patent (unitary or not) as basic patent. However, this would only apply to those Member States that have ratified the UPC Agreement.

possibility of granting national SPCs for a product covered by a unitary patent, positing that only additional legislation would allow for this.

Follow-on producers often face difficulties to ascertain the status of SPC protection in due time. This may hamper the launch of their competing product (i.e. generic or biosimilar), or their participation in tenders for the purchase of medicines. (In this regard, it is worth recalling that SPCs tend to protect medicines with significant sales). Follow-on producers face high cost and significant burden in up to date monitoring SPC protection throughout the Single Market. This can be onerous, if some of the follow-on manufacturers may need to monitor up to 27 SPCs (on average 20) per each product and the information may be dispersed across various IT systems, formats and linguistic regimes. In practice, such lack of transparency makes it much more cumbersome to enter the generic/biosimilar market, especially for SMEs.

Respondents to the 2017 Commission public consultation indicated that the information published by public authorities was not always comprehensive or up-to-date, and nearly all who had an opinion (i.e. 96% of follow-on producers - predominantly SMEs, around 80% of health professionals or patients and 70% of patent offices or lawyers) stated that access to private databases monitoring SPC status is very costly[60].

According to Medicines for Europe[61], transparency of SPC granting procedures is of utmost importance as it guarantees possible third party observations or oppositions. The generic association also claims that lack of transparency and of harmonisation results in legal uncertainty[62].

Finally, difficult access to SPC information may also cause problems for EU based manufacturers of generic and biosimilar medicines when applying for the SPC manufacturing waiver[63], as they need to establish the exact status of the exclusivity in a given jurisdiction. Thus, in order to start early export to non-EU countries or prepare pre-launch stockpiling in the EU, they need to monitor SPC protection in multiple Member States, which is especially relevant in presence of cross border value chains (e.g. logistics and outsourcing of production).

2.3.2. High cost and burden of seeking and maintaining SPC protection

SPC users face excessive costs of seeking and maintaining SPC protection in the EU, as multiple parallel procedures[64] before national patent offices (NPOs) are required to obtain SPC protection in the Single Market or part of it. While in any single Member State SPC protection was sought only for up to 81 products annually (2014-2021), SPC applications in the EU totalled around 1 550 annually. The need to seek multiple national SPCs for the same product (on average in 20 Member States)

[60] See: Annex 2.
[61] Medicines for Europe is an association representing European generic and biosimilar industry. According to its website the association members supply over 67% of all medicines in Europe. Source: https://www.medicinesforeurope.com/medicines-for-europe/
[62] Reply of the association of generics manufacturers, Medicines for Europe, to the public consultation question: 'How well do the original objectives of the SPC regulations still correspond to the needs within the EU?'
[63] SPC manufacturing waiver – Regulation (EU) 2019/933 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products.
[64] SPC applications are currently filed at the national patent office of each EU Member State where protection is sought. Each national office carries out examination and takes the decision to grant protection for its territory based on the requirements of the SPC regulations.

results in unnecessary administrative burden (e.g. preparation of several SPC dossiers, including multiple translations of the application, exchanges with the national offices, payment of administrative fees to each NPO and engagement of in-house or external legal advisors, additional communications in case of re-examinations) and high maintenance fees for the prolongation of SPC rights, separately in each jurisdiction. This may result in heavy red tape, especially burdensome for innovative SMEs.

Based on current[65] average coverage (20 Member States) and duration (3.5 years), SPC protection of a given product would cost around EUR 98 500[66] on average. In order to cover all 27 Member States for 5 years one should pay nearly EUR 192 000 in total (not including any fees charged by patent attorneys).

If the granting of SPCs remained limited to the national routes, it would remain as burdensome as today for companies to obtain and maintain SPCs based on unitary patents. An SPC applied for and maintained for 3.5 years in the 17 unitary patent countries[67] would cost around EUR 79 000[68] (EUR 117 000 for the entire period of 5 years).

In comparison to the overall cost of medicine/PPP development the direct monetary cost of obtaining SPC is relatively minor (the median capitalized R&D investment to bring a new drug to market is estimated at USD 985.3 million and the mean investment at USD 1 335.9 million[69]). Three quarters of innovators said the SPC cost is always relatively low in comparison to sales, while only 4% (including the only SME that replied) considered it high[70]. It should be noted however that the administrative cost of applying to up to 27 NPOs with accompanying costs on hiring legal advice in each country and translating the documents represent lost/unproductive resources.

As indicated earlier, one in five SPC applicants is an SME, for which these costs could be significant as SMEs have more limited financial resources, fewer in-house specialists, and limited geographical presence. They are also more likely to be a single invention companies that cannot easily compensate development cost of one medicine with a successful sales of another. Yet they face the same long authorisation process which reduces the effective time of patent protection as large firms. SMEs are key players in research on often neglected topics, like antibacterial substances (SMEs responsible for 81% of preclinical projects) or orphan medicines[71] (42% of medicines developed by

[65] Based on information about application and maintenance fees available on the NPOs' websites in the second quarter of 2022. The SPC evaluation estimated the cost (in terms of administrative fees) of 5 years of SPC protection covering all EU-27 countries at EUR 177 869 in 2016.
[66] Average between the lowest cost for an SPC lasting 3 years (EUR 68 274) and the highest cost for an SPC lasting 4 years (EUR 128 711), as provided in Annex 5B.
[67] At the time of writing this impact assessment, 17 Member States were expected to join the unitary patent system.
[68] Average cost between SPCs lasting 3 years (EUR 66 998) and 4 years (EUR 90 984) in UP Member States.
[69] Wouters, O.-J., McKee, M., Luyten, J., 'Estimated research and development investment needed to bring a new medicine to market, 2009–2018', JAMA, Vol. 323, No 9, 2020, pp. 844–853; or DiMasi, J. A., Grabowski, H. G., & Hansen, R. W., 'Innovation in the pharmaceutical industry: New estimates of R&D costs', Journal of health economics, Vol. 47, 2016, pp. 20–33.
[70] See: Annex 2.
[71] A medicine for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition that is rare (affecting not more than five in 10 000 people in the European Union) or where the medicine is unlikely to generate sufficient profit to justify research and development costs.

SME according to EMA[72]). In this regard, only one patent office in the EU offered reduced administrative fees for SPCs to universities or SMEs[73]. This is further corroborated by the public consultation results. While only 13% of originators considered SPC registration procedures as complex, this view was held by around 40% of follow-on manufacturers (generally firms with thinner resources)[74].

2.3.3. Key elements affecting the problems and consequences that are out of the scope of this impact assessment

The following issues are significantly contributing to the identified consequences, but are outside the scope of this initiative which focuses on concerns connected to SPC. Medicinal products and PPP are subject to strict requirements to ensure the safety of their users. Before being placed on the market in the EU, medicinal products have to be assessed and the conclusion concerning their benefits versus their risks has to be favourable in terms of safety, quality and efficacy[75]. The EMA medicines marketing authorisation process[76] involves, among others, clinical trials, inspections of medicines' manufacturers and compliance with good clinical, manufacturing, distribution and pharmacovigilance practices. All these are essential to ensure safe usage, yet very demanding on producers (not only in terms of cost). Moreover, there are differences in pricing schemes for medicines across the EU countries, as well as worldwide, that affect the pharmaceutical market. The price controls and different reimbursement schemes for national or private health services affect sales of manufacturers and their decisions to invest[77], as well as the prices and availability of medicines to patients. In the EU, Member States are responsible for setting and controlling the prices and reimbursement of medicines. Negotiations on pricing and reimbursement of novel medicines, or generics, are conducted irrespective of the status of any patent and SPC.

In addition, SPCs are currently enforceable before national courts.[78] For litigation enforcing an exclusive right in the EU, parties might face a cost of between EUR 40 000 and EUR 200 000 per jurisdiction[79].

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[72] Lincker, H., et al. (2014).
[73] Reply to the Commission's survey on the transparency of the SPC system.
[74] Open public consultation (OPC): 'How would you rate the degree of complexity of registration procedures for SPCs in the EU?' A majority of both originators (72 %) and follow-on manufacturers (61 %) considered the registration complexity as reasonable. Based on around 50 replies in each group (see: Annex 2).
[75] European Commission, 'Legal framework governing medical products for human use in the EU', 2022 (https://ec.europa.eu/health/medicinal-products/legal-framework-governing-medicinal-products-human-use-eu_en)
[76] European Medicines Agency, 'Marketing authorisation', 2021 (https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation).
[77] 'Today's pricing policies promote a convergence of list prices at levels that are less affordable for lower-income OECD countries […]. This practice encourages firms to launch drugs in countries where it can set a price freely at market entry or negotiate high prices. It also distorts the signals that the market sends about the value of new medicines.' Source: OECD, Pharmaceutical Pricing Policies in a Global Market, 2008 (https://www.oecd.org/els/health-systems/pharmaceutical-pricing-policy.htm).
[78] The Unified Patent Court will allow for centralised litigation of European patents within the EU for countries ratifying the UPC Agreement.
[79] Based on estimates for DE, FR and NL. Source: Cremers, K., Ernicke, M., Gaessler, F. et al., 'Patent litigation in Europe', European Journal of Law and Economics, Vol. 44, 2017, pp. 1–44.

2.4. **What are the problem drivers?**

The problem drivers form two key thematic blocks, namely “Divergent national practices on SPC” and “Lack of transparency”. Both are discussed below.

2.4.1. Divergent national practices on SPC

Multiple procedures before NPOs are required to obtain SPC protection in the Single Market or part of it. EU NPOs’ divergent national practises concern:

(1) The substantive examination of the SPC applications.

Under Article 10(5) of Regulations 469/2009 and 1610/96, Member States may allow the NPOs to grant SPCs without verifying that the substantive conditions laid down in paragraphs (c) and (d) of Article 3 are met, i.e. that (c) the product has not already been the subject of a certificate, and (d) the marketing authorisation is the first authorisation to place the product on the market as a medicinal or plant-protection product. According to Max Planck Institute for Innovation and Competition[80] – MPI (2018), NPOs of 15 Member States do not use the exemptions from verifying substantive criteria (CZ, DE, DK, FR, HR, HU, IE, IT, LT, LV, NL, PL, PT, SE, SK) while others do[81]. Moreover regarding requirement (d) three NPOs (DE, LV and IE) reported difficulties in applying it, especially when the first marketing authorisation had been issued by another Member State, while one (DK) conducts informal internet search only. In addition it adds further confusion as there were cases where examining Member States referred questions to the CJEU wishing to refuse an SPC, but they noted that the very same SPC had been granted elsewhere in the EU. The substantive conditions causing most problems have been the scope of the patent, but also difficulties to abide by the CJEU’s case law on determining which the first marketing authorisation in the EU is.

(2) The opportunities of affected 3rd parties to get involved in the grant procedure.

The SPC Regulations rule out opposition proceedings[82]. Nevertheless, one Member State (DK) introduced a possibility for any person to request administrative re-examination of SPCs.[83] Furthermore, most NPOs (at least 18 - AT, CZ, DE, DK, ES, FI, HR, HU, IE, IT, LU, LV, NL, PL, PT, RO, SE,

[80] Two studies by Max Planck Institute for Innovation and Competition are referred to in this impact assessment, namely: “Study on the Legal Aspects of Supplementary Protection Certificates in the EU”, 2018) and “Study on the options for a united supplementary protection certificates (SPCs) system in Europe”, 2022. See: Annex 1.4.

[81] Some NPOs (especially with lower number of cases) may not have the administrative capacities when conducting substantive examination, and hence make use of this legal exemption.

[82] Opposition procedures enable third parties to challenge the granting of an IP right during the grant procedure (*ex ante* opposition procedure) or during a period of time subsequent to the granting of the IP right (*ex post* opposition procedure). The 2018 Max Planck Institute study contained an analysis of SPCs/patent term extension in several non-EU countries. Based on the study, neither of the systems provided for in the two big pharmaceutical markets of US and JP seem to have a true pre-grant opposition procedure. This is contrary to, for example, Australia or Israel, which (as set out in the study) do have opposition procedures.

[83] Pedersen, J. M. and Justesen, J. in Ridderbusch & von Uexküll (eds.), European SPCs Unravelled: A practitioner’s guide to supplementary protection certificates in Europe, 2021: ‘Further, it is important to note that, in Denmark, any person may file a request for administrative re-examination of SPCs with the DKPTO (BEK, Sections 78–81), based on the grounds in Article 15 of the SPC Regulation. As any person includes third parties, this means that a type of opposition procedure is essentially available in Denmark, regardless of Article 19(2) of the SPC Regulation, although the administrative re-examination is not formally considered an opposition procedure by the DKPTO.’

SK,) allow the submission of third-party observations, although this is not formally allowed by at least two NPOs (EL, LT)[84].

(3) The duration of the grant procedure.

Time from the filing of the SPC application to the final grant decision can take, for instance, from 17 months in FR to 31 months in DE[85].

There are differences in the way NPOs process the SPCs applications. The percentage of applications pending over all SPC applications ranged from less than 10% in 8 Member States (CY, ES, IT, LU, MT, PT, SE, SI) to up to 50% in 7 NPOs (BE, BG, DE, FI, HU, PL, RO). This was due to differences in patent-office procedures, such as waiting for decisions by national courts or proceedings of differing lengths[86].

Some stakeholders consulted as part of the MPI (2018) study confirmed that there were significant differences in the duration of examination[87] (which can sometimes take more than a year), and expressed their wish for uniform timing and deadlines. Others have criticised the rules in some Member States that impose deadlines within the granting procedures. Both originators and generics companies highlighted the importance of a quick decision on a product's eligibility for an SPC.

(4) The outcome of the procedure.

Rejections: globally, 80% of SPC applications were granted[88]. The ratio of rejections per Member State was quite divergent though, reflecting different approaches by NPOs. Five countries (CY, EE, FI, IT, LU) rejected fewer than 5% of applications while 6 NPOs (DK, ES, MT, NL, PL, SE) rejected more than 15%[89].

Geographical coverage: The outcome of the procedure, typically grant or refusal, can vary across NPOs, i.e. the same product can be granted SPC protection in some Member States and not in others. Based on sample research around 26% of SPC were granted in one Member State but rejected or withdrawn in another[90].

What is protected: Some patent offices describe the scope of the granted SPC in different terms, so the same product can have different scope of protection across the EU.

[84] See: Annex 5B.
[85] Median time calculated from all SPC applications in Germany and France filed between 1995 and 2005, which receive a grant decision. Source: MPI (2018), p. 103.
[86] Cabinet Alice de Pastors, 'Latest news on medicinal product SPCs in Europe: Medicinal product SPCs filed from 1991 to 2013', SPC News 28, 2014.
[87] Question 62 of the Allensbach survey to stakeholders.
[88] Data for 2004–2014. Source: Mejer, M., 25 years of SPC protection for medicinal products in Europe: Insights and challenges, European Commission, DG GROW, 2017, p. 13.
[89] Cabinet Alice de Pastors, 'Latest news on medicinal product SPCs in Europe: Medicinal product SPCs filed from 1991 to 2013', SPC News 28, 2014.
[90] Sample of 706 applications from 2004 to 2014. Source: Mejer, M., 25 years of SPC protection for medicinal products in Europe: Insights and challenges, European Commission, DG GROW, 2017, p. 13.

The case law regarding SPCs has evolved gradually over the years[91]. For instance, after the Neurim[92] judgement (issued in 2012 and reversed in 2020 by Santen[93]) it was possible to get multiple SPCs for the same product based on different marketing authorisations. Some NPOs interpreted it as applicable only to a situation when one SPC is sought for a product of veterinary use and another of human use. Others considered that it applies only to products for the same species (e.g. only veterinary or only human). The reversal in Santen clarified these divergences. Moreover, several cases have been referred regarding the protection of combination products[94] and what would constitute a prior certificate. In Actavis I[95] and II[96], the CJEU held that once an SPC had been obtained for a mono product (a product which contains one active ingredient), no certificate based on a combination product could be obtained. Yet, it is still unclear as the two recent references to the CJEU[97] concern (among others) the protection of combination products.

Additionally, the CJEU judgement on Actavis I introduced a new requirement that the product must embody the "core inventive advance of the patent" (inventive-advance test) but it was unclear when this test should apply. The "core inventive advance" in the context of Article 3a was rejected by the court in Royalty Pharma Collection Trust[98]. Nevertheless, doubts remain, as a recent court referral (Teva, Case C-119-22) inquires, among others, about the core inventive advance in the context of Article 3c. In general, the two recent references further highlight that there is uncertainty on the side of the courts regarding the relationship between Article 3a and 3c[99]. All that shows that CJEU jurisprudence on SPC is still being developed, as new issues arise, thereby progressively clarifying the interpretation of the substance of the SPC Regulations and thus improving legal certainty.

Duration of protection: Expiry date for as much as 80% of products based on the same basic patent is not homogenous across Member States. This is driven by differences in national examination and interpretations of marketing authorization date[100].

The stakeholders feedback concerning the outcome of the procedure has shown that around 80% of innovators and follow-on manufacturers (including 6 SMEs out of the 13 SMEs responding from the

[91] It must be noted that most of the referrals concerned Articles 1 – 3 of the SPC Regulations. This suggests that uncertainty in the application of the SPC Regulations concerns rules obtaining SPCs, instead of the extent of protection or rights conferred by the SPC. MPI (2022), p.81.
[92] Judgment of the Court of Justice of 19 July 2012, Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents, C-130/11, ECLI:EU:C:2012:489.
[93] Judgment of the Court of Justice of 9 July 2020, Santen SAS v Directeur général de l'Institut national de la propriété industrielle, C-673/18, ECLI:EU:C:2020:531).
[94] See: Article 1(b) of Regulation 469/2009: 'product' means the active ingredient or combination of active ingredients of a medicinal product.
[95] Judgment of the Court of Justice of 12 December 2013, Actavis Group PTC EHF and Actavis UK Ltd v Sanofi, C-443/12, ECLI:EU:C:2013:833.
[96] Judgment of the Court of Justice of 12 March 2015, Actavis Group PTC EHF and Actavis UK Ltd v Boehringer Ingelheim Pharma GmbH & Co. KG, C-577/13, ECLI: EU:C:2015:165.
[97] Request for a preliminary ruling from the Markkinaoikeus (Finland) lodged on 17 February 2022, Teva B.V. and Teva Finland Oy v Merck Sharp & Dohme Corp., C-119/22;
Reference for a preliminary ruling from the Supreme Court (Ireland) made on 2 March 2022, Merck Sharp & Dohme Corp v Clonmel Healthcare Limited, Case C-149/22.
[98] Judgment of the Court of Justice of 30 April 2020, Royalty Pharma Collection Trust v Deutsches Patent- und Markenamt, C-650/17, ECLI:EU:C:2020:327, paragraphs 30–32.
[99] In particular, the MPI (2022) study highlights that not all the issue around Article 3a have been solved by recent cases.
[100] Mejer, M., 25 years of SPC protection for medicinal products in Europe: Insights and challenges, European Commission, DG GROW, 2017, p. 12.

generics sector), as well as nearly all patent offices, judges and lawyers (96%) responding to the Commission consultation, confirmed that authorities in different EU countries had taken different decisions (e.g. some authorities might grant a SPC while others refuse it for the same product) on SPC applications impacting at least one of their products. Only around 20% of producers reported that this had not happened to them [101].

In the Allensbach survey[102], 62% of the respondents (48% of originator respondents and 83% of the generic producer respondents) agreed or strongly agreed that the examining practice and procedures of the NPOs differed significantly in the predictability, transparency and quality of the rights granted (26% of the respondents disagreed). The MPI (2022) study highlights the complexity of the system as the main reason for the divergent granting practices at a national level, including lack of uniformity both in the length and outcome of the examination[103]. This in turn results in cross-country differences in the way SPC applications are handled[104].

To conclude, as signalled earlier in the problem tree, the increasing complexity of the SPC examination process make it more difficult for NPOs to deal with it in a coherent manner. In turn, EU NPOs' divergent national practises are the source of legal uncertainty (problem 1) and generate high cost of applying and maintaining SPC protection in the EU (problem 3). As they are in line with the SPC regulations these problems cannot be solved by Commission launching infringement actions against these Member States.

2.4.2. Lack of transparency of SPC-related information

When it comes to transparency of SPC proceedings as such, Member States' national patent offices follow uncoordinated and different practices (e.g. content of the application, public accessibility, updates of SPC data bases – to the extent these exist and the status of the granted/refused SPCs). A study conducted in 2018 by Technopolis[105] concluded that "*Whilst most* [of SPC-related] *information is in the public domain, registers are not well linked or easy to navigate without expert knowledge*" and recommended to *"Improve clarity and ease of use of EU and national data registers on protections and exclusivities for pharmaceutical products"*.

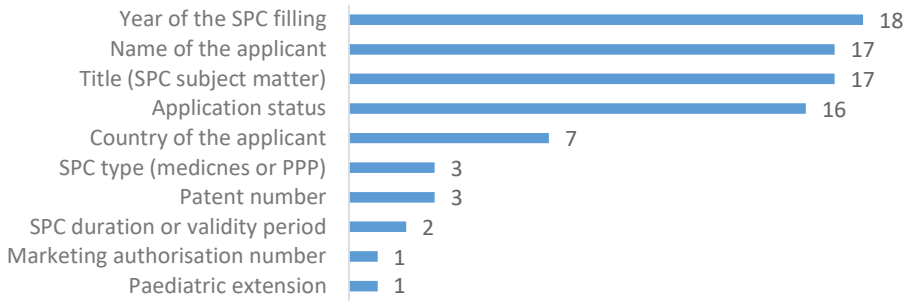
Additionally a survey of NPOs in 2020 found that publication of information can take from a couple of days to several months or even more than a year. Only 14 NPOs publish information in English in

[101] Question 11 to innovators (out of 49 answers) and 4 to follow-on manufacturers (out of 43 answers).
[102] Max Planck Institute for Innovation and Competition, Study on the Legal Aspects of Supplementary Protection Certificates in the EU, Annex III: Allensbach survey, 2018 (https://ec.europa.eu/docsroom/documents/29524).
[103] MPI (2022), p. 75.
[104] „One stakeholder has divided the NPOs into three groups: a group […] which follows strict deadlines and examines the application in depth; a group which usually waits for official actions from other offices; and a third group of NPOs which very easily grants the certificates with a low intensity examination of the substantive requirements." Source: MPI (2022), p. 75. The differences in procedural approaches are also confirmed by data on the procedural outcomes, see Table 5.5 of the MPI (2022) study.
[105] Technopolis, "Effects of supplementary protection mechanisms for pharmaceutical products", 2018 (https://www.technopolis-group.com/report/effects-of-supplementary-protection-mechanisms-for-pharmaceutical-products/).

addition to official language of the country, which could especially cumbersome for SMEs. About half of NPOs do not provide online access to SPC application documents[106].

In practice, the above translates into limited transparency about the state of play, and outcome of the SPC procedures across the EU. If available at all, the information is provided via national websites in multiple formats - from structured databases that are available for download, to selected documents in pdf format, which is cumbersome for processing. Difficulties in accessing such service can affect around 300 follow-on manufacturers[107] and procurers active in the health sector, generating an annual approximate cost of roughly 13 million EUR[108] if outsourced to private providers. Due to the complexity of accessing information on the exclusivity status of pharmaceutical products, several private companies offer specific data-intelligence products. Figure 4 summarises the availability of various pieces of information related to an SPC application that were available across EU-27 via searchable databases (i.e. with a possibility to upload search output into structured format, such as Excel or CSV file). Libraries of non-searchable PDF documents were not taken into account[109].

Figure 4: Number of Member States where selected SPC information was available in a structured format via their NPOs websites



Source: In-house analysis based on information collected from the NPO websites in April 2022.[110]

As shown above, information which is of primary importance for the generic producers, namely the SPC duration or validity, was easily available only in two countries. Alternatively, follow-on producers could calculate the SPC duration on their own by comparing patent and marketing authorisation dates[111] (with the risk of errors in case of some interruption in the administrative procedure or litigation) or else, view a pdf copy of the SPC decision (if available). Still, both approaches are error prone especially if conducted in non-native language which would be predominantly the case.

[106] See: Annex 2.
[107] See: Section 6.6.1.
[108] Based on a cost of around EUR 40 000 for a yearly subscription (own market research) and one central purchasing body in charge of procuring medicines per Member State.
[109] Article 11 of the SPC regulations requires publication (without specifying the format) of the following information: (a) the name and address of the holder of the certificate; (b) the number of the basic patent; (c) the title of the invention; (d) the number and date of the authorisation to place the product on the market (…) and the product identified in that authorisation; (e) where relevant, the number and date of the first authorisation to place the product on the market in the Community; (f) the duration of the certificate.
[110] This table is different from Table 2.1, Annex V of the 2018 Max Planck Institute study as it also takes into account the ability to search for data easily. Some information may be available in an unsearchable format (PDF as images) in the native language.
[111] Which were also hardly ever available in a structured format (i.e. basic patent number available in basic patent number or a reference to marketing authorisation ware hardly ever available in three countries, or a reference to marketing authorisation in one Member State only).

Further details on country-specific practices related to limited transparency of SPC granting procedures can be found in Annex 5B.

To summarize, in the current settings, the SPC information is incoherent, dispersed across 27 jurisdictions and not easily accessible. This is in sharp contrast to high transparency and accessibility standards concerning primary patent data. Lack of transparency drives problem 1 on legal uncertainty, as well as constitutes the main direct reason for which monitoring of the SPC system in the EU is burdensome and costly (problem 2).

2.5. **Consequences**

All market players are impacted by significant legal uncertainty of the SPC system (problem 1). SPC users face considerable administrative and management costs associated with the current fragmented SPC system (problem 3). At the same time, lack of harmonisation of SPC-related information can be an entry barrier for the follow-on manufacturers (problem 2). These triggers several consequences that are described in the following sections.

2.5.1. EU less attractive for medicines and PPP development

Temporary exclusivity in use offered by patent protection has been used across most jurisdictions and – at least in the case of pharmaceuticals – has time and again been confirmed to incentivise investment in R&D and facilitate knowledge sharing[112]. A precise causal relationship between R&D activities in a particular jurisdiction and the SPC coverage in this area, however, is difficult to capture given the plethora of confounders. Nevertheless, it could be broadly discussed at three levels: location of investment in the EU's Single Market, market share of EU-based firms and overall global levels of innovation and R&D spent.

The recent COVID-19 crisis showed how vital the localization of production is for securing supplies in times of sudden collapse of global value chains. When it comes to geographical locus of pharmaceutical investment, IQVIA (2021) shows that countries with a strong IP protection[113] (any kind, not only SPC) have eight times higher levels of clinical research activities on average[114]. On the other hand, patent holders can seek SPC protection in a country different from where the R&D or manufacturing of the novel product took place, which makes unambiguous identification of SPC effects problematic. Still, since the SPC Regulations do not differentiate between EU-based companies and their foreign competitors[115] they contribute to investment location decisions of all capital intensive firms alike[116]. Finally, and somewhat intuitively, the views of the stockholders additionally expose the different perspectives between the originators and the follow-on manufacturers. Around 90% of innovators responding to the public consultation considered that

[112] The relevant economic literature is far too vast to reference here. For a comprehensive recent meta summary see: Spulber, D., The Case for Patents, Northwestern University, 2021.
[113] Measured by the U.S. Chamber 2021 International IP Index, the IP index of the Global Innovation Policy Centre. See: Annex 5B.
[114] IQVIA Institute for Human Data Sciences, The Impact of Pharmaceutical IP Provisions in EU Free Trade Agreements, institute report, 2021.
[115] Which is in clear contrast to local manufacturing requirements contained in the SPC waiver, for example.
[116] Most developed countries (e.g. US, JP and others) have comparable patent extension regimes incentivising the development of new products. For more details see: Max Planck Institute for Innovation and Competition, Study on the Legal Aspects of Supplementary Protection Certificates in the EU, 2018 (https://ec.europa.eu/docsroom/documents/29524), pp. 603–617.

possibility of obtaining EU SPC plays a role when deciding on investments in R&D, manufacturing or marketing in the EU. 80% said that there were instances where SPC eligibility was a decisive factor for product development. Half considered that SPC impacted prioritisation of innovation in their firm (e.g. on oncology). On the contrary, nearly all follow-on manufacturers responding to the consultation favoured countries with no SPC when deciding on manufacturing localisation, or considered that while it depends on the circumstances, no SPC was a key factor[117].

We now turn to the competitive position of EU based pharmaceutical firms. Their home-base is much more fragmented than it is the case for their major global competitors originating from jurisdictions with harmonised protection systems. Currently, most big markets offer an SPC equivalent (called patent term restoration or patent term extension) of up to five years. This includes the US, JP, KR and recently also CN, which has introduced a new regime of patent term extension for pharmaceuticals. Following a single procedure in the above jurisdictions a company can not only gain protection covering the whole territory (e.g. 330 million citizens in the US or 125 million in Japan), but also pay much lower fees (for instance application and renewal fees amount to around EUR 3 000 in the US and EUR 4 200 in JP)[118]. In comparison, in the EU firms need to apply separately in each of 27 Member States, and pay considerably higher fees (for instance only in DE - 83 million citizens - the application and renewal fees of EUR 16 950)[119]. This – at least at the margin – cripples their scale up in the home base of the Single Market.

Thirdly, and in the overall global sense, the importance of SPC protection to recuperate investment is expected to grow due to the following macro trends concerning all market players:

- very high R&D intensity characterising the pharmaceutical and PPP sectors,
- decreasing productivity in pharmaceutical and PPP research and development,
- increasing regulatory pressure in both sectors.

This phenomenon can be found in many sectors, including the pharmaceutical and PPP sectors, and implies that ideas/treatments that are 'easy' to find are developed and exploited first. Then, as the stock of knowledge increases, new ideas/treatments become harder to find or inventions and output can only be sustained or increased by large increases in research effort that offset declining productivity [120].

As mentioned in the introduction, in 2020 European health industries invested more than EUR 36.6 billion in R&D. In pharmaceuticals, the clinical productivity index measured by IQVIA (composite

[117] See: Table 36 in Annex 2.
[118] For a 5-year long SPC.
The US Patent Office: extension of term of patent USD 1 180 (≈EUR 1 100) and maintenance fee after 3.5 years of USD 2 000 (≈EUR 1 900), exchange rate EUR 1 = USD 1.05 (ECB on 29.6.2022). Source: United States Patent and Trademark Office, 'USPTO fee schedule', 2022 (https://www.uspto.gov/learning-and-resources/fees-and-payment/uspto-fee-schedule).
The Japanese Patent Office: application for registration of an extension of the term of patent right JPY 74 000 (≈EUR 500) plus annually JPY 59 400 + JPY 4 600 per claim (≈EUR 450). For calculations 10 claims were assumed, exchange rate EUR 1 = JPY 144 (ECB on 29.6.2022). Source: Japan Patent Office, 'Schedule of fees', 2022 (https://www.jpo.go.jp/e/system/process/tesuryo/hyou.html).
[119] German Patent and Trade Mark Office, 'Patent fees', 2022 (https://www.dpma.de/english/services/fees/patents/index.html).
[120] OECD, Pharmaceutical Innovation and Access to Medicines, OECD Health Policy Studies, OECD Publishing, Paris, 2018.

Clinical Development Productivity Index) dropped in 2021 by 30% in comparison to a decade ago[121]. This is driven chiefly by an increase in complexity and in duration of medicines development (including clinical trials and failure rates). A common hypothesis to explain this trend is that more stringent requirements to gain marketing authorisation have increased the costs of clinical trials.

Similar patterns can be observed in the plant protection sector, where the major companies invested around 7-10% of their annual sales in R&D over the last 50 years[122]. According to a study by Deloitte[123] the agrochemicals industry has experienced declining revenues and margins that were primarily due to: longer product-development cycles, escalating costs[124] and increasing stringency of regulatory requirements: this hampers the further development of innovative technologies and the use of some types of crop-protection agents. This global trend of decreasing numbers of new active ingredients can also be observed at EU level.

Given the above described mechanism, it could be argued that the European SPC regime composed of 27 national systems[125] may not bring all benefits that could have materialised, if the rules were harmonised and more coherent across the EU. The precise impact however, is not quantifiable, but more based on the perception of the EU market as an attractive place for research, development and production. While by no means the key factor, a fragmented SPC system in the EU may contribute to lowering the incentives for the pharmaceutical and PPPs investments in the EU (especially for SMEs and innovative start-ups), as well as it may affect the global market share of EU-based firms.

2.5.2. Hampered joint cross-country public procurement

Joint cross-country procurement for pharmaceutical products in the EU is currently regulated by Directive 2014/24/EU, as well as by Decision 1082/2013/EU on serious cross-border threats to health. In Recital 33, the public procurement Directive states in particular that "*contracting authorities should be able to choose to provide jointly their public services by way of cooperation without being obliged to use any particular legal form. Such cooperation might cover all types of activities related to the performance of services and responsibilities assigned to or assumed by the participating authorities […]*". Furthermore, "*the important role joint procurement may play, not least in connection with innovative projects*" is also recognised (Recital 71). As far as Decision 1082/2013/EU is concerned, it aims at improving cooperation of the EU and Member States in case of serious cross-border threats to health, including the possibility of conducting the joint procurement initiatives.

[121] Although Phase II trials saw a decline of less than 10 %. Source: IQVIA institute for Human Data Science, Global Trends in R&D: Overview through 2021, 2022, p. 32.
[122] Phillips McDougall, Evolution of the Crop Protection Industry since 1960, 2018.
[123] Deloitte, The Future of Agrochemicals: Capturing value through innovation, resourcefulness, and digital alchemy, 2019.
[124] The average development period for a new PPP has increased from 8.3 years in 1995 to 11.3 years in 2010–2015; the overall R & D costs for a new PPP increased from USD 152 million in 1995 to USD 286 million in 2010–2014. Source: Evolution of the Crop Protection Industry since 1960, Phillips McDougal 2018; for further details see: Annex 5B.
[125] Contrary to the European patent system which is in the process of being 'defragmented', at least for certain Member States, thanks to the upcoming launch of the unitary patent system.

Furthermore, in the reaction to the COVID-19 the Commission issued guidance on using the public procurement framework in the emergency situation related to the pandemics[126], where it mentions clearly the importance of launching joint procurement actions for various medical supplies ("*public buyers […] are encouraged to procure jointly and to take advantage of the Commission's joint procurement initiatives*").

While discussing the actual EU public procurement framework, it should be also noted that pharmaceuticals could be an ideal commodity for the aggregation of demand. Once the items(s) to be procured are described by internationally recognised nomenclature (e.g. International Non-proprietary Names (INN)[127] and/or ATC[128]), they constitute relatively homogeneous goods (i.e. interchangeable and therapeutically equivalent). Yet, despite characteristics that should facilitate procurement processes (i.e. evaluation, comparability of bids, etc.), cross-country joint procurement doesn't happen at a large scale in the EU[129].

Currently public procurement of pharmaceutical products is predominantly local, but contracts are often awarded to subsidiaries of foreign firm (around 60% of deals registered at the EU level)[130]. Unfortunately, calls for tender for pharmaceuticals involving two or more countries do not occur very often, although especially in case of small countries, it could leverage their buyer power by pooling volumes and/or address various concerns in terms of security of supply.

Several cross-country initiatives have been recently established in Europe to jointly procure pharmaceuticals as described in Table 1 below.

Table 1: Overview of three European country collaborations on procuring medicines and vaccines, 2010–2021

Name of initiative	Countries	Activity
Nordic Pharmaceutical Forum[131] (established: 2015)	DK, SE, IS, NO	Joint procurement of medicines
Baltic Procurement Initiative (agreement: 2012)	EE, LV, LT	Joint procurement of vaccines
Beneluxa Initiative[132] (established: 2015)	AT, BE, IE, LU, NL	Joint negotiations on medicines

Source: Based on Vogler, S. et al., European collaborations on medicine and vaccine procurement, Bulletin World Health Organisation 2021, Policy & practice, p.717.

Currently such initiatives seem to focus on older medicines with expired patents to avoid potential legal barriers that otherwise could prevent such procurement from taking effect. It can be inferred that similar concerns also relate to newly elapsed patents where differences in SPC coverage and expiry dates could hamper the scaling-up of joint public procurement of medicines at the EU level.

[126] European Commission, Commission communication – Guidance from the European Commission on using the public procurement framework in the emergency situation related to the COVID–19 crisis, 2020/C 108 I/01, C/2020/2078.
[127] An International Non-proprietary Name (INN) is a WHO nomenclature of pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognised and is public property. A non-proprietary name is also known as a generic name.
[128] Anatomical Therapeutic Chemical (ATC) is a classification system, where the active substances (drugs) are divided into different groups according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties.
[129] This is also for historic reasons and due to country-specific structures of health systems, including different regulatory pricing and reimbursement regimes (e.g. mandatory discounts, etc.), which pose challenges when it comes to cross-country joint procurement.
[130] Contracts below EUR 200 million covered by the EU public procurement directives (See: Annex 5B).
[131] AMGROS, 'About AMGROS: International cooperation' (https://amgros.dk/en/about-amgros/cooperation-partners/international-cooperation/).
[132] https://beneluxa.org/

This in turn may make demand pooling more problematic, especially in a situation of crisis. In particular, contracting authorities intending to procure medicinal products and EU joint procurers of medicines (like the future HERA and EU Fab which aim at preparing the EU for future health emergencies by securing production capacity around the EU) could face increasing challenges to accept bids from generic and biosimilar sectors as the status of SPC protection in some Member States might not be clear. Three quarters of healthcare respondents to the public consultations considered that joint procurement by a group of countries would be easier with one SPC covering the whole EU[133].

To conclude, the patchy and incoherent SPC systems, due to its asymmetric implementation across various EU countries and insufficient transparency about the SPC status, can be perceived as a risk factor and a legal obstacle hampering joint cross-country procurement.

2.6. **How likely is the problem to persist?**

Should no action be taken, the impacts of the current problems – in particular legal uncertainty and costs of obtaining SPC protection in the EU for the innovative pharmaceutical (and PPP) industry – will only intensify, driven by the steady increase in the number of new medicines authorised every year and in the average number of Member States in which SPC protection is sought for a given product. In the context of the ongoing review of the EU's pharmaceutical legislation, it is currently envisaged to make certain regulatory incentives and rewards conditional upon the actual launch of the product concerned on the market[134]. As a consequence, shortening of the basic data protection period from 8 to 6 years is contemplated (unless the certain conditions related to market presence are met), which might impact the demand for SPC (i.e. the share of SPC as the last measure to expire[135] would increase by roughly 5% from 49.6% currently to 54.9% of molecules[136], see: Annex 5B for more detail). While recognising that there could be interaction between the two instruments, such impact is expected to be low in the context of the envisaged reform as it would potentially add from 0 up to 5 new SPCs each year depending on firms' response to the new rules[137]. The above factors will also exacerbate the transparency issues that have been identified (mostly affecting generics makers) as more and more Member States need to be monitored.

The above occurs in a global context with increasing product development time and R&D costs combined with stringent regulatory requirements. Medicine market is expected, nevertheless, to

[133] See: Annex 2, Table 27.
[134] European Commission, Revision of the EU general pharmaceuticals legislation, Inception impact assessment, 2021 (https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12963-Revision-of-the-EU-general-pharmaceuticals-legislation_en).
[135] See: section 2.2.
[136] Understood as a unique pharmaceutical active ingredient or their combination, as defined by International Non-proprietary Names (INN).
[137] Based on the preferred option of the draft impact assessment on 'Revision of the EU general pharmaceuticals legislation' which lowers the basic data protection period from 8 to 6 years but allows for an additional 2 years if all EU markets are covered. The draft estimates that potentially around 5 % of products can be affected by the change. With around 88 marketing authorisations issued each year, this could translate into 4 to 5 additional SPC applications in case firms do not choose to cover all EU markets. At the time of writing this impact assessment, this initiative was at a draft stage, thus these estimates are preliminary and dependent on initiative's adoption and its final form.

grow at 3–6% compound annual growth rate (CAGR) through 2026, reaching about USD 1.8 trillion in 2026, including spending on COVID-19 vaccines[138].

In addition, should no action be taken, the unitary patent system (expected early 2023) would not be mirrored by a unitary SPC – that would have optimally ensured the availability of unitary protection over the whole duration of the entire (patent and SPC) protection period of a given product. The pharmaceutical and PPPs sectors might thus not internalise the full advantages of the unitary patent system.

Furthermore, the EU SPC regime would keep having inferior attractiveness at the worldwide level due to its fragmentation and high costs comparing with other jurisdictions. In this regard, the European Biopharmaceutical Enterprises (EBE), which represents the interests of biopharmaceutical companies in Europe (60% of its members are SMEs) in reply to the Commission public consultation, underlined that any legal uncertainty around SPCs had the potential to deter investment, postpone development decisions and undermine Europe's reputation as a safe haven for research and development. The EBE said that any uncertainty would particularly impact EU-based pharmaceutical SMEs and start-ups, which have fewer resources to undergo lengthy development pathways for their products (they rely on the prospect of getting patent protection and a subsequent SPC in their financing strategies). This, in turn, could ultimately be detrimental to the EU's strategic autonomy.

3. WHY SHOULD THE EU ACT?

3.1. Legal basis

Article 114(1) TFEU governs measures for the approximation of the provisions by law, regulation or administrative action in Member States. It would therefore be the appropriate legal basis for a potential harmonisation or centralisation of the SPC procedures in order to address the current divergent outcomes of national procedures and different transparency mechanisms across EU Member States.

Article 118(1) TFEU allows for measures for the creation of European intellectual property rights to provide uniform protection of intellectual property rights throughout the Union and for the setting up of centralised Union-wide authorisation, coordination and supervision arrangements. The unitary patent, governed by Regulation 1257/2012, is already based on Article 118 TFEU. A unitary SPC, if proposed, would have unitary character and confer the same rights as the basic patent subject to the same limitations and the same obligations. Hence, Article 118(1) is the appropriate legal basis for a Regulation governing the unitary SPC. A language regime for the unitary SPC could be based on Article 118(2)[139].

3.2. Subsidiarity: Necessity of EU action

As explained, despite the fact that SPCs are already harmonised by EU law[140], there are still cases where some Member States have granted SPCs while identical applications have been refused in

[138] IQVIA, The Global Use of Medicines 2022: Outlook to 2026, 2022, p. 2.
[139] Note for this section that the choice of the examination authority may require Article 352 of the Treaty on the Functioning of the European Union as a legal basis should the EPO be chosen.
[140] Regulations (EC) 469/2009, 1610/96.

others, or granted with a different scope. SPC applicants thus face diverging decisions across the EU concerning the same application at hand, while incurring costs for applying and maintaining SPCs in several Member States. The above is equally burdensome for follow-on companies that need to monitor SPC status across many jurisdictions. National publication practices also vary across Member States. Consequently, further EU intervention is needed to address these issues and can, unlike national intervention by Member States, ensure a coherent framework, as well as ease the current burden of applications and renewal fees to be paid in several Member States.

EU action is necessary to provide a unitary SPC for the unitary patent. An EU IP right (such as a unitary SPC) can only be created by the EU[141]. National protection systems alone cannot achieve this objective, as a bundle of national SPC in the enhanced cooperation area of the unitary patent would not give full continuation of the unitary effect of the unitary patent in that area. Consequently, EU action is also needed to create a new unitary right to accompany the unitary patent.

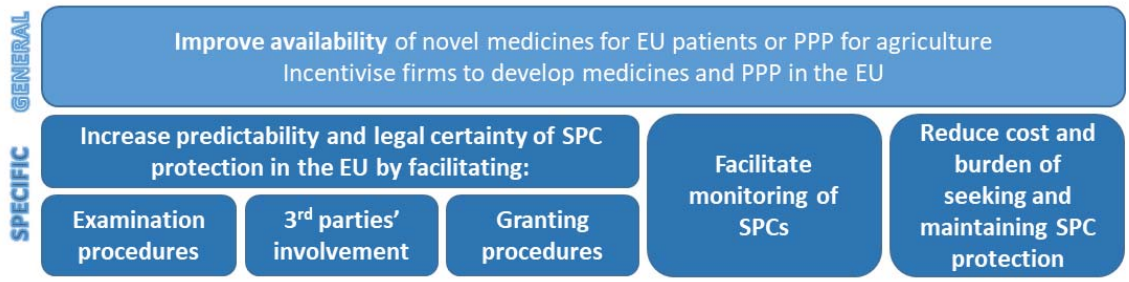
3.3. Subsidiarity: Added value of EU action

EU-level action would enhance the integrity of the internal market by providing for a unitary/centralised, balanced and transparent SPC system in the EU and mitigate the negative consequences resulting from diverging procedures that applicants face. Hence, action at EU level is also justified to ensure the smooth functioning of the internal market for innovative products subject to marketing authorisations, and to permit the benefits of an efficient industrial property framework to be reaped in the relevant product markets.

4. OBJECTIVES: WHAT SHOULD BE ACHIEVED?

With reference to the problems presented above, the following section presents the objectives that should be achieved in order to address them (Figure 5).

Figure 5: Objectives of the initiative



4.1. General objectives

The general objective of the proposed policy actions is to improve the availability of novel medicinal products for EU patients, and of plant protection products for agriculture, and to incentivise firms to develop those products in the EU.

[141] Even the unitary patent, although based on the European patent system, was created by two EU Regulations.

4.2. Specific objectives

In connection with the general objectives and with the problems identified earlier, three specific objectives have been defined:

(1) Increase predictability and legal certainty of SPC protection in the EU. This specific objective can be obtained by:
   - Facilitating substantive examination procedures;
   - Facilitating involvement of affected third parties;
   - Facilitating granting procedures.

(2) Facilitate the monitoring of SPCs in the Single Market, preferably by offering a single point of access to information about the status of SPCs in the EU (e.g. filed, granted, refused, invalidated, renounced or withdrawn), as well as access to structured data on the subject.

(3) Reduce cost and burden of seeking and maintaining SPC protection by investigating possible administrative cost reductions; improve access to procedures to all stakeholders, especially SMEs.

5. WHAT ARE THE AVAILABLE POLICY OPTIONS?

5.1. What is the baseline from which options are assessed?

The baseline scenario (Option 0) is 'no policy change'. The SPC system would continue to operate on the basis of the existing EU and national rules.

5.2. Description of the policy options

5.2.1. PO1: Guidelines for the application of the current SPC regimes

The Commission would, in cooperation with national offices, propose common guidelines/recommendations for the application of SPC rules. The guidelines would describe how to assess the eligibility of a product for SPC protection, including substantive conditions of Article 3 of the SPC Regulations. This could help narrowing gaps regarding divergent interpretations currently observed among patent offices. Guidelines would be a "living document" to be updated according to the evolution of the CJEU's jurisprudence (e.g. on how to interpret Article 3). For example, guidelines could clarify what constitutes a prior certificate (in particular as regards any combination product), and the relationship and split between the subsections of Article 3. The guidelines would further seek to identify and build on NPOs best practices, so that the practice of the examiners remains consistent and predictable[142].

Regarding SPC data, the guidelines would propose common rules for the publication and accessibility of SPC information in national registers. The rules would concern in particular:

- the scope of information that should be publicly accessible, such as: the SPC filing reference number, SPC application status (e.g. in force, cancelled, revoked, expired, annulled), name of the SPC holder(s) including change of ownership if applicable, description of product concerned by SPC, EP reference number, marketing

[142] Major NPOs develop and maintain guidelines which reflect their examination practices, any settled interpretation of certain legal provisions or any doctrines developed over years of practice, etc.

authorisation reference number, SPC date of expiry (if not revoked or annulled), implementation of the SPC manufacturing waiver for medicinal products, as well as the availability of SPC information in a multilingual format (e.g. native language and English);

- the scope of information that should be accessible to stakeholders concerned by the case[143], such as: access to formally admissible SPCs dossiers, third parties opinions, SPC opinions or grant decisions, etc.;
- the ways in which common technical rules on data exchange, storage, publication and data exploration could be agreed between NPOs[144] (e.g. via a dedicated working group of NPO IT experts).

Additionally, the guidelines should promote cooperation and data sharing between NPOs and the EPO (regarding existing European patens) and with the EMA (on marketing authorisations). These guidelines would not be legally binding, and might co-exist with nationally developed guidelines.

5.2.2. PO2: Mutual recognition of national decisions

Under this option, the Commission would propose a legislative initiative that would enable SPC applicants to file an SPC application in a designated NPO, the so-called "reference office", of its choice. Only NPOs of Member States that fulfil a number of conditions could act as reference offices. These conditions would include having sufficient resources to conduct substantive examination of all the conditions for granting an SPC (in accordance with Article 3 of the SPC Regulations)[57]. An up-to-date list of offices would be published. A system allowing third parties to submit their written observations concerning an ongoing SPC procedure would be set up at all the reference offices. All communication with the reference office would be in the language(s) accepted by that office. Following the grant of an SPC by the chosen reference office, the SPC applicant could seek SPC protection in other Member States. In other words, the decision of the reference office would be implemented by the other national patent offices. For this option to be operative, the basic patents of the designated and reference Member States should be based on the same European patent to have a common set of claims[145] (in order to result in the same scope of patent protection). In the same vein, for medicinal products, the marketing authorisation should be based on a centralised marketing authorisation for the related SPCs.

To avoid the risk of "double SPC protection" or "double attempt of SPC protection", the possibility of seeking SPC protection through purely national routes in the Member States should not be available once this mutual recognition procedure is triggered for a product.

The option should preferably be combined with PO1 as all NPOs that can act as reference offices would be expected to work on the basis of common guidelines relying on the best practices and on a

[143] For example, commercially sensitive information may involve more restricted access rules.
[144] A decentralised data management system (a data mesh) could be proposed to integrate data from the disconnected IT systems of NPOs.
[145] Rule 138 of the EPC, based on Article 139(2), provides for the possibility that at least one Member State had a different set of claims if a national patent application was filed on the same priority date of the European patent ('a national patent application and a national patent in a Contracting State shall have with regard to a European patent designating that Contracting State the same prior right effect as if the European patent were a national patent').

common interpretation of EU legislation and case law. Each NPO would be expected to cooperate in setting up an SPC data exchange system with features as described in PO1.

5.2.3. PO3: Centralised filing and examination of SPC applications resulting in a non-binding opinion

The Commission would set up a single entry point for filing SPC applications in the EU for holders of European patents and EU-centralised marketing authorisations[146]. Applicants would use a common form, attach the patent dossier and marketing authorisations and select in which Member States they seek SPC protection. Such application would be examined[147] by a dedicated "central examination authority" (potentially with involvement of experts from NPOs). All conditions for obtaining a certificate would be examined[148]. The application would be published and open to written observations as to validity/eligibility by third parties (most importantly, originators, follow-on manufacturers or public health authorities). Written observations[149] would be considered by the examiners in the process of issuing the opinion. However, examiners would not have to give reasons concerning how the observations were taken into account[150]. The outcome of the examination would be a non-binding opinion on whether the SPC should be granted or not. The examination authority could be a "virtual office" composed of SPC examiners from NPOs or an existing authority such as: the European Union Intellectual Property Office (EUIPO), the European Patent Office (EPO) (both of which are specialised in granting IP rights), or an EU regulatory agency dealing with marketing authorisations, such as the European Medicines Agency (EMA) or the European Food Safety Authority (EFSA)[151]. All interactions with the authority should be possible in electronic form in all EU languages, and the same would apply to the availability of decisions taken by the examination authority (e.g. e-submission using a standard application form and e-access to SPC documents by applicants).

Applicants would be charged a central fee. It would cover filing and examination only. It should also fully cover any additional costs of the central authority. An annual SPC maintenance fee could be collected by Member States in which the SPC is granted (no application fee at the national level). The submission of written observations could also be subjected to a fee.

The application, opinion and observations would be sent for further processing to each Member State designated by the applicant. Each NPO would decide whether to grant a national SPC in its

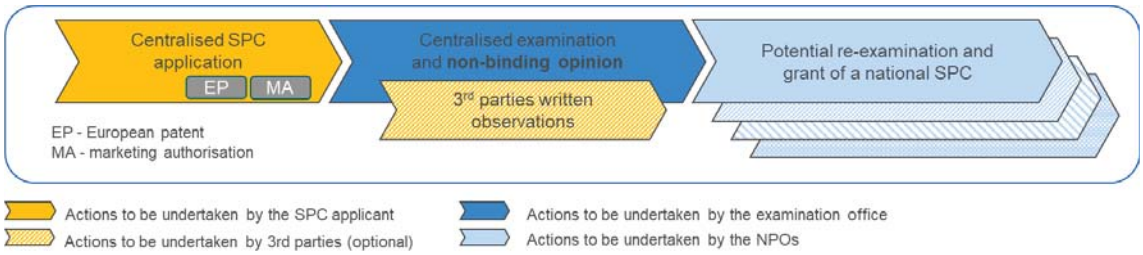
[146] In case of PPP there is no central marketing authorisation, but a mutual recognition system following a single assessment.
[147] Notably assessment of compliance with Articles 2 to 3 of the SPC regulations.
[148] As per Article 3 of the SPC regulations (see: footnote 57), exemptions of Article 10(5) would not apply to the central authority (see: Section 2.4.1).
[149] As the centralised procedure results in a non-binding opinion that does not have to be followed by the designated NPOs, opposition proceedings cannot be established.
[150] As opposed to the formal opposition proceedings in the patent system which, contrary to third-party observations, are *inter partes* proceedings.
[151] EUIPO is already responsible, *inter alia*, for the single filing, examination and grant of the EU trade mark and the registered Community design, two unitary intellectual property rights valid across the 27 Member States of the EU. EPO grants the European patents with unitary effect that serve as 'basic patents' for SPC applications under which a unitary SPC is requested. EMA is responsible for the assessment of centralised EU marketing authorisations of medicines, and EFSA - for the risk assessment of plant protection products. These organisations were the most frequently mentioned by the industry in public consultations and Allensbach survey.

territory or not. Appeals against such national decisions would be governed by national law. While the opinion of the EU examination authority would be non-binding, the freedom of NPOs to deviate from the opinion could be restricted to cases where factual circumstances in the country concerned have changed, for instance whereas the validity of the patent underlying the SPC has been challenged by means of a request for revocation or the marketing authorization for a product has been withdrawn.

The examination authority would need to develop and maintain guidelines for its own examination practice, following open and inclusive consultation with NPOs. The national SPC route could be closed for applicants able to use the centralised procedure[152].

The examination authority would provide a single access point for e-submission of SPCs using standard forms, as well as an IT system (a data warehouse) for a comprehensive recording and on-line accessibility of up-to-date data related to SPCs filed through the centralised procedure. The key building blocks of such IT system[153] should include a central database, ETL tools[154], metadata, and data access tools. The business requirements of this IT tool should be in line with common rules for the publication and accessibility of SPC information foreseen in PO1. For completeness, it would be also recommended that key information on SPCs granted by NPOs via the national route is shared with the examination authority and is made accessible through its central web portal.

Figure 6: Steps of Policy Option 3



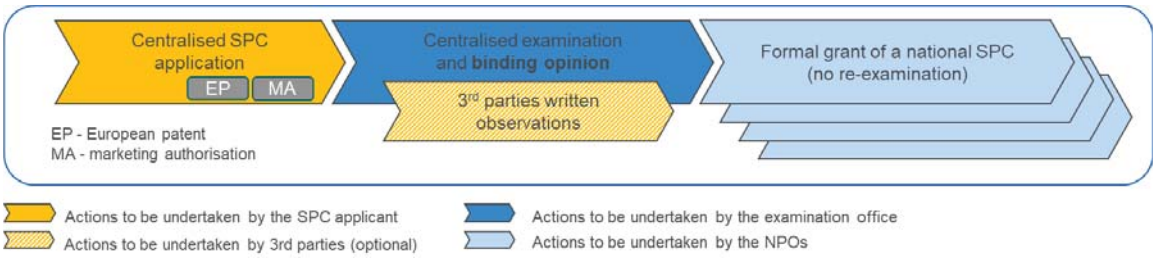
5.2.4. *PO4: Centralised filing and examination of SPC applications resulting in a binding opinion*

This option is identical to PO3, except for the key distinguishing feature that the examination authority would issue a binding opinion on the validity of a centralised SPC application. The NPO of each Member State designated in the application would have to implement it and formally grant, or refuse, the SPC in its territory. Therefore, in practice, the result of the centralised procedure under this option would be equivalent to either the granting of a bundle of national SPCs, or the rejection of the application, for all designated Member States.

[152] It may be foreseen that under certain conditions the centralised procedure has to be used in order to reduce the risk for national discrepancies (e.g. as soon as certain criteria are met, such as holding a European patent and a centralised marketing authorisation).
[153] A detailed analysis of current IT systems processing SPC data in each NPOs would precede the harmonisation of data input and further data integration into a central SPC database. It would focus in particular on the systems used, volume of data, system change management (e.g. upgrades, external provider), online accessibility, etc.
[154] ETL is a process that extracts, transforms, and loads data from multiple sources to a data warehouse or other unified data repository. Source: IBM, 'ETL (extract, transform, load)', 2020 (https://www.ibm.com/cloud/learn/etl).

Given the binding nature of the above, an applicant should be able to appeal a (negative) opinion before it is transmitted to national offices.

Figure 7: Steps of Policy Option 4

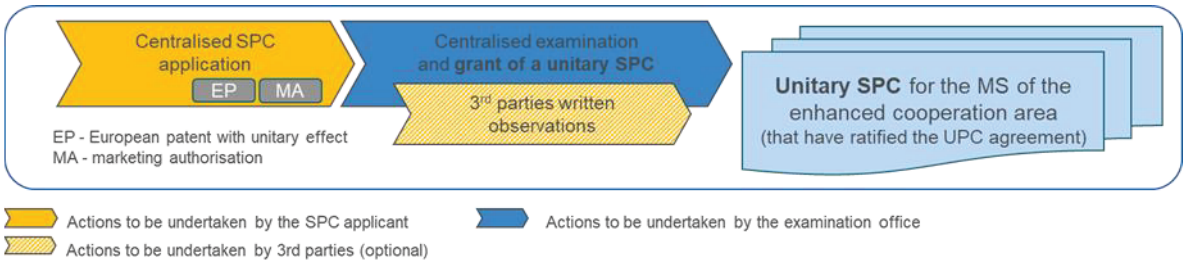


A central IT system for SPC data would be set-up, as described in PO3.

5.2.5. PO5: A 'unitary SPC' complementing the unitary patent

Under this option, the Commission would present a legislative proposal for the creation of a "unitary SPC" title, granted by an EU-level authority (the central examination authority, as in PO3 and PO4). It would take effect at the end of the lawful term of a basic patent that would be a European patent with unitary effect (i.e. the unitary patent). Therefore, it would have unitary effect only for the territories of the Member States covered by that basic unitary patent[155].

Figure 8: Steps of Policy Option 5



The unitary SPC protection would be optional for the users of the unitary patent system (it could become the only choice after a transitional period). Once it is chosen, the national route in Member States participating in the unitary patent system would be closed to avoid duplication of protection.

The key features described in policy options PO3 and PO4 (centralised procedure) would broadly apply to this option. In particular, applications for unitary SPCs would be submitted to the examination authority, which would conduct the formal and substantive examination of the applications, take written observations into due consideration and grant or refuse the unitary SPC protection. The unitary SPC protection would come into effect in the territories of the Member States participating in the unitary patent system (party to the UPCA – assuming that they are covered by the basic unitary patent concerned) without any validation by the NPOs.

The linguistic regime in this option could be as in PO3 and PO4, however instead of covering all EU official languages, it could be limited to the official languages of the unitary patent area. All

[155] The enhanced cooperation for unitary patent protection remains open to all EU Member States which may join any time. Please note that European patents to which unitary effect has been attributed at different dates might have different geographical coverages, depending on the state of play of UPCA ratifications at these dates.

administrative fees (application and annual renewal) would be paid to the central examination authority.

It should be possible to lodge an appeal against the decision on granting or refusing protection to the examination authority (the Board of Appeal)[156]. Judicial appeals related to the decision of the examination authority, if it is an EU agency/body, would be addressed to the CJEU. A central IT system for unitary SPC data would be set-up, as described in PO3.

Conversion of unitary SPCs into national SPCs

There are rare situations in which a European patent with unitary effect may see its unitary effect being denied or revoked by the UPC at the time when the validation deadlines have already expired – making it impossible to validate the European patent nationally any longer (except in few Member States where no validation formalities are required). To address such a risk, the vast majority of the UPCA Contracting States have introduced national "safety-net" legislation providing for a possibility to convert a unitary patent into a national patent. Although such situations should be quite exceptional, they remain possible, and therefore it would be advisable to provide for a procedure allowing unitary SPCs to be converted in national SPCs, under specific conditions.

5.3. Overview of policy options

The table below provides a short summary of key differentiating features of all options considered.

Table 2: Main features of the analysed policy options

<table>
<tr><th></th><th>PO1: Guidelines</th><th>PO2: Mutual recognition</th><th>PO3: Centralised procedure with a non-binding opinion</th><th>PO4: Centralised procedure with a binding opinion</th><th>PO5: Unitary SPC</th></tr>
<tr><td>NPOs examination procedures harmonisation</td><td colspan="2">Guidelines</td><td colspan="3">EA guidelines + possible national follow up</td></tr>
<tr><td>New IP right</td><td>n/a</td><td>No</td><td>No</td><td>No</td><td>Yes</td></tr>
<tr><td>Filing authority</td><td>n/a</td><td rowspan="2">One 'reference NPO' per application</td><td colspan="3">One centralised EA</td></tr>
<tr><td>Examination authority</td><td>n/a</td><td>One centralised EA + NPOs can re-examine</td><td colspan="2">One centralised EA</td></tr>
<tr><td>Third party observations</td><td>n/a</td><td>Yes</td><td colspan="3">Yes, at the centralised EA</td></tr>
<tr><td>Granting authority</td><td>n/a</td><td>NPOs, but cannot depart from the reference NPO's opinion</td><td>NPOs</td><td>NPOs, but cannot depart from the EA´s opinion</td><td>Centralised EA</td></tr>
<tr><td>For which patents</td><td>n/a</td><td colspan="3">European patents (EP)</td><td>EP with unitary effect (unitary patents)</td></tr>
<tr><td>For medicinal product: which marketing</td><td>n/a</td><td colspan="4">Centralised (marketing authorisation issued by the European Commission following EMA opinion)</td></tr>
</table>

[156] Unlike PO4, this would be a full procedure and thus entail a review against negative grant decisions by the BoA and, ultimately, the CJEU. As in Article 165 of the EU trade mark regulation, the composition of the Boards of Appeal could be comprised of three members, with the possibility of a Grand Board for specific cases.

	PO1: Guidelines	PO2: Mutual recognition	PO3: Centralised procedure with a non-binding opinion	PO4: Centralised procedure with a binding opinion	PO5: Unitary SPC
authorisations (MAs)?					
Centralised litigation	For those MS having ratified the UPCA (17 UP-MS as of 2022)				
Member States (MS) covered	All 27 MS				MS having ratified the UPCA (17 UP-MS as of 2022)
Binding nature Legal basis	Voluntary	Art. 114 TFEU + voluntary guidelines			Art. 118 TFEU
Relation with the launch of the unitary patent system	Irrespective of the unitary patent system launch				Once the unitary patent system starts

**EA – examination authority, EP- European Patent, NPOs – national patent offices*

5.4. Options discarded at an early stage

The option where the centralised examination authority would grant national SPC directly was discarded as it does not appear to be feasible based on the EU treaties (neither Article 114 TFEU on harmonisation of national laws, nor Article 118 TFEU on unitary IP rights).

Extending the 20-year term of protection of the basic patent by up to five years (the US model) as an alternative to the current SPC system – while this would have the same practical result – was also discarded. First of all, this would represent an extremely drastic change and would require very deep modifications in both legislation and Member States' (national offices') operations. This change would likely open up several years of fluctuating granting practices and case law, and is not expected to result in particular savings as each Member State concerned would still have to examine and grant extension requests. In addition, there are no evident advantages in replacing the current SPC system with a patent term extension regime. On the contrary, a *sui generis* right offers more flexibility to the EU legislator, as was shown by the introduction of the SPC manufacturing waiver in 2019 (Regulation 2019/933).

An option to amend SPC Regulations by: i) elimination of the possibility to grant SPC without verifying all the criteria[157]; and ii) codifying CJEU jurisprudence - was also rejected. From Commission's contacts with Member States it emerges that this exemption is vital for NPOs with limited resources, and even large NPOs reported problems in applying all the criteria. More importantly, even without the exemption significant divergences between NPO decisions would remain due to differences in national SPC administrative procedures. At the moment, the transposition of CJEU jurisprudence into the EU law would be premature. While the Santen case clarified some aspects of prior case law, the latest two referrals to the CJEU have demonstrated that there are still uncertainties in particular on Article 3a and 3c (see: section 2.4.1).

Finally the option to eliminate SPCs altogether is not considered further following the findings of the evaluation that SPC system supports research of new active ingredients, is fit for purpose and brings

[157] Article 10(5) discussed in Section 2.4.1 allows granting SPC without verifying if the product has not already been the subject of a certificate, and if the marketing authorisation is the first authorisation to place the product on the market.

added value. As well as the fact that all major jurisdictions (e.g. the US, JP, CN) around the world offer comparable additional patent protection. Lastly, eliminating SPCs would be incompatible with the international commitments of the EU taken in a number of bilateral and regional trade and cooperation agreements with third countries, as they include commitment to some form of extended protection.

6. WHAT ARE THE IMPACTS OF THE POLICY OPTIONS?

Further to the analysis below on the impact of the identified options, the tables in section 7 provide a detailed summary of the impact of all options described above. All quantifications quoted below are based on calculations in Annex 5D to 5G. Additional material on the impacts on SMEs is also provided in Annex 6 (the SME Test).

The most important analysis concerning objective 1 (legal certainty) and largely 2 (monitoring) is not quantifiable. Where possible, quantifications where made (mainly on objective 3 – cost reduction) using the following assumptions for EU wide impacts: around 100 SPC applications per year, out of which 80 SPC granted (based on the analysis in section 2 taking into account future increases and historical averages for the rejection rate); 300 follow-on companies[158] and at least one medicines procurement office per Member state interested in monitoring SPC status. It is also assumed that applicants use of legal advice in each Member State where they apply for SPC, as well as that SPC protection is sought in all EU Member States and maintenance fees are paid for the maximum five-year-long protection (for alternative scenarios see: Annexes 5D and 5E).

PO 0: No action (status quo or base-line scenario)

The problems identified in Section 2 would persist with the described consequences, even if the Commission continues to promote better implementation of the SPC Regulations. A *status quo* would worsen those problems considering the increasing average number of Member States in which SPC protection is sought for a given product and the entry into force of the unitary patent system.

Table 3: PO0 (baseline) costs and savings to applicants for receiving EU27 wide SPC protection (EUR).

	EUR per application
Application fee	8 800
Maintenance fees for 5 years	183 000
Translation costs	4 000
Agent/attorney's fees	54 000
Total	249 800

Source: own estimations, numbers rounded see: Annex 5E

6.1. PO1: Guidelines on application of the current SPC regimes

Several Member States already have national guidelines, which could be a source of inspiration/best practices for the common guidelines developed jointly the Commission and Member States. Four out of five patent offices responding to the public consultation, several judges and IP lawyers stated that national guidelines exist in their Member State and are frequently updated following CJEU rulings[159].

[158] "Within three years following the LoE [loss of exclusivity] the ratio of generic companies to originators is about 6:1" (source: European Commission, Directorate General Competition, Pharmaceutical Sector Inquiry, 2009, p. 74). With up to 50 molecules where competition emerges, the estimated number of follow-on producers affected is 300. Also see: section 6.6.1.

[159] See: Annex 2.

Moreover, since the CJEU line of judgements on SPC is still evolving, guidelines seem a good instrument which could be frequently and easily updated.

The main drawback of this option is that the effectiveness of any guidelines is undermined by the fact that they are not mandatory. Therefore, if this option is chosen, it is essential to secure wide acceptance by Member States. This may entail a long negotiation process to settle for the commonly accepted version. Nonetheless, the adoption of guidelines alone gives no certainty that the situation would improve. Several countries would like to continue developing their national guidelines to cater for country specific legal situation/processes. The freedom to depart from guidelines, combined with the possibility to interpret them differently, shows limitations of this option.

As far as the exchange of SPC-related information is concerned, developing common guidelines on the scope of publication and the characteristics of dedicated IT tools, can prove very useful to NPOs. The degree of data integration[160] will depend on the willingness and technical capabilities of NPOs, but having better access to standardised and searchable SPC data could undoubtedly facilitate knowledge sharing. It shall be nonetheless noted that upgrading the existing SPC databases to common standards would imply certain costs (especially if historical files needed to be converted to new formats as well). If NPOs decided to create an EU-wide central SPC database, it could actually limit the IT cost per country.

Consequently, guidelines are expected to limit divergence, but cannot eliminate it altogether. Their scope and the extent of uptake would be the deciding factor. The IT costs may limit the interest of NPOs with lower number of applications or low SPC fees. Cost to applicants would not change.

Stakeholder feedback

This option was the preferred action to improve consistency of interpretation of SPC previsions throughout the EU to around 75% of follow-on manufacturers, healthcare sector and patent offices and lawyers during the public consultations. On the contrary only 7% of originators selected it.

On 21 October 2019, the Group of Industrial Property Policy (GIPP) experts from EU Member States discussed the possibility of creating common guidelines regarding the granting of SPCs. Guidance in the form of good practices prepared by a working group of national SPC experts, possibly under co-ordination by the Commission, was the option preferred by the majority of Member States taking the floor. For many participants, this option would have an advantage of offering more flexibility compared to SPC guidelines issued by the Commission, which would have to stay within the strict limits of the case law of CJEU. Some Member States pointed out that the usefulness of any such guidance could be limited in light of the still evolving CJEU case law and the fact that Court has the final say in interpreting the provisions of the SPC Regulation. A few Member States were reluctant regarding soft-law approaches as it may be premature in light of the upcoming entry into force of the unitary patent and of the evolving case law, and result in a duplication of efforts on EU and national

[160] NPOs can for example agree to use standard specifications to structure their SPC data and enable interoperability. The scope of such data exchange can stretch from just a few key variables (e.g. the SPC identifier, date of submission or decision, identification of the applicant, subject matter, SPC status) to capturing all information that constitutes an SPC file. Similarly, NPOs could agree on periodic data feeds (hence accepting some time lags) or target real-time data processing to strengthen the informative prowess of a common IT system.

level. During the GIPP meeting in November 2022, eight Member States expressed preliminary support for this option out of 17 that took the floor.

6.2. **PO2: Mutual recognition of national decisions**

Linguistic regime

As far as PO2 (mutual recognition) is concerned, only one language would be necessary to prosecute the application at the reference office, potentially eliminating upfront translation costs. However, savings of this option could be lower, if the resulting bundle of national SPCs and the dossier on examination conducted in the reference office required translation into all official languages of the designated Member States – adding around EUR 870 per each additional language[161]. The translation cost could be covered either by an increase in fees charged by the reference office, or by diminishing the income from maintenance fees received by NPOs. It is also possible that not all NPOs would require such translations. Nevertheless, EU law cannot impose the use of any (other than local) language on national authorities as this is in Member States' competence only.

Impact on NPOs

Those NPOs that decide to act as reference office would conduct the formal and substantive examination of SPC applications (would have had to be done anyway with the current system of nationally granted SPCs, albeit the numbers of applications may differ). Since it is expected that several NPOs would obtain the status of a reference office, their SPC-related workload would decrease compared to the current situation, because the average workload would be shared by several offices. On the other hand, reference offices risk not having a homogenous workload year after year, which might create challenges regarding the employment of their SPC department. Based on an earlier analysis 15 NPOs could qualify as not applying any exemptions. Using the geographical distribution of applicants to the German office, one could expect that around 58% of applications would be in English, up to 23% in German, up to 20% in French, up to 13% in Italian, 7% in Dutch, and 3% in Swedish[162]. With around 100 SPC applications expected annually, it would be likely that only three reference offices emerge: that is IE for English applications, DE for German and FR for French[163]. Regardless of which offices become the reference ones, with an average application fee of EUR 360 charged by qualifying NPOs, the remaining NPOs would lose around EUR 0.84 million annually in application fees (on average around EUR 32 300 per NPO)[164]. Additional variable translation fees of EUR 870 per language of designated Member State would probably be charged to cover translations (around EUR 20 000 for the whole EU). Non-reference offices would get their SPC-related tasks considerably facilitated as they would receive SPC applications that had been already examined (and cleared of any formal errors, if detected). As analysed in PO1, NPOs would have to invest in the readjustment of their IT systems to common publication rules and/or invest in creating a

[161] Note there are 24 official EU languages, but translation would be needed for 23 (24 less the language of the application).
[162] For countries with several official languages (e.g. BE has three: French, Dutch and German) it was assumed that all applications can be in any of these languages, hence the sum is above 100 % and that all non-European applicants will apply in English. For details see: Annex 5C.
[163] AT (German-speaking) and BE (French-speaking) offices are using SPC examination exemptions thus are not considered.
[164] See: Annex 5F, Table 69.

central publication hub for the EU. The one-off cost of the latter is expected at EUR 19 000 per NPO with annual maintenance cost of around EUR 2 200[165].

Impact on applicants and follow-on manufacturers

Regarding problem 3 (cost and burden of applying and maintaining SPC protection), option PO2 can be expected to reduce the cost (both administrative fees and attorney fees, as well as translation related to filing and prosecution) of applying for SPC protection. This option would introduce a single filing of an SPC application at an NPO that would undergo one substantive examination followed by an automatic recognition by the EU Member State designated in the SPC application (no additional re-examination by the other NPOs is expected). The application forms and internal processes would continue to differ between NPOs. Maintenance costs would not be reduced, as the outcome of this option is a bundle of national SPCs and therefore Member States would be expected to continue to request annual maintenance fees as currently.

SPC applicants would be able to choose one reference office to examine their file. This should lead to an increase of predictability and legal certainty regarding SPC protection in the EU. Divergent examination outcomes for the same product would be eliminated. In addition, the quality of examinations should improve, as only NPOs verifying all conditions stipulated by the SPC Regulations could qualify as a reference office (therefore meeting expectations of follow-on producers - 86% of whom thought NPOs should check all conditions)[166]. However, improvements in predictability would be limited by the fact that some reference offices could be more lenient than others, and each reference office could adopt/change its own standards of assessment. Consequently it is vital that common guidelines developed in PO1 are followed. The date on which SPC is granted in each Member State could still slightly differ due to length of internal processing in each NPO. This option cannot provide unitary SPC protection for unitary patents understood as a single IP title for the EU, but a bunch of national patents.

This option would, to some extent, boost transparency because as in PO1 each NPO would be expected to publish the same kind of information in comparable formats. Alternatively, a network of reference offices could establish a common publicly available database on common SPC applications, updated with national SPCs information. Nevertheless, follow-on producers and health sector procurement offices would need to consult each NPO database to gain a complete picture of the market, unless a more integrated data exchange system is agreed between the NPOs. This should produce individual savings of around EUR 40 000 (approximate cost of acquiring commercial dataset with comparable data) and EU wide annual savings of EUR 12 and 1 million respectively. Follow-on producers and health sector would also gain opportunity to influence the SPC granting process, as each reference office should allow for submission of third party observations.

One of the main advantages of PO2 is that its implementation is not linked to that of the unitary patent system, and not restricted to those Member States (currently 17) that are not part of the enhanced cooperation area. It can be operative for all EU Member States, as soon as the related legislation is adopted.

[165] Based on the estimated cost of developing a central database of EUR 0.5 million that could be shared equally between all NPOs. See: Annex 5F.
[166] See: Annex 2.

Nonetheless, this option could create forum shopping across the internal market (e.g. SPC applicants might file applications in NPOs perceived as more lenient when assessing the requirements for granting SPC applications). It would improve harmonisation between national decision-making regarding SPC applications only as far as guidelines can allow (discussed under PO1).

This option is expected to reduce the cost of applying for five-year-long SPC protection covering the whole EU by approximately 18% (due to a single application fee, a single attorney fee, as well as potentially limited translation costs). This would result in savings of around EUR 44 200 per applicant [167]. Savings on attorney fees would at the same time represent a loss of income for this group estimated at EUR 52 000 per SPC application.

Table 4: PO2 costs and savings to applicants for receiving EU27 wide, five year long SPC protection

	EUR per application	Savings vis-à-vis baseline
Filing fees	20 400	-11 600
Maintenance fees for 5 years	183 000	0
Translation costs	200	3 800
Agent/attorney's fees	2 000	52 000
Total	205 500	44 200

Source: In-house estimations, numbers rounded to 100s, see: Annex 5E

Stakeholder feedback

On 21 October 2019, the Group of Industrial Property Policy experts from EU Member States discussed the possibility of creating a mutual recognition mechanism for the grant of SPCs across EU Member States. The majority of Member States expressed the view that a system based on a mutual recognition of SPC was not desirable.

In the Allensbach survey[168], in response to question Q70 asking which one of the listed authorities should grant unitary SPCs, only 6% of respondents supported such organisational setting (i.e. 3 originators and 16 generics companies chose "national patent offices based on a mutual recognition system" as the best option). By contrast, around 85% of originators supported this option in the Commission public consultations[169].

6.3. PO3: Centralised filing and examination of SPC applications resulting in a non-binding opinion

Linguistic regime

For reasons of accessibility (especially to SMEs) and transparency, PO3 to PO5 foresee that the SPC application filed with the examination authority, third party observations and the outcome of SPC examinations should be available in all 24 EU languages. Other language combinations are analysed in Annex 5C.

Consequently, translation costs would be generated in the examination authority which needs to process applications and third party observations in its working language(s) (e.g. for EPO: German, English, French; EUIPO: German, English, French, Italian and Spanish; EMA: English). Additionally, in

[167] Or 23 % cheaper in case of an average SPC (covering 20 Member States for 3.5 years).
[168] See: Annex 2, Figure 13.
[169] See: Annex 2, Table 28.

case of PO3-4 the examination authority would need to translate the decision into languages of the designated NPOs.

Translation costs relating to the application itself are expected to be low. A standard application form would be available in all languages. Much of it is about information not requiring any translation, such as the references of the basic patent and of the relevant marketing authorisation (already translated)[170], and in most cases the identification of the product. Additionally, as discussed under PO2, between 78% and 90% of applications have historically been filed in English, German and French, so in the working languages of the authorities considered. Translation of third party observations and of the SPC dossier for each designated NPO is expected to be the main cost-driver responsible for up to 9% and 65% of translation costs respectively.

English, French and German as the preferred languages for applying for an SPC were the first choice for originators (78%) and patent attorneys/lawyers (63%) and the second for follow-on producers (25%). The follow-on producers added Italian and Spanish to the three above as their preferred choice (34%). All EU languages were selected by 19% of follow-on producers, 8% of patent offices and 3% of originators. The language preferences are similar when it comes to publication of the granted SPCs. Finally, the healthcare sector (e.g. hospitals, health ministries, pharmacists) would welcome SPC publication in English, French and German (46%) followed by all EU languages (38%)[171].

Annual translation costs for the central authority in respect of approximately 100 SPC applications are expected to be around EUR 3 million[172]. The bulk of such cost is due to translations to national languages of NPOs when transmitting the opinion of the central authority. Machine translations (if of sufficient quality) could limit the translation costs.

The choice of an examination authority

Under options 3 to 5, a dedicated authority should be designated to conduct SPC examinations. All authorities considered (EUIPO, EPO, EMA and EFSA) are potentially suitable for that task.

When vesting an institution with SPC responsibilities a few criteria should be considered. First, there is the accountability to the EU public, in particular the European Parliament. Second, there is the need for alignment with the EU's overarching political values and current policy priorities. Third, experience with substantive SPC assessment, and more broadly post-grant patent law, is relevant. Last but not least, the possibility of judicial review by EU Courts is of an appreciable importance.

The EPO has been granting European patents for nearly four decades; hence it has accumulated valuable practical expertise in similar matters or functions (including its Boards of Appeal). It will also be granting unitary patents. However, the EPO is not an EU body, thus any decision to enhance or modify its mandate (e.g. amending fees) would go beyond the competences of the EU and require the consent of all members of the European Patent Organisation (39 countries including 12 non-EU countries). It is impossible to foresee whether or not the European Patent Organisation members would agree to take up a new duty related to SPC examination, especially if it didn't affect all the contracting parties. Finally, the decisions of the EPO are not subject to the review of the CJEU, nor to

[170] The centralised marketing authorisation issued by the EMA is already officially available in all official languages of the EU.
[171] See: Annex 2, Table 30.
[172] It would equal roughly EUR 3 million in PO4 and EUR 1 million in PO5. See: Annex 5D, Table 58.

the scrutiny of the European Parliament. Full and clear accountability of the granting body was requested by the main European association of generic and biosimilar industries.

These concerns do not affect EU agencies. When looking at experience in administering IP rights, the EUIPO would be best equipped to take up the role of centralised SPC examination authority, while the current duties of the EMA/EFSA are probably the least related to such new tasks. Furthermore, entrusting the EMA/EFSA with SPC evaluation and granting would also imply a split in the registration of SPCs for medicinal products (EMA) and PPPs (EFSA), creating room for disparity of practices.

If the role of the examination authority is taken up by any of the above organisations, a specific department for the implementation of the task related to the centralised SPC procedure should be set up. Alternatively, the substantive examination could be conducted by a pool of national SPC examiners (a "virtual office") acting alone or under the administrative support/coordination of a central body. This would allow to benefit from the experience of national SPC examiners, gathered through national procedures. A self-standing virtual office would most likely require one coordination office, thus cost-wise it would be similar to choosing an agency. It would also appear to be legally impossible for a virtual office itself to grant unitary SPCs as in PO5[173].

A system of compensation to national offices (loss or SPC revenue, remuneration to examiners) should also be set up (e.g. EUIPO already has a system of sharing its surplus with Member States)[174]. Key characteristics and consequences stemming from a decision in favour of any of the above institutions is presented in Table 46 in Annex 5C.

Around 85% of originators in the public consultation preferred that NPOs acted as such authority (either as virtual office, or through mutual recognition (PO2)). The EPO was chosen by 48% of follow-on manufacturers and 6% of originators. The EUIPO was selected by only 1-2% of those respondents[175]. Similarly, 54% of respondents to the Allensbach survey were in favour of establishing a virtual patent office composed of examiners from national patent offices[176]. The second most supported choice was the EPO (25%), followed by the EUIPO (8%) and the EMA (7%). The virtual office solution shows that stakeholders recognise that SPC expertise is located in NPOs. High support for the EPO can be due to the fact that SPC stakeholders are most familiar with this organisation as it

[173] In practice this would mean that one of the NPOs is issuing a unitary SPC to cover the whole EU in case of PO5, which in itself does not seem to be legally possible given that the unitary SPC would have effect in all Member States participating in the unitary patent system.
[174] Pursuant to Article 172 of Regulation (EU) 2017/1001 of 14 June 2017 on the European Union trade mark, the EUIPO shall offset certain costs incurred by national IPOs. More generally, Article 152 provides for financial support which may be given from the EUIPO to national IPOs for projects in the framework of promoting convergence of practices and tools. Similar provisions or amendments to allow for fee sharing could be envisaged here. The EPO already has a system in place for sharing a fraction of the renewal fees with Member States: European Patent Convention (Article 39(1)) states that 'Each Contracting State shall pay to the Organisation in respect of each renewal fee received for a European patent in that State an amount equal to a proportion of that fee […]' and Regulation (EU) No 1257/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection states in Article 13 that 'The EPO shall retain 50 per cent of the renewal fees referred to in Article 11 paid for European patents with unitary effect. The remaining amount shall be distributed to the participating Member States in accordance with the share of distribution of the renewal fees set pursuant to Article 9(2)'.
[175] See: Annex 2. A high number of follow-on producers (38 %) chose the creation of a new EU agency. This option, however, is not considered, as it would involve disproportionate costs (new management, infrastructure, personnel) for approximately 100 SPC applications a year.
[176] MPI (2018) – Annex III Allensbach survey, Question 70 (see: Figure 30 in Annex 5C).

deals with patents, while EU agencies are not associated with patents by stakeholders, which could explain the low support they enjoy.

Though such preferences are divergent, the choice in favour of the EUIPO is compatible with Medicines for Europe's (largest association of follow on producers in the EU) view that the granting authority for the unitary SPC should be accountable to the EU Institutions (e.g. CJEU and European Parliament) given the impact of SPC protection on access and affordability of medicines.

Table 5: Merits of potential candidates for the central authority

Selection criteria->	Accountability to the EU public	Alignment with the EU policies	Technical expertise with SPC examination	Other considerations*
EPO	(0/+) Some, indirectly, as EU MS have 70% of the votes	(0/+) Policy reflects views of all 39 member states; changes require the majority of them to agree	(0) None, only expertise in European patents, collaboration with NPOs	(++) Around 25% support from stakeholders regarding new SPC-related tasks
EUIPO	(++) Full, EU agency	(++) Implements EU policy/legislation	(0) None, but experience with other IP rights, collaboration with NPOs	(+) Around 8% support from stakeholders
EMA and EFSA	(++) Full, EU agencies	(++) Implement EU policy/legislation	(0) None, expertise in marketing authorisations	(+/0) Around 7% support from stakeholders; SPC responsibility split between EMA (medical SPCs) and EFSA (PPP SPCs)
Virtual office of NPO experts	(+) Accountable to the MSs concerned	(++) Implement national IP policy, as well as existing EU policy/legislation	(++) Skilled SPC experts already available	(++/-) Highest stakeholder support at 54%; no coordination centre; not suitable for granting a unitary SPC (PO5)

* Stakeholders support based on MPI (2018) – Annex III Allensbach survey

Source: Own analysis

The table above compares merits of different choices for the central authority. Against such a multi-dimensional backdrop none of these organisations is perfect for the job. It would seem however, that the best result in terms of the three criteria identified at the beginning of this section could be achieved by combining the expertise of NPOs with the EU accountability of the EUIPO (which already implements various aspects of the EU IP policy). Such solution would allow to implement both centralised (PO3 and 4) and unitary (PO5) SPC activities. The new authority would be tasked with setting up a network of examiners from NPOs, creating guidelines and standard application forms, developing working methods and an IT system, as well as dealing with the daily routine of administering the SPC procedure (implying expenses related to salaries of examiners and translations).

Cost-wise, the establishment of a centralised SPC processing function in an existing authority is expected to create one-off costs of around EUR 1.4 million (including EUR 0.5 million for creating a central database) and recurrent annual costs (without translations) of around EUR 0.75 million (PO3).

In PO3 the examination authority would only charge a single application fee. In order to cover all costs (depreciation of one-off cost and recurrent cost) the minimum fee should amount to around

EUR 19 500, accompanied by translation fees of EUR 870 per language, i.e. per designated Member State (thus around EUR 20 000 for the entire EU)[177].

Impact on NPOs

As the application fee of the examination authority would be high (at least 3.8 times higher than the sum of national application fees), NPOs might continue seeing demand for national SPCs, limited only by other costs that applicants would need to bear such as national attorney fees, or by the hassle of dealing with several offices and national procedures, in various languages and by using national agents where required (unquantifiable).

In case all applications arrived via the central authority, the workload of NPOs relating to SPCs would be substantially diminished. The patent offices would also lose income from application fees, amounting to up to EUR 32 600 per NPO (around EUR 0.88 million for the EU)[178]. NPOs would still be entitled to charge maintenance fees. At the same time, a centralised examination scheme able to cover all Member States will result in savings of resources at NPOs, compared to today's situation where multiple examination procedures are (redundantly) conducted in parallel in several Member States.

A number of examiners from NPOs would be carrying out substantive analysis of SPC applications for the examination authority. This task is expected to be equivalent to the involvement of two persons working full time to cover all SPCs per year (2 FTEs/year). It can of course be spread among a higher number of persons working on SPCs only occasionally. Their remuneration could be covered by maintenance fees charged subsequently by each designated NPO, or they could be paid by the central authority directly. The risk of the former solution is a perverse incentive to give a positive opinion, as otherwise no income would follow for that application. A further problem, could arise if examiners came from countries where protection is not sought, as it would further increase the costs of application process borne by the central authority, while the NPOs of countries that have not contributed to the evaluation would collect substantial amounts for maintenance fees. To avoid such dubious incentives, the examination authority should pay examiners directly. The NPOs additional income from such transfers is estimated at EUR 0.62 million EU-wide. The net result of this option on all EU NPOs is thus estimated at – EUR 0.26 million (or – EUR 9 500 per NPO)[179].

As regards non-binding opinions issued by the central authority, it is expected that NPOs would implement them without reopening the file, at least in the case of positive opinions – mainly because it would guarantee the maintenance of fee income for up to five years. For the same reason, however, NPOs might be tempted to reinvestigate negative opinions. Re-examination might also be triggered by appeal by an unsatisfied applicant. In any case, historically only around 20% of decisions were negative[180], so the re-opening should not concern more than around 20 applications a year. NPOs may also reinvestigate positive SPC decisions, if for various reasons they consider that the central authority is too lenient in granting SPCs. The likelihood of NPOs issuing divergent opinions

[177] Based on EUIPO estimates. See: Annex 5D.
[178] See: Annex 5F.
[179] Impact per NPO assumes that examiners remuneration is equally distributed between all NPOs. See: Annex 5F for details.
[180] Data for 2004–2014. Source: Mejer, M., 25 years of SPC protection for medicinal products in Europe: Insights and challenges, European Commission, DG GROW, 2017, p. 13.

could be limited if the central authority guidelines became a reference point also for NPOs, thus contributing to harmonisation of practices. Moreover, if the right to deviate from the central examination authority's opinion was restricted only to changes in factual circumstances (e.g. patent revocation, marketing authorisation withdrawal), the room for divergence would be almost completely eliminated.

Finally, it is also difficult to propose maintenance fees that would be much lower (so that the centralised procedure is even more cost-attractive when compared to the national route), because the central examination authority must bear all the cost of SPC examination (including translations), while not being able to recuperate it later via maintenance fees - the latter would be still collected by the NPOs. At this stage, it is not expected that NPOs would either lower the maintenance fees or remove them completely.

Impact on applicants and follow-on manufacturers

PO3 should significantly reduce the problem of divergence, as this option implies a single filing of the SPC application that would undergo one substantive examination by the same authority (unless the NPOs' discretion to reinvestigate files goes beyond changes in factual circumstances, as explained above). As no possibility to centrally challenge the non-binding opinion is envisaged, dissatisfied applicants would need to launch appeals in all designated Member States. In any case, such divergence is not expected to concern more that 20% of cases.

Applicants will be required to present a centralised marketing authorisation[181] when applying for an SPC based on the new rules. This is in line with the current situation where most of the national applications for medicinal SPCs are based on centralised marketing authorisations[182]. Although using national marketing authorisations would not be impossible, it could cause additional difficulties due to possible differences between the national decisions (such as divergent identification of products concerned[183], different permitted uses or different issuing dates[184]). Mitigating these differences within the national marketing authorisations would entail a considerably higher examination workload for the authority. It should be noted, however, that a majority of originators and follow-on manufacturers called for allowing national marketing authorisations in the process[185].

The centralised procedure reduces applicants' need for national legal assistance (estimated at EUR 2 000 per country), translations of applications and costs of dealing with separate authorities. At the same time, national appeals would entail the need to rely on legal advice in each designated country. The EU wide loss of income for IP attorneys is estimated at EUR 0.4 million. Nevertheless, the sum of

[181] The marketing authorisations for PPPs are based on a mutual recognition system. This however should not pose a significant problem, as there are much fewer SPC applications for PPPs than for medicinal products (see: Section 2.2). Differences here could be mitigated more easily by the national authority.
[182] See: Annex 5B, Table 41.
[183] Max Planck Institute for Innovation and Competition, Study on the Legal Aspects of Supplementary Protection Certificates in the EU, 2018, p. 586: 'According to what is reported in the literature, in some national marketing authorisations "the active substance is only described in terms of the active moiety, and not in the terms of the actual substance used, which may be a salt". In others, by contrast, the active substance is identified by referring to the active part of the compound, which can be shared by a several variants (salt, esters).'
[184] This is significant, as an SPC application can be filed only within 6 months after the grant of the MA. See: Article 7 of Regulation 469/2009.
[185] See: Annex 2, Table 31.

central application and national maintenance fees in PO3 for SPCs protected in the whole EU is expected to be higher than the sum of national fees by 16% due to added cost of the examination authority. Taking all the above factors into consideration, PO3 would be cheaper than the national route for applicants seeking five-year-long SPC protection in 17 or more Member States. In case of the SPC sought in EU27 for the full term of five years, PO3 is expected to be on average 6% cheaper than the baseline[186].

Despite all that, results of the public consultation suggest that for most stakeholders SPC costs are less important than legal certainty/predictability and their ability to monitor the status of SPCs. It is challenging to quantify the former factors, though.

By creating one central, multilingual SPC database[187] covering all SPCs (granted by the central procedure and preferably also by the national route) PO3 would significantly decrease the burden of monitoring SPC protection for SPC users e.g. hospital procurement, and competing generics and biosimilars. These savings are estimated at around EUR 40 000 per company with the EU wide saving of around EUR 1 and 12 million respectively. Nevertheless, the completeness, accuracy and timeliness of data would depend on cooperation among NPOs. They would provide information on whether they followed the non-binding opinion, as well as on any changes in status (e.g. withdrawal of the application or revocation of the patent). Any failures or delays in updating the database could mislead or confuse market participants and consequently undermine the credibility and usefulness of this dataset. Additionally, follow-on producers would be able to influence the SPC granting process and provide written observations in any EU language before the decision on granting an SPC is made.

PO3 would not provide unitary SPC protection based on unitary patents, but a bundle of national SPCs. As in PO2, the implementation of PO3 is not linked to the unitary patent system, and can cover all Member States irrespective of whether they are part of the enhanced cooperation area of the unitary protection.

Table 6: PO3 costs and savings to applicants for receiving EU27 wide, five year long SPC protection

	EUR per application	Savings vis-à-vis baseline
Filing fees	39 500	-30 700
Maintenance fees for 5 years	183 000	0
Translation costs	0	4 000
Agent/attorney's fees	12 800	41 200
Total	235 300	14 500

Source: In-house estimations, numbers rounded to 100s, see: Annex 5E

Stakeholder feedback

The idea to develop PO3 was a result of analysis of earlier consultations where stakeholders opted for a unitary SPC and granting by NPOs[188], hence PO3 combines "unification" at the SPC application examination level with national SPC granting.

This was also suggested by e.g. the European Federation of Pharmaceutical Industries and Associations (EFPIA) expressed that "*As the timeline for the entry into force of the unitary*

[186] Or 3 % cheaper in case of an average SPC (i.e. covering 20 Member States for 3.5 years).
[187] As the complexity of the search process increases with the number of languages, the proposed standard form for e-submission of SPC should be predominantly based on structured input (e.g. pre-defined data fields sourced from dedicated dictionaries).
[188] See: Annex 2, Table 26 and Table 28.

patent/Unified Patent Court system remains unknown, EFPIA commends the Commission's reflection to provide an intermediate solution. A single application portal and a unified grant mechanism can be helpful steps towards a unitary SPC".

During the Commission expert Group on Industrial Property Policy (GIPP) meeting in November 2022, five Member States expressed preliminary support for this option out of 17 that took the floor.

6.4. PO4: Centralised filing and examination of SPC applications resulting in a binding opinion

Linguistic regime

The rules for the use of languages would be as in PO3 (see: section 6.3).

Impact on the examination authority

Impact under this option would be as in PO3 (see: section 6.3), albeit the creation of a review mechanism (that allows for the authority's binding decision to be challenged under a simplified procedure) would increase annual costs to EUR 1.5 million. Since the examination authority could only charge an application fee, to cover all the cost it should amount to around EUR 20 800 plus variable translation fee of EUR 870 per language of designated Member State (around EUR 20 000 for the whole EU)[189].

Impact on the NPOs

The key difference between PO3 and PO4 is that the NPOs would be expected to follow the binding opinion with no room for discretion. While most Member States/NPOs should recognise the merits of a binding opinion in terms of EU-scale coherence, some of them might possibly deplore that the central examination authority is more strict, or less strict, than their average national practice. However, such concerns would be mitigated by involving NPO examiners in the centralised examination process.

The remaining impacts on the NPOs would remain as described in PO3 (in particular, the maintenance fees would be paid to NPOs). Given the relatively high application costs of the centralised procedure[190] compared to a single national SPC application (and other factors such as the requirement that the centralised procedure would only be available where the basic patent is a European patent and, for medicinal products, where the product was centrally authorised), the demand for national SPCs is expected to diminish but not disappear entirely. As in PO2 and PO3 the maximum income loss of NPO is estimated at EUR 20 000 per office and EUR 0.5 million EU-wide annually.

Impact on applicants and follow-on manufacturers

A single examination procedure and a single decision on granting protection as foreseen in PO4 would eliminate nearly all currently observed sources of divergence described in the problem statement. The central procedure would substantially increase legal certainty and predictability. Although the central fees are higher in comparison to the national route, this option produces overall cost savings of around 10% for applicants on attorney fees and translation for a EU-wide protection

[189] See: Annex 5D for details.
[190] See: Table 7 below.

for five years[191]. It would also be easier to contest the negative opinion on granting an SPC by filing a request for review. The central review system would help companies economise on attorney fees. This option would bring benefits to all EU countries regardless of their participation in the enhanced cooperation. However, it would not provide unitary SPC protection for the unitary patents, but a bundle of national SPCs.

Table 7: PO4 costs and savings to applicants for receiving EU27 wide, five year long SPC protection

	EUR per application	Savings vis-à-vis baseline
Filing fees	40 800	-32 000
Maintenance fees for 5 years	183 000	0
Translation costs	0	4 000
Agent/attorney's fees	2 000	52 000
Total	225 800	24 000

Source: In-house estimations, numbers rounded to 100s, see: Annex 5E

A central database envisaged under PO4 would provide an accurate and timely picture of the SPC status covered by the central procedure, as data feeds could occur once the binding decision is taken. Follow-on producers and health sector procurement offices would benefit from up-to-date information on SPCs with estimated savings as in PO3 of EUR 40 000 per firm or EUR 12 and 1 million EU-wide respectively. As in PO3 follow-on produces would also be able to submit written observations before an SPC is granted.

Loss of income of IP attorneys is equal to the gain of applicants and amounts to EUR 52 000 per case and EUR 5.2 million EU-wide.

European SPC title

An alternative model could be based on the EPO system for European patents. The examination authority would issue one central "European SPC title" which would be subsequently registered in each designated Member State. Such a title would have exactly the same economic consequences as described above. It might, however, require a different legal basis – Article 352 TFEU[192] - which requires unanimity of the Council and the consent of the European Parliament. This means that the Parliament would have the power to accept or reject a legislative proposal by an absolute majority vote, but could not amend it. Therefore, the Parliament would have less influence on the contents of the legislative proposal than in the ordinary legislative procedure.

Stakeholder feedback

The idea to develop PO4 was a result of analysis of earlier consultations, where stakeholders opted for a unitary SPC and granting by NPOs[193], hence PO4 combines "unification" at the SPC application examination level with national SPC granting.

This was also suggested by e.g. the European Federation of Pharmaceutical Industries and Associations (EFPIA) expressed that "*As the timeline for the entry into force of the unitary*

[191] Or 8 % cheaper in case of an average SPC (covering 20 Member States for 3.5 years). Overall this options is cheaper than the baseline for applicants seeking protection in more than 13 Member States.
[192] Consolidated version of the Treaty on the Functioning of the European Union, Part seven: General and final provisions, Article 352 (ex Article 308 TEC), OJ C 326/47 (https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12008E352:EN:HTML).
[193] See: Annex 2, Table 26 and Table 28.

patent/Unified Patent Court system remains unknown, EFPIA commends the Commission's reflection to provide an intermediate solution. A single application portal and a unified grant mechanism can be helpful steps towards a unitary SPC".

During the Commission expert Group on Industrial Property Policy (GIPP) meeting in November 2022, eight Member States expressed preliminary support for this option out of 17 that took the floor.

6.5. PO5: A 'Unitary SPC' complementing the unitary patent

Linguistic regime

The rules for the use of languages would be as in PO3 and PO4. However, as the unitary SPC would be granted directly by the central authority, 2/3 of translation costs relating to the transmission of the SPC dossier to the designated NPOs would be eliminated. This would result in a translation budget of around EUR 1 million, or EUR 10 000 per SPC application. For reasons of transparency and accessibility it could be advantageous that firms from UP Member States are allowed to communicate with the central authority in their own language.

Impact on the examination authority

As in PO3 (see: section 6.3), but the examination authority would (in addition to assessing applications) grant unitary SPCs, and collect maintenance fees. Since the costs can be spread now over the lifetime of each SPC, the application fee could be lowered to be more competitive vis-à-vis NPO fees and the outstanding cost could be recuperated via maintenance fees. Nevertheless, an application fee that would be too low could create a bias towards granting SPCs to recover all costs as they are generated mostly during the registration phase. It would also mean that successful applicants would subsidise unsuccessful ones by paying higher maintenance fees. As discussed in Annex 5D, the easiest solution is to charge all fees at the application stage with no central maintenance fees. This would mean fee of approximately EUR 28 900.

Impact on NPOs

As long as the unitary SPC fees are cost-based, they would be up to four times lower than total fees charged by the 17 UP Member States for a five-year-long SPC[194]. Taking all costs into account it appears that the national SPC route would likely be chosen only if protection is sought in less than four Member States[195] – or where the conditions for obtaining a unitary SPC (e.g. the existence of a basic European patent with unitary effect and, for medicinal products, of a centralised authorisation) are not met. As on average an SPC covers 20 countries, it is safe to assume that for the UP countries most/all applications would be for a unitary SPC (at least in the medium/long term, as explained below). If NPO experts were to be involved in the central examination network, they would receive remuneration directly from the examination authority to the tune of EUR 0.75 million EU wide. The total loss of income for the 17 UP NPOs is estimated at EUR 8.7 million (EUR 512 900 per NPO), which is equivalent to 2.6% of their income from patents[196].

However, it is to be expected that NPOs will be affected in a very progressive manner only by the introduction of a unitary SPC, due to:

[194] Almost three times lower for a typical SPC lasting 3.5 years.
[195] Less than five Member States in case of an average SPC lasting 3.5 years.
[196] See: Annex 5F.

– the progressive penetration of the unitary patent in the first years following its introduction – both because of users' initial cautiousness (as it happened when the European patent was launched) and of legal factors (e.g. where the conditions for attributing unitary effect to a certain European patent are not met), and
– the fact that the criteria for granting a unitary SPC may not be fulfilled in each and every case.

Impact on applicants and follow-on manufacturers

The unitary SPC would make it possible to extend a unitary patent in a unitary manner. For applications requesting unitary protection in the UP Member States there would be a single procedure and therefore no scope for divergent national outcomes[197]. Legal certainty and predictability could be assured. Costs associated with the SPC (application fee, maintenance fees, a single attorney fee, no translations) would be five times lower than seeking five-year-long SPC protection in each UP Member State separately[198]. The central database would provide a full, accurate and up-to-date picture of the status of unitary SPCs, while as regards nationally granted SPCs it would continue to rely on input from NPOs.

Nevertheless, this option does not cover all EU countries and would not provide any solution concerning the 10 Member States that will initially be outside the UP system. Thus, applicants wishing to obtain protection in the whole EU[199] would need to file 10 additional SPC applications. In this case, the cost of EU-wide protection for five years would amount to half of the cost of the baseline. For the applicants filing with NPOs outside the UP MSs, the problems of the baseline would continue (divergent national assessments or dates of granting SPCs). Follow-on producers and health sector procurement centres would need to monitor ten additional national databases. This means that their savings would be proportionally lower than in PO3-4 and amount to around EUR 25 000 per firm, or EUR 7.6 and 0.7 million per year respectively. That said, the UPC Agreement is open to all Member States, and more may be expected to join in the medium and longer term.

Even taking the above factors into consideration this option would produce savings of almost 50% for SPC applicants in comparison with the baseline for an EU-wide, five-year-long SPC[200]. This translates into saving of EUR 122 400 on average per applicant on a five-year-long SPC protection and may be a key factor in case of smaller firms. Legal attorneys would lose the equivalent of what applicants save – around EUR 32 000 per SPC, or EUR 0.32 million for the whole EU.

Table 8: PO5 costs and savings to applicants for receiving EU27 wide, five year long SPC protection

	EUR per application	Savings vis-à-vis baseline
Filing fees	31 900	-23 100

[197] In case of PO5, the requirement to hold a central marketing authorisation is even more important than in PO3 and PO4. In addition to concerns and differences between national MAs mentioned in Section 6.3, since a unitary SPC is valid in the territory of all UP Member States, this requires uniformity in the underlying MAs. Should one national MA be revoked, the unitary SPC would thus cover a Member State without a basis (if the unitary SPC should be considered not to have effect in the Member State concerned it would thus contradict its unitary nature).
[198] Almost 4 times lower in case of SPC lasting 3.5 years.
[199] Member States currently outside the UPC Agreement: CY, CZ, EL, ES, HR, HU, IE, PL, RO and SK.
[200] Or 62 % in case of an average SPC covering 20 Member States for 3.5 years, whereby the group of 20 Member States is assumed to consist of 17 UP Member States and 3 non-UP Member States. This option is cheaper than the baseline for SPCs covering more than 3 Member States in case of 5-year-long protection), or more than 4 Member States in case of 3.5-year-long-protection.

Maintenance fees for 5 years	71 900	111 100
Translation costs	1 600	2 400
Agent/attorney's fees	22 000	32 000
Total	127 400	122 400

Source: In-house estimations, numbers rounded to 100s, see: Annex 5E.

Stakeholder feedback

The joint position paper of 2015 of the European industry associations of innovators[201] in the field of pharmaceutical and agrochemicals (ECPA, EFPIA and IFAH-Europe), i.e. the users of the SPC system, supports the concept of unitary SPCs being granted on the basis of unitary patents. In an EFPIA statement on the Commission SPC evaluation report of 2020, EFPIA expressed that "*We particularly await the entry into force of the Unitary Patent & Unified Patent Court and further support the creation of a unitary SPC: one SPC for the EU rather than one SPC by country* […] *the unitary SPC can simplify the application procedure, reduce duplication and facilitate a consistent application of the SPC Regulation across the EU.*"[202] There was a wide support to creation of a unitary SPC across all respondents to the public consultations (see: table below). As well as among Member States participating in November 2022 GIPP meeting (11 out of 17 who expressed preliminary views).

Table 9: Do you favour the creation of a unitary SPC title for the unitary patent?

Agree answers only	Originators*	Follow-on manufacturers	Customers, health	Patent offices, lawyers	Ministries and other public authorities
Yes	74%	98%	79%	81%	100%
No	n/a	2%	21%	19%	0%
No. of answers	*68*	*55*	*11*	*27*	*5*

**response did not receive this question instead we report here those who chose "Create a unitary SPC for the unitary patent" as answer to Q37 "What would be your preferred option to improve consistent interpretation throughout the EU of the 'substantive' provisions of the SPC regulation (e.g. the scope of protection, eligibility of SPC protection)?".*
Note: "Don't know" and No answer not taken into account. Questions had slightly different formulations to each group but with the same meaning.
Source: Public Consultations on Evaluation of SPC

Respondents from all groups (originators, follow-on producers, health sector representatives, patent offices and lawyers) were expecting (almost unanimously) the following benefits of a unitary SPC: higher legal certainty, the same protection across the EU, the reduction of registration, maintenance and SPC monitoring costs, easier licensing and access to joint procurement by group of Member States, as well as a boost to investments (see: table below).

Table 10. The benefits of a unitary SPC – stakeholders' views

Agree answers only*	Originators	Follow-on manufacturers	Customers, health	Patent offices, lawyers	Ministries and other public authorities
Legal certainty	94%	100%	85%	91%	100%
Reduce cost/red tape of SPC-related litigation	98%	100%	83%	71%	100%
Same protection in all EU	98%	x	x	92%	100%
Reduce red tape relating to registration	98%	x	x	86%	80%
Specialised court	98%	94%	71%	86%	100%

[201] European Federation of Pharmaceutical Industries and Associations, Proposal for a Unitary SPC, ECPA, EFPIA and IFAH-Europe Joint Position Paper, 2015 (https://www.efpia.eu/media/15414/ecpa-efpia-and-ifah-europe-joint-position-paper-proposal-for-a-unitary-spc-july-2015.pdf).
[202] European Federation of Pharmaceutical Industries and Associations, 'EFPIA reaction to SPC evaluation publication', 2020 (https://www.efpia.eu/news-events/the-efpia-view/statements-press-releases/efpia-reaction-to-spc-evaluation-publication/).

Reduce cost and red tape relating to monitoring SPC-protected products (freedom to operate)	x	98%	83%	x	x
Reduce maintenance costs	98%	x	x	88%	100%
Make licensing easier	93%	98%	x	79%	100%
Boost value of investments	95%	x	x	x	100%
Make joint procurement by a group of EU countries easier	x	x	75%	x	x
No. of answers	*51-64*	*43-56*	*7-13*	*14-25*	*3-5*

* the residual to 100% is the number of those disagreeing; x - response not available to that group of respondents
Note: No answer and "Neither agree nor disagree" not taken into account (also in no. of answers provided).
Source: Public Consultations on Evaluation of SPC

6.6. **Common impacts**

The following section analyses impacts common to PO2-PO5. The impacts presented below are chosen because of their political and/or economic significance.

6.6.1. Biosimilar and generic market entry

Although the proposed reform does not affect the core provisions of the SPC rules (such as conditions for granting, its scope or duration), but focuses mainly on the administrative simplification of the procedures, the relationship between the loss of exclusivity of SPC-protected products and the market entry of follow-on equivalents will undoubtedly form part of the discussion surrounding the proposed review. In particular, in case of the pharmaceutical sector, it could be claimed that a more efficient and coherent SPC system could, indirectly but adversely, affect access to less expensive generic or biosimilar medicines[203]. It could also be claimed that one could expect similar patterns in the agrochemical sector.

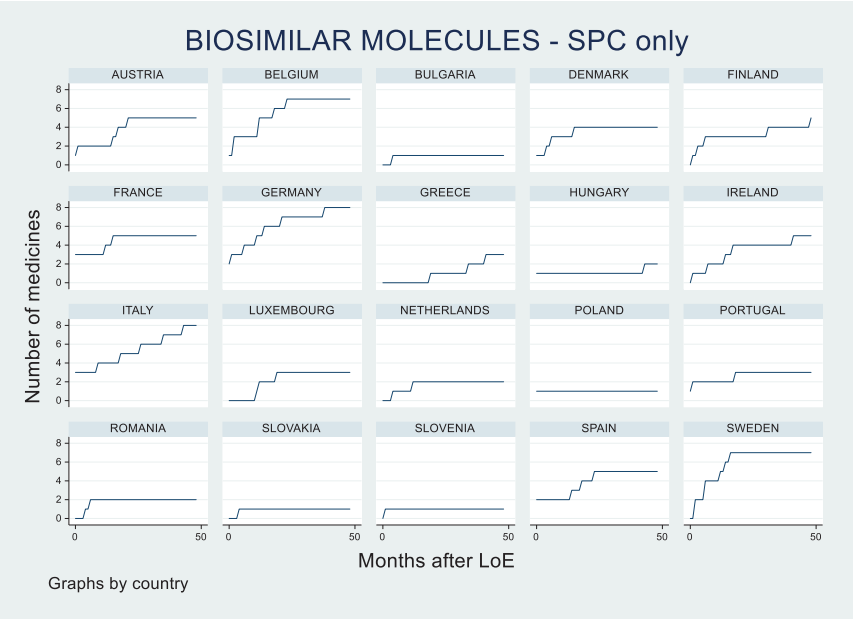
Generics and biosimilar medicines play a key role in today's pharmaceutical markets and health care systems. Since the introduction and codification of the SPC regime in 1993, the European and global markets for pharmaceuticals have undergone very significant changes. Above all, global demand for medicines has been increasing, with a significant switch towards generics and biosimilars[204] that keeps public health expenditure in check.

In this context, IQVIA data covering years 2010-2021 were used to verify whether market entry patterns differ significantly across the EU and how quickly the follow-on medicines actually start to compete with the original products. The results are presented in Figure 9 and indicate how much time (in months) it took for a first follow-on product to enter the market after the loss of exclusivity due to the SPC expiry[205]. The four-year period was chosen, as the average SPC duration is 3.5 years. The figure presents biosimilar and generic molecules separately, because the complexity of introducing these two types of products on the market differs significantly (i.e. it is much more

[203] It would as such extend a monopoly for pharmaceutical products concerned to Member States previously *de facto* not covered by any SPC.
[204] 'All OECD countries view generic and biosimilar markets as an opportunity to increase efficiency in pharmaceutical spending, but many do not fully exploit their potential'. Source: OECD, "Generics and biosimilars", 2022 (https://www.oecd-ilibrary.org/sites/fd887b83-en/index.html?itemId=/content/component/fd887b83-en). See: Figure 31 in Annex 5C for further background data.
[205] The SPC dummy variable was estimated based on the relationship between the patent expiry date, the regulatory protection expiry date and a potential SPC expiry date – further details on the methodology are provided in Annex 4.

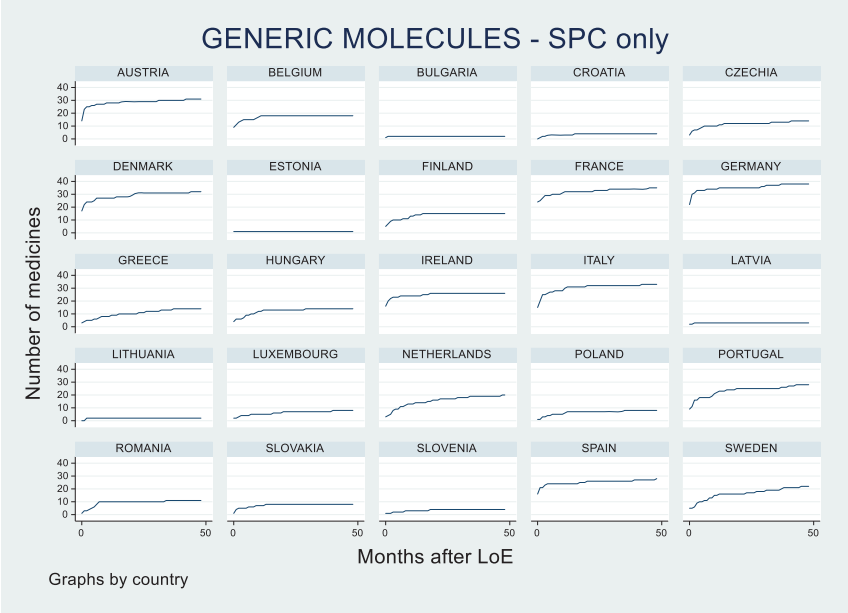
challenging in case of large biosimilar molecules). These different characteristics are also confirmed by the number of products captured in both parts of the graph – up to 10 products in case of biosimilar and 40 in generic molecules. Nonetheless, Figure 9 shows that in case of both types of products the speed of entry is much faster in lager and/or wealthier countries, which may be explained by the fact that market entry decisions are related to other factors than only the market exclusivity. In other words, in certain EU markets - especially the EU-10 enlargement countries - the entry of follow-on equivalents seem to be delayed when compared with the rest of the EU (it is not to say that the entry does not occur, but if it happens, this may take place within period longer than 4 years)[206]. This said, it should be also added that, contrary to analysis presented in section 6.6.2, the present analysis does not adjust for the turnover of considered products[207]. Markets for high turnover products are known to be more contestable and hence entry delays can be expected to be shorter for products with higher usage (and higher related health benefits) across the population.

Figure 9: Time-to entry of follow-on medicines over 1 to 48 months after the loss of exclusivity (LoE), by country - number of medicines that were previously covered by SPC



[206]The same holds true if the analysis is carried out using all observations, irrespective of the reason behind the loss of exclusivity, except for a higher number of molecules captured (i.e. 4 years after the loss of exclusivity up to 200 molecules had at least one generic product available on the market, whereas in case of biosimilar molecules the number was around 30). See: Figure 31 in Annex 5C.

[207] Nonetheless, the market entry patterns across countries in both sections section are similar.



Source: In-house analysis based on IQVIA data covering molecules with the loss of exclusivity from 01/2010 onwards.

It can be therefore concluded that a more centralised SPC system would not significantly slow down entry of follow-on products in smaller/lower income Member States, as these markets face delayed entries anyway, due to other factors than SPC[208]. Literature on the subject, as well as reports prepared by the industry corroborate the above asymmetry and point towards the price and reimbursement rules[209], legal uncertainty connected to the country, quality and readiness of healthcare systems, differences in the value assessment process, overall levels of pharmaceutical spending, size of the market, etc.[210] All these elements are outside the scope of the proposed initiative.

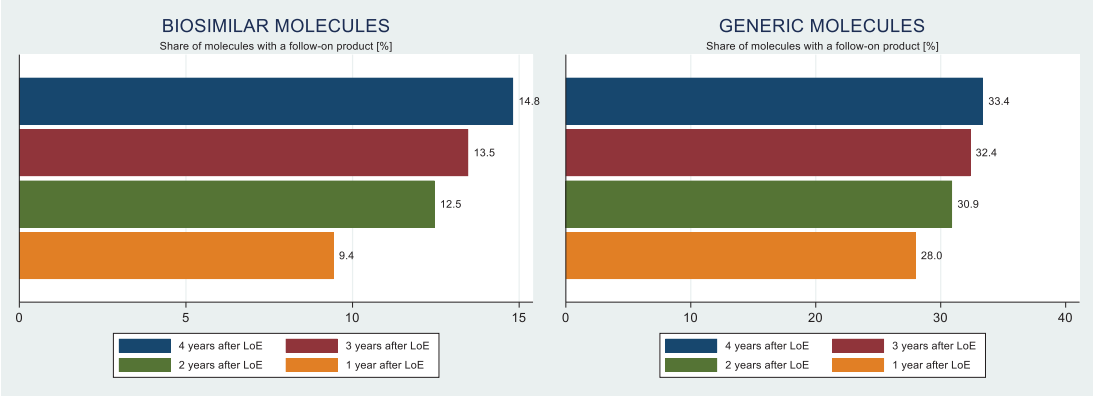
The fact that follow-on market entry usually takes several years and is especially challenging in case of biosimilar products is also confirmed when looking at the sheer number of molecules (see Figure 10 below). Only 15% of biological medicines had their first biosimilar product available on the market within less than 4 years. In case of smaller molecules (generics), the number grew from 28% of molecules in year one to roughly 1/3 of molecules having a follow-on equivalent in four years.

[208] The above is based on historic patterns, whereas in the future market access strategies of follow-on producers might well develop in a way that ensures more coherence across all parts of the EU. In such a case, the savings generated by generic entry would be higher than what the historic trends currently suggest (in that sense, the generic entry benefit calculations in this impact assessment could be seen a lower bound). On the other hand, policy efforts to assure the availability of pharmaceuticals in (so far) Member States that aren't supplied might trigger new national SPC applications in those very Member States, thus affecting the future counterfactual as well.

[209] There are significant price differences between pharmaceuticals across the EU, but as mentioned earlier, the pricing of medicines remains a national competence.

[210] Medicines for Europe, Removing access barriers in Central and Eastern Europe: How can we ensure equitable access to medicines for all European patients?, 2022; European Federation of Pharmaceutical Industries and Associations, The root cause of unavailability and delay to innovative medicines, analysis developed with the support of Charles Rivers Associates (CRA), 2020.

Figure 10: Share of molecules with a follow-on products in 1 to 4 years after the loss of exclusivity (LoE) [%]



Source: In-house analysis based on IQVIA data covering molecules with the loss of exclusivity from 01/2010 onwards.

The above doesn't preclude a situation that for some molecules the follow-on competition is quite fierce – the available data show that fewer, but more profitable substances are chosen by the generic companies for which several competitors come up with follow-on equivalents.

When analysing the generic and biosimilar market entry it should be also noted that even if an SPC is granted for a certain medicinal product it may happen that another protection measure (e.g. the 10-year market exclusivity, as defined by EU pharmaceutical legislation) expires after the SPC[211]. In such case the SPC has no decisive influence on the moment from which follow-on products may be placed on the market. Although the current proposal does not refer to any changes in the scope or duration of SPC regime, a change in the regulatory protection rules which is contemplated within other current Commission initiatives might impact the role of SPC as the last protection to expire. In this context, the impact of a hypothetical shortening of the regulatory protection by two years was estimated, showing that the share of SPC as the last exclusivity to expire would increase by roughly 5% - from 49.6%[212] currently to 54.9% of molecules (see: Annex 5C for more details). Needless to say, this relatively modest increase is not due to any SPC reform contemplated in this impact assessment, but rather the consequence of the SPC system's existence as such (i.e. it might materialise also in the status quo, should market exclusivity rules be reformed).

As mentioned above, claims that a more streamlined SPC system would affect the entry of follow-on products could also be made with regards to the agrochemical sector[213]. However, such negative impact on PPPs seems to be even less probable than in the case of medicines. First, the market is

[211] See: Table 54 in Annex 5C. It should however be noted that the number of cases where SPC is the last protection to expire is higher in terms of turnover, than when measured by molecules. In those cases, the scope of the SPC can have a decisive influence on the entry of generics and biosimilars on the market, and even on patient access to a given medicine.

[212] Commission services in the impact assessment accompanying the proposal for a revision of Regulation (EC) No 726/2004 estimate that SPC is the last protection measure to expire in 48 % of molecules– based on a basket of 217 products selected using IQVIA Ark Patent intelligence data, where the loss of protection was between 2016–2024 in four countries: FR, DE, IT and ES.

[213] It is estimated that in 2020-2027 nearly 40 active ingredients will come off-patent (12 herbicides, 17 fungicides, 8 insecticides and 2 nematicides). Source "New Generics in Crop Protection 2022", IHS Markit 2022.

highly consolidated[214] (e.g. in 2018, the top four firms controlled around 70% of the global pesticide market[215] or top six firms controlled 81% of the EU market[216]), whereas a large share of non-patent-protected products are also sold by the originators[217], leading to potentially lower price reductions[218] and hence lesser market impacts. Second, due to factors linked to the specific characteristics of the agrochemical sector and its future developments[219], including efforts to promote diversified cropping systems in the EU[220], a more coherent and streamlined SPC system could actually foster and incentivise R&D in safer and more sustainable alternatives to agrochemicals.

Finally, it should be noted that PO2-PO5 propose various instruments intended to support new entrants, such as the right to submit third party observations during the SPC procedure, as well as significantly increased transparency in the publication of SPC-related information. The central SPC database should benefit around 300 follow-on producers[221] annually, each saving up to EUR 25 000 (PO5) to EUR 40 000 (PO2-4) (approximate cost of a commercial dataset), producing EU wide savings of EUR 7.6 million (PO5) to EUR 12 million (PO2-4). These instruments are expected to be bring positive impacts on entry of competing – more affordable – generic and biosimilar products.

6.6.2. Social impacts

Healthcare budgets

Regarding likely social impacts, this initiative aims to improve incentives for pharmaceutical and agrochemical innovation in the EU and as a result generates demand for advanced skills Europe (e.g. researchers, doctors, engineers).

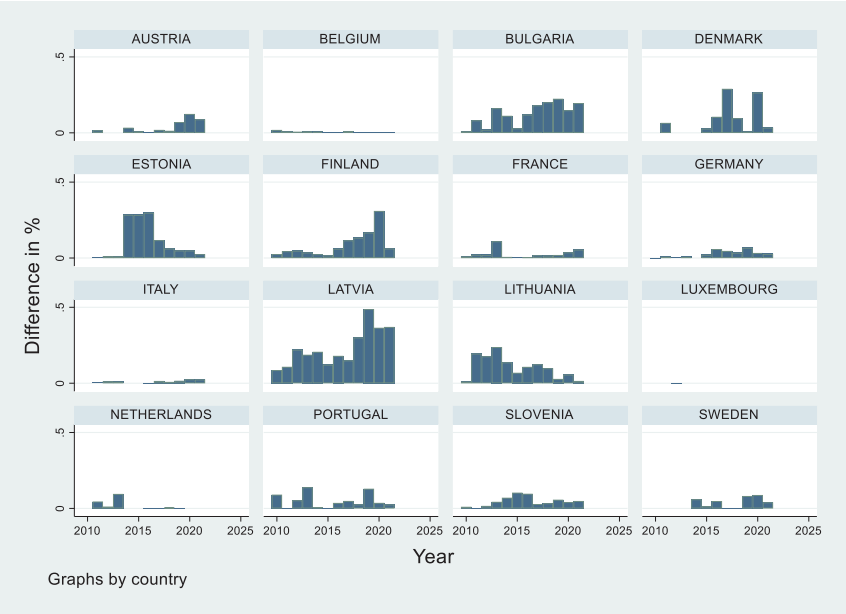
Broad social impacts in the context of healthcare can be also understood as "ensuring access to affordable medicines and that health systems remain financially sustainable" (i.e. one of the objectives of *the EU pharmaceutical strategy*). Against this background, an argument can be made that a unitary SPC (PO5) could actually worsen the supply possibilities for health systems of smaller Member States, which prior to the unitary SPC entry were typically not covered by SPC protection (and as part of the unitary patent system will now automatically be). An example might be useful

[214] Elsheikh E. and Ayazi H. "The era of corporate consolidation and the end of competition: Bayer-Monsanto, Dow-DuPont, and ChemChina Syngenta." Haas Institute for a Fair and Inclusive Society at the University of California, Berkeley, CA. October 2018, aasinstitute.berkeley.edu/shahidi
[215] Heinrich-Böll-Stiftung,"The PESTICIDE ATLAS 2022", page 12.
[216] European Commission, Evaluation of Regulation (EC) No 1107/2009 on the placing of plant protection products on the market and of Regulation (EC) No 396/2005 on maximum residue levels of pesticides, SWD(2020) 87 final, Brussels, 20.5.2020, page 11.
[217] Idem.
[218] For example, based on a selection of plant protection products a study finds that the follow–on products were placed on the market with an average price 15% lower comparing to branded pesticides (5%-35% range). Source: Stajszczak A, Majewski E., "Importance Of The Generic Segment Of The Plant Protection Products – The Case Of The Polish Market", APSTRACT Vol. 11. Number 1-2. 2017, pages 25-34.
[219] EPRS | European Parliamentary Research Service "The future of crop protection in Europe", Brussels, February 2021.
[220] The ongoing debate on the future of food system in Europe involves a discussion on the negative impacts of PPPs on human health and biodiversity. In this context, the EU Farm-to-Fork strategy calls to reduce the overall use and risk of chemical pesticides by 50% and the use of more hazardous pesticides by 50% by 2030. See: European Commission, "A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system" COM(2020) 381 final, Brussels, 20.5.2020.
[221] 'Within three years following the LoE [loss of exclusivity] the ratio of generic companies to originators is about 6:1' (source: Pharmaceutical sector Inquiry (2009), p. 74). With up to 50 molecules where competition emerges, the estimated number of follow-on producers affected is 300.

here. Latvia will be part of the unitary patent system. As a result of PO5 a unitary SPC will be binding in Latvia (through a 'blanket effect' common to all Member States participating in the unitary patent) whereas in the counterfactual/baseline, there might not be an SPC binding in Latvia (possibly due to delayed generic entry into smaller Member States, described earlier and thus limited incentive to apply for an SPC).

In order to investigate the size of such an effect in practice the same IQVIA dataset for years 2010-2021 was used to estimate the budgetary impacts of a hypothetical unitary SPC, if it resulted in a longer period of exclusivity in some countries otherwise not covered by an SPC[222]. The estimated hypothetical expenditure was defined as the supplementary payment for original medicines in the period concerned in the absence of generic products. Figure 11 below presents the results of such analysis using 2010-2021 sales data for UP Member States[223], as only those countries would be concerned by the proposed unitary SPC.

Figure 11: Estimated (theoretical) budgetary impacts of a hypothetical unitary SPC, as % of overall spending on pharmaceuticals by country



Source: In-house analysis based on IQVIA data covering molecules with the loss of exclusivity from 01/2010 onwards.

As shown on the graph, the estimated additional expenditure to healthcare systems could reach up to 0.48% in LV, while being negligible for many other countries (e.g. LU, BE, and IT). Figure 11 also confirms what has been argued earlier, that SPC protection has been sought less frequently in smaller Member States, potential benefits would not play out equally across countries.

Overall, for all countries covered by this analysis (i.e. UP Member States except for Malta) the total lost benefits of a unitary SPC would amount to EUR 37 million budgetary impact per year.[224] If the above costs (lost benefits) for public healthcare budgets was re-invested by innovative companies in R&D, the option would produce a neutral cost-benefit outcome.

[222] For further details concerning the methodology applied, please see: Annex 4.
[223] Except for MT, which is not available in the available IQVIA dataset.
[224] The average difference in 2010–2021 was compared with the total pharmaceutical expenditure in the last available year, as reported by Eurostat. See: country-by country estimates in Table 55 of Annex 5C.

Healthcare stakeholders

Health stakeholders along with others would be able to influence SPC granting process by submitting third party observations during the SPC procedure. Additionally, central database for SPCs envisaged under PO3-5 and possibly also PO2 would benefit national medicines procurement offices and can facilitate cross-border joint purchases. At least 27 central purchasing bodies (there could be more than one per Member State though) could benefit from savings of up to EUR 25 000 (PO5) to 40 000 (PO2-4) per year (commercial database access cost), resulting in EU-wide savings of EUR 0.7 million (PO5) to EUR 1 million (PO2-4).

IP attorneys

The changes proposed in PO2 to PO5 by creating one central application procedure are likely to reduce demand for legal advice/representation before NPOs in each Member State where SPC is sought. Under assumption of an average cost of legal help of EUR 2 000 per country and SPC, the loss of income for this group in case of SPCs protected in the whole EU and 100 SPC applications per year can amount up to EUR 0.3 million (PO5), EUR 0.4 million (PO3) to EUR 0.5 million (PO2 and PO4)[225].

6.6.3. Digital impacts

With regards to the potential digital impacts, this initiative fulfils the objectives of the *European Strategy for data*, insofar as the establishment of the centralised SPC procedure and a single database is concerned. In particular, the digital accessibility to all steps of the SPC procedure would be ensured (e.g. e-submission via one-stop-shop, e-access to SPC documents). The new database would also contribute to a single market for data[226] by facilitating the availability of data, as well as data quality and its interoperability across Member States. The envisaged SPC database would improve the cross-border access, exchange (in particular by better sharing of data between national public authorities i.e. NPOs) and analysis of data on the market exclusivity status of pharmaceuticals and PPPs, which consequently should support the earlier market entry of the follow-on equivalents.

6.6.4. Environmental impacts

None of the proposed options influences the current EU legal provisions concerning the environmental protection directly. However, sustainability is one of the four key pillars of Pharmaceutical Strategy for Europe[227]. Similarly, as far as PPP are concerned, there is a number of initiatives concerning the sustainable use of pesticides[228]. Against such backdrop, modernising the SPC regime and thus – at the margin – increasing resources available to pharmaceutical and plant protection firms is to be expected to generate also an environmentally positive impact. Consequently

[225] In case of an average SPC covering 20 Member States, the losses are EUR 0.3 million (PO3 and PO5), EUR 0.4 million (PO2 and PO4).
[226] The proposed initiative is aligned with the following actions of the European strategy for data: i) the establishment of a cross-sectoral governance framework for data access and use; ii) investments in data and strengthening Europe's capabilities and infrastructures for hosting, processing and using data, interoperability.
[227] European Commission, Commission communication – Pharmaceutical Strategy for Europe, COM(2020) 761 final, 2020 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0761).
[228] European Commission, 'Sustainable use of pesticides', 2022 (https://food.ec.europa.eu/plants/pesticides/sustainable-use-pesticides_en).

the considered options “do no significant harm” in terms of achieving the EU’s environmental objectives[229].

7. HOW DO THE OPTIONS COMPARE?

7.1. Comparison of impacts

Table 11 provides information comparing the policy options in the light of the effectiveness and efficiency criteria as well as impact on most affected stakeholders (see: also Annex 6 for the SME test). Table 12 overleaf provides information comparing the policy options in the light of the criteria of effectiveness (how each option achieves the specific objectives) and efficiency (cost-benefits analysis).

[229] European Commission, Better regulation toolbox – tool 36 Environmental impacts, 2021 (https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how/better-regulation-guidelines-and-toolbox/better-regulation-toolbox-0_en).

Table 11: Comparison of policy options against the effectiveness and efficiency criteria

Options	Increase predictability and legal certainty of SPC protection in the EU by facilitating:			Facilitate SPC monitoring	Reduce cost of applying and maintaining SPC protection	Cost efficiency[230] (EUR million) only quantifiable costs and benefits for all stakeholders (see next table for details)
	Examination procedures	3rd parties involvement	Granting procedures			
Baseline	(0)	(0)	(0)	(0)	(0)	(0)
PO 1: Guidelines	(0/+) Guidelines can provide examining best practices, but would not be mandatory and could be interpreted differently across NPOs			(+) Guidelines can provide data publication best practices, but would not be mandatory	(0)	**Net effect** 0-13 **Benefits** 0-13.1 **Cost** 0-0.1
PO 2: Mutual recognition	(++) One examination instead of many. Risk of forum shopping	(++) Written observations possible	(++) One grant decision valid in all MS, but need of some administrative steps in each NPO (including payment of national maintenance fees)	(+) Some level of data integration could be achieved, but there will not be a single authority hosting a centralised database because several offices can act as reference office.	(++) One procedure, 18% lower costs (attorney, translations)) for protection in the whole EU. Maintenance fees might be due in 27 EU MS.	**Net effect** 11.3 **Benefits** 20.6 **Cost** 9.3
PO 3: Centralised procedure with a non-binding opinion	(++) One examination instead of many, but NPO can still re-examine	(+ +) Written observations possible.	(++/+) One opinion, but re-examination possible (the practice of the EA can influence national practices).	(++) EA would host a central SPC register and publicly accessible database on centrally-examined SPCs, but some risks as data also depend on NPOs input.	(++/+) One procedure, 6% lower costs (attorney, translations)) for protection in the whole EU. Maintenance fees might be due in 27 MS.	**Net effect** 10.1 **Benefits** 18.2 **Cost** 8.1
PO 4: Centralised procedure with a binding opinion	(+++) One examination instead of many.	(+ +) Written observations possible.	(++) One opinion with validity binding upon all MS.	(+++) EA would host a central SPC register and publicly accessible database on centrally-examined SPCs.	(++) One procedure, 10% lower costs (attorney, translations) to obtain SPC protection across the EU. Maintenance fees might be due in 27 MS.	**Net effect** 10.1 **Benefits** 19.4 **Cost** 9.3
PO 5: Unitary SPC	(+++UP-MS, 0 others) One examination instead of many. (limited to UP-MS).	(+++UP-MS, 0 others) Written observations possible and access to review within the EA.	(+++UP-MS, 0 others) One grant procedure and decision instead of many (17 UP-MS).	(+++ UP-MS, 0 others) EA would host a central unitary SPC register and publicly accessible database on unitary SPC.	(+++ UP-MS, 0 others) One procedure, 49% lower costs (attorney, translations)) for protection in the whole EU. Significantly reduced maintenance fee paid centrally.	**Net effect** 6.3 **Benefits** 58.3 **Cost** 52

Note: For details of calculations see Annex 5G. Quantifications present maximum potential impacts. Not all impacts are quantifiable. Numbers rounded.

[230] Only quantifiable costs (including income losses) and savings/benefits presented (not covering options impact on objective 1, and only to a certain extent objective 2). Annual effects refer to an EU-wide, 5-year long SPC protection from the fifth year onwards. In the preceding years benefits would be lower, as the system would not yet be fully operational (the number of active SPCs is assumed to increase gradually until year 5).

Table 12: Comparison of the impacts of policy options on stakeholders (including quantifiable annul costs and benefits).

	Originators, including SMEs	**Generic/biosimilar manufacturers, including SMEs**	**Healthcare sector, patients and users of PPPs**	**Patent offices (NPOs)**	**IP agents/attorneys**
No. affected	100 applicants and up to 400 SPC owners paying maintenance fee	300	At least 27 (one healthcare authority per MS)	PO1-4: 27 PO5: 17 (UP-MS)	Up to 2700 cases (1 per MS per SPC) except for PO3: up to 2 060 and PO5: 1 600
Baseline	(0)	(0)	(0)	(0)	(0)
PO 1: Guidelines	(0/+)Improvement of the predictability of the national procedures if guidance followed. Divergence in NPO practices would continue. No reduction of cost or administrative burden.	(0/+) Improvement of the predictability of the national procedures and improvement monitoring of SPC protection across the EU if guidance followed.		(+) Potential for introducing best examining and publication practices. Exchange of information to facilitate examination. (–) impacts depend on the extent of voluntary uptake. (+) information exchange	(+)Improvement of the predictability of the national procedures if guidance followed. No impact on the number of application handled
Costs (€)	0	0	0	Updates to IT: 0 up to EUR 4 100 per NPO per year EUR 0.1 million EU-wide.	0
Benefits (€)	0	EUR 0 - 40 000 per firm (database access); EUR 12 million EU-wide	EUR 0 - 40 000 (database access); EUR 1 million EU-wide	0	0
Net (€)	0	EUR 0 - 40 000 per firm; EUR 12 million EU-wide	EUR 0 - 40 000; EUR 1 million EU-wide	0	0
PO 2: Mutual recognition	(++) One application to one reference office with substantially lower overall costs. . Maintenance fees still due at the national level. Despite common PO1 guidelines, possible divergent practices of reference offices.	(+) Easier search for active SPC due to harmonized IT system (either 27 harmonized national systems, or one central); Possibility to influence granting process through written observations. (=/-) Risk of forum shopping towards more lenient reference offices that could result in additional grants of SPCs.		(+) As in PO1 + Reduced workload and application income of all NPOs Reference NPOs can face irregular workload. Less workload for the non-reference NPOs.	(-) Loss of income generated by managing national SPC applications as less application would be handled by the non-reference offices and to some extent by reference offices as well (if there is more than one reference office).
Costs (€)	EUR 11 600 on application fee per firm EUR 1.2 million EU-wide	0	0	Updates to IT systems (up to EUR 4 100 per NPO per year; EUR 0.1 million EU-wide); Application fee loss 26 NPOs: up to EUR 32 300 (EUR 0.84 million EU wide)	Loss of EUR 2 000 per application per MS; EUR 5.2 million EU-wide
Benefits (€)	EUR 55 800 savings per application per firm EUR 5.6 million EU-wide	Up to EUR 40 000 (database access) EUR 12 million EU-wide	Up to EUR 40 000 (database access); EUR 1 million EU-wide		
Net (€)	+ EUR 44 200 per application per firm + EUR 4.4 million EU wide	+ EUR 40 000 per firm; + EUR 12 million EU-wide	+ EUR 40 000; + EUR 1 million EU-wide	- EUR 36 400 per NPO; - EUR 0.95 million EU wide	- EUR 2 000 per application per MS - EUR 1.2 million EU-wide
PO 3: Centralised decision with a non-binding opinion	(+/++) One application to central authority. PO1 guidelines mandatory for the central authority NPOs can request examination potentially for up to 20% of cases – room for divergent outcomes on the same file. Savings on attorney fees. Maintenance fees still due at the national level.	(+/++) Easier search for active SPC due to once central database managed by the examination authority (e.g. when launching competing products or for joint cross border procurement). Database completeness depends on NPOs cooperation and timely updates (e.g. for SPC granted via national route); Up to 20% of products may continue to receive divergent SPC decisions in MS. Possibility to influence SPC granting process through written observations.		(=+) As in PO1 + Lower workload for the NPOs, if no re-examination, dependent on usage of central procedure. Lower income from application fees, however the income generated by SPC application fees is negligible (0.1%) compared to the total patent fee revenue.	(-) Benefits to specialised IP agents/attorneys that will handle centralised SPC applications. Other agents may lose income earlier generated by managing national SPC applications. National appeals (in up to 20% of SPC cases) may to some extent limit income losses.
Costs (€)	EUR 30 700 on application fee per firm	0	0	Marginal cost for data feeding the	Loss of EUR 2 000 per application

	Originators, including SMEs	Generic/biosimilar manufacturers, including SMEs	Healthcare sector, patients and users of PPPs	Patent offices (NPOs)	IP agents/attorneys
	EUR 4.5 million EU-wide			central database; Application fee loss 27 NPOs: up to EUR 32 600 (EUR 0.88 million EU wide).	per MS; EUR 4.1 million EU-wide
Benefits (€)	EUR 45 200 savings per application per firm EUR 5.6 million EU-wide	EUR 40 000 (database access) EUR 12 million EU-wide	Up to EUR 40 000 (database access) EUR 1 million EU-wide	Examiners remuneration: EUR 23 100 (if shared equally between all NPOs); EUR 0.6 million EU-wide.	0
Net (€)	+ EUR 14 500 per application per firm + EUR 1.5 million EU-wide	+ EUR 40 000 per firm; + EUR 12 million EU-wide	+ EUR 40 000; + EUR 1 million EU-wide	- EUR 9 500 per NPO; - EUR 0.26 million EU-wide	- EUR 2 000 per application per MS - EUR 4.1 million EU-wide
PO 4: Centralised decision with a binding opinion	(++) As in PO3 but no re-examination by NPOs. No divergent outcomes on the same file. Savings on attorney fees. Maintenance fees still due at the national level.	(++) as in PO3, but better quality information as no room for conflicting NPO decision on centrally applied SPCs. Possibility to influence SPC granting process through written observations.		(+) As in PO1 + Lower workload for the NPOs (just registration of central SPCs) dependent on usage of central procedure. Lower income for the NPOs equal up to 0.1% of income from patent fee.	(-) Benefits specialised IP agents/attorneys that would handle centralised SPC applications, while other agents may lose income earlier generated by managing national SPC applications.
Costs (€)	EUR 32 000 on application fee	0	0	Marginal cost for data feeding the central database. Application fee lost (27 NPOs): up to EUR 32 600 (EUR 0.88 million EU wide)	Loss of EUR 2 000 per application per MS; EUR 5.2 million EU-wide
Benefits (€)	EUR 56 000 overall savings per application	EUR 40 000 (database access) EUR 12 million EU-wide	Up to EUR 40 000 (database access) EUR 1 million EU-wide	Examiners remuneration: EUR 27 700 (if shared equally between all NPOs); EUR 0.75 million EU wide	0
Net (€)	+ EUR 24 000 per application per firm + EUR 2.4 million EU-wide.	+ EUR 40 000 per firm; + EUR 12 million EU-wide	+ EUR 40 000; + EUR 1 million EU-wide.	- EUR 4 900 per NPO; - EUR 0.13 million EU-wide.	- EUR 2 000 per application per MS - EUR 5.2 million EU-wide.
PO 5: Unitary SPC	(+++/0) One application and one granting body. All fees paid just to the central authority. Benefits limited to 17 UP-MS. No change for applications to the remaining MS.	(++/0) For UP-MS database with complete information. Need for monitoring national SPCs in all MS. (-) Some negative impact on healthcare systems in those MS where SPC would not apply, if not for the unitary coverage.		(=/--) Lower work load for the NPOs of UP-MS dependent on usage of central procedure. No SPC application and maintenance fees, equal to up 0.4% of patent fee income. Less income for the NPOs of UP-MS, however the income generated by SPCs is relatively small compared to the total budget.	(-) Benefits specialised IP agents/attorneys that would handle unitary SPC applications, while other agents in UP-MS may lose income earlier generated by managing national SPC applications. No impact on non UP-MS.
Costs (€)	EUR 23 100	0	higher pharmaceutical costs of up to EUR 2.2 million per UP country (due to wider SPC coverage); EUR 37 million in total.	Up to EUR 34 100 - application fee lost (17 NPOs) – EUR 0.58 million Up to EUR 522 800 - maintenance fee loss (17 NPOs); EUR 8.9 million in total.	Loss of EUR 2 000 per application per MS; EUR 3.2 million in total
Benefits (€)	EUR 34 400 savings on application fee : EUR 22 200 – annual savings on maintenance fee per SPC owner	EUR 25 000 (database access for 17 UP-MS) EUR 7.6 million	Up to EUR 25 000 (database access for 17 UP-MS) EUR 0.7 million (+) more R&D on novel medicines - EUR 37 million in total.	Examiners remuneration: EUR 44 000 (if shared equally between all 17 NPOs); EUR 0.75 million in total.	
Net (€)	+ EUR 26 000 per firm (application)	+ EUR 25 000 per firm;	+ EUR 25 000;	- EUR 512 900 per NPO;	- EUR 2 000 per application per MS

	Originators, including SMEs	Generic/biosimilar manufacturers, including SMEs	Healthcare sector, patients and users of PPPs	Patent offices (NPOs)	IP agents/attorneys
	+ EUR 22 200 per SPC owner (maintenance) + EUR 10 million in total.	+ EUR 7.6 million in total.	+ EUR 0.68 million in total.	- EUR 8.7 million in total.	- EUR 3.2 million in total.

Note: For details of calculations see Annex 5G. Quantifications present maximum potential impacts. Not all impacts are quantifiable. Numbers rounded.

All the options are expected to improve on the *status quo*, but to a varying extent.

PO1 is the least effective as it is uncertain whether guidelines would be followed by all Member States, and how they would be interpreted. Thus the same application would continue to be assessed separately by different NPOs, which might - as currently - result in different SPC granting decisions. It is equally uncertain if best practices on the publication of SPC information would be followed by all NPOs. Consequently, the benefits of PO1 are low and uncertain. SCP applicants will most likely not benefit in terms of legal certainty or the costs of procedure. In NPOs where an SPC database is setup, follow-on manufacturers or national health public procurement authorities may get a slightly better picture of the SPC situation, yet they would still need to collect such information across multiple websites containing information on other jurisdictions.

PO2 should improve the situation substantially, as SPC applications would be examined by only one office. This means no risk of divergent decisions on the same file. However, if there were more than one reference office, the applicants may tend to choose a more lenient one over others (the risk of forum shopping). SPC would continue to be granted by several NPOs and the duration of such procedure may be different in each of them. Applicants would be charged one application fee, but would continue to pay national maintenance fees to each office where an SPC is sought. Their savings would come mainly from the reduced need for legal assistance in the filing process and savings on translation cost which would be no longer necessary (estimated savings of 18% in comparison to the baseline). Follow-on manufacturers and health sector would be able to influence the SPC process by providing written observations to the reference office. They are also expected to benefit from the improved access to SPC data (saving of up to EUR 40 000 per company), although it is uncertain whether such information is to be available in one central or several local databases. NPOs other than the reference office are expected to lose revenue from the application fees of up to EUR 32 300 per year, but would also take advantage from significantly reduced workload while still receiving maintenance income. The demand for legal advice is also expected to be reduced especially in Member States without the reference office. To summarise, although PO2 provides substantial benefits, it cannot however guarantee the same level of examination quality in situations, where there is more than one reference office.

PO3 eliminates the problem of forum shopping and inconsistencies in the examination process of PO2, as there would be only one central authority following the same methodology. It would however allow NPOs to re-examine the SPC application (estimated to occur in up to 20% of cases), which could still result in divergent decisions on the same file. This option is also slightly more expensive than PO2, as the centralised examination authority would be established and its expenses would need to be covered by the application fees (including the costs of translations of documents to be transmitted to NPOs, as the latter would continue to grant SPCs). Thus the cost of PO3 are only 6% lower in comparison to the baseline. The follow-on producers and the healthcare representatives should benefit from the possibility of providing written observations, as well as an access to one central SPC database. The loss of revenue for NPOs would be lower than in PO2 (EUR 9 500 to EUR 36 400 per NPO). The patent attorneys would also see their revenues diminished, but to a lesser extent than in PO2 as they might still handle national appeals in cases of negative decisions. Overall, PO3 thus appears slightly more efficient in terms of reaching the objectives, but still carries the risk of national challenge to the centralised opinion.

PO4 eliminates the NPO's discretion, as the central opinions would be binding. There would also be no risk of forum shopping as in PO2. The only difference could be the potential difference in the registration date, as the granting would still take place at the NPOs (these however are expected to be minor differences). This option scores highest in terms of providing legal certainty and predictability, which should also benefit follow-on producers and health sector procurers seeking an up-to-date information on the SPC status. Nevertheless this option is producing only limited savings of around 10% in comparison to baseline, as the application fees should cover the cost of the central authority and applicants would have to pay maintenance fees to each selected national office. The bulk of savings would come from the reduced need for legal advice and elimination of applicant own translation costs. The follow on producers and health sector procurement officers would have access to the most complete and up to date database on SPC and would be able to submit written observations during the application examination process. Patent attorneys are likely to lose income to the amount similar to PO2. Also, the national patent office are likely to lose revenues from application fees, but would see significant reduction of the workload and would continue receiving maintenance fees. This option is producing the best results in terms of objective 1 and 2 albeit with only moderate cost reductions.

PO5 scores best across all the objectives but only for holders of a European patent with unitary effect. Applicants seeking protection in the (currently) 17 Member States participating in the unitary patent system would only need to interact with the central authority in order to have their applications assessed and SPC granted. Consequently all the fees would be paid only to one authority, and due to elimination of most of the translation costs this option is producing significant cost reductions. However, applicants seeking to cover the whole EU would need to additionally apply individually to each NPO outside the UP system. Consequently the cost of covering the whole EU is expected to be halved in comparison to the baseline. But the savings of this option would increase as more countries join the UP system and as unitary patents become more widely used. Similarly to PO4, the follow-on producers and health procurement officers would be able to influence SPC examination and would have access to the most accurate SPC database (nonetheless, containing information limited to unitary SPCs only). Patent attorneys are likely to lose income in the UP-MS. The NPOs in the UP-MS are likely to lose both application and maintenance fees. This option may result in a wider territorial SPC coverage, as unitary SPC would automatically cover all UP-MS. This may mean that SPC would be protected in countries where it was not the case before – resulting in delayed entry of generic/biosimilar competitors and increased spending on medicines (by up to EUR 2.2 million on average per Member State per year). These additional resources as well as savings on administrative fees should however contribute to higher R&D spending on novel medicines.

7.2. Best option and possible combinations of options to improve it further

As discussed above PO5 is the best option to fulfil the policy objectives and produce the highest benefits. However, PO5 provides for a single examination (and granting) procedure only for the (currently 17) Member States participating in the unitary patent system. As the UP system still covers only a subset of Member States, in order to eliminate the key problem of divergences between national SPC systems, it is necessary to combine the unitary SPC with another option to cover the remaining (currently 10) Member States that are not part of the UP enhanced cooperation - at least in the interim, until the UP system covers the whole EU. In other words, given the current coverage

of the unitary patent system, a dual system that differentiates between the participating and non-participating Member States must be proposed. Although a combination of two options means that two different administrative settings would need to be implemented, it seems to be the only method to ensure implementation across the whole EU. Moreover, there may be cases where the basic patent may not be a unitary patent, thus requiring the applicant to file applications in up to 27 Member States. A combination of options would therefore also cater to these scenarios, allowing applicants to benefit from a centralised examination, despite not meeting the granting criteria for a unitary SPC. When deciding on which option could best complement PO5, all possible combinations are analysed below, notably PO1, PO2, PO3 and PO4.

Combining PO1 with PO5 would not bring much change for SPC applicants in the 10 non-UP MS. Even if the guidelines were followed and NPO practices were aligned, there would still be 10 different authorities deciding on the SPC application, resulting in potentially contradictory decisions. Thus predictability and legal certainty of the SPC procedures would not improve much.

The situation would ameliorate if PO5 was combined with PO2 (mutual recognition). However, companies would still need to file two applications: one to the central authority to cover the 17 UP-MS and another one to the NPO acting as a reference office for the remaining Member States. As two different authorities would evaluate and grant SPCs, the risk of divergent decisions would remain. Also any third party willing to submit written observations (either electronically or in traditional way) would need to run the procedure twice.

PO3 or PO4 envisage that the central authority (the same as in PO5) would receive applications, conduct their examination and issue either a non-binding (PO3) or binding (PO4) opinion regarding whether a national SPC should be granted or not in the various Member States designated in the application. PO3, however, allows NPOs to depart from the central examination outcome (e.g. an NPO could grant an SPC even if the central authority concluded it should not be granted, or vice-versa). This would create a risk of perpetuating the problem of divergence. Only PO4 eliminates the risk of NPOs diverging from the central examination, as it envisages a binding opinion which the NPOs of the designated Member States would need to follow.

Consequently a combination that provides the highest level of legal certainty and predictability, while covering all Member States, is the combination of PO5 with PO4.

7.3. Coherence with other EU policies and the charter of fundamental rights

The EU policy areas which have the closest links with the proposed initiative are those concerning the protection of public health, especially with regards to pharmaceuticals, and food safety – the latter with regards to PPP.

As far as the medicinal products are concerned, the proposed initiative is aligned with the following objectives of the Pharmaceutical Strategy for Europe:

- **Equal and affordable access to medicines**: As discussed in section 2.3, follow-on producers face difficulties to ascertain the status of SPC protection in due time. This may hamper the launch of their product (i.e. generic or biosimilar), their participation in tenders for the purchase of medicines, or their reliance on the SPC manufacturing waiver. The proposed centralised SPC procedure would increase predictability and

legal certainty for generic/biosimilar companies by improving overall transparency of the SPC protection status across the EU. This is expected to facilitate market entry of generic and/or biosimilar products, which by inflicting downward pressure on medicine prices, should positively impact the access to affordable medicines for EU patients.

- **Enhancing crisis preparedness and response mechanisms, strengthening the resilience of pharma supply chains**: The pharmaceutical supply chains are increasingly complex and exposed to vulnerabilities, including the EU's dependency on third countries for materials or ingredients used in pharmaceutical manufacturing. In this context, the proposed review of SPC rules is expected to strengthen the EU's industrial base, and our manufacturing capacity for medicines. The proposed SPC reform would provide additional transparency in the process, as well as a single access point to up-to-date information on SPC status. This should help the EU (generic) industry to map dependencies, and facilitate cross-border procurement of medicines (e.g. better pricing and procurement practices are recognised as enablers to security of supply). Given the competition for raw materials and (relatively) fewer dependencies on patented drugs, assuring the right balance of investment incentives through robust SPCs enhances resilience.
- **Administrative burden reduction**: As explained earlier in this impact assessment, the fact that SPCs are administered at national level creates significant red tape and entails extra costs for businesses, which is especially challenging for SMEs (nearly 19% of all SPC holders). As the result of the proposed changes, the cost and burden of obtaining and maintaining SPC protection in the EU will be significantly reduced. Additionally, the cost of monitoring the SPC status should also decrease (currently follow-on manufacturers need to assess it separately for each Member State), as such information would be publicly available through a single access point provided by a new central website. The central database could also provide information on the RDP status of SPC medicines.
- **Supporting competitiveness, innovation and sustainability of the EU's pharmaceutical industry**: As mentioned above, the improved coherence and legal certainty as regards SPCs will facilitate and thus promote the operation of pharmaceutical firms in the EU. A more coherent SPC protection provided for these products is expected to generate savings and encourage investment in research and development for innovative medicines and treatments.

Finally, it is important to highlight that the proposed pharmaceutical legislation revision does not affect the incentives pertaining to intellectual property rights (patents and SPCs), however as mentioned earlier, both policies are interlinked[231].

As far as PPPs are concerned, the proposed initiative is aligned with the integrated Food Safety policy of the EU with regards to plant health and approval of active substances used in PPPs.

[231] In particular, as a marketing authorisation is a pre-condition for granting an SPC thus, if a marketing authorization is withdrawn, the SPC lapses. The so-called "sunset clause" present in pharma legislation ensures that a marketing authorisation becomes invalid where, within three years of its granting, it is not followed by the actual placing on the market of the authorised product. Where such invalidity leads to withdrawal, the SPC can therefore also lapse.

Finally, the proposed options do not extend the scope of the existing SPC protection which is already defined by the EU regulations. The options proposed do not conflict with other EU international treaties or EU pharmaceutical and phytosanitary legislations. The SPC-related procedures would be available to applicants from the EU and third countries alike. To summarise, all the considered options are compatible with the goals of the EU health and food safety policies. Finally, the initiative is also coherent with the Charter of Fundamental Rights (e.g. Article 35 on access to health[232]).

7.4. **Compliance with the proportionality principle**

None of the options go beyond what is necessary to achieve the identified problems/objectives. Their respective scope is limited to those aspects that Member States cannot achieve satisfactory on their own and where the Union action can produce better results (for example, in terms of consistent decisions on SPC applications in order to remove current legal uncertainty, as well as transparency) or is necessary (as in case of creating a new EU IP right - a unitary SPC to complement the unitary patent). Options considered provide a mix of Member States and EU level actions with gradual increase of the EU level intervention. Possible legal instruments for implementing policy options are in case of PO1 a set of recommendations; and in case of PO2-5 an amendment (or recasting) of the existing SPC regulations.

8. PREFERRED OPTION

The preferred option of this impact assessment is policy option PO5 (the establishment of a unitary SPC, i.e. a new IP right) combined with policy option PO4 (a centralised procedure with a binding opinion). It combines the advantages of a one-stop-shop SPC procedure with the possibility to obtain unitary SPC protection in countries where the corresponding unitary patent takes effects (i.e. Member States participating in the enhanced cooperation area of the unitary patent that have ratified the Unified Patent Court Agreement at the date of the grant). The preferred option would encompass:

- a centralised procedure for the filing and examination of SPC applications that rely on European patents, with the possibility to request a unitary SPC (if applicable);
- the possibility to submit third parties' observations during the examination;
- stakeholders' right to use any EU language when contacting the examination authority in relation to the centralised SPC procedure;
- a single access-point providing information on the SPC status, also available in all official languages of the EU.

As discussed in section 6.3 the EUIPO managing a virtual office of SPC experts from NPOs would be the preferred choice for the central examination authority. This solution combines both the expertise in the assessment of SPCs with accountability to the EU public and assurance that EU IP policy goals are implemented.

[232] 'Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.'

The considered combination of options (PO4 and PO5) would not replace the existing nationally-filed SPCs, however it may be foreseen that under certain conditions the centralised procedure has to be used in order to reduce the risk for national discrepancies.

The implementation of the preferred option would require adopting a new regulation establishing unitary SPC protection in the Member States where the unitary patent has effect, and amending Regulation (EC) No 469/2009 on medicinal product and Regulation (EC) 1610/96 on PPPs to introduce the centralised procedure with a binding opinion that can operate in all 27 Member States. The mandate of EUIPO would have to be extended to cover new responsibilities. Additional legislation to establish the linguistic regime of the unitary SPC might also be required.

This option offers the most balanced and proportionate approach, which also takes into account the views and concerns of stakeholders. The preferred option would fully address the three identified problems (i.e. legal uncertainty, cumbersome monitoring of SPCs and high costs and burden of seeking and maintaining SPC protection). It would:

- Increase predictability and legal certainty in the Single Market regarding SPC protection by eliminating the possibility of divergent national decisions on granting SPC protection across the EU. Such outcome would be achieved through unitary SPC protection for the participating EU Member States in the enhanced cooperation area and through a binding opinion of the examination authority about the validity of the SPC in the non-participating Member States;
- Significantly decrease the cost of monitoring SPC protection across the EU and therefore improve transparency, because such information would be publicly available through a single access point provided by means of a website with search functions.
- Significantly decrease the cost and burden of SPC protection in the EU, as it would simplify the SPC procedure and reduce the current cost of up to 27 application and renewal fees. For instance a five-year long, EU-wide SPC would cost 55% less than the baseline[233], producing savings of around EUR 137 000 per product. The bulk of savings would result from the unitary SPC, as the firms would avoid paying high renewal fees annually in each of the Member States of the unitary patent protection (initially 17). In addition, the filing and prosecution of one single SPC application could potentially be carried out by one patent agent/attorney office, thus also leading to savings as compared to the necessity to involve potentially up to 27 patent agents/attorneys.

Table 13: PO4+5 costs and savings to applicants for receiving EU27 wide, five year long SPC protection

	EUR per application	Savings vis-à-vis baseline
Filing fees	38 800	-30 000
Maintenance fees for 5 years	71 900	111 100
Translation costs	0	4 000
Agent/attorney's fees	2 000	52 000
Total	112 700	137 100

Source: In-house estimations, numbers rounded to 100s, see: Annex 5E

This preferred combination of two options (PO4 and PO5) would overcome the limitations in scope that characterise PO5 (i.e. creating a unitary SPC). First, the unitary SPC would be limited to EU Member States of the unitary patent area (initially 17 Member States). Second, a unitary SPC could

[233] Or 65 % in case of an average SPC covering 20 Member States for 3.5 years, whereby the group of 20 Member States is assumed to consist of 17 UP Member States and 3 non-UP Member States. See Annex 5E

only be granted on the basis of a unitary patent, whereas many SPC users might still continue using European patents without unitary effect to protect some of their products (or, in certain cases, the conditions for attributing unitary effect to the basic patent may not be met). The preferred combination of PO4 and PO5 would provide for a centralised procedure able to result in the granting of national SPCs in some or all Member States, and/or in a unitary SPC (covering those Member States in which the basic unitary patent has effect). Applying for a unitary SPC would never be mandatory.

Regarding the options set out in the Call for Evidence, there was overall support for an EU initiative which would comprise a combination of the unitary SPC and a centralised granting procedure (sometimes referred to by the respondents as a "dual" system). Some stakeholders took the view that a centralised granting mechanism alone may not be sufficient to tackle the problems identified. Respondents further highlighted the need for a transparent system. In particular, some stakeholders emphasised that there was a need for a balanced system and that the initiative should not shift the current relation between generics and originators. The combination of a centralised grant mechanism for national SPCs based on European patents and a unitary SPC system for unitary patents, was supported by representatives from all key groups of market players, namely manufacturing new products based on own R&D and producers of generics in both sectors (i.e. pharmaceuticals[234] and PPPs[235]) .

Table 14: How the preferred option achieves the policy objectives?

Objective		**Preferred option:** PO5 (unitary SPC) + PO4 (centralised procedure with a binding opinion)
Reducing cost of applying and maintaining SPC protection		(++) One procedure, 55% lower costs (fees, attorney, translations) for a five-year long, protection in the whole EU (national maintenance fees might be still due for non UP-MS).
Increase predictability and legal certainty of SPC protection in the EU by facilitating:	Examination procedures	(+++) One examination procedure eliminated divergent outcomes on the same file
	3rd parties involvement	(+++) Right to submit third parties opinions
	Granting procedures	(+++) One granting procedure for UP- MS and a binding decision for the remaining MS.
Facilitate SPC monitoring		(+++) One single register and publicly accessible data of SPCs hosted by the EA
Cost efficiency (EUR million)		**Net effect** 10.5 from 5th year operations; **Benefits** 65.4; **Cost** 54.9

Table 15: Impacts of the preferred option (PO4 + PO5) on stakeholders (qualitative analysis)

Stakeholder	**Impacts**
Originators, including SMEs (100 applications, 400 owners paying maintenance fees)	(+++/++) For 17 UP-MS: one application and one granting body. All fees paid to the central authority only. The same registration date. No divergent outcomes. For the remaining 10 MS: one application + NPOs grant SPC based on central authority opinion. Registration date might still differ depending on NPO process. Maintenance fees still due at the national level.
Costs	EUR 30 000 per application, EUR 3 million EU-wide

[234] For example, Medicines for Europe (association of generic and biosimilar producers of pharmaceuticals) stated that a unitary SPC should be created for coherence with the unitary patent system and with the objective to tackle fragmentation and legal uncertainty (https://www.medicinesforeurope.com/wp-content/uploads/2021/02/Medicines-for-Europe-Position-Paper-on-Unitary-SPC-Unified-Mechanism-for-SPC-granting-March-2021.pdf)

[235] For example, one of the largest associations of PPP producers in the EU, which expressed support for the combination of the centralised examination and unitary SPC - meeting with the Commission Services on 4 October 2022.

Benefits	EUR 56 000 per application, EUR 22 200 per maintenance fee; EUR 14.5 million EU-wide
Net	EUR 26 000 per application, EUR 22 200 per maintenance fee; EUR 11.5 million EU-wide
Follow-on manufacturers, SMEs (300 firms) **Healthcare sector, patients and users of PPPs** At least 27 (one healthcare authority per MS)	(++) Database with almost complete information on centrally assessed/granted SPCs. NPOs participation necessary for nationally granted SPCs. Possibility to influence SPC granting process through written observations.
Costs	Follow-on manufacturers: 0 for generics; Healthcare: (+) up to EUR 2.2 million per UP country (due to wider SPC coverage). EU total of EUR 37 million
Benefits	Up to EUR 40 000 (database access) per firm/authority (+) EUR 37 million more R&D on novel medicines (EU total)
Net	EUR 12 million (follow-on firms) and EUR 1 million (healthcare authorities) EU-wide
Patent offices (NPOs) 27 MS	(=/-) Loss of examining work load in the NPOs of the 27 EU MS. Loss of revenue for UP-MS equal to 0.4% and for others 0.3% of patent fee income.
Costs	(-) Loss of application fee: up to EUR 32 600 per NPO; Loss of maintenance fee: up to EUR 522 800 per UP NPO; EUR 9.8 million
Benefits	Examiners remuneration: EUR 32 300 (if shared equally between all NPOs); EUR 0.87 million EU-wide
Net	- EUR 8.9 million EU-wide
IP agents/attorneys Up to 2700 (1/per MS per SPC)	(-) Benefits specialised IP agents/attorneys that would handle centralised and unitary SPC applications, while other agents in UP-MS may lose income earlier generated by managing national SPC applications.
Costs	Loss of EUR 2 000 per application per country
Benefits	
Net	- EUR 5.2 million EU-wide

Note: Tables present maximum potential impacts from 5th year of new system operation; numbers rounded.
Assumptions: 100 SPC applications per year, 80 SPC granted; 5-year-long SPC protection.
Source: In-house analysis.

8.1. REFIT (simplification and improved efficiency)

The following table summarises cost savings of the preferred option, in relation to the single grant mechanism (which would be introduced as amend existing legislation on SPC).

Table 16: REFIT – cost savings

REFIT Cost Savings – Preferred Option(s)		
Description	*Amount*	***Comments***
Reduction of SPC application costs	EUR 11.5 million	Due to replacement of 27 national procedures by one central with lower fees and need for just one legal representative. Materialising in full from 5th year onwards.[236]
Reduction of monitoring cost for follow-on producers and health sector.	EUR 13 million	Corresponds to cost of purchasing private SPC database access. Consisting of approximate savings of EUR 40 000 for around 300 follow-on manufacturers and at least 27 national health procurement offices.

8.2. Application of the 'one in, one out' approach

This initiative would allow SPC applicants to use a single filing and examination procedure instead of up to 27 national procedures. It would in particular lower the translation costs incurred by applicants

[236] This is a net figure consisting of higher application costs for around 100 SPC applicants or EUR 3 million and lower cost of legal advice (EUR 5.2 million) and translations (EUR 0.4 million) for 100 SPC applicants as well as lower cost of SPC maintenance of EUR 8.9 million for around 80 companies which should receive SPC given historical application rejection rate of 20%. Detailed calculations available in Annexes 5E and 5G.

before filing an SPC and limit the need for legal advice while dealing with each NPO. This is expected to produce annual EU-wide savings of EUR 5.6 million. This figure includes annual savings of EUR 52 000 on legal advice and EUR 4 000 on translation for approximately 100 SPC applicants per year.

9. HOW WILL ACTUAL IMPACTS BE MONITORED AND EVALUATED?

The legislation to be proposed would include a provision requiring an evaluation every five years, the first one five years after the grant of the first SPC under the new procedure. This should be done taking due account of the combined effect of other features of the EU legislation, especially in the pharmaceutical sector. The objective of the monitoring would be to determine whether or not the new initiative impacted long-term trends in the availability of novel medicinal products and plant protection products (albeit, it should be recognised that a direct causal link may be difficult to establish). To that aim, the available data on medicines[237] and PPPs[238] should be monitored, for example in 5-year intervals (in line with the evaluation schedule), as well as using other monitoring tools (e.g. dedicated surveys among SPC holders to test perceptions). The historical data on new product entries before this legislation enters into force should serve as a baseline. Additionally, the following indicators will be established and monitored with regards to each objective:

Table 17: Monitoring indicators

Research question	Indicators	Sources of information
Objective 1. Increase predictability and legal certainty of SPC protection		
How do the new system compares with the baseline in terms information available on SPC protection?	- Duration of the protection, as defined in the SPC decision; - Share of negative decisions (i.e. number of negative decisions divided by the total number or applications received); - Number of countries covered by an SPC for a given product (a non-divergent decision); - Number of unitary-SPC; - Number of SPC-related referrals to the CJEU.	- Centralised EA's SPC database; - CURIA website, - PATSTAT database; - Data from this impact assessment (comparison with the baseline).
Objective 2. Monitoring SPC protection		
How do the new system compares with the baseline in terms of accessibility and completeness of SPC information?	- Number of variables available (e.g. state of the procedure, date of entry into force, date of expiry, status of the paediatric extension, SPC holder's identification, usage of the SPC manufacturing waiver); - Quality of information available (e.g. share of observations with non-missing information provided in key variables[239]); - Timeliness of the information available, determined by general characteristics of the IT system to be established and its frequency of updates (i.e. what is the time lag between an administrative action and accessibility of such information in the database?).	Centralised EA's SPC database.
Objective 3. Reduce cost and burden of seeking and maintaining SPC protection		
How do the new system compares with the baseline in terms of number of procedures per year and its duration?	- Number of SPCs applications submitted, including a subset: number of applications requesting the unitary SPC; - Number of SPCs granted following the centralised procedure, including a subset: number of the unitary SPCs granted; - Country distribution of the SPC holders (to allow comparisons by country); - Duration of the SPC procedure in moths (i.e. date of filing less the date of the decision).	- Centralised EA's SPC database; - EA annual reports; - Data from this impact assessment (comparison with the

[237] EMA, EPAR summaries of opinions for human and veterinary medicines (https://www.ema.europa.eu/en/medicines/download-medicine-data).
[238] EU Pesticides Database (https://food.ec.europa.eu/plants/pesticides/eu-pesticides-database_en).
[239] Some of the information may be mandatory (e.g. the identification of the applicant), hence in such cases the accessibility would be 100 %.

Research question	Indicators	Sources of information
How do the new system compares with the baseline in terms of the cost per SPC procedure?	- Cost of the SPC protection (i.e. fees paid per SPC following the centralised procedure and/or unitary-SPCs).	baseline).
Is the cost of SPC procedure significant for SMEs?	- Number of SMEs among SPC holders[240]; - Cost of the SPC protection for the SMEs (i.e. fees paid per SPC following the centralised procedure and/or unitary-SPCs).	

[240] Based solely on the identification information provided in the application, or by combining this information with other databases where the firm's size classes can be determined (e.g. Orbis, see Annex 4).

ANNEX 1: PROCEDURAL INFORMATION

1. LEAD DG, DECIDE PLANNING/CWP REFERENCES

DG for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW).

2. ORGANISATION AND TIMING

The deadline for adoption of a proposal by the Commission is April 2023.

Inter-service meetings took place on 26.01.2021, 06.05.2022, 19.07.2022 and 24.08.2022.

The following Commission services participated: DG COMP, EUIPO, SANTE, SJ, SG, TRADE, RTD and GROW.

3. CONSULTATION OF THE RSB

A meeting with the RSB took place on 28.09.2022. On 30.09.2022 the RSB delivered a negative opinion. On 23.11.2022 a revised version of the impact assessment was submitted to the RSB. The table below shows RSB initial comments and how they were addressed in the revised text.

Table 18: RSB comments to the initial version of the impact assessment

RSB comments	***DG GROW replies***
(1) The report is neither sufficiently clear about the main problem that needs to be tackled nor how important it is.	The report now presents in section 2.3 "legal uncertainty" as the main problem. The SME angle of the "high cost" problem was supported by extracting elements from the "SME test" annex into the main text. Additionally the fact that upcoming unitary patent would not be met with a unitary SPC at the EU level is highlighted throughout the impact assessment.
(2) The report does not sufficiently explain the coherence between this initiative and the parallel revision of the general pharmaceuticals legislation.	The report now explains in section 2.2 the differences between the SPC system and alternative (not related to patent protection) instruments available to pharmaceutical firms, such as market protection or data protection offered by the pharmaceutical legislation. In addition to already presented assessment of the impacts of the pharmaceutical reform on the current SPC system (which is independent of the proposed reform) in section 2.6 and the impact on biosimilar/generic entry in section 6.6.1., the coherence of the preferred option with pharmaceutical reform is now further elaborated in section 7.3.
(3) The net impacts of each option and combination of options are not sufficiently analysed. The comparison of options does not unequivocally allow the identification of the preferred option, including in terms of proportionality. The choice of the preferred examination authority is not sufficiently argued.	The report now in addition to tables in section 7.1 provides explanation of the tables with net impacts of each option (a combination of mainly unquantifiable impacts and quantifiable ones where available). Section 7.2 was added to explain which combination of options is better in view of meeting the first objective of legal certainty. It is now clearly stated that all options are proportional and do not go beyond what is needed to achieve the objectives. The argumentation for choosing the examination authority in section 8 has been expanded and refers clearly to the selection criteria and analysis in section 6.3.
(4) The presentation of the views of different stakeholder categories is not sufficiently accurate or balanced throughout the report.	The views of different stakeholders are now more prominently presented drawing on the analysis in Annex 2. Additional subsection was added to Annex 2, which explains how available consultation results were matched with the policy options and what were the methodological limitations of the public consultation used

	in this impact assessment.

On 16.12.2022 delivered a positive opinion on the revised text. The table below shows further changes implemented in the impact assessment in order to align it with RSB comments expressed in the second opinion.

Table 19: RSB comments to the revised version of the impact assessment

RSB comments	***DG GROW replies***
(1) The report is not sufficiently clear about the drivers behind the divergences of national practices for SPCs.	Further insights on the underestimated complexity of the SPC examination procedure was added to section 2.4.1, as well as stakeholder's feedback on NPOs approaches to implementing the SPC procedures.
(2) The report does not sufficiently justify the choice of the preferred option.	Section 8 was reedited, so that the choice of the preferred option was substantiated in a more comprehensive manner.

4. EVIDENCE, SOURCES AND QUALITY

The analysis presented in this impact assessment is based on the following key sources:

- Max Planck Institute for Innovation and Competition, *Study on the Options for a Unified SPC System in Europe*, 2022 (https://op.europa.eu/en/publication-detail/-/publication/94cb20ea-2ff0-11ed-975d-01aa75ed71a1/language-en).
- European Commission, Evaluation of EU Regulations 469/2009 and 1610/96 on supplementary protection certificates for medicinal and plant protection products, SWD(2020)292, 2020 (https://ec.europa.eu/docsroom/documents/43847).
- Max Planck Institute for Innovation and Competition, *Study on the Legal Aspects of Supplementary Protection Certificates in Europe*, 2018 (https://ec.europa.eu/docsroom/documents/29524).
- *Technopolis*, 'Effects of supplementary protection mechanisms for pharmaceutical products', 2018 (https://www.ivir.nl/publicaties/download/effects-of-supplementary-protection-mechanisms-for-pharmaceutical-products.pdf).
- Copenhagen Economics, *Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe*, Publications Office of the European Union, Luxembourg, 2018 (https://ec.europa.eu/docsroom/documents/29521).
- European Commission, Summary of the replies to the public consultation on Supplementary Protection Certificates and patent research exemption for sectors whose products are subject to regulated market authorisations, SWD(2018)242, 2018 (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018SC0242).
- Mejer, M., *25 years of SPC protection for medicinal products in Europe: Insights and challenges*, European Commission, DG GROW, 2017.

Additionally, the following data sources were used in order to perform in-house analysis:

- MIDAS database provided by IQVIA, as a flat file covering EU–27 except for MT and CY, for the years 2010–2021;
- National data related to the cost of SPC (application and maintenance), as collected from respective NPO websites in March 2022.
- German Patent and Trade Mark Office, Data uploaded from the German national patent office, DPMA concerning SPCs - *Schutzzertifikat* (https://register.dpma.de/DPMAregister/pat/basis).

The remaining sources are provided in the footnotes, whenever they are referred to in the text.

ANNEX 2: STAKEHOLDER CONSULTATIONS

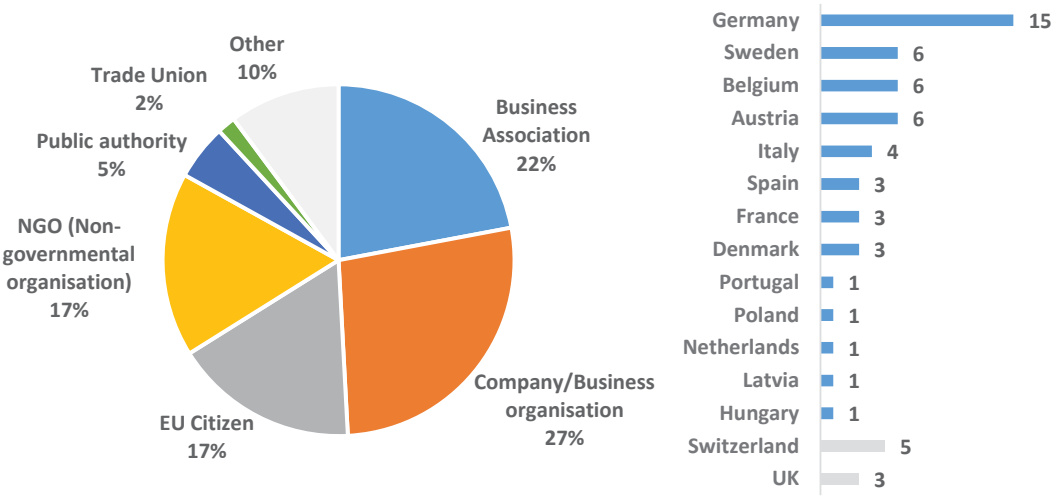
This annex documents all the consultation activities conducted in the context of the revision of SPC regulation.

From 8 March to 5 April 2022 interested parties could provide feedback to Commission's Call for Evidence[241]. In 2020 there was a dedicate survey to Member States on SPC transparency. Questions relevant to this initiative were also asked in earlier consultations: on evaluation of the EU SPC system (took place between 12 October 2017 and 4 January 2018)[242] and as part of a legal study (between 22 May and 23 June 2017)[243]. Additionally several bilateral meetings with stakeholders took place between 2018 and 2022, including meetings with Member States as part of the Commission expert Group on Industrial Property Policy[244], representatives of associations of pharmaceutical companies (originators, generic and biosimilar producers) and plant protection products manufacturers.

Feedback on call for evidence

By the end of consultation period 59 replies arrived (51 from the EU Member States). Almost half of responses came from business and business organizations. One in six was from EU citizens and similar number of NGOs. Five percent came from authorities and two percent from trade unions.

Figure 12. Distribution of respondents to call for evidence by type of respondent and country of origin.



Source: Commission services' own analysis

While the answers or the respondents were grouped into businesses, NGOs, citizens[245], etc., the analysis also looks at the subgroups of originator companies and generic companies and their

[241] For complete summary of replies see: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13353-Medicinal-plant-protection-products-single-procedure-for-the-granting-of-SPCs_en
[242] https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1593699690365&uri=CELEX:52018SC0242
[243] MPI (2018) - Allensbach survey.
[244] https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?lang=en&do=groupDetail.groupDetail&groupID=3434
[245] Note that the feedback received from individuals, while pertaining to a considerable percentage here, almost exclusively did not relate to the initiative.

respective associations into account to reflect the group of stakeholders' views best. The following feedback could be broadly observed:

The originator companies and their associations supported the introduction of a unitary SPC and the creation of a centralised procedure. Guidelines could help as supporting measures, but not as a standalone solution to the problems highlighted in the Call for Evidence. In particular, using the expertise of NPOs through a virtual examination body, was favoured by a majority of stakeholders.

The generic companies and their associations highlighted that a Unitary SPC may tackle the current fragmentation with several advocating that a single procedure should only be considered if there were pre-grant opposition proceedings (a procedural element that should ideally be introduced for both procedures). They further took the view that the timely access to generic medicine as well as the impact on generics should be taken into account, in particular regarding the potential extension of the geographical scope through the Unitary SPC. Moreover, it was underline that multiple litigation in several Member States was also a problem faced by stakeholders at the moment.

More broadly, the main takeaways from the feedback are discussed below. Regarding the options set out in the call for evidence, there was overall support for an EU initiative which would comprise a combination of the unitary SPC and a centralised granting procedure. National procedures should still exist alongside them. Some stakeholders took the view, that a single granting mechanism alone may not be sufficient to tackle the problems identified. Respondents further highlighted the need for a transparent system. In particular, some stakeholders emphasised that there was a need for a balanced system and that the initiative should not shift the current balance between generics and originators.

Those respondents that addressed guidelines, mostly favoured them as measures to support the new system, but not as a standalone option. In particular, these guidelines may for example either codify or clarify CJEU case law, or be based on best practices from NPOs, and thus provide guidance for national procedures.

Responses were split on point c2) of the Call for Evidence regarding targeted amendments of the SPC Regulations on the basis of the best practices of national patent offices and CJEU case law aimed at further harmonising the current SPC system. Some responses were in favour of this option, while others cautioned that any further amendments might lead to even more cases and would therefore cause further uncertainties. As regards the granting authority, the majority of feedback received favoured a virtual granting authority. Some organisations favoured the EPO, while others highlighted the need for a central EU granting authority which would also be accountable to the CJEU. Expert knowledge, whether this be within the authority itself or its appellate body, was also pointed out as an important criterion by some stakeholders.

Last, while only very few respondents represented the PPP industry, the feedback received also favoured the single procedure in combination with the unitary SPC to address the current fragmentation.

Survey to Member States on SPC transparency

The European Commission conducted a targeted survey among national patent offices in early 2020 to obtain details on their transparency practices. Based on this survey, different practices across NPOs have been identified. Most national patent offices (NPOs) provide for an online searchable database, although the search criteria are very variable (in two Member States, only the SPC number can be used as a search criterion). Publishing SPC-related information takes varying amounts of time, ranging from a few days to several months, and even more than a year in specific situations. Only a slight majority of NPOs (14) publish SPC-related information in English in addition to their official languages. Only about half of the NPOs make the documents of the file of a given SPC application accessible online (e.g. in PDF format). However, the other ones usually provide for file inspection and/or are able to provide copies. Only a slight majority of NPOs (15) provide the European Patent Office with detailed information on SPCs (which the EPO then publishes). When asked which source they would consider to be the most suitable for providing centralised access to SPC information, seven NPOs mentioned the EPO databases (possibly with improvements), four did not express any preference, and 14 mentioned a new centralised website.

Public consultation (responses relevant to this initiative)

A total of 231 replies were provided to the on-line consultation: 43 replies from the general public, 71 from originators industry/associations, 63 from generics and biosimilars industry/associations, 15 from health authorities/doctors/patients groups (mostly from national organisations dealing with health insurance/reimbursement/health technology assessment, from a doctors' organisation, and 2 from patients' associations), 34 from patent offices/practitioners, and 5 from industry/trade authorities. The tables below present statistics on those respondents who took a position that is "don't know" answers and "no answers" are not taken into consideration[246].

Problems with current SPC rules: Respondents broadly support the way in which SPC issues are regulated at EU level, which is found to be globally effective. However, most respondents claim that there are different practices for registration and SPC enforcement across Member States (a few originators and generics manufacturers disagree).

Table 20. Have authorities in different EU countries ever taken different decisions on SPC applications for one (or more) of your products? Examples: some EU countries granted SPC national applications for one of your products but refused others; you were granted different durations of SPC protection for one of your products in different EU countries; national grant authorities interpreted EU Court of Justice rulings differently). Q11 (to Originators) and Q4 (to Follow on manufacturers) Q2 (to to Patent offices, judges, lawyers)

	Yes	No	No. of answers
Originator/innovator	82%	18%	49
Follow on manufacturer	79%	21%	43
Patent offices, judges, lawyers	96%	4%	28

Note: "Don't know" and No answer not taken into account (also in no. of answers provided).
Source: Public Consultations on Evaluation of SPC

[246] The number of "don't know" and "no reply" answers is the difference between number of all responses in a given category of respondent and the number of answers (of those taking a position) presented in each table either in the last column or the last row.

Generics manufacturers mostly support SPC registration with substantive examination, but consider that transparency is not optimal (information published by public authorities is not always comprehensive or up-to-date, and private databases monitoring SPC status are expensive).

Table 21: Based on your experience, do you think that all EU countries' national patent offices should conduct substantive examination (i.e. actual verification of the conditions stipulated in the SPC Regulation) of SPC applications? Q28 (to Follow-on manufacturers)

	%
Yes	86%
No – some of them might not have the necessary administrative capacity/resources	5%
No – it's unnecessarily cumbersome, even for the offices with enough resources	9%
No. of answers	56

Note: "Don't know" and No answer not taken into account (also in no. of answers provided).
Source: Public Consultations on Evaluation of SPC

Table 22: About your use of databases to monitor the status of your competitors' SPC protection across EU Member States. Q6 (to Follow on manufacturers), Q5 (to Customers, health), Q4 (to Patent offices, judges, lawyers)

Agree answers only*	**Follow on manufacturers**	**Customers, health**	**Patent offices, lawyers**
specialised databases are very costly	96%	83%	69%
to our knowledge, there are no databases available to conduct such monitoring	4%	75%	30%
No. of answers	*55*	*14*	*16-23*

* the residual to 100% is the number of those disagreeing.
Note: "Don't know" and No answer not taken into account (also in no. of answers provided).
Source: Public Consultations on Evaluation of SPC

The level of registration fees or litigation costs is predominantly acceptable for SPC holders, as such costs can be compensated by additional sales resulting from the SPC protection.

Table 23: How would you rate the degree of complexity of registration procedures for SPCs in the EU? Q13 (to Originators) and Q9(to Follow on manufacturers)

	High	**Reasonable**	**Low**	**No. of answers**
Originator/innovator	13%	72%	15%	54
Follow on manufacturer	39%	61%	0%	51

Note: "Don't know" and No answer not taken into account (also in no. of answers provided).
Source: Public Consultations on Evaluation of SPC

Table 24: Is the cost of registering and maintaining an SPC in all 28 EU countries proportionate?. Q15 (to Originators):

	%
YES, the cost is always relatively low compared with product sales	77%
The cost of SPC protection barely exceeds the value of sales in some small markets. But we always register the SPC in all EU countries where the corresponding patents are in force.	2%
The cost of SPC protection barely exceeds the value of sales in some small markets. So we do not register the SPC in all EU countries where the corresponding patents are in force.	0%
NO, the administrative burden to register and maintain it in all EU countries is high	4%
Other: please specify	17%
No. of answers	53

Note: "Don't know" and No answer not taken into account (also in no. of answers provided).
Source: Public Consultations on Evaluation of SPC

Respondent noted however that other jurisdictions such as the US or Japan provide more attractive SPC-type protection than the EU system.

Table 25: In your experience, do other jurisdictions (e.g., the US or Japan) provide for SPC-type protection to certain types of innovations you develop that are not eligible for an SPC in the EU? Q26 (to Originators) and Q13 (to Follow on manufacturers)

	Yes	No	No. of answers
Originator/innovator	95%	5%	44
Follow on manufacturer	79%	21%	34

Note:"Don't know" and No answer not taken into account (also in no. of answers provided).
Source: Public Consultations on Evaluation of SPC

Unitary SPC: A very large majority of the respondents across all categories favour the creation of a unitary SPC, which would extend unitary patents once such exclusive rights expire.

Table 26: Do you favour the creation of a unitary SPC title for the unitary patent? Q37 (to Originators), Q29 (to Follow on manufacturers), Q15 (to Customers, health), Q27 (to Patent offices, judges, lawyers). Q9 (to Other public authorities)

	Originators*	Follow-on manufacturers	Customers, health	Patent offices, lawyers	Ministries and other public authorities
Yes	74%	98%	79%	81%	100%
No	x	2%	21%	19%	0%
No. of answers:	*68*	*55*	*11*	*27*	*5*

* respondents did not receive this question instead we report here those who chose "Create a unitary SPC for the unitary patent" as answer to Q37 "What would be your preferred option to improve consistent interpretation throughout the EU of the 'substantive' provisions of the SPC regulation (e.g. the scope of protection, eligibility of SPC protection)?".
Note: "Don't know" and No answer not taken into account (also in no. of answers provided). Questions had slightly different formulations to each group but with the same meaning.
Source: Public Consultations on Evaluation of SPC

Regarding the benefits of a unitary SPC, a great majority of originators consider that it could boost the value of investments, reduce the red tape related to registration and litigation, provide a uniform protection across the EU, improve legal certainty, reduce maintenance costs, offer a specialised court, and finally - it would make licensing easier. A large majority of follow-on manufacturers, including SMEs, shared these views.

One Member State considered that it would also simplify and enhance the efficiency of the SPC application process.

Table 27. What would be the benefits of a unitary SPC?:Q43 (to Originators), Q35 (to Follow on manufacturers), Q17 (to Customers, health), Q34 (to Patent offices, judges, lawyers). Q12 (to Other public authorities)

Agree answers only*	Originators	Follow-on manufacturers	Customers, health	Patent offices, lawyers	Ministries and other public authorities
Legal certainty	94%	100%	85%	91%	100%
Reduce cost/red tape of SPC-related litigation	98%	100%	83%	71%	100%
Same protection in all EU	98%	x	x	92%	100%
Reduce red tape relating to registration	98%	x	x	86%	80%
Specialised court	98%	94%	71%	86%	100%
Reduce cost and red tape relating to monitoring SPC-protected products (freedom to operate)	x	98%	83%	x	x
Reduce maintenance costs	98%	x	x	88%	100%
Make licensing easier	93%	98%	x	79%	100%
Boost value of investments	95%	x	x	x	100%

Make joint procurement by a group of EU countries easier	x	x	75%	x	x
No. of answers	*51-64*	*43-56*	*7-13*	*14-25*	*3-5*

* the residual to 100% is the number of those disagreeing;x - response not available to that group of respondents
Note: No answer and "Neither agree nor disagree" not taken into account (also in no. of answers provided).
Source: Public Consultations on Evaluation of SPC

Opinions diverge regarding the practicalities for implementing such a new title[247]. While some respondents favour the grant of that title by a virtual office composed of national experts working on behalf of an EU agency, others prefer either to entrust the EPO with this task, or to set up a new EU agency to do so.

Amongst SMEs manufacturing generics and biosimilars, half of them favoured the grant of unitary SPCs by a new EU agency, while the other half favour the EPO for this purpose.

Table 28: Which granting authority would you favour to grant and register a unitary SPC? Q38 (to Originators), Q30 (to Follow-on manufacturers), Q10 (to Other public authorities)

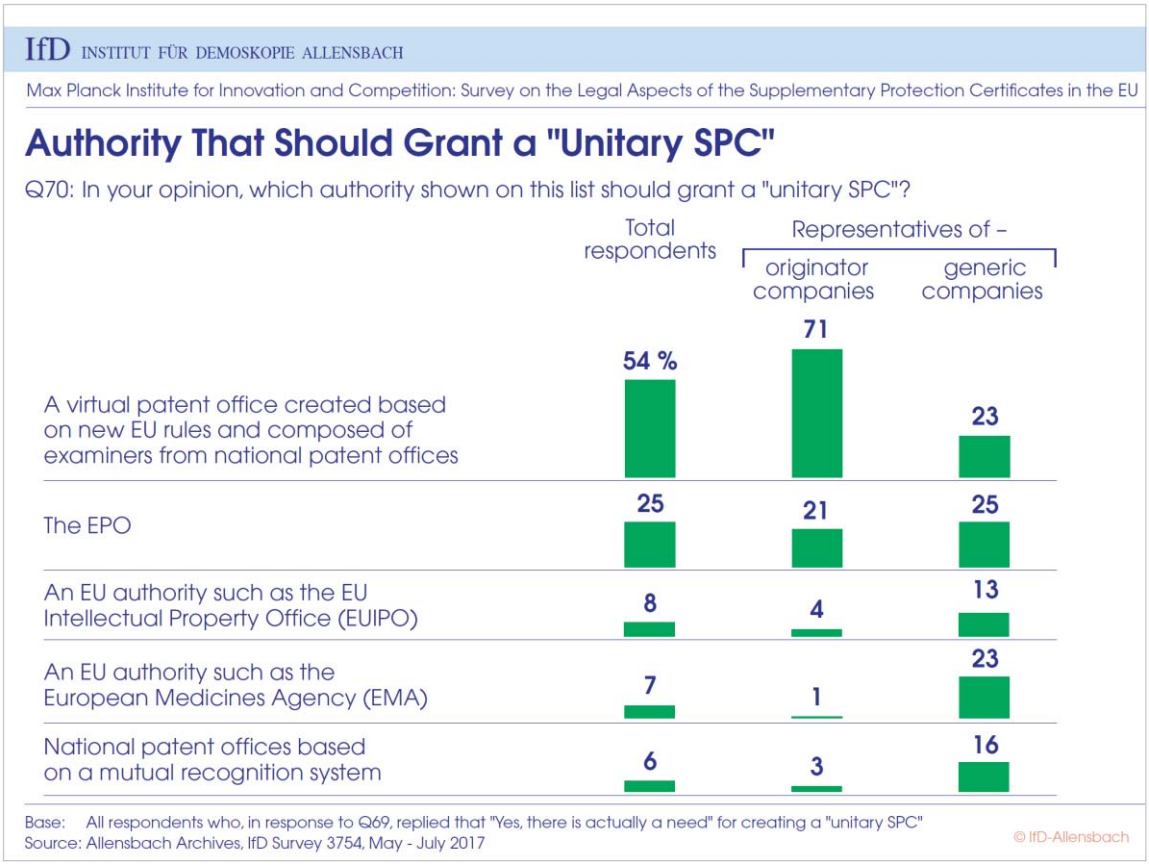
Agree answers only*	**Originators**	**Follow-on manufacturers**	**Ministries and other public authorities**
EU Intellectual Property Office	1%	2%	0%
European Patent Office	6%	48%	20%
A new EU agency	1%	38%	0%
European Medicines Agency	1%	0%	40%
EU countries' patent offices (e.g. virtual office approach or mutual recognition with reference offices, under EU rules)	86%	7%	20%
None of the above, please indicate your alternative preference	4%	5%	20%
No. of answers	*69*	*50*	*5*

* the residual to 100% is the number of those disagreeing.
Note: "Don't know" and No answer not taken into account (also in no. of answers provided). Not all groups of respondents have received this question.
Source: Public Consultations on Evaluation of SPC

Similar results emerged from the MPI (2018) study:

[247] A position document of 2021 of Medicines for Europe proposes to take into consideration the following aspects for the set-up of a centralised procedure: i) that the European Parliament oversees the granting body; ii) if an SPC is revoked in one EU Member State, the granting authority should revoke the SPC protection automatically in all other EU Member States; iii) the procedure for invalidating SPCs (i.e. oppositions) should be also unified; iv) only products with European marketing authorisations should be eligible; v) ensure the highest level of transparency (e.g. publication of data) in the SPC granting procedures; vi) provide for third party observations. https://www.medicinesforeurope.com/wp-content/uploads/2021/02/Medicines-for-Europe-Position-Paper-on-Unitary-SPC-Unified-Mechanism-for-SPC-granting-March-2021.pdf

Figure 13. Authority to grant SPC title - study survey, MPI (2018)



Source: MPI (2018), Annex III

Concerning the languages to be used for a unitary SPC, a clear majority favoured the EPO language regime (English, French, German), which is the regime that is applicable to the unitary patent. However, SMEs manufacturing generics and biosimilars preferred the five-language regime of the EUIPO (English, French, German, Italian and Spanish).

Table 29: Which language combination would you prefer for registering unitary SPC applications? Q39 (to Originators), Q31 (to Follow on manufacturers), Q29 (to Patent offices, judges, lawyers). Q9 (to Other public authorities)

Agree answers only*	Originators	Follow-on manufacturers	Patent offices, lawyers	Ministries and other public authorities
English, French, German, Italian and Spanish (as for the EU Intellectual Property Office)	6%	34%	8%	0%
English, French, and German (as for the European Patent Office)	78%	25%	63%	40%
All EU official languages (as for the centralised marketing authorisations)	3%	19%	8%	40%
English only	9%	22%	17%	20%
None of these (please state your alternative preference)	3%	0%	4%	0%
No. of answers	*64*	*59*	*24*	*5*

* the residual to 100% is the number of those disagreeing.

Note: No answer not taken into account (also in no. of answers provided). Source: Public Consultations on Evaluation of SPC

Table 30: Which language combination would you prefer for publishing unitary SPCs? Q39 (to Originators), Q31 (to Follow on manufacturers), Q16 (to Customers, health), Q29 (to Patent offices, judges, lawyers). Q9 (to Other public authorities)

Agree answers only*	Originators	Follow-on manufacturers	Customers, health	Patent offices, lawyers	Ministries and other public authorities
English, French, German, Italian and Spanish (as for the EU Intellectual Property Office)	6%	34%	x**	8%	0%
English, French, and German (as for the European Patent Office)	77%	22%	46%	58%	40%
All EU official languages (as for the centralised marketing authorisations)	5%	21%	38%	17%	40%
English only	9%	22%	15%	13%	20%
None of these (please state your alternative preference)	3%	0%	x**	4%	0%
No. of answers	*64*	*58*	*13*	*24*	*5*

* the residual to 100% is the number of those disagreeing. ** response not available to that group of respondents

Note: No answer not taken into account (also in no. of answers provided). Source: Public Consultations on Evaluation of SPC

The majority of respondents considered that national marketing authorisations should be also allowed (in addition to the EU marketing authorisations) as a basis for getting a unitary SPC, even though the latter would then not be enforceable in those Member States where no marketing authorisation would have been granted (through mutual recognition or decentralisation procedure).

Table 31: Should the unitary SPC be available only for products authorised by way of a centralised marketing authorisation (e.g. assessed by the European Medicines Agency)? Q40 (to Originators), Q32 (to Follow-on manufacturers), Q30 (to Patent offices, judges, lawyers).

Agree answers only*	Originators	Follow-on manufacturers	Patent offices, lawyers
Yes	5%	38%	58%
No	95%	62%	42%
No. of answers	59	37	24

Note: "Don't know" and No answer not taken into account (also in no. of answers provided).

Source: Public Consultations on Evaluation of SPC

In the absence of a unitary SPC, a majority of the respondents were of the opinion that NPOs could grant – pursuant to the current legislation – national SPCs for products covered by future unitary patents.

How SPC rules should be updated: EFPIA suggests that guidance at EU level would improve the situation. This should not extend to amending the SPC *acquis*, as EFPIA considers that such an amendment process could lead to years of uncertainty; generics manufacturers seem to be split on whether to clarify aspects of the SPC Regulation implementation via legislative amendments.

IP practitioners (including patent offices), generics manufacturers and health practitioners support 'guidance' approach, especially since court proceedings in some Member States may take too long. Additionally many IP practitioners already have experience with national guidance.

Table 32: How to improve consistent interpretation throughout the EU of the 'substantive' provisions of the SPC regulation (e.g. the scope of protection, eligibility of SPC protection)? Q37 (to Originators), Q27 (to Follow on manufacturers), Q14 (to Customers, health), Q25 (to Patent offices, judges, lawyers).

	Originators	Follow-on manufacturers	Customers, health	Patent offices, lawyers
Create a unitary SPC for the unitary patent	74%	55%	55%	59%
Guidelines developed jointly by the European Commission and EU countries	7%	75%	73%	74%
Amend the SPC Regulations to provide extra clarity	1%	46%	45%	55%
Don't change the current SPC system - rely on referrals to the Court of Justice of the EU	18%	x*	x*	x*
No. of answers	*68*	*54-57*	*11*	*22-23*

* Stakeholder was not presented with this answer

Note: Single choice question to Originators, multiple choice question for the rest. "Don't know" and No answer not taken into account (also in no. of answers provided). Questions had slightly different formulations to each group but with the same meaning. Source: Public Consultations on Evaluation of SPC

Table 33: National implementing guidelines and their updates. Q6 (to Patent offices, judges, lawyers).

	Yes	No	No. of answers
Q6. Has your country (e.g. your national patent office) adopted implementing guidelines for examining and registering SPCs?	81%	19%	27
If 'yes' to Question 6, do you usually update the guidelines following a judgment from the Court of Justice of the EU?	80%	20%	20

Note: "Don't know" and No answer not taken into account (also in no. of answers provided).

Source: Public Consultations on Evaluation of SPC

Impact on innovation. SPCs are considered to have a proportionate impact on investment along all steps of the value chain: R&D, clinical trials, manufacturing, distribution and commercialisation. Some innovators consider SPC availability as the main factor for investment decisions in manufacturing. However, the importance that the majority of innovators ascribe to SPCs is moderate, as they consider that SPCs are one factor in a package of elements: aside from the availability of SPCs, decisions on investments in research (excluding clinical trials and field trials) are driven by a combination of factors such as access to high skilled labour and recruitment of patients. With regard to the most important factors when investing in clinical trials, innovators consider health infrastructure and proximity of research universities.

Table 34: For innovative products or potential innovative products, does the possibility of getting EU SPC protection play a role when your company/organisation is deciding on the following investments? Q6 (to Originators)

	Yes*	No	No. of answers
Clinical trials (medicinal products), or field trials (for plant protection products)	97%	3%	34
Manufacturing	94%	6%	33
Marketing in EU Countries	91%	9%	33
R&D (excluding clinical/field trials)	88%	12%	34
Distribution	80%	20%	30

* Composed of answers: YES, always, YES, to some extent, YES, but only if the investment will take place in the EU

Note: "Don't know" and No answer not taken into account (also in no. of answers provided).

Source: Public Consultations on Evaluation of SPC

Table 35: Impact of SPC on originators decision on innovation (Q7 and 8 to Originators)

	Yes	No	No. of answers
Q7. Has a prospective product's eligibility for SPC protection ever been a decisive factor in its development (i.e., without an SPC you would have discarded it despite having already invested in part of its development)?	80%	20%	41
If you answered 'yes' to Question 7, was the prospective product being developed (or did most of its development take place) in the EU?	94%	6%	18
Q8. Have the SPC regulations influenced the prioritisation of certain types of innovation in your organisation? (e.g. oncology or highly sought-after treatments)	50%	50%	38

Note: "Don't know" and No answer not taken into account (also in no. of answers provided).
Source: Public Consultations on Evaluation of SPC

On the other hand follow-on manufacturers favour countries without SPC when deciding where to produce generic/biosimilar medicines.

Table 36: Do you favour countries with no SPC protection when looking for a location to base or outsource your biosimilars manufacturing? Q19 (to Follow on manufacturers):

	%
Yes	71%
Depends on the circumstances but it is a key factor.	27%
No	2%
No. of answers	45

Note: "Don't know" and No answer not taken into account (also in no. of answers provided).
Source: Public Consultations on Evaluation of SPC

The Commission expert Group on Industrial Property Policy (GIPP)

The meeting of the Commission expert Group on Industrial Property Policy (GIPP) on 18 November 2022 was dedicated solely to the SPC reform. Several Member States shared their preliminary positions regarding the policy options presented in this impact assessment in the meeting and/or in written contributions in advance (see table below).

Table 37: Preliminary support of the Commission expert Group on Industrial Property Policy (GIPP) to policy options expressed during 18 November 2022 meeting:

	PO1	PO2	PO3	PO4	PO5
No. of answers	8	0	5	8	11
Total number of Member States expressing preliminary position: 16					

Source: GIPP meeting 18 November 2022.

Among 17 Member States who took a preliminary position, a clear majority (11) supported PO5 – unitary SPC to complement unitary patent. Regarding the current national SPC framework Member States taking the floor agreed that current SPC fragmentation is a problem. To solve this fragmentation, some called for solely guidelines (PO1) others for a centralised procedure and/or the unitary SPC. Among those recognising the need for a centralised procedure, more Member States opted for PO4 where the examination opinion is binding on national authorities (8 Member States) than PO3 where it is not binding (5 Member States).

As regards functioning of the central procedure all Member States who replied (9) considered that opposition procedure should not be added to SPC examination process – some noting that such an opposition is not even available during patent granting process. Five Member States agreed that

third party observations should be allowed (no Member State was against). As regards adding a possibility to review a central SPC decision (and consequently reduce the risk of post-grant national litigation) three Member States were in favour and one was against.

In addition to the questions sent in advance, some Member States taking the floor also referred to the need for more transparency in the system.

Last, the role of NPOs was emphasised by several Member States. In particular, more information on the exact design of a system in practice would be required. Some Member States referred to the need to uphold the high quality of substantive examinations.

How stakeholders' views were matched with different policy options

This section explains how we used the available consultations to gauge stakeholders' opinion on the different policy options presented in this impact assessment.

Stakeholders views on PO1 (guidelines) are based on responses presented in Table 32 (second row). Views on PO2 (mutual recognition) are approximated by responses presented in Table 28 (fifth row) and Figure 13 (last row). There were no questions that could directly show stakeholders views on PO3 and PO4 (centralised application examination, with national SPC granting following non-binding or binding opinion respectively). We indirectly infer these from i) general support for a unitary SPC (Table 26), as both these options provide "unification" at the SPC application examination level; and ii) support for granting of a unitary SPC by NPOs (Table 28, fifth row). All consultations point to generally wide support for creating a unitary SPC to supplement the unitary patent (PO5) – see for instance Table 26 above or Table 27 for the expected benefits of a unitary SPC.

The binding vs. non-binding nature of the central opinion was discussed during several meetings where Member State participated, the views however were not systematically collected, so we decided to assess these two option mostly on efficiency of achieving the objectives (especially predictability and legal certainty) without presenting the views of stakeholders.

Table 28 shows stakeholders views on the most appropriate authority to grant SPC. While Table 29 and Table 30 present language preferences for SPC application and publication respectively.

Finally, amendment of the Regulations to clarify SPC rules was favoured by several stakeholders (Table 32, third row) - it was however an early discarded option due to reasons explained in section 5.4.

ANNEX 3: WHO IS AFFECTED AND HOW?

Practical implications of the initiative

The proposed initiatives (a centralised SPC granting procedure and/or unitary SPC) are of a procedural nature, in the sense that they would not provide new rights, or alter the scope of the rights already conferred by the existing national SPCs. These initiatives are intended to simplify the granting of SPCs, through a centralised application and examination procedure. This would reduce the cost and administrative burden for the applicants, increase legal certainty and facilitate access to information on SPCs status (which is beneficial for all stakeholders, including for instance generic and biosimilar manufacturers). The proposed changes also secure more stakeholders involvement through the new rules on third parties observations.

Summary of costs and benefits

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Amount***	***Comments***
Direct benefits		
Lower SPC maintenance fees for SPC holders	EUR 111 100	Savings per SPC holder for EU-wide, five year long protection. Affecting up to 400 firms per year (SPC owners).
Saving on legal advice for SPC applicants	EUR 52 000	Savings per applicant. Due to dealing with one authority instead of 27 with different procedures and requirements. Affecting up to 100 firms per year.
Saving on translation cost for SPC applicants	EUR 4 000	Savings per applicant. As application can be in one of the official EU languages, instead of languages of each Member State. Affecting up to 100 firms per year.
Saving on SPC search cost for generic/biosimilar manufacturers and health sector	EUR 40 000	Saving per firm/healthcare authority. Concern identification of active SPC on a given territory. Based on cost of acquiring commercial database. Affecting up to 300 generic/biosimilar firms and at least 27 central pharmaceutical procurement bodies.
Indirect benefits		
Potentially higher investments in novel medicines	EUR 37 million	Estimated total annual additional income of originators due to extended territorial coverage of unitary SPC protection.
Administrative cost savings related to the 'one in, one out' approach*		
Saving on legal advice for SPC applicants	EUR 52 000	As above
Saving on translation cost for SPC applicants	EUR 4 000	As above

II. Overview of costs – Preferred option							
		Citizens/Consumers		**Businesses**		**Administrations**	
		One-off	**Recurrent**	**One-off**	**Recurrent**	**One-off**	**Recurrent**
Action (a)	Direct adjustment costs					EUR 1.4 million for the central authority	

	Direct administrative costs						EUR 1.8 million annually for central authority
	Direct regulatory fees and charges			Application fee potentially higher by EUR 30 000 per applicants in comparison to baseline			
	Direct enforcement costs						
	Indirect costs		EUR 37 million estimated total additional spending on medicines due to extended territorial coverage of unitary SPC protection.				
Costs related to the 'one in, one out' approach							
Total	Direct adjustment costs						
	Indirect adjustment costs						
	Administrative costs (for offsetting)						

Relevant sustainable development goals

III. Overview of relevant Sustainable Development Goals – Preferred Option(s)		
Relevant SDG	**Expected progress towards the Goal**	**Comments**
SDG no. 3 – good health and wellbeing	By facilitating access to SPC for innovators this initiative might marginally incentivise more R&D expenditures for novel medicines, especially the complex ones, requiring longer development and testing, and thus longer time to recuperate investment costs.	

ANNEX 4: ANALYTICAL METHODS

Section 1.2

Key economic indicators for the two sectors of interest provided in Section 1.2. of this impact assessment are based on Structural Business Statistics of Eurostat (Annual detailed enterprise statistics for industry, NACE Rev. 2, B-E)[248]. The sectors are defined according to NACE Rev.2 classification[249] namely group 20.2 with its only sub-class 20.20 and the entire division 21 with all its subcomponents:

- 20.2 Manufacture of pesticides and other agrochemical products[250],
  - 20.20 Manufacture of pesticides and other agrochemical products
- 21 Manufacture of basic pharmaceutical products and pharmaceutical preparations[251],
  - 21.1 Manufacture of basic pharmaceutical products,
    - 21.10 Manufacture of basic pharmaceutical products[252]
  - 21.2 Manufacture of pharmaceutical preparations,
    - 21.20 Manufacture of pharmaceutical preparations[253].

The remaining analytical methods applied in each of the above-mentioned studies and consultations are explained in the respective documents.

[248] Eurostat [sbs_na_ind_r2] last update: 18.05.22; extracted on: 05.06.22.
[249] NACE Rev.2 - Statistical classification of economic activities in the European Community, Eurostat, https://ec.europa.eu/eurostat/documents/3859598/5902521/KS-RA-07-015-EN.PDF
[250] This class includes: - manufacture of insecticides, rodenticides, fungicides, herbicides, acaricides, molluscicides, biocides, - manufacture of anti-sprouting products, plant growth regulators, - manufacture of disinfectants (for agricultural and other use), - manufacture of other agrochemical products n.e.c.; this class excludes: - manufacture of fertilisers and nitrogen compounds, see: 20.15. source NACE Rev. 2 – Statistical classification of economic activities in the European Community, Structure and explanatory notes European Commission, Eurostat, Office for Official Publications of the European Communities, Luxembourg, 2008.
[251] This division includes the manufacture of basic pharmaceutical products and pharmaceutical preparations; this also includes the manufacture of medicinal chemical and botanical products.
[252] This class includes: - manufacture of medicinal active substances to be used for their pharmacological properties in the manufacture of medicaments: antibiotics, basic vitamins, salicylic and O-acetylsalicylic acids etc., - processing of blood; this class also includes: - manufacture of chemically pure sugars, - processing of glands and manufacture of extracts of glands etc. source NACE Rev. 2 – Statistical classification of economic activities in the European Community, Structure and explanatory notes European Commission, Eurostat, Office for Official Publications of the European Communities, Luxembourg, 2008.
[253] This class includes: - manufacture of medicaments: antisera and other blood fractions, vaccines, diverse medicaments, including homeopathic preparations, - manufacture of chemical contraceptive products for external use and hormonal contraceptive medicaments, - manufacture of medical diagnostic preparations, including pregnancy tests, - manufacture of radioactive in-vivo diagnostic substances, - manufacture of biotech pharmaceuticals; this class also includes: - manufacture of medical impregnated wadding, gauze, bandages, dressings etc., - preparation of botanical products (grinding, grading, milling) for pharmaceutical use; this class excludes: - manufacture of herb infusions (mint, vervain, chamomile etc.), see: 10.83, - manufacture of dental fillings and dental cement, see: 32.50, - manufacture of bone reconstruction cements, see: 32.50, - manufacture of surgical drapes, see: 32.50, - wholesale of pharmaceuticals, see: 46.46, - retail sale of pharmaceuticals, see: 47.73, - research and development for pharmaceuticals and biotech pharmaceuticals, see: 72.1, - packaging of pharmaceuticals, see: 82.92; source NACE Rev. 2 – Statistical classification of economic activities in the European Community, Structure and explanatory notes European Commission, Eurostat, Office for Official Publications of the European Communities, Luxembourg, 2008.

Section 2.1.

The estimates on the SMEs shares among the SPC holders were based on data uploaded from the German national patent office – DPMA (https://register.dpma.de/DPMAregister/pat/basis) concerning SPCs (*Schutzzertifikat*). The SPC holders names (*Anmelder/Inhaber*) were matched with Orbis database[254] in order to obtain their size classes and information on the global ultimate owner name and type. The above was implemented using the batch matching tool available in Orbis and complemented by manual inspection of the output that resulted in some further corrections.

Finally, 86% of German SPC holders (present or past) were successfully matched with Orbis. At this point, only data covering years 2010-2021 were kept for further analysis (by the year of submission provided in the *Anmeldetag* variable). Firms' company size classes as provided by Orbis (i.e. very large companies, large companies, medium-sized companies and small companies) were compared with their corporate ownership information and all SMEs belonging to a corporate group were removed from their initial size class. As a result, 8% of SPC holders were identified as SMEs. Within the retained dataset, another 11% of observations had no size class allocated, ether because such information was missing in Orbis or because it was not matched. It can be assumed that Orbis coverage is are biased towards large companies therefore if a company is not found/matched, it is more probable that it is a smaller organisation. Such assumption backed the 8% to 19% estimate for SMEs presented in section 2.1.

The universities were identified by text search of SPC holder's names using the following or similar terms: university, universität, academy, research institute, college, education, research council, research foundation, forschungszentrum, etc. The search resulted in 4.4% of observations being captured. Then, the SPC holders with a global ultimate owners classified by Orbis as "Foundation, research Institute" were added to the count (another 2.8%) resulting in the final estimate of 7%, as mentioned in section 2.1.

Sections 6.6.1 and 6.6.2

The dataset underpinning the findings presented in sections 6.6.1 and 6.6.2 was the MIDAS database of IQVIA[255], containing various descriptive variables characterising the pharmaceutical market[256]. The dataset used in this impact assessment covered sales from 2010 to 2021 and its geographical coverage was 25 Member States, notably EU-27 except for CY and MT. In case of several countries, only retail market data was available – these included DK, ET, EL, LV, LU and SI. For all remaining countries, data for the retail and hospital markets were combined and used (238 215 observations).

[254] Orbis by Bureau Van Dijk (a Moody's Analytics company) is a database containing information on private companies and entities across the globe, including their financial information and corporate linkages (https://orbis.bvdinfo.com/).

[255] https://www.customerportal.iqvia.com/sites/portal

[256] In particular: country to which the data pertained, corporation (i.e. company owning the medicine), molecules list, product name, product launch date, generic/non-generic product classification, identification of biologic molecules, volume measures such as ex-manufacturer sales (i.e. wholesaler purchase price and the manufacturers' selling price in EUR) and standard units sold (i.e. the number of standard 'dose' units sold).

The IQVIA dataset contains a variable *e_dt_prtexp*, which refers to the estimated protection expiry date of a given product. Unfortunately, this variable may refer to various reason behind the loss of protection, namely not only the SPC expiry date, but also the estimated patent expiry date, data exclusivity expiry date, orphan drug exclusivity expiry date, SPC extension expiry date granted for a paediatric formulation or even on-going litigation. In order to establish whether or not the loss of exclusivity was due to the expiry of SPC, a publicly available dataset containing information on the central marketing authorisations was uploaded from the EMA website[257]. After basic text cleaning of both dataset (i.e. the *intprd* variable referring to the international product name in IQVIA and the medicine name from the EMA), the names of medicines were matched. As a result, the IQVIA working dataset has been expanded by the marketing authorisation date. Based on this, the standard regulatory protection date could be established by adding 10 years to the EMA decision date[258]. Only observation having at least one of the following dates were retained for further analysis: the patent expiry date, the estimated protection expiry date of the original product (per country) or the estimated regulatory protection date (EMA-based). At this stage, the potential SPC expiry date was calculated, as follows:

- Step 1: Patent filling date was calculated by subtracting 20 years from the patent expiry date available in IQVIA (*pat_exp_dt*).
- Step 2: Time elapsing between the patent filling date and marketing authorisation was calculated.
- Steps 3 and 4: The above period was shortened by 5 years and adjusted to 5 years maximum.
- Step 5: A potential SPC expiry date was established by adding the above period to the patent expiry date.

In order to generate an SPC dummy variable[259] the expiry dates of the three instruments were compared (i.e. the patent expiry date, the EMA plus 10 years date and the potential SPC expiry date). If the potential SPC expiry date was the last one to lapse and it was shorter than the loss of exclusivity as provided by IQVIA, then the observation was identified as positive[260]. In case of observations where the IQVIA loss of exclusivity date was missing, but the potential SPC expiry date, the EMA plus 10 date or the patent expiry dates were available, the dataset was completed by using one of these dates, depending on which one elapsed the last. Observations without the loss of exclusivity date were removed from the dataset, as well as those where the above date lapsed before 1 January 2010[261]. As a result 61 080 observations were retained for further analysis.

[257] https://www.ema.europa.eu/en/medicines/download-medicine-data

[258] The 6 months of a paediatric extension, as well as the orphan drugs regulatory protection were ignored, as it was impossible to identify them within the available datasets. Instead, a general 10 year extension was used for all matched products.

[259] A Boolean variable that can only take the value 0 or 1 to indicate the absence or presence of a specified condition (i.e. determining whether or not a medicine was covered by an SPC).

[260] If the potential SPC expiry date lapsed after the IQVIA loss of exclusivity date, it was assumed that an SPC could have been the last protection to expire, but it was either not requested or awarded for the particular observation in question.

[261] Although SPC entered into force in 1993, taking such an early cut-off date would confound the results of market entry analysis for Member States joining the EU more recently. Instead, year 2010 was chosen, as it was aligned with the available sales data (2010-2021).

The biosimilar and generic molecules entry was first calculated only for products, which entered the market following an SPC expiry (determined by the earlier created SPC dummy variable) and then separately for all follow-on products entering the market (i.e. irrespective of the instrument behind the loss of exclusivity, notably the patent expiry or regulatory protection expiry). The market entry was defined as the first launch of a follow-on product on a local market after the loss of exclusivity (or SPC expiry in particular[262]). The number of competitors that could have appeared on the market after the first entry was not taken into account.

The budgetary impact of the unitary SPC has been estimated using the same IQVIA database, but using only data for the enhanced cooperation countries[263]. The following steps were undertaken:

- Step 1: An average SPC expiry date per substance was calculated across all UP Member States, where this substance was awarded an SPC.
- Step 2: The sales at manufacturing prices, as well as the volume of sales in standard units for years 2010-2021 were summed up by country, molecule and by four product classes[264].
- Step 3: Sales in each year were divided by sales volume expressed in standard units to obtain unit prices for each group (i.e. for a particular molecule in a given country, when it was sold as an original product and/or as a follow-on product).
- Step 4: For each molecule in a given country and year (e.g. *Adalimumab* in Austria, in 2018) a ratio between the price of the original product and its follow-on version was calculated, if the latter was actually put on the market. In rare cases where the calculated ratios per product were lower than 1 (i.e. biosimilar or generic product would be more expensive than the original) or higher than 10 (i.e. the follow-on product would enter the market at a price of 10% of the original product) the results were judged implausible and replaced by nulls.
- Step 5: For each country and year, a median ratio of price differences between the original products and their follow-on equivalents was calculated[265], separately for biological and small molecules (i.e. two ratios per country for each year in 2010-2021).
- Step 6: The yearly sales of follow-on products (generic and biosimilar) after the loss of exclusivity were identified for each molecule in a given country. Then, they were retained only if the sales occurred under no SPC coverage and before the year of an average SPC expiry date per substance calculated across all UP Member States where this substance was awarded an SPC (see: Step 1 above). The period between the individual loss of exclusivity in a given country with no SPC and the year where SPCs for a given molecule would on average lapse in all SPC-covered countries is referred to as the "gap years".
- Step 7: The sales in gap years were retained and multiplied by the ratios of price differences for each country (see: Step 5 above), molecule and year. As a result, a hypothetical value of sales of original products was obtained (i.e. the "would-be" cost of

[262] The results in such case, as presented on Figure 9 in section 6.6.1, partially depends on the number of SPCs previously in force in a given country.
[263] Except for Malta, as the available IQVIA data do not cover this country.
[264] Defined as follows: biologic original, biosimilar (large molecules follow-on products), small molecules original, generic (small molecules follow-on products).
[265] The present analysis does not consider whether, in particular markets, generics may enter in the absence of their respective originator for a given product (albeit such instances are still rather exceptional). In this regard, potential negative health effects on the population (from the delayed availability of therapeutic options) are not assessed.

medicines purchased in the gap years, if original products were bought these countries instead of follow-on equivalents).

- Step 8: A difference between the amounts spent on follow-on medicines and the estimated cost of original products was calculated to obtain a hypothetical extra cost that would have been borne by the healthcare systems if the generic entry did not occur in the gap years.
- Step 9: The extra cost was compared with the overall yearly spending on pharmaceuticals by country, as provided by Eurostat in the COFOG database[266] and presented in Table 55.

[266] Eurostat COFOG - general government spending on medical products, appliances and equipment, extracted on 04.08.22.

A. Evidence supporting section 1 (introduction)

Regulatory context of the current SPC rules - patent systems ***in the EU***

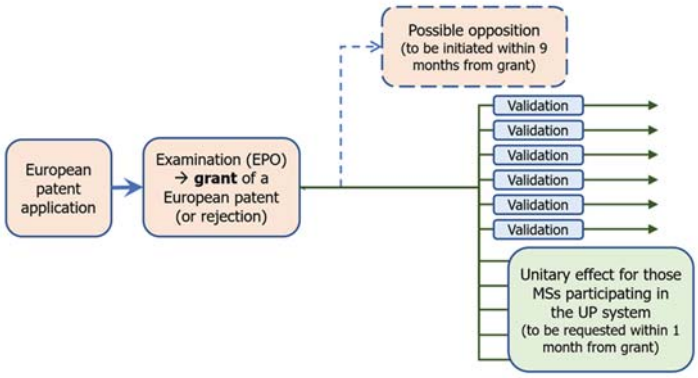
SPCs are granted only for products protected by a 'basic patent' in force in the respective Member States. In the EU, patents are governed, and can be implemented, according to the following three different levels (the table below displays the applicable levels in each EU Member State):

(1) The national legislation of the 27 Member States for national patents, which are filed, examined and granted in each Member State where protection is sought, and are enforceable before their national courts. Contrary to other IP rights, there is no EU directive on patent law and, therefore, the national patent legislation of EU Member States is not harmonised by EU law.

(2) The European Patent Convention (EPC), which establishes a one-stop-shop for the filing, examining and granting of European patents by the European Patent Office (EPO). Once granted, a European patent requires validation in most of the Member States where protection is sought. It confers to its owner the same rights as national patents, enforceable before national courts

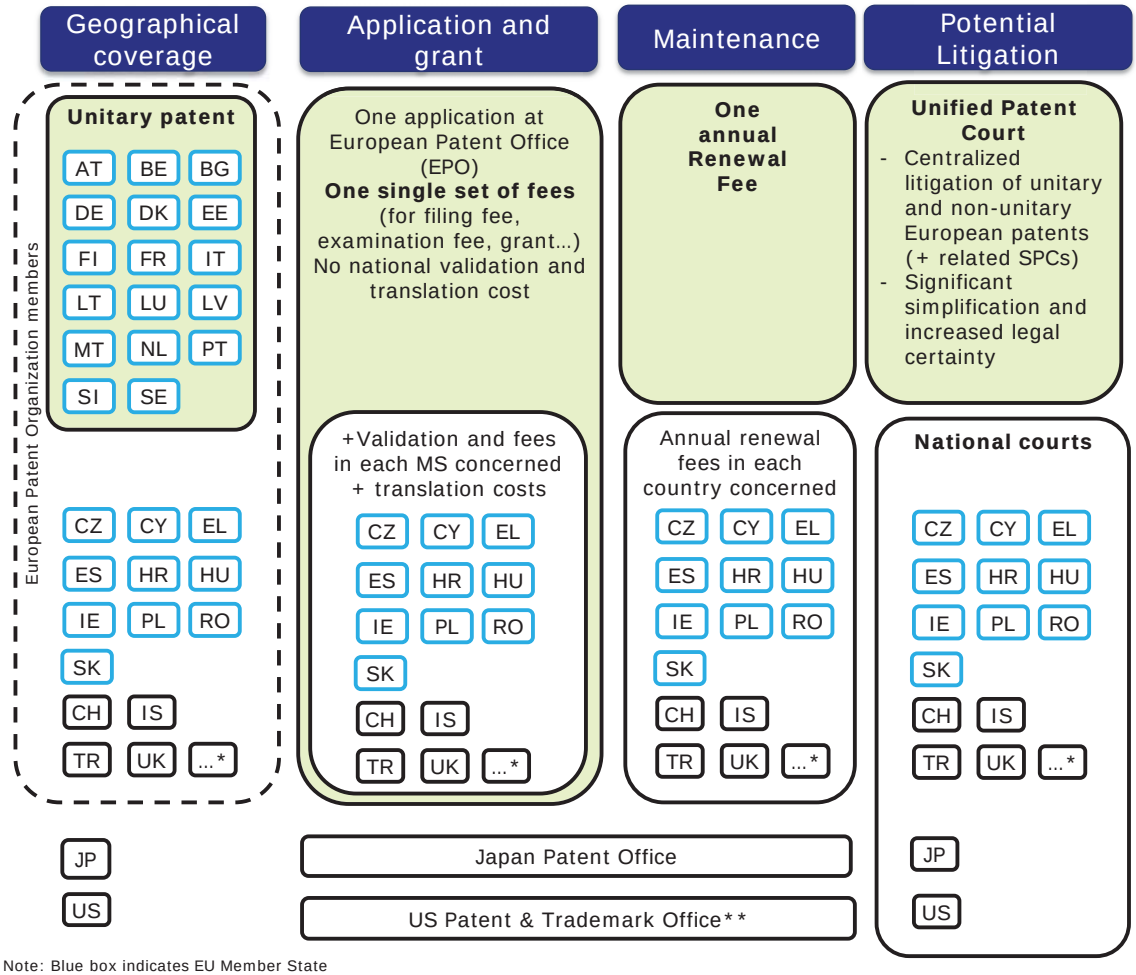
(3) The unitary patent package , which will introduce a European patent with unitary effect (the unitary patent) – that is single patent not requiring national validation – and a single jurisdiction, the Unified Patent Court (UPC), for the Member States having ratified the UPC Agreement. Regarding the UPC, once operational, all European patents (unitary or not) as well as any SPCs based on them may be enforced before the UPC (optionally during a transitional period of 7 years) for these Member States.

*Figure 14****: Example of patent application following points (2) and (3) above***



A key advantage of the unitary patent system is that centralised litigation before the UPC will apply not only to unitary patents but also to non-unitary European patents and to SPCs based on (unitary or non-unitary) European patents (see: Art. 3.b Unified Patent Court Agreement together with Art. 2.g). The figure below explains the procedural simplifications for patent applicants brought about by the unitary patent in the participating Member States.

Figure 15. Unitary Patent system, participating Member States and applicable procedures for registration. state of play expected as of mid-2022.



Note: Blue box indicates EU Member State
* Altogether additional 11 non-EU countries are members of the European Patent Organization (AL, CH, IS, LI, MC, MK, NO, RS, SM, TR, UK);
** in US, the renewal fees are paid after 3½, 7½ and 11½ years);

Source: Commission services' own analysis

The table below summarises EU Member States' profiles regarding patent and SPC protection, as well as EU official languages (updated in March 2022).

Table 38: Patent protection across the EU

Member State	"Purely" national patent system, based on national patent law	Part of the European patent system (i.e. a granted European patent can be validated as a national patent)	Part of the enhanced cooperation for unitary patent protection	UPC Agreement ratified	Could unitary SPCs of PO 5 take effect?	EU official languages
Austria	Yes	Yes	Yes	Yes	Yes	German
Belgium	Yes	Yes	Yes	Yes	Yes	Dutch French German
Bulgaria	Yes	Yes	Yes	Yes	Yes	Bulgarian
Croatia	Yes	Yes	No	No	No	Croatian
Cyprus	Yes	Yes	Yes	No	No	Greek
Czech Republic	Yes	Yes	Yes	No	No	Czech
Denmark	Yes	Yes	Yes	Yes	Yes	Danish
Estonia	Yes	Yes	Yes	Yes	Yes	Estonian

Finland	Yes	Yes	Yes	Yes	Yes	Finnish Swedish
France	Yes	Yes	Yes	Yes	Yes	French
Germany	Yes	Yes	Yes	Yes[267]	Yes	German
Greece	Yes	Yes	Yes	No	No	Greek
Hungary	Yes	Yes	Yes	No	No	Hungarian
Ireland	Yes	Yes	Yes	No	No	English Irish
Italy	Yes	Yes	Yes	Yes	Yes	Italian
Latvia	Yes	Yes	Yes	Yes	Yes	Latvian
Lithuania	Yes	Yes	Yes	Yes	Yes	Lithuanian
Luxembourg	Yes	Yes	Yes	Yes	Yes	French German
Malta	Yes	Yes	Yes	Yes	Yes	Maltese English
Netherlands	Yes	Yes	Yes	Yes	Yes	Dutch
Poland	Yes	Yes	Yes	No	No	Polish
Portugal	Yes	Yes	Yes	Yes	Yes	Portuguese
Romania	Yes	Yes	Yes	No	No	Romanian
Slovakia	Yes	Yes	Yes	No	No	Slovak
Slovenia	Yes	Yes	Yes	Yes	Yes	Slovene
Spain	Yes	Yes	No	No	No	Spanish
Sweden	Yes	Yes	Yes	Yes	Yes	Swedish

Regulatory context of the current SPC rules - marketing authorisations (MA) in the EU, other relevant legislation

An SPC shall be granted if, among other conditions, in the Member State in which the SPC application is submitted and at the date of that application, the product is protected by a basic patent in force and a valid marketing authorisation to place the product on the market as a medicinal product (or PPP) has been granted in accordance with the relevant EU legislation[268].

Under Union law, medicinal products for human or veterinary[269] use, as well as PPPs, need a marketing authorisation before they can be placed on the EU market.

Marketing authorisations for medicinal products

In the EU, a medicinal product for human use may be authorised either by the European Commission through the centralised procedure or by national competent authorities through a mutual recognition, decentralised or national procedure.

Table 39: Overview of marketing authorisation types available for medicinal products

Authorising body	Procedure	Body assessing	Geographic scope
European Commission	Centralised	European Medicines Agency (EMA)	EU-27
National authorities	Mutual recognition, decentralised, national	National authorities	MS concerned

[267] Germany still has to deposit its instrument of ratification with the Council (as of July 2022).
[268] https://ec.europa.eu/health/human-use/legal-framework_en
[269] The centralised procedure is mandatory for all veterinary medicinal products listed in the Annex to European Regulation (EC) No 726/2004. In addition, optionally, an application for an authorisation for veterinary medicinal products can be made if the requirements of Article 3 (2) of Regulation (EC) 726/2004 are met (e.g. if they contain a new active substance).

According to calculations of the Max Plank Institute study of 2022[270], based on the example of Germany, the number of new active ingredients authorised for the first time by the national authorities is negligible. Therefore, almost all recently SPC applications for medicinal products rely on an EU-wide marketing authorisation.

The SPC aims to incentivise investments for new active ingredients of medicines and PPPs that require lengthy development times. With the exception of the 6-month paediatric extension of the SPC[271], the SPC does not target specifically medicines for specific parts of the population or specific conditions (e.g. orphan diseases or antibiotics). The EU legislation has specific incentives for orphan and paediatric medicines that are out of the scope of this impact assessment.

Additional incentives relevant to pharma and PPP are:

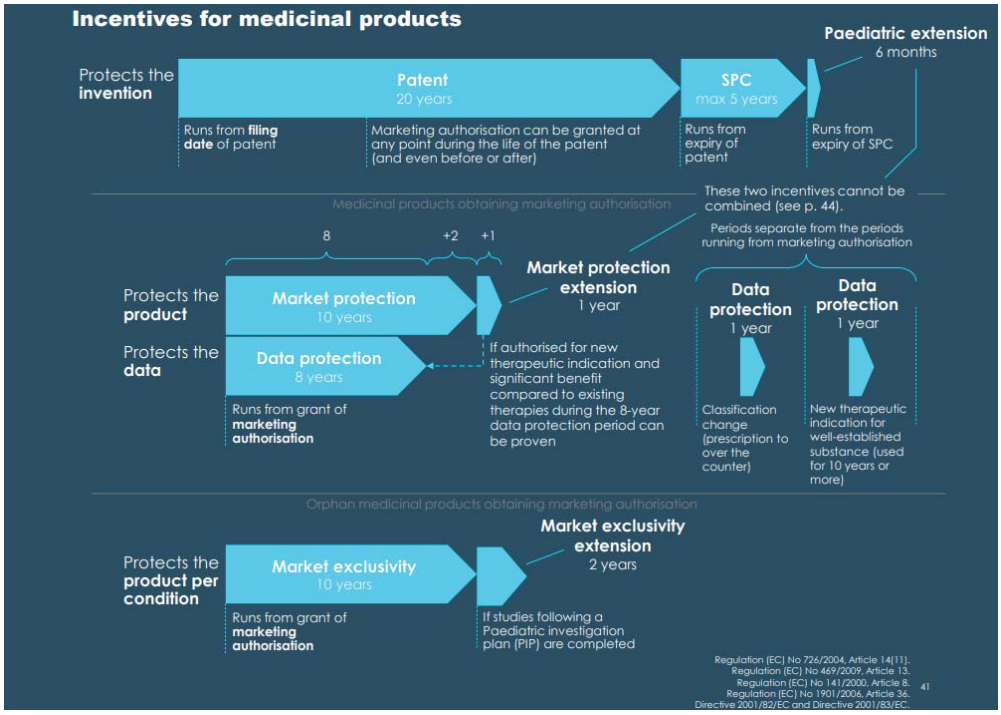
- EU regulatory protections that apply to medicinal product and PPPs (e.g. Regulatory Data Protection (RDP) for medicinal products and PPPs and market protection for medicinal products) as of the date of their authorisation, and that basically guarantee the innovator pharmaceutical, or agrochemical, company a minimum of protection of its new medicinal product, or PPP, of 10 years even where the original patent and SPC protection would sum up to fewer than ten years.
- A 10-year market exclusivity for orphan medicinal products (medicines for conditions that affect a small number of the EU population).

The graphics below summarises the concepts discussed above, as well as visualises their impacts on the effective protection period.

[270] Max Planck Institute for Innovation and Competition, Study on the Options for a Unified SPC System in Europe, 2022, p. 70.

[271] Paediatric investigations of medicinal products are rewarded with 6 months of extension of the SPC if an SPC exists. Paediatric means that it can be used for treating children aged 0 to 18. If the paediatric investigation concerns an orphan medicinal product, the market exclusivity may be extended from 10 to 12 years.

Figure 16: The pharmaceutical incentives in the EU – summary



Source: Copenhagen Economics, Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe, European Commission, Directorate General for Internal Market, Industry, Entrepreneurship and SMEs, 2018, p.41

Marketing authorisations for plant protection products (PPPs)

Regulation (EC) No 1107/2009 is the legislation concerning the placing of plant protection products on the market in the EU. PPPs (e.g. pesticides) are products consisting of, or containing active substances, safeners or synergists, and intended for uses such as protecting plants against harmful organisms, preserving plant products, etc. PPPs contain at least one approved active substance (these may include micro-organisms, pheromones and botanical extracts).

Regarding the procedure of granting of marketing authorisation for PPPs[272], a zonal system of authorisation operates in the EU to enable a harmonised and efficient system to operate (i.e. generally there is no unitary EU-wide marketing authorisation for PPPs[273]). The EU is divided into three zones: North, Central and South. EU Member States assess applications on behalf of other Member States in their zone, and sometimes on behalf of all zones (for some uses the EU is considered a single zone), and subsequently mutual recognition takes place in the remaining zones. The actors in the procedure can be the applicants, EU Member States, the European Commission and the European Food Safety Authority (EFSA).

[272] https://ec.europa.eu/food/plants/pesticides/authorisation-plant-protection-products/ppp-auth_en

[273] Each plant protection product is subject to national authorisation. The so called mutual recognition procedure under Article 40 of Regulation (EC) No 1107/2009 aims to facilitate the recognition of a national authorisation issued in one Member State in other Member States, from the same zone or not.

Number of marketing authorisations for medicinal and plant protection products

The table below presents the total number of marketing authorisations for human and veterinary medicinal products issued to originators (that is without generic and biosimilar marketing authorisation), as well as plant protection products. The total represents an upper bound for SPCs applications which can be obtained half a year after receiving marketing authorisation.[274] Hence SPC application should take place in the year of marketing authorisation (for marketing authorisation issued in the first half of the year) or in the year of marketing authorisation or the following year (for marketing authorisation issued in the second half of the year).

Table 40: Number of marketing authorisation issued per year for products that potentially can apply for SPC protection

Year	Human*	Veterinary*	PPP	Total
2004	27	4	7	38
2005	18	10	3	31
2006	28	4	7	39
2007	45	4	23	72
2008	35	10	7	52
2009	53	7	131	191
2010	26	6	21	53
2011	36	15	31	82
2012	35	6	14	55
2013	53	11	23	87
2014	56	18	28	102
2015	59	15	18	92
2016	44	5	23	72
2017	54	17	21	92
2018	62	9	14	85
2019	42	17	22	81
2020	63	14	9	86
2021	62	13	15	90
Avg. (2004-2021)	44	10	22	78
Avg. (2010-2021)	48	12	19	81
Avg. (2014-2021)	55	14	19	88

** does not include marketing authorisation issued for generics or biosimilar*
Source: In-house analysis based on European Medicines Agency database[275] and EU Pesticides database.[276]

[274] Article 7(1) of the SPC Regulations: "The application for a certificate shall be lodged within six months of the date on which the authorisation referred to in Article 3(b) to place the product on the market as a medicinal/plant protection product product was granted."
[275] https://www.ema.europa.eu/en/medicines/download-medicine-data
[276] https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=search.as

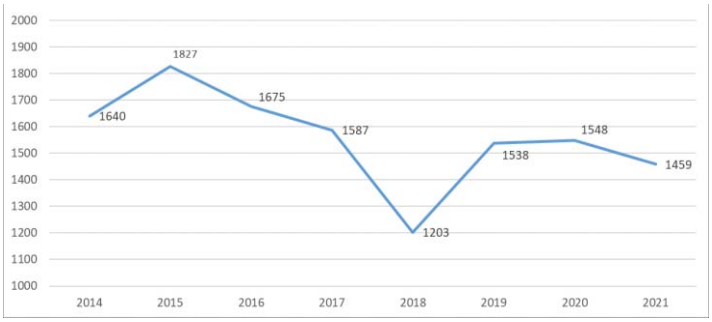
B. Evidence supporting section 2 (problem statement)

Market context - SPC statistics

As far as the reliance on SPC protection is concerned, it is significant and still growing in the Single Market. The total number of SPC applications filed in all Member States increased from about 500 applications in 1993 (in then EU-12) to a total of 1 459 SPC applications filed in the EU-27 in 2021[277]. To put the SPC data into a broader context of IP protection sought by the industry, the EPO reports that in 2021 the pharmaceutical sector filed 9 026 European patent applications, ranked as the 7th in terms of the number of applications submitted (interestingly, the medical technology sector was the 2nd)[278].

As shown in Figure 17 below, the yearly number of SPC application filed in EU-27 between 2014 and 2021 ranged from roughly 1 250 to 1 827, with a peak in 2015 and slight fluctuations in the trend afterwards. Additional (survey-based) data on the number of SPC applications is presented in Table 31 overleaf.

Figure 17: Number of SPC request filed in 2014-2021



Source: "Current trends in activity at the NPOs and at the EPO", Administrative Council of the EPO (documents: CA/36/19, CA/31/18, CA/13/17, CA/9/16) and "Exchange of information on current trends in activity at the NPOs and at the EPO", May 2022. Note: data missing for the following countries and replaced by country averages – 2014: BE, SE, 2015: SE. [279]

[277] Exchange of information on current trends in activity at the NPOs and at the EPO, European Patent Office, May 2022.

[278] European Patent Office, Patent Index 2021, Statistics at a glance, p.4.

[279] Another reason for the higher amount of applications in the first half of the graph may be observed due to in the Neurim judgment of 19 July 2012 (C/130/11). Here, the Court took a far reaching approach in its interpretation of Article 3(d) of Regulation 469/2009 as to which SPCs could be protected. Following this, national patent offices also took different approaches on how to apply Neurim (some NPOs took a strict, literal approach, while most NPOs took a wider approach. See: page 229f. of MPI (2018)). Moreover, it is recognised in the sector that SPC users started to apply for a high amount of SPCs around this time in order to test the boundaries of the system. In 2020, the CJEU rejected Neurim in its Santen decision (C-673/18).

Table 41: SPC applications in selected NPOs in 2018-2019

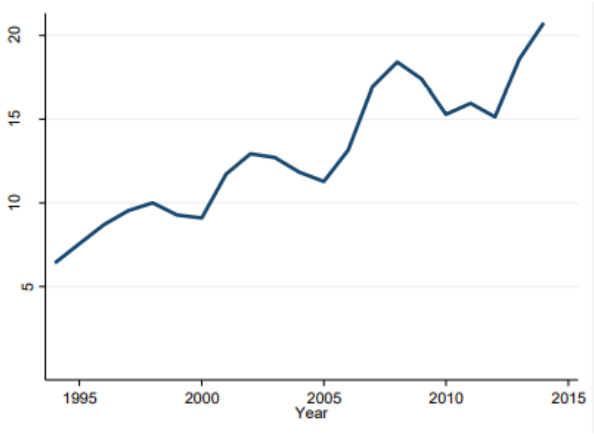
Country	Q20: Applications filed in 2018	Q20: Applications filed in 2019	Q21: Medicinal products relying on national MAs [280]	Q22: Relying on national patents [281]	Q23: Single active ingredient [282]	Q23: Combinations of active ingredients [283]
Austria	50	61	2	0	89	22
Belgium	46 (43 MP; 3 PPP)	65 (60 MP; 5 PPP)	3	0	94	17
Croatia	23	36	3	0	46	13
Czechia	50	52	16	2	78	24
Denmark	41 (40 MP; 1 PPP)	58 (58 MP)	2	0	83	16
Finland	42	59	6	0	n.a.	n.a.
France	58 (48 MP; 10 PPP)	77 (68 MP; 9 PPP)	23 (4/116 MP; 19/19 PPP)	0	106 (100 MP; 6 PPP)	29 (16 MP; 13 PPP)
Germany	65 (56 MP; 9 PPP)	83 (67 MP; 16 PPP)	4	0	102	21
Greece	48	59	5	0	85	22
Hungary	46	56	5	7	84	18
Ireland	46	62	5	0	91	17
Italy	46	65	2	0	98	13
Lithuania	34	42	1	0	n.a.	n.a.
Luxembourg	83	47	0	0	n. a.	n. a.
The Netherlands	47 (41 MP; 5 PPP)	68 (61 MP; 7 PPP)	4	0	75	24
Poland	58	59	6	15	84	33
Portugal	47 (41 MP; 6 PPP)		4	0	86	22
Romania	43 (38 MP; 5 PPP)	63 (56 MP; 7 PPP)	3	0	69 (64 MP; 5 PPP)	30 (23 MP; 7 PPP)
Slovak Republic	41 (38 MP, 3 PPP)	44 (41 MP, 3 PPP)	3	1	70	15 (11 MP; 4 PPP)
Spain	61	73	3	0	107	27
Sweden	47	60	5	0	n.a.	n.a.

Note: MP-medical product, PPP – plant protection product, MA – marketing authorisation
Source: Study on the options for a unified SPC system in Europe, Max Planck Institute for Innovation and Competition, 2022, p. 71-72; Questionnaire for the NPOs. .

[280] How many of the SPC applications filed in 2018 and 2019 for medicinal products relied on a national MA?
[281] How many SPC applications filed in 2018 and 2019 relied on national patents?
[282] How many applications filed in 2018 and 2019 with your office were for single active ingredients and how many of them were for combinations of active ingredients?
[283] Idem

As far as the use-patterns in SPCs are concerned, an increase in the number of new molecules protected can be observed, as well as in the expansion in geographic coverage. According to Kyle (2017), in the early 1990s, 75% of new drug introductions had an SPC in at least one country, and on average in 6-7 countries. In more recent years, the share is 86% with at least one and 18-19 countries on average[284]. Likewise, Mejer (2017) concluded that SPCs are granted in an increasing number of Member States for a given product (see: Figure 18, below). Since its entry into force until 2014, SPCs were applied for in 20 countries on average[285].

Figure 18: Average number of countries where SPC protection is applied for the same product



Source: Mejer, M., 25 years of SPC protection for medicinal products in Europe: Insights and challenges, European Commission, Directorate General for Internal Market, Industry, Entrepreneurship and SMEs, 2017, Figure 2, page 8.

As mentioned in section 2.2, the SPC are predominantly held by companies belonging to large corporate groups – around half of the SPCs belong to 16 multinationals.

Table 42: List of 20 most frequent global ultimate owners of companies holding an SPC in Germany (submission year 2010-2021)

	Global ultimate owner's name	Freq.	Percent	Cum.
1	BAYER AG	44	6.33	6.33
2	NOVARTIS AG	40	5.76	12.09
3	GSK PLC	29	4.17	16.26
4	MERCK & CO., INC.	29	4.17	20.43
5	ASTRAZENECA PLC	25	3.60	24.03
6	SANOFI	23	3.31	27.34
7	C.H. BOEHRINGER SOHN AG & CO. KG	22	3.17	30.50
8	PFIZER INC	21	3.02	33.53
9	SYNGENTA GROUP*	20	2.88	36.40
10	ABBVIE INC.	18	2.59	38.99
11	AMGEN INCORPORATED	15	2.16	41.15
12	GILEAD SCIENCES INC	15	2.16	43.31
13	ROCHE GROUP*	14	2.01	45.32
14	TAKEDA PHARMACEUTICAL COMPANY LIMITED	14	2.01	47.34
15	NOVO NORDISK FONDEN	13	1.87	49.21
16	BASF SE	11	1.58	50.79
17	JOHNSON & JOHNSON	11	1.58	52.37
18	ELI LILLY AND COMPANY	9	1.29	53.67

[284] Kyle, M. (2017), p. 18-19.
[285] Mejer, M. (2017), p. 7.

19	GENMAB A/S	9	1.29	54.96
20	ZOETIS INC.	9	1.29	56.26

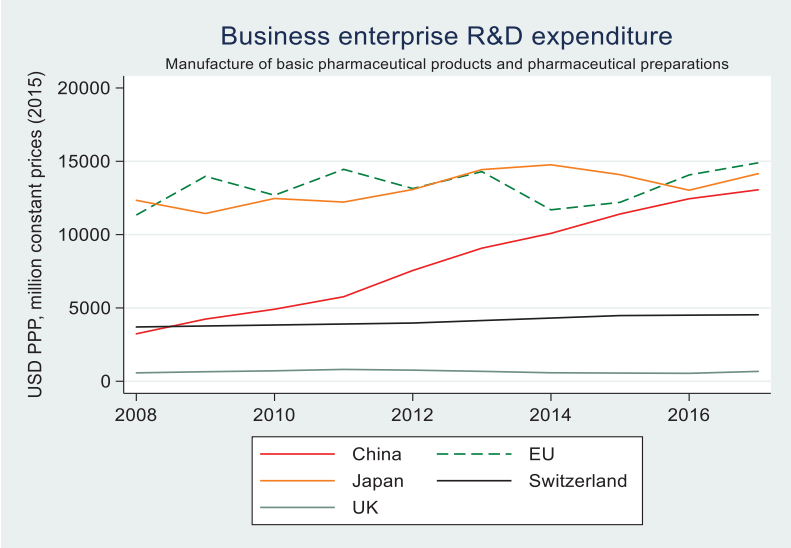
Source: In-house analysis based on DPMA register matched with IQVIA data SPC. Note: Syngenta group is owned by the government of China; Roche group is owned by a physical person.

Market context - changes in the global market

Although extremely important for the European economy, the EU pharmaceutical sector is no longer in a dominant position globally. Looking at the history of the pharmaceutical industry, it can be seen that it has undergone profound changes since the introduction and codification of the SPC regime in the EU in 1992 and 2009 respectively. These changes can be seen as not only driven by the growing global demand for medicines, but also a significant switch towards generics and biosimilars to alleviate public health expenditure (and indirectly push originators to develop more innovative medicines). Additionally, significant transition in the global market structure have been observed as well. The fast-growing economies of Asia, Central and South America – the so-called "pharmerging" regions – combined with ageing populations in the traditional industrialised regions, have driven massive global demand for medicines over the last decades. In 2017, most sales (in value terms) on the world pharmaceutical market were made in North America (48.1%), followed by Europe (22.2%) and Africa, Asia & Australia (excluding JP, 17.0%). The amount of sales in JP was at 7.7%, with the least amount of sales in Latin America at 5.1%.[286]

Pharmaceutical R&D worldwide used to be mainly situated in the US, the EU and JP[287], but the situation changes dynamically with a remarkable increase in R&D spending in CN (see: Figure 19 below).

Figure 19: Business enterprise research and development expenditure in pharmaceuticals in 2008-2017 [USD PPP, million constant prices]



[286] Breakdown of the world pharmaceutical market -2017 sales, EFPIA based on IQVIA (MIDAS) data Note : Europe includes Turkey and Russia, source : https://www.efpia.eu/publications/data-center/the-pharma-industry-in-figures-economy/world-pharmaceutical-market

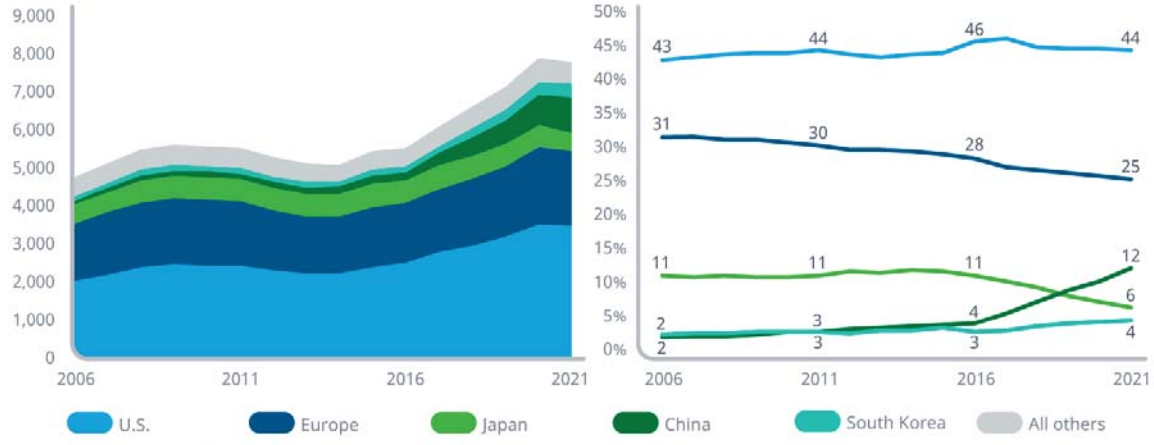
[287] Gambardella, A., Orsenigo, L., & Pammolli, F. (2000), Global competitiveness in pharmaceuticals: a European perspective, available at https://mpra.ub.uni-muenchen.de/15965/1/MPRA_paper_15965.pdf

Source: In-house analysis based on Business enterprise R&D expenditure by industry, Joint OECD-Eurostat international data collection on resources devoted to RD, Data extracted on 06 Jun 2022 from OECD.Stat. Note: data missing for the following EU countries: CY, BG, HR, LU, MT; PPP - purchasing power parity.

To complete the above, JRC (2021) provides more recent figures on the magnitude of differences between the key market players. In 2020 the US spent EUR 93.4 billion on health innovation compared to nearly EUR 36.6 billion by the EU[288].

The dynamics of R&D investments mirror the patterns that can be observed between the EU and the key market players in the number of medicines that are in clinical trials for a potential future regulatory approval (see: Figure 20, below).

Figure 20: Number of drugs and country share of pipeline Phase I to regulatory submission, based on company headquarters location, 2006-2021



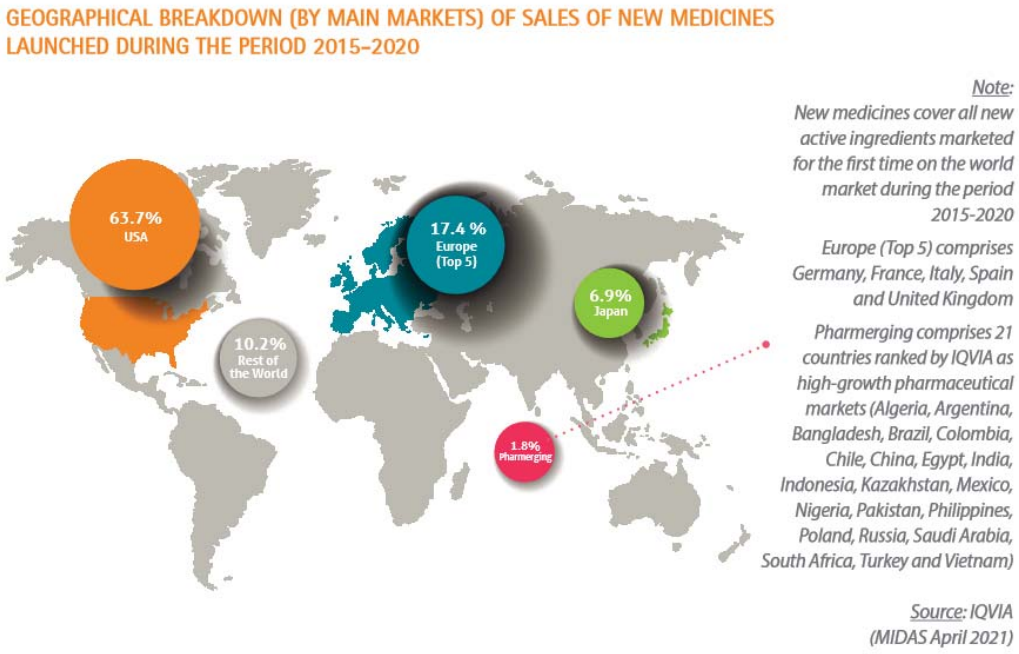
Source: IQVIA Pipeline Intelligence, Dec 2021; IQVIA Institute, Jan 2022.
Notes: Includes drugs with an active research program, with phase determined by the highest phase of research in each year regardless of indication. Each company involved in a drug's development is counted individually, so products with more than one company involved are counted more than once and may be included in more than one region. Europe is defined as any country in continental Europe.

Source: Global Trends in R&D: Overview through 2021. IQVIA institute for Human Data Science, February 2022.

The US dominance in the number of prospective drugs is also clearly correlated with the availability of new medicines on the market (see: Figure 21, below), with a significant gap between the leader and the following main geographical areas.

[288] The 2021 EU Industrial R&D Investment Scoreboard, European Commission, JRC/DG RTD, page 12.

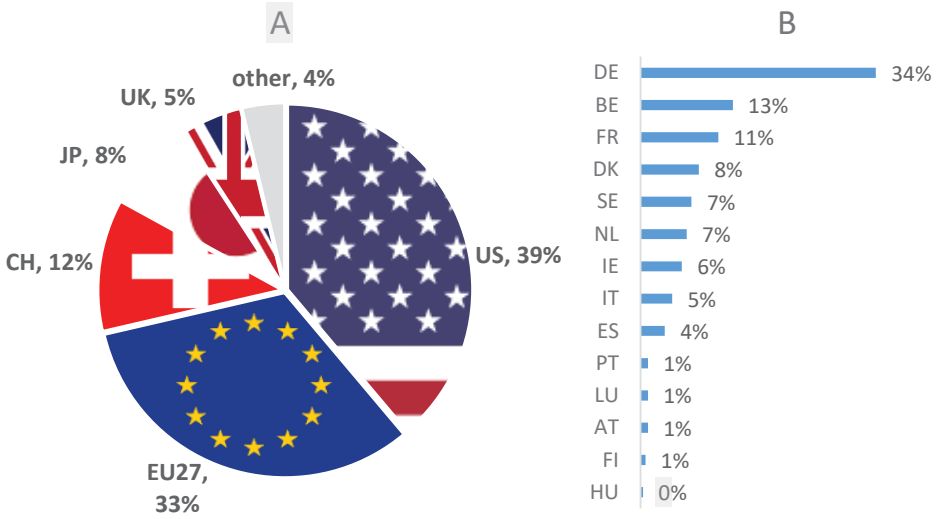
Figure 21: Main global markets in the sales of new medicines



Source: www.efpia.eu, The Pharmaceutical Industry in Figures, Key Data 2021

The US also leads in the number of SPC filings in Europe. For instance the US applicants accounted for around 39% of all SPC applications in the German NPO[289] over the period 2010-2022, while the EU-27 firms accounted for 33% of applications.

Figure 22: SPC applications to German NPO, by country of origin, between 2010-2022 (A) and distribution of EU27 applications by Member State (B).



Source: In-house analysis based on DE NPO data - DPMA register (https://register.dpma.de/DPMAregister/pat/basis)

[289] DE was chosen as the largest economy and the market with the highest number of SPC applications in the EU (see: Figure 1).

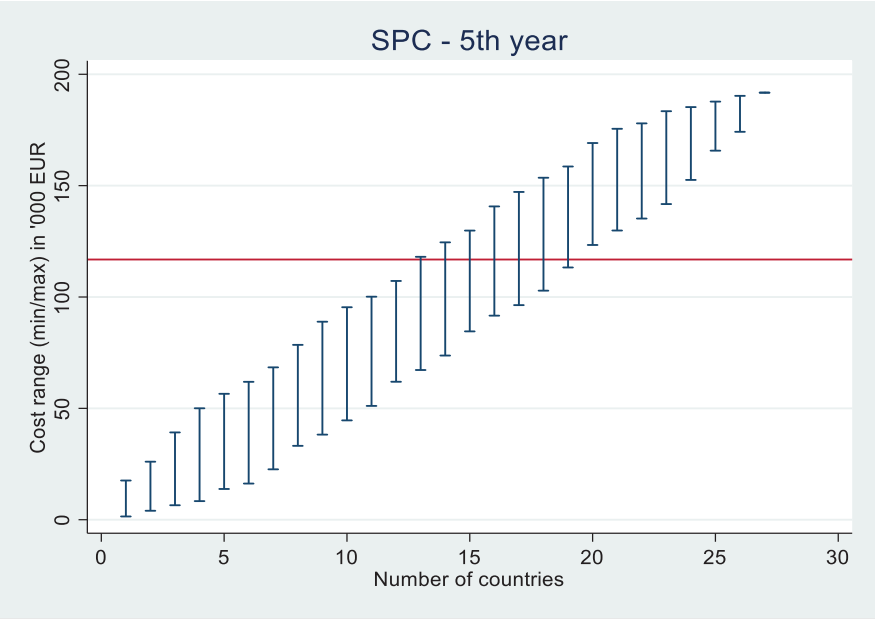
As for the plant protection industry, between 2003 and 2011 Europe was the leading regional agrochemical market worldwide, but in 2012 it was overtaken by Asia[290]. The number of new active ingredients introduced and in development, between the 1980s and the 2005 to 2014 period has fallen by 40.7% in PPP. However, the proportion of these active ingredients focussed on the European market has fallen from 33.3% to only 16.4%[291].

Problem drivers - high cost and burden of applying and maintaining SPC protection

According to the most recent data submitting an SPC in 27 countries and paying fees for the duration of 5 years (without the paediatric extension) would cost nearly EUR 192 000 in total.[292] Currently, an SPC applied in 20 Member States for a period of 3.5 years would cost around EUR 98 500[293] on average. The same SPC submitted and maintained for 3.5 years in the unitary patent countries[294] would cost around EUR 79 000[295] (compared to the cost of EUR 117 000 for the entire period of 5 years). The figure below shows the ranges of total application and renewal fees for a 5-year long SPC across various numbers of Member States in 2022 (i.e. the vertical spikes show the minimum and maximum cost among all combinations of a given number of Member States), as well as the cost level for UP Member States (the red line, as mentioned above: EUR 117 000). Detailed data about the cost ranges by each year and each combination of countries are provided in Table 43.

[290] R&D trends for chemical crop protection products and the position of the European Market, ECPA, Phillips McDougall, September 2013, p.11.
[291] Idem, p.15.
[292] Based on information about application and maintenance fees available on the NPOs' websites in second quarter of 2022. SPC evaluation estimated the cost (in terms of administrative fees) of five years of SPC protection covering all EU-27 countries at EUR 177 869 in 2016.
[293] Average between the lowest cost for an SPC lasting three years (EUR 68 274) and the highest cost for an SPC lasting four years (EUR 128 711).
[294] At the time of writing this impact assessment, 17 Member States were expected to initially participate in the unitary patent system.
[295] Rounded average between an SPC lasting three years (EUR 66 998) and four years (EUR 90 984) in UP-MS countries.

Figure 23: Cost ranges for the application and maintenance fees depending on the number of countries where the SPC was sought – the 5th year (cumulative)



Source: In-house analysis based on information collected from the NPO websites in March 2022.

It should be underlined that on the one hand this figure presents costs of SPC maintenance for 5 years, whereas the SPC average duration is 3.5 years. On the other hand, due to data availability issues, it doesn't cover the cost of paediatric extensions, which would increase the total even more. Still, it can be assumed that it is a good proxy of the magnitude of the administrative cost involved. It is also important to note that the above cost calculations do not include in-house and external patent-lawyer fees, which typically largely exceed the administrative fees (hence, constituting a lower bound of the cost range).

Table 43: Cumulative cost ranges by years and number of countries where SPC application was submitted and maintained [EUR]

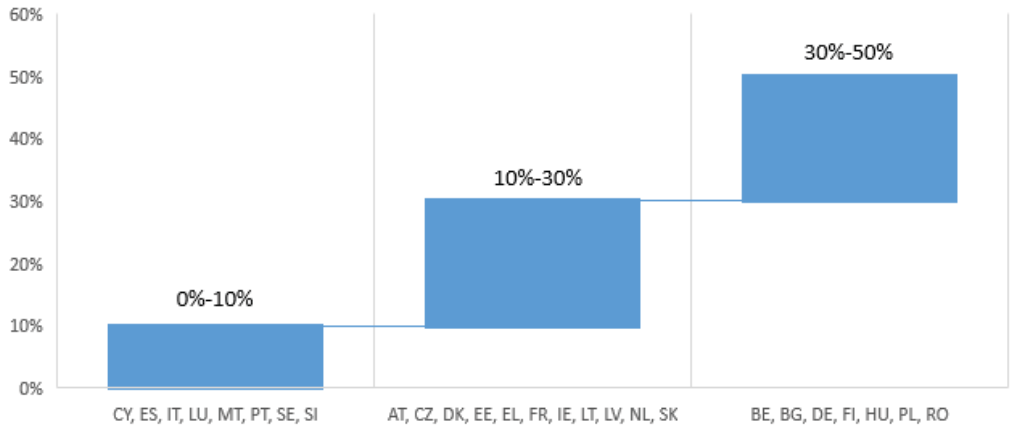
Number of countries	Year 1		Year 2		Year 3		Year 4		Year 5	
	min	max	Min	Max	min	Max	min	max	min	max
1	361	2974	617	6003	885	9451	1165	13315	1456	17597
2	892	5079	1659	9152	2436	13627	3223	19455	4020	26060
3	1461	6579	2687	12716	3935	20327	5205	29187	6496	39196
4	1923	9214	3496	17643	5091	27226	6708	38057	8346	50037
5	3338	10714	5922	20243	8528	31026	11156	43157	13805	56537
6	3901	11897	6953	22234	10027	33878	13123	47037	16240	61912
7	5377	13332	9411	24983	13632	37941	18038	52301	22628	68412
8	7369	15476	13355	28927	19576	43885	26182	60445	33172	78508
9	8664	16326	15637	31481	22886	48587	30411	67726	38211	88908
10	10139	17801	18095	34081	26492	52387	35326	72826	44599	95408
11	11587	18985	20695	36072	30292	55239	40426	76592	51099	100143
12	13037	20420	23936	38821	36237	59303	48812	81970	61940	107201
13	13772	22564	25301	42765	38508	65247	52912	90114	67222	118042

14	14861	23653	27076	44540	40968	67707	56635	93838	73722	124542
15	17005	24388	31020	45905	46912	69978	64779	97938	84563	129824
16	18440	25838	33769	49146	50976	75923	70157	106323	91621	140665
17	19624	27285	35760	51746	53827	79723	73923	111423	96357	147165
18	21098	28761	38360	54203	57627	83328	79023	116338	102857	153553
19	21948	30055	40913	56486	62330	86639	86304	120567	113256	158592
20	24092	32048	44857	60430	68274	92583	94448	128711	123352	169136
21	25527	33524	47606	62887	72337	96188	99713	133626	129852	175524
22	26711	34087	49597	63918	75189	97687	103593	135593	135227	177959
23	28211	35502	52197	66344	78989	101124	108693	140041	141727	183418
24	30846	35964	57125	67153	85888	102280	117563	141544	152568	185268
25	32346	36533	60689	68181	92588	103779	127295	143526	165704	187744
26	34451	37064	63837	69223	96764	105330	133434	145584	174167	190308
27	37425	37425	69840	69840	106215	106215	146749	146749	191764	191764

Problem drivers - divergent national practices on SPC

The practical differences in the way NPOs process the SPCs applications are presented on the the two figures below[296]. The percentage of applications pending over all SPC applications ranged from less than 10% in 8 Member States to up to half of them in 7 NPOs (Figure 24).

Figure 24: Percentages of SPC applications pending by Member States

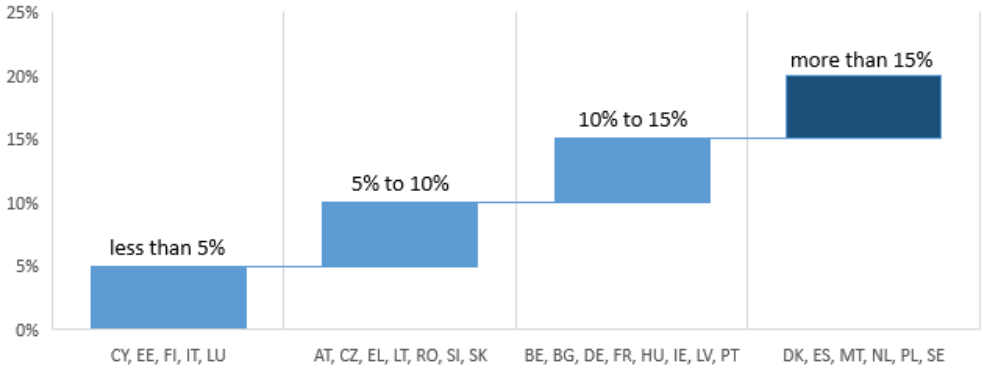


Source: Figure based on data from Alice de Pastors "Latest news on medicinal product SPCs in Europe - Medicinal Product SPCs filed from 1991 to 2013", SPC News 28 – September 2014. Note: HR is not taken into account as insufficient time elapsed between Croatia's entry to the EU and the data collection.

The ratio of rejections was also quite divergent, with 5 countries rejecting less than 1 in 20 applications while 6 NPOs rejected more than 15% (see: Figure 25).

[296] 'Latest news on medicinal product SPCs in Europe - Medicinal Product SPCs filed from 1991 to 2013', SPC News 28, Cabinet Alice de Pastors, 2014.

Figure 25: Percentages of SPC applications rejected by Member States



Source: Figure based on data from Alice de Pastors "Latest news on medicinal product SPCs in Europe - Medicinal Product SPCs filed from 1991 to 2013", SPC News 28 – September 2014. Note: HR is not taken into account as insufficient time elapsed between Croatia's entry to the EU and the data collection. The last category is an open one.

The above presented discrepancies in the SPC applications pending stem mainly from differences in patent-office procedures, such as waiting for decisions by national courts or lengthy proceedings, whereas SPC applications refused relate mainly to different approaches by NPOs. The following section presents additional evidence on practices related to substantive examination of the SPC applications and involvement of third parties that may add further insight on the source and magnitude of the observed discrepancies.

Problem drivers - EU Member States' practices related to substantive examination of the SPC applications and involvement of third parties

According to the first MPI (2018) study on the SPC system, the examination of SPC applications in the various national patent offices (NPOs) differs significantly. The study found that:

- A majority of the NPOs (CH, CZ, DE, DK, FR, HR, HU, IE, IT, LT, LV, NL, PL, PT, RS, SE, SK, UK) have declared that they provide for an examination of all four requirements stipulated in Art. 3 SPC Regulations.
- The NPOs of AT and LU examine only Art. 3(a) and 3(b) Reg. 469/2009.
- The FI, EL, RO, and ES NPOs do not examine compliance with the requirements under Art. 3(d) Reg. 469/2009.
- Several NPOs have confirmed that the capabilities to examine Art. 3(d) Reg. 469/2009 are limited. For example, the LV NPO has pointed out that it is difficult to examine compliance with Art. 3(d) SPC Regulations concerning the first marketing authorisation; therefore, in case of doubt the LV NPO requires the applicant to clarify this by confirming that the information provided is correct. Ireland stated that it does not perform an *ex-officio* search for all marketing authorisations and makes the examination of Art. 3(d) by searching for marketing authorisations in the online register of the Health Products Regulatory Authority.
  Such difficulties are relevant according to the German NPO with respect to the application of Art. 13 SPC Regulations, when the first relevant marketing authorisation in the EU is a national marketing authorisation granted in another EU Member States.

  The UK IPO informed that examination of Art. 3(d) is conducted on the basis of an "informal (basic internet) search" using information provided by the applicant, a third party, or information that can be obtained by consulting other SPC applications

concerning the same product. However, the IPO does not conduct a formal search in order to establish compliance of SPC applications with the requirements of Art. 3(d). Similar practice is also followed by the DK NPO.

Regarding the participation of third parties in the grant procedure:

- A majority of the NPOs of the countries examined (AT, CZ, DE, DK, ES, FI, HR, HU, IE, IT, LU, LV, NL, PL, PT, RO, RS, SE, SK, UK) allow the submission of third-party observations.
- In some states there is an express legal basis for third party submissions (DE, DK, FI, HU, IE, NL, PL, PT, RS, SE, SK, UK).
- In others, it is just standard practice to accept third party observations (AT, HR, ES, IE, RO, LU, LV).
- In EL LT and CH it is not possible for a third party to file observations regarding SPC applications.
- With the exception of DK, none of the countries examined informs the third party about the reasons why his or her observations were not taken into account and the SPC was granted.
- In no country does the third party become a party to the procedure, which remains *ex parte*.
- In DE, DK, FI, HR, IE, NL, PL, PT, SE, SK and UK it is possible to file observations anonymously and/or through a front man.
- With the exception of DK, no country allows for opposition to SPCs.

Problem drivers - EU Member States' practices related to access to information on SPC and procedural transparency

According to the Allensbach survey conducted in the framework of the MPI (2018) study, most respondents agree that, when it comes to examining SPC applications, '*the practice and procedures of the national offices in the EU Member States differ significantly in terms of predictability, transparency and quality of the rights granted*'.

The study report mentions in particular (in § 20.2.5.6) that:

- Some NPOs publish almost the entire file (e.g. DE, FI, FR, NL, SE, ES).
- Other countries make only such information public as referred to in certain provisions of the SPC Regulations.
- Still others publish the information required by the SPC Regulations as well as additional information, e.g. on the applicants' agent(s) and the status of the application.
- A clear majority of NPOs (AT, CH, DE, DK, ES, FI, FR, EL, HR, HU, IE, LT, LU, LV, NL, PT, RS, SE, SK, UK) allow for public access to almost all information concerning the procedure of granting an SPC with exceptions regarding business secrets, personal data, records of consultations and parts of files relating solely to internal office procedure, trade or business secrets, documents protected by copyright law, documents containing sensitive information about individuals or documents the applicant has asked to be kept confidential.

The Commission conducted a survey among NPOs in early 2020 to obtain details on their transparency practices that may be summarised as follows:

- Most NPOs provide an online searchable database, although the search criteria are very variable (in two Member States, the only search criterion that can be used is the SPC number).
- Publishing SPC-related information takes varying amounts of time, ranging from a few days to several months, and even more than a year in specific situations.
- Only a slight majority of NPOs (14 out of 27) publish SPC-related information in English in addition to their official languages.
- Only about half of NPOs make the documents in a file for a given SPC application accessible online (e.g. in PDF format). However, the other NPOs usually allow file inspection and/or are able to provide copies.
- Only a slight majority of NPOs (15) provide the European Patent Office (EPO) with detailed information on SPCs (which the EPO then publishes, although it is often mixed with other legal information).
- When asked which source they would consider to be the most suitable for providing centralised access to SPC information, 7 NPOs mentioned the EPO databases (possibly with improvements), 4 did not express any preference, and 14 mentioned a new centralised website.
- These transparency issues are in line with those already identified in the WIPO's surveys of 2019[297] and of 2002[298].

Consequences – EU less attractive globally

Currently most big markets offer SPC equivalent (called patent term extension) of up to 5 years (see Table 44).

Table 44: SPC Situation around the world

Country	Type and period of maximum protection
Australia	Patent extension by up to 5 years
Canada	Certificates of supplementary protection for up to 2 years
Israel	Patent extension by up to 5 years
Japan	Patent extension by up to 5 years
South Korea	Patent extension by up to 5 years
Singapore	Patent extension by up to 5 years
USA	Patent extension by up to 5 years
Taiwan	Patent extension by up to 5 years
China*	Patent extension comparable to the EU SPC regime
India*	No such extension mechanism

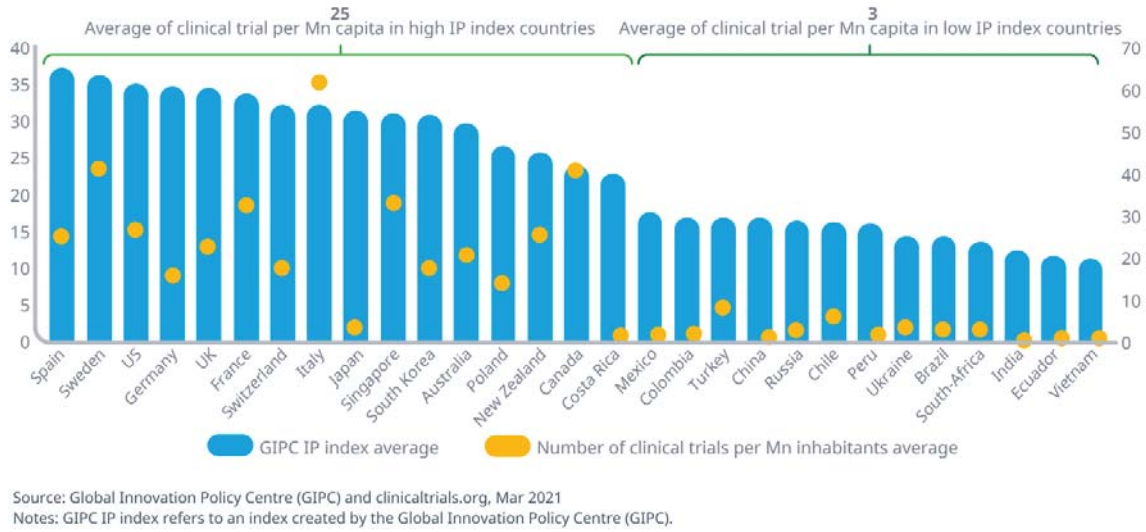
*Source: Study on the Legal Aspects of Supplementary Protection Certificates in the EU, MPI (2018); *own research*

The SPC Regulations clearly aim at supporting pharmaceutical and agrochemical innovation in the EU[299]. While the economic literature provides vast empirical evidence in support of positive impacts of IP rules on R&D activities, it is nonetheless not possible to infer direct causal relationships between the implementation of an SPC system in a particular jurisdiction and an actual change in research and development activities in that area. For example, IQVIA (2021) shows a positive

[297] https://www.wipo.int/edocs/mdocs/classifications/en/cws_7/cws_7_23.pdf
[298] https://www.wipo.int/export/sites/www/standards/en/pdf/07-07-01.pdf
[299] Recitals 2 to 5 of Regulation (EC) 469/2009, Recitals 3 to 5 of Regulation (EC) 1610/96.

correlation between the strength of IP protection[300] and the number of clinical trials ("countries with a strong IP index have higher levels of clinical research activities on average"[301], see: Figure 26 below), but the level of granularity of the analysis concerning the IP rules does not allow to distinguish the impact of rules on SPC or patent term restoration (PTR)[302]. As a consequence, although the above research supports the basic claim in favour of relevance of strong IP protection in the sector, it is not SPC/PTR-specific[303].

Figure 26: Strength of IP framework and the number of clinical trials per million inhabitants (2014-2020)



Source: Global Innovation Policy Centre (GIPC) and clinicaltrials.org, Mar 2021
Notes: GIPC IP index refers to an index created by the Global Innovation Policy Centre (GIPC).

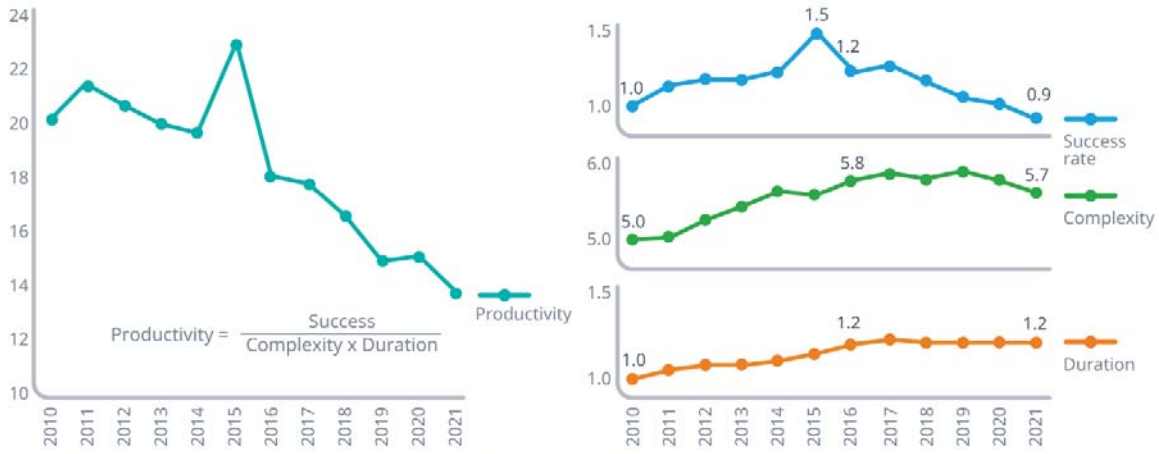
Source: The Impact of Pharmaceutical IP Provisions in EU Free Trade Agreements, IQVIA Institute for Human Data Sciences, November 2021.

The main difficulty in identifying the direct effects of the SPC/PTR on innovation intensity in the jurisdiction(s), where such rules are introduced also stems from the fact that patent holders can seek such extended protection irrespective of the country where the R&D or manufacturing of the novel product took place. In other words, the SPC Regulations do not differentiate between EU-based companies and their foreign competitors[304]. The same "geographic" neutrality towards innovators applies for example to the Japanese or US patent extension terms[305]. Such architecture of the SPC/PTR rules reflects the core nature of the pharmaceutical industry, which is by no means a global one. In view of the above, it is evident that the consequences of the current the SPC regime do not concern the Single Market only. They stretch beyond the EU borders and must be evaluated from such perspective, as well.

[300] Measured by the IP index of the Global Innovation Policy Centre (GIPC), U.S. Chamber 2021 International IP Index.
[301] The Impact of Pharmaceutical IP Provisions in EU Free Trade Agreements, IQVIA Institute for Human Data Sciences, November 2021.
[302] Patent term restoration (PTR) is a term used in USA and Japan to describe extension of patent right equivalent to European SPC.
[303] Although the authors argue that „The combination of RDP and PTR provisions has the strongest effect on R&D and clinical research", Idem, p. 27.
[304] Which is in clear contrast to for example local manufacturing requirements contained in the SPC manufacturing waiver.
[305] Most developed countries (e.g. the US, JP and others) have similar patent extension regimes incentivising the development of new products. For more details see: MPI study (2018), p. 603-617.

In pharmaceuticals, this is confirmed by productivity data, where an ever-increasing back catalogue of effective medicines, and a shift towards more complex conditions that has increased the complexity of clinical trials and failure rates. Figure 27 illustrates the decreasing productivity index. As mentioned above, a common hypothesis to explain this trend is that more stringent requirements to gain marketing authorisation have increased the costs of clinical trials.

Figure 27: Clinical Productivity Index and elements of productivity indexed to 2010 values



Source: IQVIA Pipeline Intelligence, Dec 2021; Citeline Trialtrove, IQVIA Institute, Jan 2022.
Notes: Success rates and durations are indexed to the mean value for all diseases in 2010 equal to 1. The five complexity metrics are indexed to all diseases in 2010 equal to 1, and then summed, equaling 5.

Source: Global Trends in R&D: Overview through 2021. IQVIA institute for Human Data Science, February 2022.

Similar patterns can be observed in the plant protection sector, where as mentioned earlier, the major companies invested around 7-10% of their annual sales in R&D over the last 50 years[306]. Yet, according to a study by Deloitte[307] the agrochemicals industry has experienced declining revenues and margins that were primarily due to:

- Longer product-development cycles: the average development period for a new PPP has increased from 8.3 years in 1995 to 11.3 years in 2010-2015 (see: Table 45 below).

Table 45: Time to develop a new crop protection product

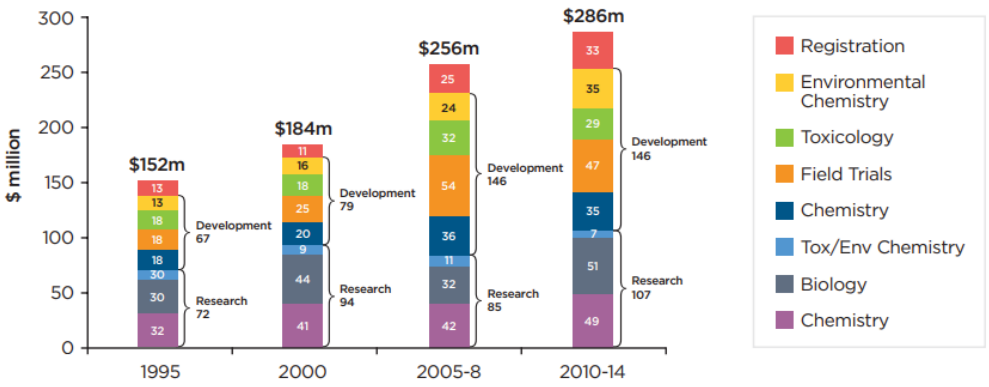
	1995	2000	2005-8	2010-15
Number of years between the first synthesis and first sale of product	8.3	9.1	9.8	11.3

Source: Evolution of the Crop Protection Industry since 1960, Phillips McDougall, November 2018 (from Phillips McDougall, 2016), p.8.

- Escalating costs: the overall R&D costs for a new PPP increased from USD 152 million in 1995 to USD 286 million in 2010-2014 (see: Figure 28, below).

[306] Evolution of the Crop Protection Industry since 1960, Phillips McDougall, November 2018.
[307] The future of agrochemicals | Capturing value through innovation, resourcefulness, and digital alchemy, Deloitte, 2019, p.4.

Figure 28: Discovery and development costs of a new crop protection product



Source: Evolution of the Crop Protection Industry since 1960, Phillips McDougall, November 2018, p.8.

Consequences - Hampered joint cross-country public procurement

According to available data on public procurement, "medical equipment, pharmaceuticals and personal care products" accounted for around 14.1% of contracts below EUR 200 million covered by the EU public procurement Directives and were characterised by very high share of indirect[308] cross-border procurement[309]. Namely, as much as 50.2% of such awards in 2016-2019 were won by local subsidiaries of foreign firms, accounting for 61.3% of the total value of procurement under division 33 of CPV[310]. The propensity to indirect cross-border procurement in CPV33 (medical equipment, pharmaceuticals and personal care products) was actually the highest among all sectors[311]. However, although it confirms the multinational character of the sector (supply side), the above data in principle concern calls for tender launched by contracting authorities from a single Member State (demand side), as different from a cross-country joint procurement. Unfortunately, calls for tender for pharmaceuticals involving two or more countries do not occur very often, although especially in case of small countries, it could leverage their market power by pooling volumes and/or address various concerns in terms of security of supply.

How likely is the problem to persist?

The medicine market is expected to grow at 3–6% CAGR through 2026, reaching about USD 1.8 trillion in 2026, including spending on COVID-19 vaccines[312] (see: Figure 29 below).

[308] Companies located in the same country as the contracting authority but controlled by companies in a foreign country

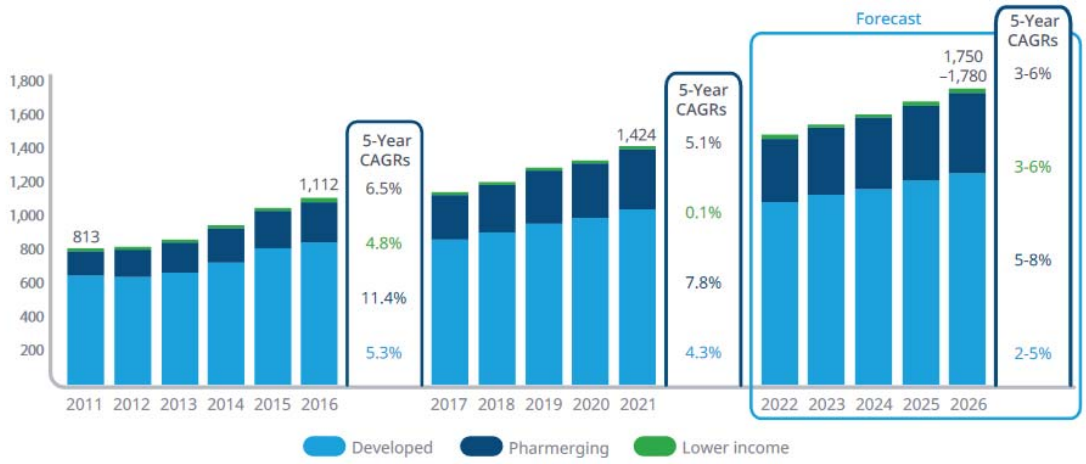
[309] Study on the measurement of cross-border penetration in the EU public procurement market, Prometeia SpA, European Commission, DG for Internal Market, Industry, Entrepreneurship and SMEs, 2021, p.65.

[310] Common Procurement Vocabulary (CPV) is a single classification system for public procurement aimed at standardising the references used by contracting authorities and entities to describe the subject of procurement contracts.

[311] Prometeia SpA (2021), p.65.

[312] IQVIA, The Global Use of Medicines 2022: Outlook to 2026, 2022, p.2.

Figure 29: Global medicine market size and growth 2011-2026 [USD billion, constant]



Source: IQVIA Market Prognosis, September 2021, IQVIA Institute, November 2021

C. Evidence supporting section 6 (impacts), except for the cost-benefit analysis[313]

The choice of the examination authority

Table 46: Key elements impacting the choice between the EUIPO/EMA/EFSA and EPO

	EUIPO/EMA/EFSA	EPO
EU body?	Yes	No
Legal basis	Art. 118 (unitary SPC) and Art. 114 (centralised procedure) →(codecision)	Probably Art. 352 (unanimity of the Council, and mere consent by the EP)
Supervision by the European Parliament?	Yes	No
Decisions subject to review of the CJEU?	Yes	No (to the EPO´s Board of Appeal, instead)

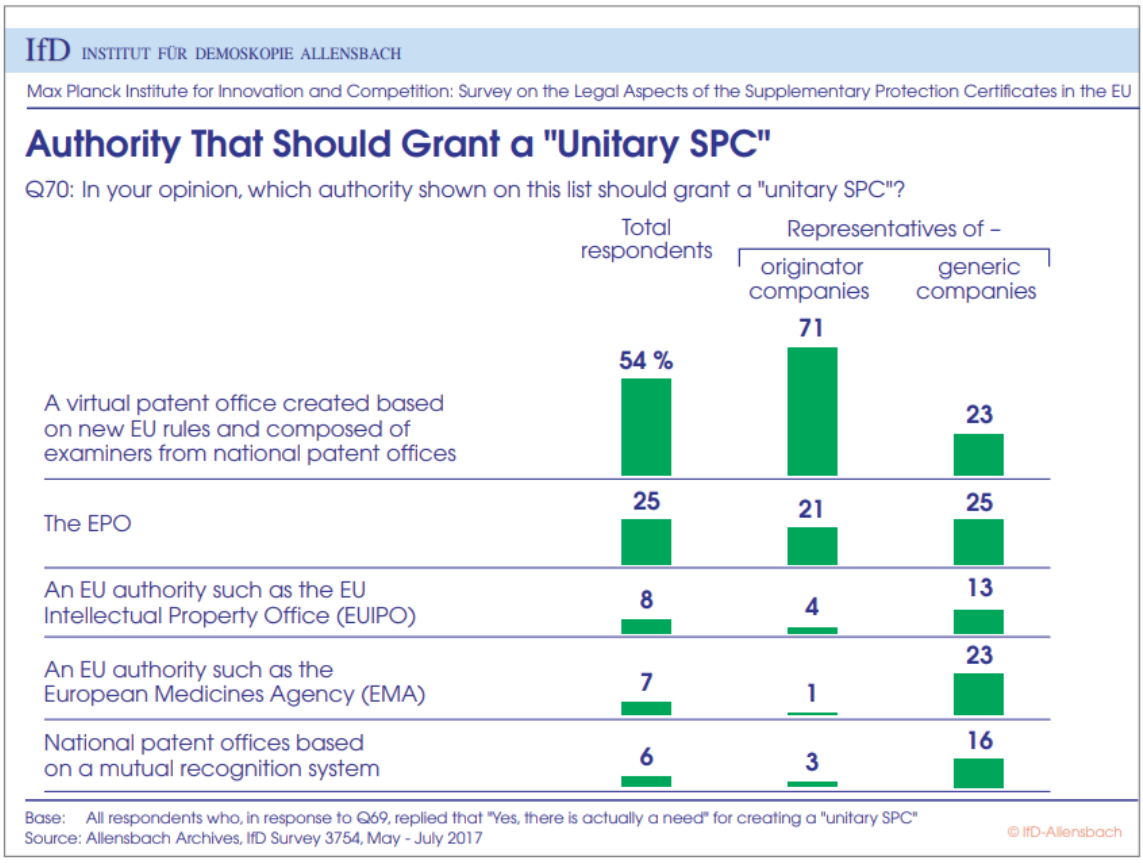
Table 47: Public Consultations results: Which granting authority would you favour to grant and register a unitary SPC? Q38 (to Originators), Q30 (to follow-on manufacturers), Q10 (to other public authorities).

Agree answers only*	Originators	Follow-on manufacturers	Ministries and other public authorities
EU Intellectual Property Office	1%	2%	0%
European Patent Office	6%	48%	20%
A new EU agency	1%	38%	0%
European Medicines Agency	1%	0%	40%
EU countries' patent offices (e.g. virtual office approach or mutual recognition with reference offices, under EU rules)	86%	7%	20%
None of the above, please indicate your alternative preference	4%	5%	20%
No. of answers	*69*	*50*	*5*

[313] The background data supporting cost-benefit analysis presented in section 6 of the impact assessment is provided in Annexes 5D to 5G.

* the residual to 100% is the number of those disagreeing.
Note: "Don't know" and No answer not taken into account. Not all groups of respondents have received this question.
Source: Public Consultations on Evaluation of SPC

Figure 30: Allensbach survey on the choice of examination authority (question 70)



The choice of linguistic regime – advantages and disadvantages

As mentioned in sections 6.2 to 6.5, the table below identifies advantages and disadvantages per each linguistic regime with regards to selected steps of the centralised SPC procedure. The columns define selected actions in the SPC examination process, where a particular linguistic settings could have significant impacts on the objectives of this initiative defined in Section 4.

Table 48: Advantages and disadvantages of each linguistic regime for a centralised SPC procedure (PO3 to PO5)

Linguistic regime	Application for the SPC (standard form[314]) and filing of 3rd parties observations	Procedure at the single authority (working language(s))	Transmission of the examination results to NPOs (ONLY in PO3 and PO4)
Parties concerned	Applicant (firm)	Examination authority	Examination authority and NPOs

[314] A standard form for an SPC application would be agreed and translated into the languages of each linguistic regime (one-off cost).

Linguistic regime	Application for the SPC (standard form[314]) and filing of 3rd parties observations	Procedure at the single authority (working language(s))	Transmission of the examination results to NPOs (ONLY in PO3 and PO4)
English only (EN)	(0) Although acceptable for the industry (as indicated in the public consultation, stakeholders usually communicate in EN), but there would be access barriers for non-EN speaking firms, such as smaller follow-on producers. (++) High cost-effectiveness (translation costs to one language only, if at all).	(+ + +) Minimum cost (no translation costs for the EA). (+ + +) Facilitated exchange of expertise, streamlined administrative processes within the EA and w.r.t.: - the recruitment of members of the BoA - the working of BoA; - the recruitment of formality officers and setting up of a VNE.	(+++) Minimum cost (no translation costs for the EA). (++) Facilitated exchange of expertise, fast and streamlined administrative processes for the EA, but necessitate more effort from NPOs (if acceptable).
Any official language of the EU	(+ + +) Fully accessible for all stakeholders. (+ + +) Very high cost-effectiveness (no translation costs[315] as submission in the native language of the applicant always possible[316]).	(- - -) High translation costs, need for additional administrative staff with specific language skills. (- - -) Exchange of expertise difficult due to number of languages, cumbersome administrative processes, within the EA and w.r.t.: - the recruitment of members of the BoA (very challenging if not impossible); - the working of the BoA; - the recruitment of formality officers and setting up of a VNE.	(*Any official language of the EU, within the languages relevant to the requested SPC coverage*) (0) Neutral cost-effectiveness (significant translation costs for the EA and delays) (- -) Very limited exchange of expertise, but respects the linguistic regime of each NPOs.
EN, FR or DE (any language of the EPO linguistic regime)	(+) Reasonably accessible for stakeholders. (+ +) High cost-effectiveness (translation costs to one language only, if at all).	(+ +) High cost-effectiveness (reasonable translation costs,) (+ +) Facilitated exchange of expertise, acceptable level of linguistic impact on the complexity of administrative processes within the EA and w.r.t.: - the recruitment of members of the BoA; - the working of the BoA; - the recruitment of formality officers and setting up of a VNE.	(+ +) High cost-effectiveness (reasonable translation costs, acceptable level of linguistic impact on the complexity of proceedings). (+ +) Facilitated exchange of expertise, but the linguistic regime of majority of NPOs is not respected.
EN, FR, DE, IT or ES (any of the languages used by EUIPO)	(+ +) Accessible for the prevailing majority of stakeholders. (++) High cost-effectiveness (translation costs to one language only, if at all).	(+) Positive cost-effectiveness (moderate translation costs) (+ +) Facilitated exchange of expertise, acceptable level of linguistic impact on the complexity of administrative processes within the EA and w.r.t.: - the recruitment of members of the BoA; - the working of the BoA; - the recruitment of formality officers and setting up of a VNE.	(+) Positive cost-effectiveness (moderate translation costs, some negative impacts on the delays and complexity of proceedings due to number of languages). (+ +) Facilitated exchange of expertise, but the linguistic regime of majority of NPOs is not respected

[315] As mentioned earlier, it is assumed that EP and MA are always available in the language of the country for which the SPC is requested, as MA is published in all EU languages and the EP have been validated in the requested countries.

[316] If an SPC application for the same product covered several MS, it could be submitted in one language with several attachments (PE and MA) for each language of the the countries where the protection is sought.

Linguistic regime	Application for the SPC (standard form[314]) and filing of 3rd parties observations	Procedure at the single authority (working language(s))	Transmission of the examination results to NPOs (ONLY in PO3 and PO4)
All official languages of the EU (or of the enhanced cooperation area)	(*not possible*) It would dissuade (or practically block) the submission of SPC applications. It would dissuade (or practically block) the filing of observations.	(- - -) Very low cost-effectiveness (significant translation costs, need for additional administrative staff with specific language skills). (- - -) Exchange of expertise difficult due to number of languages, cumbersome administrative processes, within the EA and w.r.t.: - the recruitment of members of the BoA (very challenging if not impossible in view of linguistic requirements) - the working of the BoA; - the recruitment of formality officers and setting up of a VNE (extremely difficult, if not unfeasible).	*(not possible)* The translation into more languages than selected languages relevant to the requested SPC coverage would generate redundant costs (serves no purpose).
Parties bearing the translation costs	The translation costs would be borne by the applicant.	The translation costs of would be borne by the examination authority.	The translation costs would be borne by the examination authority.

Note: EA - the examination authority; VNE - a virtual network of examiners (i.e. a pool of SPC examiners delegated from NPOs); BoA – Board of Appeals.

The choice of linguistic regime – translation costs for the applicants

Table 49 below estimates the yearly cost of translations borne by SPC applicants under the current regime (two scenarios – SPC coverage sought in 27 Member States or 17 Member States of the enhanced cooperation) and the newly proposed centralised filing. If the SPC was to be submitted centrally, the cost of translation of the application from applicant's own language to the working language of the examination office would amount to 17 400 EUR yearly (100 SPC applications yearly * 2 pages per applications * 87 EUR/ page). This would be roughly 7.5% of costs borne by firms currently, when they seek an SPC protection in 27 Member States (translations to 23 official EU languages[317] * 58 application * 2 pages per application * 87 EUR/page).

In case of no translation requirements in the centralised procedure (the applications are accepted in any of the EU official languages), the translation cost to firms would drop to zero.

[317] 24 official EU languages, less the applicant's own language.

Table 49: Estimated annual EU wide translation costs for firms – comparison of current situation and a centralised submission

Combined translation costs for firms - yearly estimates		SPC sought in 27 MS	SPC sought in UP-17 MS	Centralised filing
Is the SPC application to be translated (application language is NOT the working language of the NPO or EA)?		yes, for all except for the SPC application language	yes, for all except for the SPC application language	yes
Scope	Number of Offices for which an SPC application needs to be submitted	*27*	*17*	*1*
	Number of languages into which an SPC application needs to be translated	23	14	*1*
SPC application				
Number of SPC applications to be submitted		1566	986	100
Number of SPC applications to be translated before submission		**1334**	**812**	**100**
Number of pages for translation (2 per SPC application)		2668	1624	200
TOTAL cost of translation		**232 116 €**	**141 288 €**	**17 400 €**
Translation cost per product		**4 002 €**	**2 436 €**	**174 €**

*Note: Number of SPC applications to be submitted = number of countries * 58 (average yearly number of SPC submitted in 2014-2021 per country); Number of SPC applications to be translated before submission = number of languages into which an SPC application needs to be translated * 58 (average yearly number of SPC submitted in 2014-2021 per country). Assumptions – number of SPC applications per year in the centralised system: 100; number of pages per an SPC application: 2; Translation cost per page: 87 EUR.*

The typical cost of translation per product in case of submission in 27 Member States would be EUR 4 002 (i.e. 23 languages * 2 pages * EUR 87 per page) and EUR 2 436 in case of submission in the current 17 UP Member States (i.e. 14 languages * 2 pages * EUR 87 per page).

The choice of linguistic regime – translation costs for the examination authority

The below cost estimate is based on the assumption that, the SPC applicants or 3rd parties wishing to file written observations can use any official EU language in order to submit documents to the examination authority. This being said, Table 50 and Table 51 below present such costs incurred in the following stages of the centralised SPC procedure:

- reception of an SPC application (any EU official language),
- publication of the SPC application (all EU official languages),
- reception of third parties written observations (any EU language),
- transmission of the SPC dossier to NPOs (all EU official languages where the SPC is sought[318]),
- publication of the SPC examination results (all EU languages).

Furthermore, the number of SPC applications submitted per year in the new centralised procedure is expected to be 100 (as it was the case for the estimate of firm's translation costs). The SPC procedures are expected to be quite contentious, therefore three scenarios concerning the number of 3rd parties interventions are considered, ranging from 50% of SPC being subject to reactions from other stakeholders to 100% of SPC receiving written observations. The expected number of written observations per SPC procedure is three. This number is based on the assumption that half of future

[318] Table 50 is based on an upper bound scenario of a coverage sought in 27 Member States.

generic competitors[319] would address such observations concerning medicinal products that they may consider producing.

Table 50: Translation costs for the examination authority under the centralised SPC procedure – reception of documents

Steps in the administrative procedure	Actions to be undertaken by the EA	Number of documents to be translated and the cost of translation		
Reception of an SPC application	*Translation into the EA working language for admissibility inspection (1 translation per SPC application)*	*Documents received need to be translated to the EA working language?*		
		yes-100%	yes-50%	no-0%
		100	50	0
	Number of pages to be translated (2 per SPC application)	200	100	0
Cost of translation		**17 400 €**	**8 700 €**	**- €**
Reception of 3rd parties written observations	*Translation of written observations into the EA working language (1 translation per observation dossier), in case of:*	*Documents received need to be translated to the EA working language?*		
		yes-100%	yes-50%	no-0%
	100% of SPCs will receive 3 observation dossiers	*300*	*150*	*0*
	75% of SPCs will receive 3 observation dossiers	*225*	*113*	*0*
	50% of SPCs will receive 3 observation dossiers	*150*	*75*	*0*
	Ranges taken for the estimate	300	113	0
	Number of pages to be translated (10 per observations dossier)	3000	1125	0
Cost of translation		**261 000 €**	**97 875 €**	**- €**

Notes: Assumptions – number of SPC applications per year in the centralised system: 100; number of pages to be translated per SPC application: 2; number of pages to be translated per written observations dossier: 10; Translation cost per page: 87 EUR.

Two steps of the procedure are to be published: i) information that an SPC request has been received by the examination office and it fulfils basic admissibility conditions (including some key elements of its contents to enable the submission of written observations) and ii) the summary of results of the SPC examination procedure (this publication may be less detailed than what is transmitted to the parties concerned and/or NPOs in PO3 and PO4), yet it should contain all necessary elements to allow the follow-on producers make their decisions with regards to potential market entry.

It shall be noted that the transmission of the SPC examination outcome to NPOs (foreseen under PO3 and PO4) has the highest impact on the overall translation costs for the examination authority (around EUR 2 million). It would be therefore highly recommended to agree that the SPCs dossiers passed to NPOs are not translated into all languages, but transferred and processed in the examination procedural language only.

[319] "Within three years following the LoE [loss of exclusivity], the ratio of generic companies to originators is about 6:1." (source: Pharmaceutical sector Inquiry (2009), p. 74).

Table 51: Translation costs for the examination authority under the centralised SPC procedure – publication of documents (upper bound for 27 Member States)

Steps in the SPC administrative procedure	Number of documents to be translated	Number of pages per document	Number of pages to be translated	Cost of translation
Publication of an abridged SPC application	2300	2	4600	400 200 €
Transmission of the SPC dossier to NPOs	2300	10	23000	2 001 000 €
Publication of the SPC examination results	2300	2	4600	400 200 €

Notes: Assumptions – number of SPC applications per year in the centralised system: 100; number of languages: 23 (i.e. 24 languages, less 1 language of the dossier); number of pages to be translated per published SPC application: 2 (although the published version of the application may be abridged due to the removal of sensitive information, the same number of pages is kept); number of pages to be translated per SPC dossier before transmission to NPOs: 10; number of pages to be translated per SPC examination dossier to be published (only key elements of the complete file submitted to the NPOs): 2; Translation cost per page: 87 EUR.

Table 52: SPC maintenance fees and their estimated share in the NPOs revenues from patent maintenance

Country	Renewal fees for granted patents in 2021 ['000 EUR]	Share of SPC fees in renewal fees for granted patents (application)	Share of SPC fees in renewal fees for granted patents (maintenance)
AT	25 142	0.1%	0.9%
BE	10 810	0.1%	0.5%
BG	2 272	0.6%	3.4%
CY	1 113	0.4%	3.3%
CZ	6 206	0.2%	1.0%
DE	218 360	0.0%	0.1%
DK	10 657	0.2%	0.4%
EE	1 533	0.3%	1.8%
EL	4 236	0.4%	2.5%
ES	22 618	0.2%	0.9%
FI	10 520	0.3%	0.5%
FR	77 771	0.1%	0.1%
HR	740	1.7%	10.5%
HU	6 396	0.6%	1.1%
IE	7 513	0.1%	0.4%
IT	45 653	0.1%	0.2%
LT	1 287	0.4%	1.2%
LU	1 661	0.1%	1.5%
LV	1 210	0.4%	1.9%
MT	370	0.8%	1.8%
NL	44 168	0.1%	0.3%
PL	5 272	0.1%	1.4%
PT	6 098	0.5%	0.9%
RO	3 573	0.8%	1.9%
SE	16 474	0.3%	0.7%
SI	1 737	1.2%	7.4%
SK	2 584	0.3%	3.2%
	535 974	**0.1%**	**0.4%**

Source: Renewal fees for granted patents from "EPO Financial Statements 2021", p. 61; shares – own calculations based on renewal fees collected from NPOs websites in March 2022 multiplied by average yearly number of SPC filed, as presented in Figure 1.

The choice of linguistic regime – languages of applications to the German NPO.

Based on the geographical distribution of applications submitted to the German NPO in 2010-2022 (as described in Annex 5B) we can estimate which languages are most frequently used. It is assumed that all non-EU applicants would apply in one of the official EU languages – most often it is English, but in case of Canada it could be also English or French, and for Switzerland: French, German or Italian, etc. The language distribution resulting from the above analysis is presented in Table 53 (the columns refer to variations in the use of a second or third language).

Table 53: Estimated language distribution of applications to German NPO in 2010-2022

Language	Using 1st language	Using 2nd language*	Using 3rd *or in absence 2nd language
English	57.8%	56.9%	56.9%
French	20.0%	4.6%	4.6%
German	11.5%	23.4%	16.2%
Italian	1.5%	1.5%	13.1%
Dutch	2.2%	6.5%	2.2%
Danish	2.8%	2.8%	2.8%
Swedish	2.4%	2.6%	2.6%
Spanish	1.1%	1.1%	1.1%
Total	*99.3%*	*99.5%*	*99.5%*
Share of English, French and German	*89.3%*	*84.9%*	*77.7%*

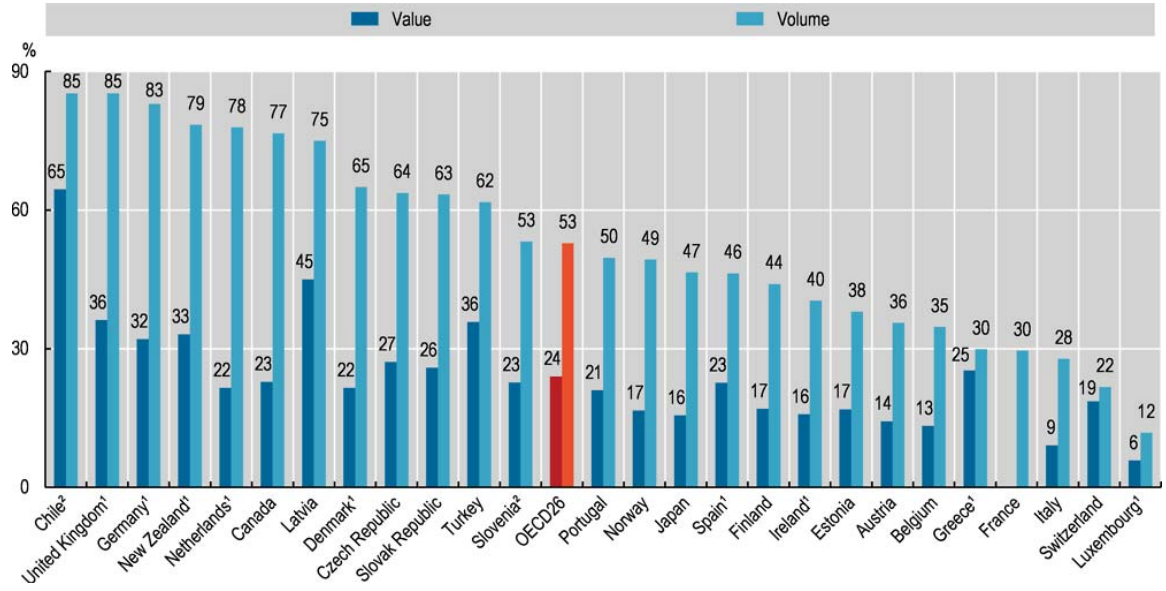
** if available*
Note: Ranges depict variation due to existence of second or third language in some countries that could potentially be used. Assumptions: The assumption was that all non-EU applicants would apply in one of EU languages – most often English, but for e.g. for Canada in English or French, and for Switzerland: French, German or Italian.
Source: Own estimation based on German NPO data.

Consequently, between 78% and 90% of applications have historically been filed in English, German and French. These findings are in line with the MPI (2022) study, which analysed the use of languages at the EPO and concluded that up to 65% of patent applications between 2016 and 2020 were submitted in English, up to 14% in German and up to 5% in French.[320]

[320] MPI (2022), page 13. It must be noted however that EPO has three official languages: English, French and German, and a European application can be filed in any language under Art 14(1) EPC. However, it must be translated into one of the official EPO languages, if it was filed in any other language.

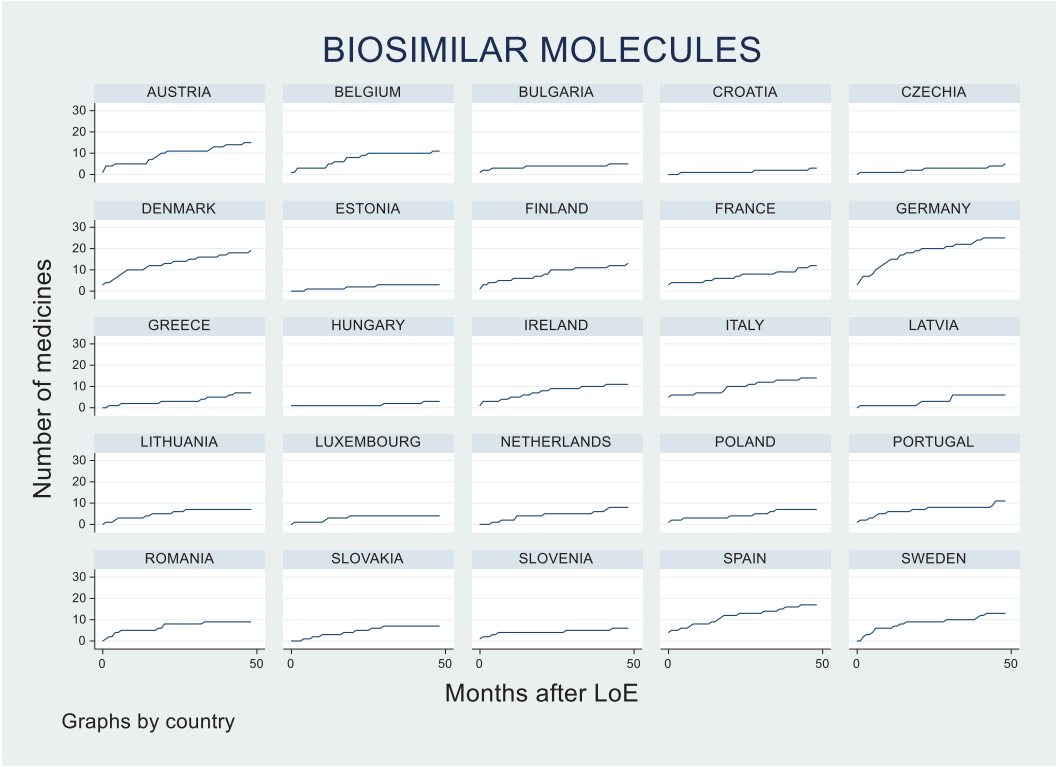
Background information concerning impacts on the follow-on products entry

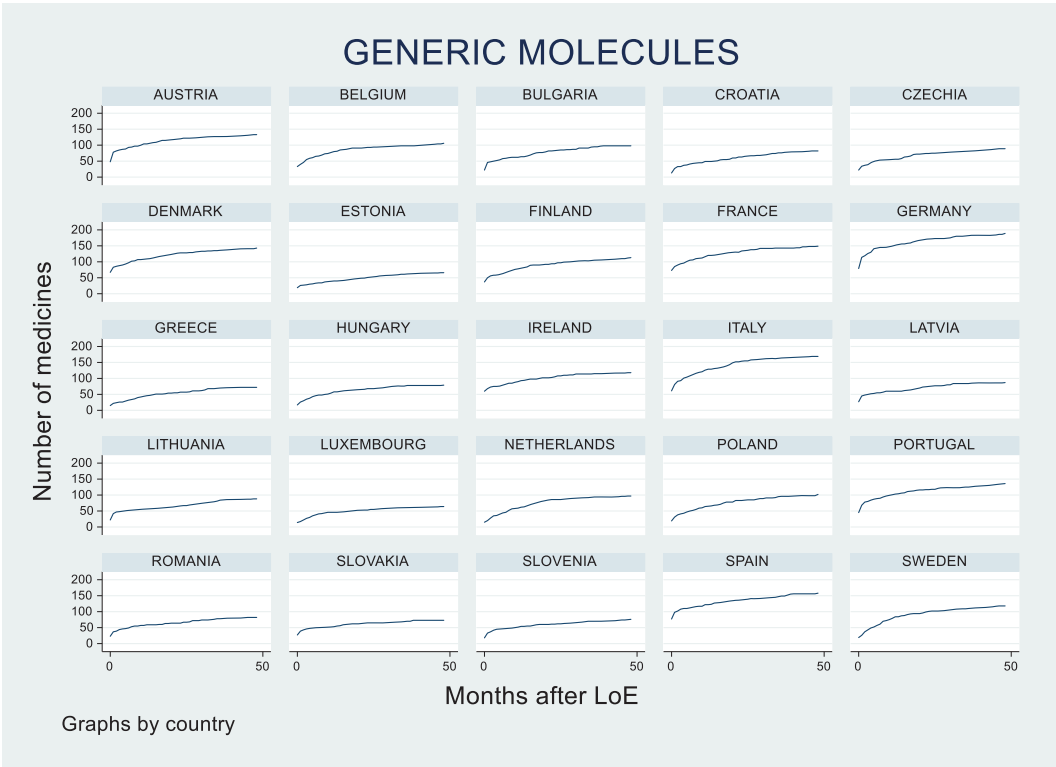
Figure 31: Share of generics in the total pharmaceutical market, 2019 (or nearest year)



Source: Source: OECD Health Statistics 2021 (https://stat.link/uyjgok)

Figure 32: Time-to entry of follow-on medicines over 1 to 48 months after the loss of exclusivity (LoE), by country - number of medicines that were previously covered by any type of protection





Source: In-house analysis based on IQVIA data covering molecules with the loss of exclusivity from 01/2010 onwards.

In the context of this initiative, the impact of a hypothetical shortening of the regulatory protection by two years was estimated (Table 54 below), showing that the share of SPC would increase by roughly 5% from 49.6%[321] currently to 54.9% of molecules.

Table 54: SPC as the last protection to expire – comparison between the current situation and a hypothetical shortening of the duration of regulatory protection by two years

	Molecules[322]		Molecule-country pairs	
	Number	%	Number	%
Current length of the RP (8+2)	342	49.6	3 253	31.6
Shorter length of the RP (6+2)	379	54.9	3 644	35.4

Source: In-house analysis based on IQVIA data covering molecules with the loss of exclusivity from 01/2010 onwards; only EMA-matched molecules were taken into account.

Yet, it seems more adequate to perform such analysis at the level of country-molecule pairs, as the same molecule may have different SPC status across different Member States. In such case the SPC share would increase from roughly 32% to 35.4% if the regulatory protection was shortened by two years. Nonetheless, the above analysis also shows that irrespective of the unit of measure chosen, in 2/3 of cases (or roughly ½ of molecules), the SPC is not the last protection measure to expire and thus does not have a decisive influence on generic entry.

Table 55: Estimated (theoretical) lost benefits from longer SPC protection caused by its unitary application in million EUR, compared to the overall spending on pharmaceuticals by country based on COFOG 2020 data

	General government expenditure on medical products, appliances and equipment in 2020 [million EUR]	**Estimated average difference in 2010-2021 [%]**	**Estimated lost benefits [million EUR]**
AUSTRIA	4 624.4	0.033	1.5
BELGIUM	3 696.1	0.005	0.2
BULGARIA	460.1	0.139	0.6
DENMARK	1 793.6	0.077	1.4
ESTONIA	208.9	0.101	0.2
FINLAND	1 683.0	0.094	1.6
FRANCE	34 955.0	0.027	9.4
GERMANY	60 200.0	0.027	16.5
ITALY	16 955.0	0.011	1.8
LATVIA	202.5	0.248	0.5
LITHUANIA	439.0	0.096	0.4
LUXEMBOURG	1 247.4	0.000	0.0
NETHERLANDS	7 247.0	0.015	1.1
PORTUGAL	1 293.5	0.049	0.6
SLOVENIA	479.0	0.046	0.2
SWEDEN	3 696.7	0.026	1.0

[321] Commission services in the impact assessment accompanying the proposal for a revision of Regulation (EC) No 726/2004 estimate that SPC is the last protection measure to expire in 48 % of molecules, based on a basket of 217 products selected based on IQVIA Ark Patent intelligence data where the loss of protection was between 2016–2024 in four countries: FR, DE, IT and ES.

[322] A molecule is identified as positive if it was covered by an SPC in at least one Member State.

	139 181.2		37.0

Source: In-house analysis based on IQVIA data covering molecules with the loss of exclusivity from 01/2010 onwards; Eurostat COFOG - general government spending on medical products, appliances and equipment, extracted on 04.08.22.

D. Cost analysis supporting section 6 (impacts) – the central authority and reference office's perspective

The assumption of new functions by any of the considered authorities (reference offices in case of PO2, or central authority in case of PO3-5) would involve additional costs.

The below analysis is based on estimates provided by the EUIPO reflecting their experience with managing EU Trademarks and Designs. The presented cost estimate is expected to be in the same range regardless of which of the considered bodies takes the new role.

Central examination authority: one-off costs (PO3-5)

In order to prepare for the new role the examination authority would have to incur the following set-up expenses:

Table 56: Set up costs of the central authority (FTE and EUR).

Cost item:	FTE*	Cost (EUR thousands)
Evaluate and appoint examiners from NPOs	1.0	124.8
Guidelines and work instructions	1.0	124.8
Set up collaborative working methods	1.9	249.5
Set-up quality controls	1.0	124.8
Templates	0.5	62.4
Training	1.0	124.8
Set up case management/distribution system	0.5	62.4
Set up Board of Appeals at the EU level (PO4-5, and PO4+5)	0.5	62.4
IT (analysis, design, quality control and development)	3.9	512.0
Total PO3	**10.6**	**1 385.3**
Total PO4, PO5, and PO4+5	**11.1**	**1 447.7**

** FTE – full time equivalent*
Assumptions: Number of SPCs per year: 100, salary of FTE: EUR 131 000 (average EUIPO salary for 2021-2022 based on its budget)[323]
Source: In-house analysis based on EUIPO estimates.

Set-up costs for all three options involve: the evaluation and appointment of examiners from NPOs that would conduct substantive examination of applications, preparation of guidelines and work instructions, as well as collaborative methods and quality controls in order to ensure a consistent approach to the SPC examination. It would further involved the creation of common templates for applicants and examiners, training of all involved in new working methods and the creation of a case management system. The bulk share of one-off costs would be devoted to creation of an IT system for processing SPC data. Additional cost for PO4-5 is connected with the setting up of a Board of Appeals.

[323] https://euipo.europa.eu/ohimportal/en/transparency-portal/economic/office-budget

The IT system for SPC is expected to contain the following features:

- Front office: i) (e-submission) with: a standard e-form for SPC filing, validation of the Market Authorisation (EMA), validation of the base patent (EPO), sourcing of other structured information, if necessary; ii) publication and search functions.
- Register: register of SPCs.
- Back Office: data management, fees management, documents management.
- Virtual Network: ensuring the exchange of data with NPOs for SPC examinations.

For the purpose of subsequent calculations, the setup cost is expected to be depreciated over 10 years period according to the number of applications received each year[324].

Central examination authority: recurrent costs (PO3-5)

The running costs of dealing with SPCs is expected to consist of the following items (excluding translations).

Table 57: Recurrent costs of the central authority (FTE and EUR).

Cost item:	FTE*				Cost (EUR thousands)			
	PO3	PO4	PO5	PO4+5	PO3	PO4	PO5	PO4+5
Administrative processing of the SPC applications	0.5	0.5	0.5	0.5	66	66	66	66
Examiners remuneration (examination + revision)	4.8	5.7	5.7	6.7	624	749	749	873
BoA appeal			3.8	3.8			499	499
EGC/ECJ			1.9	1.9			250	250
Recordals**			0.48	0.48			62	62
IT maintenance	0.5	0.5	0.45	0.45	59	59	59	59
Total	**5.7**	**6.7**	**12.9**	**13.8**	**748**	**873**	**1 684**	**1 809**

** FTE – full time equivalent, **an entry in the SPC register*
Assumptions: Number of SPCs per year: 100, salary of FTE: EUR 131 000 (average EUIPO salary for 2021-2022 based on its budget)[325]
Source: In-house analysis based on EUIPO estimates.

The recurring costs for PO3 would involve administrative processing of the SPC applications, remuneration of examiners from NPOs[326] and maintenance of IT systems. PO4 would have higher examiners' cost, as they would also handle reviews (a second examiner or a panel of examiners would be asked to look at a contested case). The cost items under PO5 cover an appeal process at the Board of Appeals and handle potential litigations in CJEU[327], as well as processing entries into the SPC register (recordials).

The combination of PO4 and PO5 takes the cost of the latter, but with more examiners, as foreseen under PO4.

[324] For instance if over 10 year period 1 000 SPC applications will arrive, cost of handling each application will include 1/1 000 of total set up cost.
[325] https://euipo.europa.eu/ohimportal/en/transparency-portal/economic/office-budget
[326] Under the assumption that an SPC examination would take up to 10 working days and there are 100 examinations per year in PO3. In PO4 and PO5, the estimate is based on 120 cases to take into account an additional workload, related to re-examination of the file that may be requested. Finally, 140 in PO4+5 reflects a potential need to involve examiners from UP and non-UP Member States to deal with appeals.
[327] We expect up to 5 referrals to CJEU a year (out of approximately 20 rejections for 100 applications). The number of referrals reported by MPI (2022) in Table 5.5, p. 79 for years 2012-2020 was doubled to reflect a potentially higher share of negative opinions covering all 17 UP-MS.

Translation costs (PO2-5)

Additionally, the publication of SPC applications and examination results in all 24 EU languages and the possibility to submit written observations in any language (proposed for transparency reasons in PO3-5) would create a fixed translation cost per SPC application. The translation of an examination dossier to languages of the Member States where an SPC is sought (PO2-5) would create variable translation costs. These were analysed earlier (Annex 5C) and are summarised in the table below:

Table 58: SPC translations costs per option

	Pages	Languages	Costs per SPC (EUR)	Annual cost (EUR million)
Publication of SPC application in all EU languages (PO3, 4, 4+5)	*2*	*23*	*4 002*	*0.4*
Written observations* (PO3, 4, 4,+5)	*30*	*1*	*2 610*	*0.26*
Publication SPC examination result in all EU languages (PO3, 4, 4,+5)	*2*	*23*	*4 002*	*0.4*
Total fixed translation cost per SPC application				*1.06*
Examination dossier translation for NPOs** (PO2, 3, 4 and 4+5)	*10*	*1 to 23*	*870 to 20 010*	*0.09 to 2*

Note: there are 24 official languages, so at maximum an applications needs to be translated into the remaining 23.
** Assumption that an SPC will receive three 10-page-long observations that need to be translated in to working language of the examination authority; ** variable dependent on the number of Member States designated by the applicant, in case of options where national NPO is granting an SPC.*
Assumptions: Number of SPCs per year: 100, cost of one page translation EUR 87 by professional translator
Source: In-house analysis

Application fee

As changes proposed under this initiative should be self-financing, the minimum fees charged should at least cover all additional costs. The above cost analysis also shows that almost all recurrent costs (except for the IT maintenance) are generated during the pre-grant phase, thus it would seem logical to recover them in the application fee (as opposed to annual maintenance fees, which are charged after the SPC is granted).

In case of PO2 the additional cost would consist of the translation of the examination dossier for the designated NPOs. Consequently, the reference office could charge a variable translation fee of between EUR 870 (1 Member State) and 20 000 (27 Member States) depending on the number of countries/languages chosen[328].

In case of PO3-5 and PO4+5, the application fee could be composed of a fixed component matching the recurrent cost, depreciation and the fixed translation cost amounting to EUR 19 500 (PO3), EUR 20 800 (PO4), EUR 28 900 (PO5) and EUR 30 100 (PO4+5). For PO3-4 a variable component of between EUR 870 and 20 000 (27 Member States) would cover the translation cost and depend on the number of countries/languages chosen. For PO4+5, in

[328] This cost might be reduced if NPOs agreed to receive examination dossier in e.g. one working language. However this might not always be legally possible, thus for the purpose of this analysis we assume translation for each designated NPO.

cases where an EU-wide coverage is sought, an additional translation fee could be necessary to cover non-UP Member States (currently 10) which would amount to EUR 8 700[329].

Table 59: Minimum SPC application fees to cover authority's new cost for SPC protection in the whole EU (EUR)

	PO2	PO3	PO4	PO5	PO4+5
Fixed fee	x*	19 500	20 800	*28 900*	*30 100*
Variable translation fee (27 MS)**	20 000	20 000	20 000		*8 700*[329]
Total	20 000	39 500	40 800	*28 900*	*38 800*

** No new fee, this would be a fee charged already by the NPO; ** variable dependent on the number of Member States designated by the applicant, in case of options where national NPO is granting an SPC.*
Assumptions: Number of SPCs per year: 100, fixed cost depreciated over 10 years.
Source: In-house analysis based on EUIPO estimates.

Maintenance Fee

While for PO3-4 the central authority could only charge an application fee, for PO5 and PO4+5 the costs could be recuperated via both the application and annual maintenance fees. This possibility could be used to make the centralised procedure more attractive to applicants, as the national application fees are currently lower than those proposed above and for an EU-wide protection - they amount to around EUR 8 800 (plus EUR 183 000 in maintenance fees for a five-year-long SPC protection in the whole EU). There are however, drawbacks of such an approach. With an application fee not covering all examination cost, there could be an incentive for the authority to be more lenient towards granting SPCs, as only for granted SPCs the full cost could be recovered. Alternatively, to recover the full cost in case applications are rejected (historically around 20% national SPC were rejected), the maintenance fee should be higher as the cost is spread over a lower number of successful applicants. Finally, with maintenance fees the central authority can run into deficit during the first years of the new system, as there would not be enough SPCs to collect the fees (see: Table 60 below).[330]

Table 60: Base for maintenance fees collection over a decade

Year	1	2	3	4	5	6	7	8	9	10
Applications	100	100	100	100	100	100	100	100	100	100
Granted SPC	80	80	80	80	80	80	80	80	80	80
No. of SPC for which maintenance fee can be collected	**80**	**160**	**240**	**320**	**400**	**400**	**400**	**400**	**400**	**400**

Assumptions: 100 SPC applications per year; 80% grant rate; five year long duration of an SPC.
Source: In-house analysis.

Table 61 below presents the total minimum maintenance fee for a given application fee and SPC duration to cover authority's cost during ten years' time in case of the combination of PO4 and PO5.

Table 61: Minimum maintenance fee by the level of application fee and SPC duration allowing the authority to break even during a ten-year-long period

Application fee:	0	5 000	10 000	15 000	20 000	25 000	30 000	35 000	38 800
SP 1	48 600	42 300	36 100	29 800	23 600	17 300	11 100	4 800	0

[329] However for those applicants that do not wish or cannot obtain a unitary SPC but seek a central examination resulting in a bundle of national SPC, the translation fee for EU wide protection would amount to EUR 20 000.

[330] This only applies if fees are set to break even. In case of higher fees the authority may cover all cost from year one, and produce significant surpluses over longer run

2	51 100	44 500	38 000	31 400	24 800	18 200	11 600	5 100	0
3	54 000	47 000	40 100	33 100	26 200	19 200	12 300	5 300	0
3.5	55 700	48 600	41 400	34 200	27 000	19 900	12 700	5 500	0
4	57 100	49 800	42 400	35 100	27 700	20 400	13 000	5 700	0
5	60 700	52 900	45 100	37 300	29 500	21 600	13 800	6 000	0

Note: Total maintenance fee due for the SPC duration; numbers rounded to 100s
Assumptions: 100 SPC applications per year; 80% grant rate;
Source: In-house analysis.

As shown above, a split into an application and maintenance fee increases the total fee level to cover the authority costs. From the perspective of successful applicant it would be more advantageous if there was no maintenance fee but just an application fee.

Number of applications impact on costs and fees

The number of SPC applications submitted under the centralised procedure would most probably not immediately reach 100 (i.e. the assumed number of applications per year used as a reference throughout this impact assessment). Firstly, stakeholders need to become familiar with the new system and start using it. Secondly, it would also take some time before the first SPC under the newly proposed procedures is granted, due to the time necessary to complete the entire process (e.g. the examination via a group of experts, third party observations, efficiency of instruments and institutions involved in the process e.g. issuing of European patents with unitary effect).

The table below estimates the minimum level of application fee (assuming this is the only fee collected) to cover the central authority costs, depending on the number of years before the annual number of applications received reaches 100.

Table 62: Minimum level of SPC application fees to cover authority's cost, depending on the length of period before 100 applications per year is reached (EUR).

Run-up period length	Number of applications during 10 years	Application fee (EUR)
10 years	550	40 000
5 years	800	39 200
2 years	950	38 900
1 year	1 000	38 800

Assumptions: fixed cost depreciated over 10 year,.20% refusal rate
Source: In-house analysis based on EUIPO estimates.

The longer it takes to reach 100 applications annually, the lower the overall number of applications during the 10 year period, and consequently the higher share of fixed costs (depreciation of one-off expenses) per application. As a result, longer run-up period (or the less applications received) would increase the minimum application fee necessary to cover authority's costs.

Maximum fee level

The above discussion aimed at identifying the minimum fee level to cover new costs of the central authority (notwithstanding the fact that an agreement can be reached at a later stage to fix the actual fee at a higher level).

The SPC fee could be modelled on the approach used for the European patent (EPC/UPC) where the EPO fees reflect fees charged by the four largest Member States in terms of the number of patent applications. For instance, among UP Member States, the highest average number of applications for period 2014-2021 was recorded in DE, IT, FR and NL. The sum of application fees of these four amounts to around EUR 1 770 and the sum of maintenance fees for a five-year long protection amounts to EUR 36 460. The sum of these two components would result in a total fee of EUR 38 230. This fee is very similar to the minimum fee calculated for PO4+5, much above the fee proposed for PO5 and slightly below PO3 and PO4 minimum fees.

In case we took all Member States into account, the top four countries in terms of SPC applications would be: DE, ES, IT and FR. The level of fees due in those four countries altogether is around EU 42 250 (i.e. EUR 1 750 for application and EUR 40 500 for maintenance). This fee is slightly above the minimum fees calculated for PO3, PO4 and PO4+5, and much higher than the fee estimated for PO5.

Maximum fee: the next section "Cost analysis for the SPC applicant" calculates the total cost for an applicant (including besides the central authority fees, also fees collected by NPOs, attorney remuneration or own translation costs). It could be argued that the maximum fee a central authority could charge to remain an attractive option for applicants should not make the total application cost higher than in the baseline. The table below calculates such maximum central authority fee for all options for two combinations in the number of Member States and SPC duration: i) 27 Member States and an SPC lasting five years and ii) 20 Member States and the current average duration of an SPC of 3.5 years.

Table 63: Maximum total fee of PO3 to PO5 and PO4+5 in respect of selected combinations of SPC duration and MS covered (EUR)

	PO3	**PO4**	**PO5**	**PO4+5**
27 MS, five-year-long SPC	54 000	64 800	151 300	175 900
20 MS, 3.5 year-long SPC	39 500	47 500	114 100	121 300

Note: Based on total applicants fee calculation from Annex 5E. Maximum fee calculated as follows: Baseline total cost to applicants (of obtaining SPC protection in selected MS and of selected duration) minus fees paid to NPOs (application and maintenance), attorney fees and own translation costs.
Source: In-house analysis using NPO fee data and EUIPO cost estimates.

As indicated above, a combination of PO4+5 offers the greatest flexibility in terms of the maximum fee setup, while PO3 offers the narrowest price range.

The table below presents the maximum fee for PO4+5 for all combinations of the number of Member States covered and years of SPC duration. It also marks in red all combinations where the authority's cost per SPC is higher than the maximum fee and in green where it is lower.

Table 64: Maximum total fee of PO4+5 in respect of SPC duration and MS covered

SPC duration						
Years =>	1	2	3	3.5	4	5
1	1 400	2 600	3 900	4 700	5 400	7 100
2	4 900	7 300	10 000	11 500	13 000	16 400
3	8 500	12 100	16 100	18 400	20 700	25 700
4	12 100	16 900	22 300	25 300	28 300	34 900
5	15 600	21 600	28 400	32 100	35 900	44 200
6	19 200	26 400	34 500	39 000	43 500	53 500
7	22 700	31 200	40 600	45 800	51 100	62 800
8	26 300	35 900	46 700	52 700	58 700	72 000
9	29 900	40 700	52 800	59 600	66 300	81 300
10	33 400	45 400	58 900	66 400	73 900	90 600
11	36 800	50 000	64 800	73 100	81 400	99 700
12	40 400	54 800	70 900	80 000	89 000	109 000
13	43 900	59 500	77 100	86 800	96 600	118 200
14	47 300	64 100	83 000	93 500	104 000	127 300
15	50 900	68 900	89 100	100 400	111 600	136 600
16	54 400	73 600	95 200	107 200	119 200	145 900
17	58 000	78 400	101 300	114 100	126 800	155 200
18	60 600	81 000	103 800	116 500	129 200	157 300
19	63 100	83 500	106 300	118 900	131 500	159 300
20	65 700	86 100	108 800	121 300	133 800	161 400
21	68 300	88 700	111 300	123 700	136 200	163 500
22	70 800	91 200	113 700	126 100	138 500	165 600
23	73 200	93 600	116 100	128 400	140 700	167 500
24	75 800	96 200	118 500	130 800	143 000	169 600
25	78 400	98 800	121 000	133 200	145 300	171 700
26	80 900	101 300	123 500	135 600	147 700	173 800
27	83 500	103 900	126 000	138 000	150 000	175 900

Member States covered

Note: Based on total applicants fee calculation from Annex 5E. Maximum fee calculated as follows: Baseline total cost to applicants minus fees paid to NPOs (application and maintenance), attorney fees and own translation costs. The most common combination of Member States coverage and SPC duration is marked with a red box. Red background denotes combinations where the maximum fee does not cover all cost of the authority.
Assumptions: For PO5 and PO4+5 from 1 to 17 Member States covered are assumed to be UP Member States and above non-UP Member States.
Source: In-house analysis using NPO fee data and EUIPO cost estimates.

E. Cost analysis supporting section 6 (impacts) – the SPC applicant's perspective

Full cost of obtaining EU-wide SPC protection for five years

The overall costs of application are of primary importance for the applicants. Besides fees paid to NPOs, these also include other costs such as: IP attorney fees, translation costs, time and internal firm's resources spent on dealing with different procedural requirements of each NPO.

The table below summarises the total cost for obtaining SPC protection covering all 27 Member States for a period of five years that would be borne by applicants across all options.

The overview is based on minimum fees that cover additional costs for authorities in each option (as presented in Annex 5D).

Table 65: Total cost for an applicant of obtaining a five-year-long SPC protection in the whole EU (EUR)

	PO0	PO1	PO2	PO3	PO4	PO5	PO4+5
NPO application fee	8 800	8 800	400	0	0	3 000	0
NPO translation fee	0	0	20 000	0	0	0	0
EA application fee	0	0	0	19 500	20 800	28 900	30 100
EA translation fee	0	0	0	20 000	20 000	0	8 700
Total application fee	*8 800*	*8 800*	*20 400*	*39 500*	*40 800*	*31 900*	*38 800*
NPO maintenance fees	183 000	183 000	183 000	183 000	183 000	71 900	71 900
EA maintenance fees	0	0	0	0	0	0	0
Total maintenance fee for 5 years	*183 000*	*183 000*	*183 000*	*183 000*	*183 000*	*71 900*	*71 900*
Application+ 5 years maintenance fee	*191 800*	*191 800*	*203 400*	*222 500*	*223 800*	*103 800*	*110 700*
Translation costs	4 000	4 000	200	0	0	1 600	0
Agent/attorneys' fees	54 000	54 000	2 000	12 800	2 000	22 000	2 000
Total	*249 800*	*249 800*	*205 600*	*235 300*	*225 800*	*127 400*	*112 700*
% baseline	100%	100%	82%	94%	90%	51%	45%

EA – examination/central authority
Note: fees as calculated in Annex 5D; numbers rounded to nearest 100s. 5 years maintenance fee not discounted.
Source: In-house analysis using NPO fee data and EUIPO cost estimates.

In the baseline (PO0), applicants need to translate SPC application documents into an official language of each NPO, file them with the 27 NPOs following national forms and rules (most likely with the help of a local attorney), pay 27 application fees and, when the SPCs are granted, also pay 27 annual national maintenance fees over several years. PO1 is identical in terms of costs and procedures when compared with the baseline.

In case of PO2, applicants would need to deal with just one reference office and pay one application fee. Although the application and maintenance fees are higher than in the baseline by 6% (due to an estimated additional translation fee charged by the reference office), the applicant would need to pay the attorney fees just once, instead of 27 and could save on own translation costs (i.e. translation of the application to just one reference office/language instead of 23 languages that are used by 27 NPOs). The maintenance fees would be collected by each NPO and stay the same as in the baseline. Overall savings of PO2 would amount to around 18% in comparison with the baseline. As discussed in section 6, if all/some NPOs refrained from requesting translations of the examination dossier the savings could be even higher (respectively 25% if all NPOs accepted dossier without translations and 22% if half would do so – data not presented in the table).

In PO3, applicants would address just one central authority that collects application fees. Nevertheless that fee would be around 4.5 times higher than the application fees collected by 27 NPOs in the baseline. Altogether, the application fees and maintenance fees (collected as currently by the NPOs) would be 16% higher than in the baseline. However, applicants would be saving on attorney's and own translation fees. The attorney fees are estimated at EUR 12 800 to take account of a potential need for national representations in case an applicant would like to challenge the negative opinion (it can only do so at national level in this option). The latter is based on an assumption of 20% negative opinions. Taking all the above elements into account, PO3 produces 6% savings on all costs in comparison with the baseline.

In case of PO4, the application fee is slightly higher than in PO3, however applicants can benefit from the central review system thus can save on national attorney fees, as well as on own translations since the application could be submitted in all EU languages). Overall savings of PO4 amount to 10% of the baseline.

The centralised procedure envisaged under PO5 would cover only 17 UP-Member States thus to obtain an EU-wide protection, applicants would need to file additional SPC applications in ten non-UP Member States to complement the one filed with the central authority. This entails own translations and attorney representation before 11 authorities. In line with the earlier assumptions, all cost of the central authority are covered by the application fee, therefore the only maintenance fees that a successful applicant would need to pay are the national fees to each of the ten non-UP NPOs. The above combination produces a very significant saving of around 50% in comparison to the baseline. In the future, with more Member States joining the UPCA, the savings of this option would be even higher, reaching up to 88% of the baseline in case of all EU countries joining (estimation not presented in the table above).

In case of combination of PO4+5, applicants would be in contact only with the central authority to obtain one unitary SPC for 17 UP Member States and ten national SPC for the remaining countries. The application fee would be higher than in PO5 mainly due to translation cost needed when the examination dossier is transmitted to the ten non-UP NPOs. As only one attorney might be required and there would be no own translation fees, this option produces the largest savings of up to 55% when compared to the baseline costs. If however, an applicant is not able to apply for a unitary SPC (e.g. because it does not have an European patent with unitary effect), this option would be similar to PO4, albeit with higher fees (needed to cover for additional infrastructure of PO5, such as a fully-fledged Board of Appeals), thus producing savings of just 6% in comparison to the baseline (data not shown). Therefore the ultimate savings of this option would depend on the take-up of the unitary SPC versus just the central procedure leading to national SPC. It is expected that at least in the initial year(s) the balance would be toward the latter, but with the rollout of unitary patents, the former (unitary SPC applications) should be more prominent. Consequently the savings of this options would be in the range of 6 to 55% of the baseline.

Option producing the most savings – sensitivity analysis

From the analysis above we can conclude that the option with the highest saving potential for obtaining SPC protection covering the whole EU, lasting for the maximum term of five years is PO4+5.

The table below looks at the most cost efficient option (taking into account all applicant costs for the whole duration of an SPC), in case less than 27 Member States are designated and/or when SPC protection is shorter than five years[331].

[331] Under the assumption that in case of PO5 and PO4+5 from 1 to 17 Member States covered are UP Member States and above non-UP Member States.

Table 66: The most cost efficient option depending on the number of Member States covered and SPC duration (% of baseline cost in brackets).

Member States covered \ SPC duration (Years =>)	1	2	3	3.5	4	5
1	PO0 (100%)	PO0 (100%)	PO0 (100%)	PO0 (100%)	PO0 (100%)	PO0 (100%)
2	PO2 (92%)	PO2 (94%)	PO2 (95%)	PO2 (96%)	PO2 (96%)	PO2 (97%)
3	PO2 (79%)	PO2 (85%)	PO2 (88%)	PO2 (89%)	PO2 (90%)	PO2 (92%)
4	PO2 (73%)	PO2 (80%)	PO2 (84%)	PO2 (86%)	PO2 (87%)	PO5 (84%)
5	PO2 (69%)	PO2 (77%)	PO2 (82%)	PO2 (84%)	PO5 (82%)	PO5 (67%)
6	PO2 (67%)	PO2 (75%)	PO2 (81%)	PO5 (75%)	PO5 (68%)	PO5 (56%)
7	PO2 (65%)	PO2 (74%)	PO5 (73%)	PO5 (65%)	PO5 (58%)	PO5 (48%)
8	PO2 (63%)	PO2 (73%)	PO5 (63%)	PO5 (56%)	PO5 (51%)	PO5 (42%)
9	PO2 (62%)	PO2 (72%)	PO5 (56%)	PO5 (50%)	PO5 (45%)	PO5 (37%)
10	PO2 (62%)	PO5 (65%)	PO5 (51%)	PO5 (45%)	PO5 (41%)	PO5 (33%)
11	PO2 (59%)	PO5 (59%)	PO5 (46%)	PO5 (41%)	PO5 (37%)	PO5 (30%)
12	PO2 (59%)	PO5 (54%)	PO5 (42%)	PO5 (38%)	PO5 (34%)	PO5 (28%)
13	PO2 (58%)	PO5 (50%)	PO5 (39%)	PO5 (35%)	PO5 (31%)	PO5 (26%)
14	PO2 (56%)	PO5 (47%)	PO5 (36%)	PO5 (32%)	PO5 (29%)	PO5 (24%)
15	PO2 (56%)	PO5 (44%)	PO5 (34%)	PO5 (30%)	PO5 (27%)	PO5 (22%)
16	PO5 (55%)	PO5 (41%)	PO5 (32%)	PO5 (28%)	PO5 (25%)	PO5 (21%)
17	PO5 (52%)	PO5 (38%)	PO5 (30%)	PO5 (27%)	PO5 (24%)	PO5 (20%)
18	PO4+5 (53%)	PO4+5 (41%)	PO4+5 (33%)	PO4+5 (30%)	PO4+5 (28%)	PO4+5 (24%)
19	PO4+5 (53%)	PO4+5 (43%)	PO4+5 (36%)	PO4+5 (33%)	PO4+5 (31%)	PO4+5 (27%)
20	PO4+5 (53%)	PO4+5 (44%)	PO4+5 (37%)	PO4+5 (35%)	PO4+5 (33%)	PO4+5 (30%)
21	PO4+5 (53%)	PO4+5 (45%)	PO4+5 (39%)	PO4+5 (37%)	PO4+5 (36%)	PO4+5 (33%)
22	PO4+5 (53%)	PO4+5 (46%)	PO4+5 (41%)	PO4+5 (39%)	PO4+5 (38%)	PO4+5 (36%)
23	PO4+5 (53%)	PO4+5 (46%)	PO4+5 (42%)	PO4+5 (41%)	PO4+5 (40%)	PO4+5 (38%)
24	PO4+5 (53%)	PO4+5 (47%)	PO4+5 (44%)	PO4+5 (42%)	PO4+5 (41%)	PO4+5 (40%)
25	PO4+5 (53%)	PO4+5 (48%)	PO4+5 (45%)	PO4+5 (44%)	PO4+5 (43%)	PO4+5 (42%)
26	PO4+5 (53%)	PO4+5 (49%)	PO4+5 (46%)	PO4+5 (45%)	PO4+5 (44%)	PO4+5 (44%)
27	PO4+5 (53%)	PO4+5 (49%)	PO4+5 (47%)	PO4+5 (46%)	PO4+5 (46%)	PO4+5 (45%)

Note: Based on fees as calculated in Annex 5D. The most common combination of Member States coverage and SPC duration is marked with a red box
Assumptions: For PO5 and PO4+5 from 1 to 17 Member States covered are assumed to be UP Member States and above non-UP Member States.
Source: In-house analysis using NPO fee data and EUIPO cost estimates.

Based on the duration/coverage combinations and assuming that each combination is equally likely, the baseline (PO0) is the least expensive option in 4% of cases – when SPC is sought in just one Member State, irrespective of SPC duration. PO2 is the least expensive choice in 22% of duration/coverage combinations (producing in those cases an average saving of 22% in comparison to baseline). PO2 is especially beneficial when the SPC duration is shorter (e.g. for 1 year-long SPCs, PO2 is the best choice for up to 15 Member States covered). PO5 (understood as unitary SPC in 17 UP Member States and national SPC via the national route in the remaining ones) is the least costly choice in 37% of cases (average savings of 56%), when only UP countries are covered. The combination of PO4+5 is the least expensive option as well in 37% of cases (average savings of 58%), when on top of unitary SPC for 17 UP countries, a central procedure is used to obtain national SPCs in the remaining ones.

From earlier research we know, however, that currently SPC protection is sought most often in 20 Member States and lasts for 3.5 years. In this case the combination PO 4+5 is the least expensive one, reducing cost of the baseline by 65%.

Savings of the preferred option– sensitivity analysis

The table below presents total costs for applicants of applying and maintaining SPC of different duration and Member States coverage as percentage of cost of the baseline, in case the combination of PO4+5 is selected.

Table 67: PO4+5 costs for applicant as percentage of baseline cost depending on the number of Member States covered and SPC duration.

Member States covered \ SPC duration (Years =>)	1	2	3	3.5	4	5
1	948%	700%	541%	480%	432%	353%
2	462%	343%	267%	237%	213%	175%
3	306%	228%	177%	157%	142%	116%
4	228%	170%	132%	118%	106%	87%
5	182%	136%	106%	94%	85%	69%
6	152%	113%	88%	78%	71%	58%
7	130%	97%	75%	67%	60%	50%
8	113%	85%	66%	59%	53%	43%
9	101%	75%	59%	52%	47%	39%
10	91%	68%	53%	47%	42%	35%
11	83%	62%	48%	43%	39%	32%
12	76%	57%	44%	39%	35%	29%
13	70%	52%	41%	36%	33%	27%
14	65%	49%	38%	34%	30%	25%
15	61%	45%	35%	31%	28%	23%
16	57%	42%	33%	29%	26%	22%
17	54%	40%	31%	28%	25%	20%
18	53%	41%	33%	30%	28%	24%
19	53%	43%	36%	33%	31%	27%
20	53%	44%	37%	35%	33%	30%
21	53%	45%	39%	37%	36%	33%
22	53%	46%	41%	39%	38%	36%
23	53%	46%	42%	41%	40%	38%
24	53%	47%	44%	42%	41%	40%
25	53%	48%	45%	44%	43%	42%
26	53%	49%	46%	45%	44%	44%
27	53%	49%	47%	46%	46%	45%

Note: Based on fees as calculated in Annex 5D. The most common combination of Member States coverage and SPC duration is marked with a red box
Assumptions: For PO5 and PO4+5 from 1 to 17 Member States covered are assumed to be UP Member States and above non-UP Member States.
Source: In-house analysis using NPO fee data and EUIPO cost estimates.

The combination of PO4+5 produces savings in comparison to the baseline in 81% of considered Member States/SPC duration combinations. On average the costs are lower than the baseline by 53%. The option always produces savings when ten or more Member States

are covered. In case of the most common SPC duration of 3.5 years, the option is beneficial for covering five or more Member States.

In the remaining 19% of cases, PO4+5 is more expensive than the baseline by on average 260%. It is always more expensive when up to three Member States are covered by an SPC.

F. Evidence supporting section 6 (impacts) – quantification of impacts on NPOs

As regards one-off costs the NPOs under PO1 and PO2 would need to develop a common SPC database. The cost of an EU-wide database is estimated at EUR 0.5 million; if shared equally between all NPOs it would amount to around EUR 19 000 per NPO. For the annual cost calculations below we will assume that these costs are depreciated over ten years adding EUR 1 900 to the annual cost of each NPO. Additionally, the annual database maintenance cost is estimated at EUR 59 000 EU wide, or EUR 2 200 per NPO.

In case of all options but PO1, NPOs could see their annual SPC application fee income reduced as such fee would be paid to either the reference office(s) (PO2) or to the newly established central authority (PO3 to PO5 and PO4+5). The extent of the income loss would depend on the uptake of the centralised procedure. The below figures present the most extreme situation where all 100 SPC applications are submitted via the central procedure. Figures are based on the SPC application and maintenance cost per Member State concerned presented in Table 69. It is also assumed that SPC protection is sought in all EU Member States for the maximum protection period of five years.

Table 68: SPC fee schedule per NPO in 2022 (EUR).

	SPC application	1st renewal	2nd renewal	3rd renewal	4th renewal	5th renewal
AT*	363	2 611	3 029	3 448	3 864	4 282
BE*	200	650	700	750	800	850
BG*	256	1 023	1 278	1 534	1 790	2 045
CY	100	700	740	780	820	860
CZ	195	1 014	1 092	1 170	1 248	1 326
DE*	300	2 650	2 940	3 290	3 650	4 120
DK*	403	686	686	686	686	686
EE*	105	630	630	630	630	630
EL	250	1 200	1 300	1 400	1 500	1 800
ES	528	820	1 722	2 715	3 806	5 007
FI*	500	900	900	900	900	900
FR*	520	950	950	950	950	950
HR	398	1 594	1 992	2 391	2 789	3 188
HU	657	819	982	1 147	1 310	1 473
IE	95	468	468	468	468	468
IT*	404	1 011	1 011	1 011	1 011	1 011
LT*	115	347	347	347	347	347
LU*	20	410	420	430	440	450
LV*	120	550	550	550	550	550
MT*	116	245	256	268	280	291
NL*	544	1 600	1 800	2 000	2 200	2 400
PL	120	1 314	1 314	1 314	1 314	1 314
PT*	430	753	807	861	915	969
RO	500	1 000	1 100	1 200	1 300	1 400
SE*	986	1 971	1 971	1 971	1 971	1 971
SI*	420	1 702	2 102	2 504	3 004	3 404
SK	166	996	1 328	1 660	1 992	2 324
Total	*8,811*	*28,613*	*32,416*	*36,374*	*40,534*	*45,015*
Average	*326*	*1 060*	*1 201*	*1 347*	*1 501*	*1 667*

*Note: for non-euro countries, amounts converted to EUR using ECB exchange rates of mid 2022; * UP-MS;*
Source: In-house analysis based on NPO websites.

The maximum application fee revenue loss for PO5 is estimated at EUR 0.58 million EU-wide, or on average of EUR 34 100 for the 17 UP-MS NPOs. In case of PO2, applicants will always apply to one "reference office" NPO – thus all remaining NPOs would lose on average EUR 32 300 with an EU wide loss of EUR 0.84 million. As explained in the option description/analysis the reference office is expected to collect an additional translation fee that should cover the translation cost, thus is expected to have no impact on the financial position of that office. In case of PO3, PO4 and PO4+5 all application income of around EUR 32 600 per NPO is lost amounting to EUR 0.88 million EU wide.

In case of PO3 to PO5 and PO4+5 the central authority is going to rely on experts from the willing NPOs to conduct SPC examinations in exchange for remuneration. These transfers[332] from the central authority to the participating NPOs are estimated at EUR 0.62 million for PO3, EUR 0.75 million (PO4 and PO 5) and EUR 0.87 million (PO4+5).

In case of PO5 and PO4+5 the NPOs in the 17 UP-MS may also lose SPC maintenance fee income. The maximum annual loss from the fifth year from activation of the new system[333] is estimated at EUR 0.5 million per NPO, amounting to EUR 8.9 million EU wide. The real maintenance fee loss will be determined by the demand for the unitary SPC (which among others will be driven by the demand of pharmaceutical and PPP companies for European patents with unitary effect).

Combining all of the above, NPOs income would be least affected by PO1 (cost of EUR 4 100 per annum per NPO and EUR 0.1 million EU-wide). PO3 and PO4 would reduce the NPOs bottom line by around EUR 9 500 and EUR 4 900 per NPO respectively (assuming equal transfers from the central authority to the NPOs) or EUR 0.26 million and EUR 0.13 million EU-wide respectively. PO2 would reduce NPOs revenues by on average EUR 36 400 per NPO and EUR 0.95 million for the whole EU. The highest impact of around EUR 0.5 million per NPO or around EUR 8.7 million to 8.9 million EU-wide could come from PO5 and PO4+5 respectively, mainly driven by the loss of the SPC maintenance fee by the 17 UP-MS. Nevertheless, these losses do not seem significant when compared to other sources of NPOs revenue. For instance, they account for just 0.02% (PO1 and PO4), 0.05% (PO3), 0.2% (PO2) or 1.6% (PO5 and PO4+5) of NPOs income on patent renewal fees. The table below provides a summary of all discussed monetary impacts.

Table 69: Maximum impact on NPOs – income losses and new costs in case of an EU-wide five year long SPC protection (EUR).

	PO1	**PO2**	**PO3**	**PO4**	**PO5** (only 17 UP-MS affected)	**PO4+5**
One off costs						
Database development (all NPOs)	512 000	512 000	0	0	0	0
Database development (per NPO)	19 000	19 000	0	0	0	0
Recurrent (EU wide) costs and fee losses						
application fee loss (annual)	0	840 000	880 000	880 000	580 000	880 000
maintenance fee loss (17 UP-MS only, annual)	0	0	0	0	8 888 000	8 888 000

[332] For calculations see: Annex 5D above.
[333] As explained earlier (see Table 60) only from the fifth year the full impact of the proposed changes on maintenance fees collection could be observed.

	PO1	PO2	PO3	PO4	PO5 (only 17 UP-MS affected)	PO4+5
Database maintenance (annual)	59 000	59 000				
Database one-off cost depreciation over 10 years (annual)	51 200	51 200				
New translation costs for the PO2 reference office(s) only		2 000 000				
Benefits (EU wide)						
Additional Translation fee (PO2 only)		2 000 000				
Examiners remuneration from the central authority			623 800	748 600	748 600	873 300
Net result	- 110 200	- 950 200	- 256 200	- 131 400	-8 719 400	-8 894 700
Net result as % of PO0 total EU27 SPC revenue (100 SPC, 5 years protection)	0.7%	6.1%	1.7%	0.8%	56.2%	57.3%
Net result as % of NPOs patent annual renewal fees collected in 2021 of EUR 536 million (PO5: EUR 337 million)	0.02%	0.18%	0.05%	0.02%	2.6%	1.66%
Recurrent (per NPO) costs and fee losses						
application fee loss (annual)	0	32 300	32 600	32 600	34 100	32 600
maintenance fee loss (17 UP-MS only, annual)	0	0	0	0	522 800	522 800
Database maintenance	2 200	2 200	0	0	0	0
Database depreciation over 10 years (annual)	1 900	1 900				
New translation costs for the PO2 reference office(s) only		2 000 000				
Benefits (per NPO)						
Additional Translation fee (PO2 only)		2 000 000				
Examiners remuneration from the central authority (assuming equal distribution among NPOs)			23 100	27 700	44 000	32 300
Net results	- 4 100	- 36 400	- 9 500	- 4 900	- 512 900	- 523 100

Note: Table presents maximum potential impacts; maintenance fee loss from fifth year of new system operation; numbers rounded. Assumptions: 100 SPC applications per year, 80 SPC granted and maintained for five years.
Source: In-house analysis using NPO fee data and EUIPO cost estimates. Renewal fees for granted patents from "EPO Financial Statements 2021", p. 61.

G. Evidence supporting section 6 (impacts) – the EU-wide costs and savings per stakeholder

The tables below summarise the quantifiable impacts of the considered policy options on different stakeholders. The effects are calculated under the assumption of a five-year-long SPC duration and EU-wide coverage. Costs include both additional expenditures and loss of income. Savings include both cost savings and additional income.

It should be noted that not all impacts are quantifiable. Quantification was possible for objective 3 "Reduce cost of applying and maintaining SPC protection" – and concerns originators, patent offices and IP agents. The quantification of objective 2 "Facilitate SPC monitoring" concerning follow-on (generic/biosimilar) manufacturers and healthcare sector to the extent possible is presented below. The quantification of objective 1 "Increase predictability and legal certainty of SPC protection in the EU" concerning originators, follow-on manufacturers and health sector was not possible. To understand the full impact of options on objectives 1 and 2, please refer to the qualitative description provided throughout chapter 6 and the comparison of options against all criteria presented in chapter 7 of the main text of this impact assessment.

Table 70: EU-wide quantifiable annual additional cost (including additional expenditures and loss of income) and additional benefits (including cost savings and additional income) in comparison to the baseline by policy option in case of an EU wide, five year long SPC protection from the fifth year of the new system (EUR).

	Originators/ SPC applicants	Follow-on (generic/ biosimilar) manufacturers	Healthcare sector, patients and users of PPPs	Patent offices (NPOs)	IP agents/ attorneys	Total
PO1						
Δ costs	0			110 200	0	110 200
Δ benefits	0	12 000 000	1 080 000	0	0	13 080 000
net	0	12 000 000	1 080 000	- 110 200	0	12 969 800
PO2						
Δ costs	1 160 000	0	0	2 950 200	5 200 000	9 310 200
Δ benefits	5 580 000	12 000 000	1 080 000	2 000 000		20 660 000
net	4 420 000	12 000 000	1 080 000	- 950 200	-5 200 000	11 349 800
PO3						
Δ costs	3 070 000	0	0	880 000	4 120 000	8 070 000
Δ benefits	4 520 000	12 000 000	1 080 000	623 800		18 223 800
net	1 450 000	12 000 000	1 080 000	- 256 200	-4 120 000	10 153 800
PO4						
Δ costs	3 200 000	0	0	880 000	5 200 000	9 280 000
Δ benefits	5 600 000	12 000 000	1 080 000	748 600		19 428 600
net	2 400 000	12 000 000	1 080 000	- 131 400	-5 200 000	10 148 600
PO5						
Δ costs	2 310 000	0	37 000 000	9 468 000	3 200 000	51 978 000
Δ benefits	12 328 000	7 556 000	37 680 000	748 600		58 312 600
net	10 018 000	7 556 000	680 000	-8 719 400	-3 200 000	6 334 600
PO4+5						
Δ costs	3 000 000	0	37 000 000	9 768 000	5 200 000	54 968 000
Δ benefits	14 488 000	12 000 000	38 080 000	873 300		65 441 300
net	11 488 000	12 000 000	1 080 000	-8 894 700	-5 200 000	10 473 300

Note: Table presents maximum potential impacts. Based on minimum fees as calculated in Annex 5D; NPO costs from Annex 5F (NPO fee data and EUIPO cost estimates) and healthcare impacts from section 6.6.2; numbers rounded.
Assumptions: 100 SPC applications per year, 80 SPC granted; EUR 40 000 – cost of accessing private SPC database; EUR 2 000 - SPC attorney fee.
Source: In-house analysis.

Table 71: Individual quantifiable annual additional cost (including additional expenditures and loss of income) and additional benefits (including cost savings and additional income) per entity affected in comparison to the baseline by policy option in case of an EU wide, five year long SPC protection (EUR).

	Originators/SPC applicants	Follow-on (generic/ biosimilar) manufacturers	Healthcare sector, patients and users of PPPs	Patent offices (NPOs)	IP agents/ attorneys
Number of affected	Application: 100 firms Maintenance: 400 firms	300 firms	At least 27 (one healthcare authority per MS)	Up to 27 NPOs (except PO5 – 17 UP-MS NPOs)	Up to 2 600 cases (except PO3: 2 060; PO5: 1 600)
PO1					
Δ costs	0	0	0	Database 27 NPOs: 4 100	0
Δ benefits	0	Monitoring: 40 000	Monitoring: 40 000		
net	0	40 000	40 000	27 NPOs: - 4 100	0
PO2					
Δ costs	11 600	0	0	Application fee loss 26 NPOs: 32 300 database cost 27 NPOs: 4 100	2 000
Δ benefits	Application: 55 800 Maintenance: 0	Monitoring: 40 000	Monitoring: 40 000	Reduced SPC workload	
net	Application: 44 200 Maintenance: 0	40 000	40 000	- 36 400	- 2 000
PO3					
Δ costs	30 700	0	0	Application fee loss 27 NPOs: 32 600	2 000
Δ benefits	Application: 45 200	Monitoring:	Monitoring:	Examiners remuneration:	

	Originators/SPC applicants	Follow-on (generic/ biosimilar) manufacturers	Healthcare sector, patients and users of PPPs	Patent offices (NPOs)	IP agents/ attorneys
	Maintenance: 0	40 000	40 000	23 100	
net	Application: 14 500 Maintenance: 0	40 000	40 000	27 NPOs: - 9 500	- 2 000
PO4					
Δ costs	32 000	0	0	Application fee loss 27 NPOs: 32 600	2 000
Δ benefits	Application: 56 000 Maintenance: 0	Monitoring: 40 000	Monitoring: 40 000	Examiners remuneration: 27 700	
net	Application: 24 000 Maintenance: 0	40 000	40 000	- 4 900	- 2 000
PO5					
Δ costs	23 100	0	Higher medicines cost 17 UP-MS: 2 176 500	Application fee loss 17 NPOs: 34 100 Maintenance fee loss 17 NPOs: 522 800	2 000
Δ benefits	Application: 34 400 Maintenance: 22 200	Monitoring: 25 200	Monitoring: 25 200 More innovative medicines: 2 176 500	Examiners remuneration 17 NPOs: 44 000	
net	Application: 11 300 Maintenance: 22 200	25 200	25 200	- 512 900	- 2 000
PO4+5					
Δ costs	30 000	0	Higher medicines cost 17 UP-MS: 2 176 500	Application fee loss 27 NPOs: 32 600 Maintenance fee loss 17 NPOs: 522 800	2 000
Δ benefits	Application: 56 000 Maintenance: 22 200	Monitoring: 40 000	Monitoring: 40 000 More innovative medicines: 2 176 500	Examiners remuneration: 32 300	
net	Application: 26 000 Maintenance: 22 200	40 000	40 000	- 523 100	- 2 000

Note: Table presents maximum potential impacts. Based on minimum fees as calculated in Annex 5D; NPO costs from Annex 5F (NPO fee data and EUIPO cost estimates) and healthcare impacts from section 6.6.2; numbers rounded.
Assumptions: 100 SPC applications per year, 80 SPC granted; EUR 40 000 – cost of accessing private SPC database; EUR 2 000 - SPC attorney fee.
Source: In-house analysis.

The impact on SPC applicants was described in Annex 5E. It would concern around 100 new applicants annually and up to 400 SPC holders paying maintenance fees. PO5 and PO4+5 provide the highest benefits to the originators amounting to EUR 10 million and EUR 11.5 million respectively EU-wide. This includes savings on both application cost (EUR 11 300 and EUR 26 000 per application respectively) and maintenance fees (EUR 22 200 per SPC holder annually for five years). Global benefits of PO2 are the third-highest and amount to EUR 4.4 million. They come from a reduction of application cost of EUR 44 200 per applicant. Benefits of PO3 and PO4 amount to EUR 1.5 million and EUR 2.4 million respectively and are explained by lower per-company application cost of EUR 14 500 and EUR 24 000 respectively. Cost savings of PO1 are not expected, the benefits of that option are not quantifiable. It is important to note that the full benefits presented in the table would only materialise from the fifth year after the new system becomes operational.

As regards the follow-on manufacturers, around 300[334] would benefit annually from savings on the access to SPC data, estimated at around EUR 25 000 (PO5) to EUR 40 000 (PO2-4 and PO4+5) per

[334] „Within three years following the LoE [loss of exclusivity] the ratio of generic companies to originators is about 6:1" (source: Pharmaceutical sector Inquiry (2009), p. 74). With up to 50 molecules where competition emerges the estimated number of follow-on producers affected is 300.

firm[335]. The same savings are expected for the health sector where it is assumed that at least 27 central purchasing bodies could benefit from the new system (a conservative estimate of one user per Member State, whereas the real number may be higher). Additionally, as discussed in 6.6.2, the healthcare systems in 17 UP-MS may bear higher cost of pharmaceutical purchases of up to EUR 37 million per year EU-wide. As this can translate into additional R&D on medicines by innovators, the benefits on the health sector (due to more innovative medicines) are expected to increase by the corresponding amount.

The NPOs cost was analysed in detail in section 5F. It would include the development and maintenance of a common database (PO1, PO2). Based on EUIPO experience, the cost of an EU wide database development is estimated at EUR 0.5 million, with EUR 59 000 of annual maintenance costs. If shared equally by each NPO it would amount to an annual expense of around EUR 4 100 per country (depreciation of database setup costs over 10 years and annual maintenance cost). NPOs could also experience various degree of loss of revenue due to a lower number of national SPC application fees collected (except for PO1), amounting to up to around EUR 32 300 (PO2 concerning all NPOs but the reference office(s)), EUR 32 600 (PO3-4 and PO4+5 concerning all NPOs) and EUR 34 100 (PO5 and concerning only 17 UP-MS). Additionally, in case of PO5 and PO4+5 the 17 UP-MS may lose their maintenance fee income to the amount of EUR 0.5 million annually from the fifth year of the new system operation. NPOs contributing to the pool of experts conducting SPC examinations for the central authority will receive additional income (EU wide figures due to uncertainty which NPOs will participate) of EUR 0.6 million (PO3), EUR 0.75 million (PO4 and 5) and EUR 0.87 million (PO4+5).

IP attorneys are expected to lose clients due to the introduction of some form of central procedure in PO2 to PO4+5 which reduces the need for national representation before each NPO. An average IP attorney fee was estimated at EUR 2 000[336] per Member State per SPC application. In case of applicants seeking SPC protection in the whole EU for PO2, 4 and 4+5 the need for legal advice should diminish from 27 to 1 (with demand for legal assistance eliminated for up to 2 600 cases[337]), hence around EUR 5.2 million EU-wide loss in revenue in comparison to the baseline. In case of PO3, where there is no possibility to centrally appeal the evaluation outcome, it is assumed that legal representation for national appeals would be necessary in 20% of cases on average, hence it would trigger a lower loss of revenue of around EUR 4.1 million EU-wide (up to 2 060 cases affected[338]). In case of PO5, where applicants would need to apply for national SPCs in 10 non-UP Member States, the loss would be even lower and estimated at EUR 3.2 million EU-wide (need for IP assistance eliminated for around 1 600 cases[339]).

[335] Approximate cost of a yearly subscription to commercial database with SPC information (own market research).
[336] The estimated attorney fees take into account feedback received from the industry representatives and fall within the costs range reported by Fédération Internationale des Conseils en Propriété Intellectuelle FICPI (https://ficpi.org/system/files/FICPI_The_IP_Practitioner.pdf), taking into account the lower complexity of an SPC dossier, when compared with a patent file.
[337] No need for legal assistance in 26 countries time 100 applications per year
[338] Legal assistance potentially needed for applications to the central authority (100 cases) and for potential appeals in 20 cases in up to 27 Member states (up to 540 cases). Compared to the baseline (legal assistance needed for 100 applications in each of 27 NPO = 2 700 cases) the reduction in demand by up to 2 060 cases.
[339] Legal assistance needed for SPC applications to the central authority (100 cases) and to ten non-UP-MS (10 x 100 = 1 000 cases). Reduction of demand in comparison to baseline by 1 600 cases.

In case of PO1, the cost/benefits effects are uncertain and depend on the implementation of the voluntary guidelines by NPOs. For the remaining options the presented numbers depict the maximum effects under assumption that all 100 SPC applications annually will go through the new system and SPC protection will cover the whole EU for a duration of five years. The real impacts, however, would depend on the extent of use of the central procedure, the number of Member States covered by an SPC and its duration, and in case of PO5 and PO4+5 the demand for a unitary SPC.

ANNEX 6: SME TEST

Small and medium-sized enterprises (SMEs)[340] are often referred to as the backbone of the European economy, providing a potential source for jobs and economic growth. Also in the pharmaceutical sector, SMEs play a key role. They are the motor of innovation and play a major role in the development of new medicines for patients. Around 27% of new EMA-authorised medicines in the above period originated from SME[341]. Small and medium enterprises were responsible for 81% of the preclinical projects in the antibacterial pipeline.[342] According to EMA, 53% of successful applications for marketing authorisation submitted by SME between 2005 and 2015 contained a new active substance and 42% of the medicines they developed were orphan medicines[343]

The potential impacts of the proposed initiative on SMEs have therefore been considered; they are reported throughout the impact assessment and below in an aggregated format.

This impact assessment and the preferred policy option have taken into account the pharmaceutical SMEs, and an SME-test has been conducted in line with the 4-steps foreseen in following:

Step-1: Identification of affected businesses

The SPC is a general incentive to incentivise investment in innovation related to novel medicinal and plant protection products. It does not specifically target SME. However, different types of SMEs are affected by the SPC protection, either because they are potential or actual users of the SPC system, or their businesses depend on the status of SPC protection of competing products. For the purpose of assessing the effects of this proposal, the following types of SMEs active in the medicinal products and the plant protection products (PPPs) sectors can be distinguished:

(1) *SMEs engaging in R&D with a view to developing innovative pharmaceuticals and PPPs* (i.e. potential future SPC holders).

These SMEs are potential users of the SPC. Most of SPC applicants are large corporations. SMEs accounted for at least 8% to 19% of the SPC holders of SPCs submitted to the German NPO in 2010-2021, whereas the SMEs share among the holders of EU-centralised marketing authorisation was around 13% in 2010-2012.

In the field of pharmaceutical innovation, start-ups and SMEs are playing an important role, especially in the initial steps of innovation. The Commission's pharmaceutical sector inquiry[344] reported that approximately 25% of molecules in clinical development were

[340] SMEs are defined by the European Commission as having less than 250 persons employed. They should also have an annual turnover of up to EUR 50 million, or a balance sheet total of no more than EUR 43 million - Commission Recommendation (2003/361/EC) of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises and its subsequent amendments.

[341] https://www.ema.europa.eu/en/news/supporting-innovative-smes-major-drivers-new-pharmaceutical-developments

[342] Theuretzbacher U, Outterson K, Engel A, Karlén A. The global preclinical antibacterial pipeline. Nat Rev Microbiol (2020) p. 278

[343] EMA, Report on the 10th anniversary of the SME initiative, EMA/155560/2016, https://www.ema.europa.eu/en/documents/report/report-10th-anniversary-sme-initiative_en.pdf p.8

[344] European Commission, Directorate General Competition Pharmaceutical Sector Inquiry, 2009, (https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf)

acquired from other companies, including SMEs. This shows that pharmaceutical companies are increasingly externalising their R&D. According to EBE, when the EMA analysed the origin of new medicines, 27% of all new medicines, and 61% of new medicines for orphan indications originated from SME. Newer figures confirm that significant medical innovation comes from SMEs. The cumulative figures from the EMA's PRIME scheme[345] indicate that 40% (39 out of 98) of PRIME applications granted by 2022 came from SMEs. [346]

The SMEs register, at 15 May 2022, of the EMA has 185 SMEs registered with a focus on new formulations/delivery methods, and 124 SMEs developing complex biologically derived proteins and peptides. We can observe a high number (236) of SMEs specialised in orphan treatments (these category of SMEs especially relies on orphan incentives, under Regulation (EC) No 141/2000 on orphan medicinal products, for their investments in innovation). We can also observe a high number, 123, of SMEs specialised in paediatric treatments. 83 of these SMEs are also involved in orphan treatments, with 37 of them having less than 10 employees.

IP protection is very important for these SMEs. The EPO, for instance, has produced a series of case studies on European SMEs[347], including SMEs dealing with biotechnology, which are leveraging the power of patents and other IP rights to achieve business success. The resulting case studies illustrate how new and established SMEs have developed the IP management capabilities they need, and how they are using IP to their advantage.

Often large corporations hold pharmaceuticals in their portfolios that were initially developed by start-ups. The latte are frequently purchased by large corporations to pursue the latest stages of clinical trials (which can be capital and human resources intensive) and regulatory approval of their medicines under development.

(2) SMEs engaged in research supporting the development of biosimilars, and SMEs engaged in manufacturing activities related to generics and biosimilars.

This category includes companies manufacturing on their own behalf as well as companies working as a subcontractor (e.g. such as contract development and manufacturing organisations, 'CDMOs').

According to Eurostat, in 2015 in the EU28 there were 3 724 SMEs active in pharmaceutical manufacturing, representing 88% of the firms and 22% of the workforce, in the pharmaceutical sector. This includes only those SMEs whose primary activity is pharmaceutical manufacturing[348], and does not necessarily capture SMEs specialized in other activities such as pharmaceutical R&D, commercialisation of generics or innovative products.

The SMEs covered by point (1) are the direct beneficiaries of the proposal as they are potential users of the SPC system. SMEs under point (2) are expected to benefit from the

[345] Priority medicines, a scheme to enhance support for the development of medicines that target an unmet medical need. https://www.ema.europa.eu/en/human-regulatory/research-development/prime-priority-medicines

[346] The register of the EMA's SME office contains more than 1 500 companies with SMEs status registered as active in the pharmaceutical sector in the EEA. This is a sharp increase over recent years (10 times more SMEs than in 2006). There were 185 SMEs registered with a focus on new formulations/delivery methods, and 256 SMEs specialised in orphan treatments.

[347] https://www.epo.org/learning/materials/sme/innovation-case-studies/sme-case-studies.html

[348] It includes both SMEs manufacturing original as well as generic/biosimilar products.

greater legal certainty and transparency to be induced by this proposal, which would facilitate conduction of their business activities.

Step-2: Consultations of SME Stakeholders

This impact assessment has been elaborated paying due consideration to the input provided by stakeholders. The SME angle has been taken into account throughout the consultation process, bilateral meetings, and the participation of the Commission services in seminars/round tables.

(1) Commission's public consultation on SPCs

This public consultation included a set of six specific sub-questionnaires for the six groups of stakeholders, including (II) originators industry/associations and (III) generics and biosimilars industry/associations, both of which included SMEs.

The questionnaires addressed to these industrial-related stakeholders (groups (II) and (III) above) included identification-related questions allowing for the identification of submissions corresponding to start-ups and SMEs. The statistics corresponding to respondents identified as SME or start-up profiles are the following:

- Among the 63 respondents defining themselves as mostly manufacturers of generics/biosimilars (group III), 12 respondents identified themselves as an SME and one as a start-up. All of the 13 respondents deal with human medicinal products, with one respondent also dealing with veterinary medicinal products and one with medical devices.
- Among the 71 respondents defining themselves as mostly originators (group II), only 2 respondents identified themselves as an SME involved in medicines biotechnology and one as a start-up in the field of biopesticides.

In addition, as reflected in this impact assessment, several European pharmaceutical associations such as Medicines for Europe (representing generics and biosimilars) and ECPA, EFPIA and IFAH-Europe (representing originators in the pharmaceutical and agrochemical sectors) conveyed the views of their start-ups and SME members in their submissions and accompanying letters sent to the Commission during the public consultation. A few national pharmaceutical associations with start-ups and SMEs-members also provided their views. In this regard, another industry association – EBE, which represents the interests of biopharmaceutical companies in Europe (60% of its members are SMEs), reported to the Commission as part of the SPC public consultation.

(2) Max Planck Institute's SPC stakeholders consultation

Several SMEs and universities (in total: 14 small-sized companies, 20 medium-sized companies and 5 universities) replied to the consultation launched by Max Planck Institute in the context of their study on the SPC of 2018.

(3) Participation of the Commission in round tables and seminars

The Commission was active in participating in events organised, or co-organised, by representatives of the pharmaceutical industry (including SMEs), as follows:

- 8th SPC Experts meeting from the national patent offices, remote, 5 March 2021.

- Medicines for Europe Legal Affairs Committee - Exchange of Views with DG GROW on IP/Pharma Review, 23 February 2022 (remote).

- Seminar organised by the University of Barcelona in collaboration with Farmaindustria (the Spanish association of originators), FARMATALK-Estrategia Farmacéutica Europea: retos y oportunidades para la industria farmacéutica europea, 1 March 2022

- Videoconference with the Polish Association of Pharmaceutical Industry Employers, 11 May 2022.

- Medicines for Europe Legal Affairs Conference, 28-29 June 2022, Sitges, Barcelona (Spain).

(4) *Bilateral meetings of the Commission representatives with pharmaceutical industry representatives*

Commission representatives have had numerous bilateral meetings with representatives from the pharmaceutical and agrochemical industries, who conveyed the position of SMEs impacted by this initiative.

(5) *Letters sent by pharmaceutical and agrochemical associations, which also represent the interest of SMEs and start ups*

Following the publication of the SPC evaluation report (November 2020) and the Call for Evidence on the SPC (March 2022) international, European and national pharmaceutical associations with significant members representing SME, start-ups and universities sent letters to the Commission stating their position on the unitary SPC and the single grant mechanism (following up also on the position provided by the SPC-holders, generics and biosimilar manufacturers during the Commission public consultation). These associations included Medicines for Europe, ECPA, EFPIA and IFAH-Europe.

Step-3: Assessment of the impact on SMEs

On the data collection, we refer to the previous section. The impact assessment analyses a number of policy options (from PO0 to PO5 plus the preferred option), which pay particular attention to, and have features especially relevant for, the SME-angle.

As set out in section 5 and the table below, options PO2 and PO3, but especially both PO 4 and PO 5, take into account the interests of innovative SMEs and SMEs dealing with generics and biosimilars. In particular, referring to the feedback from the public consultation as set out above, some options would address the points on simplification (e.g. less redundant steps in the SPC grant procedures in the EU, accessible and pragmatic linguistic regime), cost of registration and maintenance of protection, and cost of monitoring SPC protection throughout the EU. The impact assessment also addresses the involvement of third parties in the grant procedure, a feature of significant important for SMEs in the generics/biosimilars sector.

When considering the impact of the options on SMEs in detail (see table below), it must be borne in mind that many SMEs have a limited financial resources and are thus confronted with a significantly higher burden than larger pharmaceutical companies. The fragmentation and costs in the current system as identified above could best be reduced with the following options:

Table 72: Impacts of the policy options on SMEs

	Originators SMEs (potential SPC users)	Generic/biosimilar SMEs
PO 0: Baseline scenario: no action	The identified problems would persist, with greater impact on innovative SMEs. They have less financial and human capital resources than large companies to pursue SPC protection in multiple jurisdictions.	The problems related to legal uncertainty would persist, with greater impact on generic/biosimilar SMEs. They have less financial and human capital resources than large follow-on manufacturers to monitor the SPC protection, and scope of the competing innovative product in each jurisdiction.
PO 1: Guidelines	As the impact of guidelines is likely to be limited and would only marginally improve the situation of the base-line scenario, the impact on SMEs of PO1 is as describe above for PO 0.	
PO 2: Mutual recognition	This option would bring advantages to innovative SMEs, as it would reduce administrative fees and attorney fees related to the filing and examination (maintenance fees would remain in each jurisdiction), as well as limit translation costs related to filing and examination of SPC protection in the EU.	This option would bring advantages to generic/biosimilar SMEs as it would increase of predictability and legal certainty regarding SPC protection in the EU (e.g. divergent SPC outcomes for the same product would be eliminated). However, the risk of having reference offices with different practice would remain and therefore result in "forum shopping" for SPC applicants to file the examination procedure in lenient offices. It would reduce the cost and administrative burden of monitoring SPC protection in the EU, something especially challenging for generic/biosimilar SMEs.
PO 3: Centralised procedure resulting in a non-binging opinion	This option would bring advantages to innovative SMEs, as it would reduce administrative fees and attorney fees related to the filing and examination (maintenance fees would remain in each jurisdiction), as well as limit translation costs related to filing and examination of SPC protection in the EU. However, SMEs could still face national re-examinations of the SPC file resulting in legal uncertainty.	This option would bring advantages to generic/biosimilar SMEs as it would increase of predictability and legal certainty regarding SPC protection in the EU (e.g. divergent SPC outcomes for the same product would be eliminated). However, the risk of divergent SPC outcomes for the same product would not be eliminated. It would reduce the cost and administrative burden of monitoring SPC protection in the EU, something especially challenging for Generic/biosimilar SMEs.
PO 4: Centralised procedure resulting in a binding opinion	This option would bring advantages to innovative SMEs, as it would reduce administrative fees and attorney fees related to the filing and examination (maintenance fees would remain in each jurisdiction), as well as limit translation costs related to filing and examination of SPC protection in the EU. Legal uncertainty linked to the SPC process would be significantly reduced.	This option would bring advantages to generic/biosimilar SMEs as it would increase of predictability and legal certainty regarding SPC protection in the EU (e.g. divergent SPC outcomes for the same product would be eliminated). Above all, the risk of divergent SPC outcomes for the same product would be eliminated therefore adding predictability with regards to possible market entry and legal certainty for the follow-on producers. It would reduce the cost and administrative burden of monitoring SPC protection in the EU, something especially challenging for generic/biosimilar SMEs.
PO 5: Unitary SPC	In addition to the advantages of PO 4 above, this option would provide additional savings like a single annual maintenance fee to keep the protection in the EU. However, these benefits would be limited to the EU MS participating in the unitary patent.	This option would bring advantages as PO4, however, they would be limited to the EU MS participating in the unitary patent.
Preferred option: PO 4 combined with PO 5	I wold bring to SMEs the benefits of PO 5 above in the EU MS participating in the unitary patent, and the advantages of PO 4 above in the non-participating ones.	

Step-4: Minimising negative impacts on SMEs

As described in the table above, the preferred option would ensure more registration savings/simplification for innovative SMEs, legal certainty (predictability, consistency, etc.) for both innovative and competing generics/biosimilars SMEs, and monitoring savings/simplification (more transparency) for both innovative and competing generics/biosimilars SMEs compared to the other options. Contrary to this, option PO1 and, to some extent, PO 3 would provide limited positive effects for SMEs vis-à-vis the base line scenario, as the legal uncertainty would remain (in PO3 due to the non-binding character of the opinion issues by the examination authority).

Finally, the preferred option (a centralised SPC procedure and the unitary SPC) introduces features easy to comply with by SMEs as described in section 8. It would entail enhanced transparency and legal certainty in the SPC-protection of the pharmaceutical and agrochemical industries in the EU by comparison with the base line scenario.