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Subject:	COMMISSION STAFF WORKING DOCUMENT EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT Accompanying the documents Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006

Delegations will find attached document SWD(2023) 193 final part 1/2.

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PART 1/2

COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT

Accompanying the documents

Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC

Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006

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1. Need for action

What is the problem and why is it a problem at EU level?

EU pharmaceutical legislation has enabled the authorisation of safe, efficacious and high-quality medicines. However, patient access to medicines across the EU and security of supply are growing concerns, mirrored by recent Council conclusions and resolutions of the European Parliament. The pharmaceutical legislation includes regulatory incentives and attracts innovation, but the innovation is not always focused on unmet medical needs, and there are market failures, especially in the development of novel antimicrobials that can help address antimicrobial resistance (AMR). Scientific and technological developments, and digitalisation are not fully exploited, while the environmental impact of medicines needs attention. The authorisation system itself could usefully be simplified to keep up with global regulatory competition. The problems are exacerbated by factors outside the scope of the legislation, such as global research and innovation activities or national pricing and reimbursement decisions. Hence, not all problems can be addressed by the revision of the legislation alone. However, EU legislation can be an enabling and connecting factor for innovation, access, affordability and environmental protection.

What should be achieved?

The initiative builds on the high level of public health protection and harmonisation achieved for the authorisation of medicines, so that patients across the EU have timely and equitable access and a reliable supply of the medicines they need. To support the sector's global competitiveness and innovative power, the right balance needs to be struck between giving incentives for innovation, including for unmet medical needs, and measures on access and affordability. The framework needs to be simplified, adapted to scientific and technological changes and contribute to reducing the environmental impact of medicines.

What is the added value of action at EU level (subsidiarity)?

Ensuring access to medicines is a clear public health interest in the EU. The current level of harmonisation shows that the authorisation of medicines can be effectively regulated at EU level. Uncoordinated measures by Member States may result in distortions of competition and barriers to intra-EU trade for products that are relevant for the entire EU. The initiative respects national exclusive competence in health services and pricing and reimbursement of medicines.

2. Solutions

What are the various options to achieve the objectives? Is there a preferred option or not? If not, why?

Three options were assessed, all of which are complemented by a set of common elements:

1) streamlined regulatory procedures;
2) measures to cater for technological and scientific advances, including new concepts (e.g. real world evidence), use of health data and electronic submissions and electronic product information;
3) enhanced cooperation and early dialogue with other regulatory frameworks and actors in the lifecycle of medicines e.g. on medical devices and health technology assessment;
4) adapted requirements for environmental risk assessment of medicines consisting or containing genetically modified organisms; and

5) prudent-use measures for antimicrobials.

Option A maintains the current system of regulatory protection for innovative (originator) medicines (8 years data + 2 years market protection) and adds 1 year of protection for products addressing unmet medical need and 6 months for comparative clinical trials. It also adds 6 months of regulatory protection if an innovative product is made accessible in all Member States within 5 years of authorisation. Novel antimicrobials that reduce AMR are granted from a transferable exclusivity voucher. The voucher gives a 1-year extension of regulatory protection and can be sold to another company and used for a product in that company's portfolio. Current requirements on security of supply are retained (notification of withdrawal at least 2 months in advance). The existing requirements on the environmental risk assessment continue with additional information obligations.

Option B provides 6 years data + 2 years market protection for all innovative medicines. It adds an extra 2 years of regulatory protection for medicines addressing unmet medical need or demonstrating no return on investment. Companies must either have an antimicrobial in their portfolio or pay into a fund to finance the development of new ones. Companies are obliged to launch medicines with an EU-wide authorisation in the majority of Member States (small markets included) and be transparent about public funding received. Current requirements on security of supply are retained and companies are obliged to offer their marketing authorisation for transfer to another company before withdrawal. The environmental risk assessment comes with additional responsibilities for companies.

Option C provides for a variable duration of regulatory protection combined with obligations. Regulatory protection for originator products is split into standard and conditional periods. The standard period is 6 years data + 2 years market protection which can be extended by a (conditional) period of 1 or 2 years, if the product is made accessible in all Member States. The protection can be also extended by 1 year for originator medicines addressing an unmet medical need and by 6 months for comparative trials. Incentives can be combined but cannot exceed current (8+2 years) regulatory protection. To tackle antimicrobial resistance, transferable exclusivity vouchers are explored as in option A. Companies must provide information on public funding for clinical trials. Arrangements for reporting shortages are harmonised, and only critical shortages are escalated to EU level. Companies are obliged to notify possible shortages earlier and to offer their marketing authorisation for transfer to another company before withdrawal. Requirements on the environmental risk assessment and conditions of use are strengthened, as in option B, with the additional inclusion of aspects of antimicrobial resistance in good manufacturing practices.

<u>What are the different stakeholders' views? Who supports which option?</u>

There is broad consensus that the current pharmaceutical system guarantees a high level of patient safety on which the revision can build to address new challenges and improve supply of safe and affordable medicines, patient access and innovation, especially in areas where the medical needs of patients are not met. Citizens, patients and civil society organisations expect equitable access to innovative therapies across the EU, including for currently unmet medical needs, and continuous supply of their medicines. Public authorities and patient organisations opt for a variable duration for the current main incentive, as reflected in option C. The pharmaceutical industry argues against any modulation or shortening of incentives and favours the introduction of additional or novel incentives. Industry has also highlighted the need for stability of the current legal framework and predictability for incentives. Option C contains elements on environment, regulatory support for non-commercial entities and

repurposing of medicines that were supported by other key stakeholders such as healthcare providers, academia and environmental organisations.

3. Impacts of the preferred option

What are the benefits of the preferred option (if any, otherwise of main ones)?

The modulated incentive scheme strikes a balance between providing attractive incentives for innovation and supporting timely patient access to innovative treatments across the EU. The additional incentive for unmet medical needs will lead to more medicines with a public health benefit. Measures to foster development of novel antimicrobials and prudent use will address the problem of increasing antimicrobial resistance. Measures to facilitate earlier market entry of generic and biosimilar medicines will support affordability. Future-proofing the framework will accommodate disruptive technologies and digitalisation. Measures on security of supply will reduce shortages. Simplification and long-term benefits from digitalisation offer savings (falling in the range of EUR 525 million to EUR 1 050 million over the next 15 years for industry) and are likely to offset any new administrative costs and result in more timely authorisation and efficient use of resources. Public health budgets would benefit from stronger competition and transparency measures around public funding for clinical trials. A more robust environmental risk assessment will support environmental goals.

What are the costs of the preferred option (if any, otherwise of main ones)?

Industry will incur costs from the more stringent reporting of shortages and environmental risks and implementation of market access conditions. Companies that do not ensure that their product reach patients in all Member States may see a more limited return on investment. Option C would offer significantly higher patient access (+8 to +15%) to innovative medicines and an increased proportion of medicines addressing unmet medical needs.

Investment in antimicrobials will come at a cost of around EUR 500 m in public funding, and generic industry and comparative trials that support future pricing and reimbursement decisions would increase the costs for health systems (by EUR 326 m to EUR 408 m). However, these costs would be offset by the cost savings from the modulated incentives and benefits, such as faster and better reimbursement decisions due to comparative trials. New obligations designed to prevent shortages and meet environmental standards will result in additional costs for businesses (EUR 30 m a year). The generic and biosimilar industry will benefit from measures for earlier market entry, simplification of requirements and streamlining of procedures.

Companies that provide for unmet medical needs and patient access across the EU will keep current incentives. The EU will therefore remain an attractive market for medicine developers with an increased output of medicines, especially in areas of unmet medical need.

What are the impacts on small and medium-sized enterprises (SMEs)?

SMEs may find it more difficult to adjust to a modulation of incentives linked to market launch as they often lack capacity to serve all Member States in a timely manner. However, specific conditions could be envisaged for SMEs to mitigate these impacts. They may in turn benefit more from the incentive for unmet medical needs as they are more involved in riskier R&D in unserved areas. For the same reasons, the introduction of transferable exclusivity vouchers for novel antimicrobials would help SMEs to attract investment for research and development. Additional obligations (environmental and supply-related) would add to administrative and compliance burdens. On the other hand, SMEs would be more likely to

benefit from 'systemic' changes. Simplification of procedures, wider use of electronic processes and reduction of the administrative burden are particularly important and expected to reduce costs. Moreover, SMEs stand to benefit from enhanced scientific advice, regulatory support and fee reductions.

Will there be significant impacts on national budgets and administrations?

Monetary impacts on national health budgets from measures on access and for products for unmet medical needs would be positive or neutral. An additional positive indirect impact on budgets is expected from savings from avoided hospitalisation and outpatient treatments. Transferable exclusivity vouchers would increase costs for health systems, which must be seen in the context of the threat of resistant bacteria and costs incurred from AMR such as deaths (33 000 a year), healthcare costs and productivity losses (EUR 1.5 bn a year in the EU).

Will there be other significant impacts?

The most significant impact will be broader and quicker EU-wide patient access to innovative medicines. In addition, R&D investment would increase treatment options and benefit patients, particularly for unmet medical needs. Strengthened requirements on environmental risk assessment are expected to have a positive environmental impact. Prudent-use measures for antimicrobials will reduce the risk of resistance. Comparative trials and better lifecycle coordination would provide a better evidence base for pricing and reimbursement decisions at national level and may support medicines becoming more readily available after authorisation. The horizontal elements will increase the efficiency of the system and decrease costs for businesses and administrations.

Proportionality?

The initiative does not go beyond what is necessary to achieve the objectives of the revision. It does so in a way that is conducive to national action, which would otherwise not be sufficient to achieve those objectives in a satisfactory way.

4. Follow up

When will the policy be reviewed?

The development of new medicines can be a long process that can take up to 10-15 years. The effect of incentives and rewards is therefore felt many years after the marketing authorisation date. The benefit for patients also needs to be measured over a period of at least 5-10 years after a medicine is authorised. The Commission intends to review the initiative periodically. However, a meaningful evaluation of the results of the revised legislation will only be possible at least 15 years after it comes into force.