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PART 1

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

Accompanying the document

Proposal for a
DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems

{COM(2012) 84 final}
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GLOSSARY

*The expressions below are identified in this document with the sign **

- **Co-payment**: share of the cost of a medicinal product which is not financed by public authorities and therefore paid exclusively by the patient or private insurance.

- **External reference pricing**[1]: the practice of using the price(s) of a medicinal product in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country.

- **Generic medicinal product**[2]: a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as a reference (originator) medicinal product and whose bioequivalence with the reference medicinal product has been demonstrated. If these conditions are met, a generic applicant for marketing authorisation is exempted from the requirement to prove safety and efficacy through pre-clinical tests and clinical trials, and the competent authority relies on the proof of safety and efficacy provided by the reference product.

- **Health technology assessment**[1]: health technology is the application of scientific knowledge in healthcare and prevention. Health technology assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective health policies that are patient focused and seek to achieve best value.

- **Internal reference pricing**[1]: the practice of using the price(s) of identical or similar medicines, or even therapeutically equivalent treatments (not necessarily medicines) in a country in order to derive a benchmark or reference price for the purposes of setting or negotiating the price or reimbursement of the product in a given country.

- **Loss of exclusivity**[2]: loss of the different forms of protection attached to medicinal products, namely (1) loss of patent protection (the medicinal product no longer falls under the protection period provided by a patent, including supplementary protection certificates) and (2) protection through marketing exclusivity and data exclusivity (the medicinal product is no longer subject to data protection).

- **Managed entry agreement**[3]: an arrangement between a manufacturer and payer/provider that enables access to (coverage/ reimbursement of) a health technology subject to specific conditions. These arrangements can use a variety of mechanisms to address uncertainty about the performance of technologies or to manage the adoption of technologies in order to maximise their effective use or limit their budget impact.

- **Medical device**: medical device within the meaning of Article 1 of Directives 90/385/EEC, 93/42/EC and 98/79/EC.

- **Medicinal product**: medicinal product within the meaning of Article 1 of Directive 2001/83/EEC as amended.

- **Off-patent market**: market composed of a reference (originator) product having lost exclusivity and any generic versions of this product. The off-patent market is characterised by competition between products containing the same active pharmaceutical ingredient.

- **Originator medicinal product**[2]: a novel medicinal product that was under patent protection when launched onto the market.

- **Patent linkage**[2]: the practice of linking the granting of marketing authorisation, the pricing and reimbursement status or any regulatory approval for a generic medicinal product, to the status of a patent (application) for the originator reference product.

- **Pharmaco-economic evaluation**[1]: the comparative analysis of alternative courses of action in terms of both their costs and consequences.

Sources:

[1] Glossary developed by the PPRI project – see http://ppri.oebig.at/index.aspx?Navigation=r|4-

[2] Commission Staff Working Document on the Pharmaceutical Sector Inquiry – see http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html

[3] Klemp, M Frønsdal KB, Facey K., What principles should govern the use of Managed Entry Agreements? (2011) *International Journal of Technology Assessment in Health Care*, pp.77-83.

LIST OF ABBREVIATIONS

CJEU: Court of Justice of the European Union

EFPIA: European Federation of Pharmaceutical Industry Associations

EGA: European Generic Medicines Association

EU: European Union

EUCOMED: one of the EU organisations representing medical device technology industries

GDP: Gross Domestic Product

HTA: Health Technology Assessment

INN: International Non-proprietary Name for pharmaceutical substances

R&D: Research and Development

SME: Small and Medium sized Enterprise

TFEU: Treaty on the Functioning of the European Union

ANNEXES

1. Summary of responses to the public consultation
2. Evolution of the pharmaceutical market and of public expenditure on medicines
3. Overview of the provisions of Directive 89/105/EEC
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1. INTRODUCTION

Council Directive 89/105/EEC[1] lays down a general procedural framework to ensure the transparency of measures regulating the pricing and reimbursement of medicinal products; for this reason, it is often referred to as the "Transparency Directive". Its overall objective is to enable market operators to verify that national measures do not create barriers to trade prohibited by Articles 34-36 TFEU. To this purpose, the directive lays down a series of procedural requirements applicable to any national measure regulating the prices of medicines and their inclusion in the scope of health insurance systems.

Directive 89/105/EEC has never been amended since its adoption in 1988. A revision was foreseen by the legislator within two years following its entry into force.[2] In the early 1990s, the Commission prepared a draft proposal to amend the directive, together with a draft recommendation on measures taken by Member States as regards the pricing and reimbursement of medicines. However, both failed to gather sufficient support during the consultation phase and the review process was eventually abandoned in 1992.

The present initiative examines the need to update the directive more than twenty years after its entry into force. It focuses on the possible clarification of the general procedural requirements for pharmaceutical pricing and reimbursement, while taking into account the responsibilities of the Member States for the organisation and financing of their health insurance systems.

2. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

The review of Directive 89/105/EEC was announced by Vice-President Antonio Tajani in January 2010 during his European Parliament hearing as Commissioner-designate for Enterprise and Industry. The impact assessment roadmap was first published in April 2010.[3] The review is currently scheduled in the Commission's Agenda Planning under reference 2011/ENTR/005.

2.1. Organisation and timing

The impact assessment exercise was initiated in the spring 2010. Upon invitation by DG Enterprise, an inter-service Steering Group was established with representatives from the following Directorates-General: COMP, SANCO, MARKT, EMPL, INFSO, RTD, Legal Service and Secretariat-General. Five meetings of the inter-service group were held on the following dates: 26 May 2010 (discussion of objectives, timing of the review and terms of reference for the external study); 5 October 2010 (discussion of problem definition); 1 February 2011 (discussion of public consultation questionnaire); 11 May 2011 (discussion of options) and 5 July 2011 (discussion of the draft impact assessment as a whole).

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1 Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion within the scope of national health insurance system (OJ N°40, 11.2.1989, p. 8).

2 Directive 89/105/EEC, Article 9.

3 Impact Assessment Roadmap: http://ec.europa.eu/governance/impact/planned_ia/docs/2011_entr_005_national_health_insurance_en.pdf

2.2. Internal and external studies

Two existing reports provided key input to this impact assessment:

- The results of the *Competition Inquiry into the Pharmaceutical Sector* carried out by the Commission in 2008-2009 (hereinafter "Pharmaceutical sector inquiry").[4] The issues examined by the sector inquiry included the impact of pricing and reimbursement processes on market entry and competition in the pharmaceutical market.

- A study concerning the *Competitiveness of the EU market and industry for pharmaceuticals* (hereinafter "Pharmaceutical market monitoring study").[5] A major part of it addressed the role of pricing and reimbursement policies in the functioning of the EU market for medicines.

Other studies were used as sources of information, in particular the *Analysis of differences and commonalities in pricing and reimbursement systems in Europe*[6] commissioned by DG Enterprise and Industry in 2007 and the report on *Differences in costs of and access to pharmaceutical products in the EU*[7] published by the European Parliament's Committee on Environment, Public Health and Food Safety in April 2011.

Additional research was carried out by an external consultant, Matrix Insight Ltd, to collect information regarding the evolution of the pharmaceutical market in the last twenty years and to examine the innovative approaches to pharmaceutical pricing and reimbursement in the Member States. This preparatory work also analysed pricing and reimbursement policies in the medical devices* market in order to assess their relevance in the context of Directive 89/105/EEC.

2.3. Stakeholder consultation

The consultation of stakeholders took place in two steps. First, a stakeholder meeting was organised on 15 December 2010. Participants included competent authorities from the Member States and representatives of European organisations representing the interests of the

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[4] Commission inquiry into the European pharmaceutical sector pursuant to Article 17 of Regulation 1/2003. The results of the inquiry were published on 8 July 2009 in the Communication from the Commission: "Executive Summary of the Pharmaceutical Sector Inquiry Report" (COM(2009)351 final) and the annexed Staff Working Document: "Report on the Pharmaceutical Sector Inquiry". http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html

[5] Ecorys (2009) Study on the competitiveness of the EU market and industry for pharmaceuticals; Volume I: Welfare Implications of Regulation and Volume II: Markets, Innovation and Regulation. This study was commissioned in 2009 by DG Enterprise and Industry in the framework of the Commission's internal market monitoring exercise. http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/vol_1_welfare_implications_of_regulation_en.pdf; and http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/vol_2_markets_innovation_regulation_en.pdf

[6] Andalusian School of Public Health (2007) Analysis of differences and commonalities in pricing and reimbursement systems in Europe. http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/study_pricing_2007/andalusian_school_public_health_report_pricing_2007_en.pdf

[7] European Parliament, Directorate-General for Internal Policies (2011) Differences in costs of and access to pharmaceutical products in the EU. http://www.europarl.europa.eu/activities/committees/studies/download.do?language=es&file=35108

pharmaceutical industries, the medical devices sector, public health insurers, patients, consumers, doctors, hospitals, wholesalers and pharmacists. This meeting aimed at raising awareness of the review and presenting the main objectives and timetable of the exercise. It was followed by a public consultation held from 28 March 2011 to 30 May 2011.

The Commission received 102 responses from a wide range of stakeholders, including national authorities, public health insurers, individual companies and organisations representing the research-based pharmaceutical industry, the generic industry and the medical devices industry and other interested parties such as representatives of the distribution chain, health professional organisations, patients and citizens. Small and medium sized enterprises (SMEs) were also consulted via the Enterprise Europe Network. A summary of the contributions is provided in Annex 1.

The Commission's minimum standards have been adhered to: the public consultation was open for nine weeks and announced to the public, it was accessible on the Commission's 'Your Voice in Europe' webpage with guidance in all EU languages and respondents received an individual reception notice.

2.4. Scrutiny by the Impact Assessment Board

A draft version of this impact assessment was submitted to the Commission's Impact Assessment Board on 2 August 2011. The Board met with representatives of DG Enterprise and Industry on 7 September 2011 and issued its opinion on 9 September 2011.

On the basis of this opinion, the report was adapted to clarify or strengthen a number of elements. In particular, this final version:

- Presents in more detail the general situation as regards health and pharmaceutical expenditure in EU countries and clarifies the analyses and assumptions made in relation to the impact of innovative medicines;

- Better explains how the preferred policy options will be able to take into account the evolution of pharmaceutical markets and pricing and reimbursement policies;

- Includes an overview of the expected impacts of the combination of preferred policy options on each of the main stakeholders;

- Provides a more detailed discussion of the expected administrative burden/costs for Member States, in particular with respect to the reduction of time-limits for the pricing and reimbursement of generic medicines.

- Defines and presents specific progress indicators in the context of monitoring and evaluation arrangements.

More technical comments from the Board were also taken into account where appropriate.

3. PROBLEM DEFINITION

3.1. Context

The pharmaceutical sector plays a strategic role in Europe by contributing to public health, scientific innovation and economic wealth. Medicines improve the level of welfare of European citizens. They are also vital to our economy as the pharmaceutical sector relies upon a highly skilled, research-driven industry which generates employment and fuels economic growth. There are approximately 4,000 pharmaceutical companies in the European Union, representing 630,000 employees and generating a global turnover close to 200bn EUR. Roughly three fourth of these companies develop originator medicinal products*, while the remaining fourth manufactures generic medicinal products*. In 2007, the pharmaceutical market accounted for nearly 2% of annual EU GDP and an average of 430 EUR was spent annually on medicines for each European.[8]

3.1.1. Structure and characteristics of the pharmaceutical sector

The structure of the pharmaceutical sector is specific and unique. It is characterised by a wide variety of market players and a high degree of regulation across the supply chain. Public intervention in the pharmaceutical market is crucial to achieve multiple objectives, which range from ensuring a high level of public health to supporting innovation and keeping public expenditure under control. A major specificity of the market is that the end users (patients) largely rely on expert intermediaries (health professionals) to decide on appropriate treatments on their behalf.[9] For a more detailed description of the specific features of the pharmaceutical sector, reference is made to the Pharmaceutical sector inquiry[10], the Pharmaceutical market monitoring study[11] and the report on Differences in costs of and access to pharmaceutical products in the EU.[12]

Pharmaceutical legislation is essential to ensure the provision of safe and efficacious medicines to European citizens. It is also widely accepted that the pharmaceutical market requires specific forms of regulation to avoid market distortions and to guarantee the provision of goods serving not only individual needs but also broader societal goals. In all EU countries, healthcare expenditure is to a large extent subsidised by public budgets and governments seek to ensure the sustainable provision of medicines to their citizens in the framework of public health insurance systems. This is another major characteristic of the EU pharmaceutical market: a large share of pharmaceutical expenditure is publicly financed, with 50 to 80% of the pharmaceutical bill paid from public budgets in the Member States (Figure 1). The share of pharmaceutical expenditure which is not financed by the State is either supported by patients or covered by private health insurance schemes.

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8 Commission Communication on the Pharmaceutical sector inquiry, Section 1; Staff Working Document, §1.

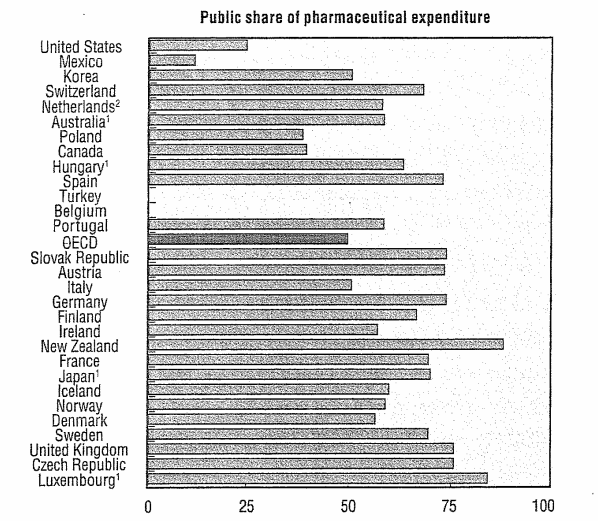
9 Differences in costs of and access to pharmaceutical products in the EU, p. 16.

10 Staff Working Document on the Pharmaceutical sector inquiry, §39 et seq.

11 Pharmaceutical market monitoring study, Volume I: Welfare Implications of Regulation, p. 24.

12 Differences in costs of and access to pharmaceutical products in the EU, p. 18.

Figure 1: Public share of pharmaceutical expenditure in OECD countries

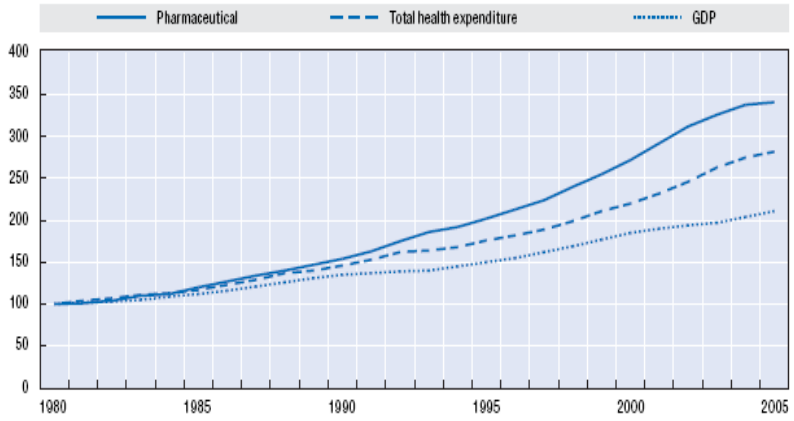


Note: data for Belgium and Greece not available

Source: OECD Health Data 2007 in Pharmaceutical Pricing Policies in a Global Market (OECD Health Policy Studies, 2008).

Since the 1980s, EU countries have been confronted to a constant increase in health and pharmaceutical expenditure. Nevertheless, public spending on medicines has been increasing more than total health expenditure and at a quicker rate than economic growth measured in terms of GDP (Figure 2). Further information on this evolution is provided in Annex 2.

Figure 2: Growth in pharmaceutical expenditure, total health expenditure and GDP – 15 OECD countries, 1980-2005



Source: OECD Health Data 2007 in Pharmaceutical Pricing Policies in a Global Market (OECD Health Policy Studies, 2008).

3.1.2. Pharmaceutical regulation at EU and Member State level

In the European Union, medicinal products can be placed on the market only if they have received a marketing authorisation from the European Commission or from the competent national authorities. Marketing authorisations are granted in accordance with harmonised

rules intended to ensure the quality, safety and efficacy of medicines.[13] EU legislation pursues the dual objective of guaranteeing the highest possible level of public health, while facilitating the free movement of medicinal products across the European Union. This common regulatory framework has been instrumental in the development of a single European market for medicines, contributing both to the general health status of European citizens and to the competitiveness of the pharmaceutical industry.

Even though marketing authorisation requirements are fully harmonised at European level, national health policies continue to play a critical role in the provision and delivery of medicines to patients after marketing authorisation. In accordance with Article 168(7) of the Treaty on the Functioning of the European Union (TFEU), Member States retain exclusive power to organise and manage their healthcare systems. National responsibilities include the management of health services and medical care and the allocation of the resources assigned to them. Consequently, each Member State has the capacity to regulate the prices of medicines, to manage their consumption and to establish the conditions of their public funding in the framework of national, regional or local health insurance systems.

3.1.3. Impact on the internal market

The allocation of powers defined by the EU Treaty has important implications for the functioning of the internal market in medicinal products. Indeed, a medicine which has been granted a marketing authorisation in accordance with EU rules (either by the European Union or by a Member State) may be subject to additional regulatory requirements at Member State level before it can be placed on the market or dispensed to patients under the health insurance system.

In practice, all Member States have adopted measures to regulate the prices of medicines and the conditions of their public funding[14]. Such measures influence the prescription and utilisation of medicines in each country. They are susceptible to create barriers to trade within the EU insofar as they affect the capacity of pharmaceutical companies to sell their products in domestic markets. By way of example, the exclusion of a medicinal product from reimbursement in a given country will result *de facto* in its exclusion from the national market because the product is unlikely to be prescribed by doctors and used by patients. Pricing and reimbursement measures may thus provide an opportunity for Member States to protect their national industry by making the sales of imported products impossible or more difficult than that of domestic products.

The impact of national pricing and reimbursement measures on pharmaceutical trade has led the Court of Justice of the European Union (CJEU)[15] to examine their compatibility with the

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[13] Directive 2001/83/EC as amended, OJ L311, 28/11/2004, p. 67, and Regulation (EC) N°726/2004, OJ L 136, 30.4.2004, p. 1.

[14] The public funding of medicines through their inclusion in public health insurance systems is traditionally referred to as "reimbursement". For the sake of simplicity, the term "reimbursement" will be used throughout this report.

[15] The Court of Justice of the European Union was previously called the Court of Justice of the European Communities. This document will refer to it as the Court of Justice, the Court or the CJEU.

rules governing the free movement of goods (Articles 34-36 TFEU)[16]. According to settled case-law, EU law does not detract from the power of the Member States to organise their social security systems. The Court recognises the Member States' right to adopt provisions intended to govern the consumption of medicinal products, including pricing and reimbursement measures, in view of promoting the financial stability of their health insurance system. Hence, national measures to control the pricing and reimbursement of medicines do not, as such, constitute a restriction to the free movement of goods prohibited by Articles 34-36 TFEU. However, Member States must comply with EU law when exercising their power. In its landmark judgements *Roussel* (1983) and *Duphar* (1984), the Court of Justice established that such measures must satisfy certain conditions in order to be compatible with the rules of the Treaty. In particular, they shall be free of discrimination against imported medicinal products and they must be based on objective and verifiable criteria that are independent of the origin of the products.[17] These obligations have been confirmed in subsequent case-law.[18]

3.1.4. Role of Council Directive 89/105/EEC

In light of the Court's judgements in the *Roussel* and *Duphar* cases, the Commission issued in 1986 a Communication outlining the principles to be applied to ensure the compatibility of national pricing and reimbursement measures with the rules of the Treaty on the free movement of goods.[19] It also submitted a proposal to codify in a legislative instrument the minimum requirements set forth by the Court of Justice[20], which resulted in the adoption of the directive under examination.

Directive 89/105/EEC sets out procedural requirements to ensure the transparency of national pricing and reimbursement measures. The main obligations to be implemented in national legislation are presented in figure 3 below. A more detailed description of the directive can be found in Annex 3.

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16 Articles 34-36 TFUE (formerly Articles 28-30 EC and Articles 30-36 EEC) prohibit Member States from adopting and maintaining unjustified restrictions on intra-EU trade and define limited exceptions to this principle.

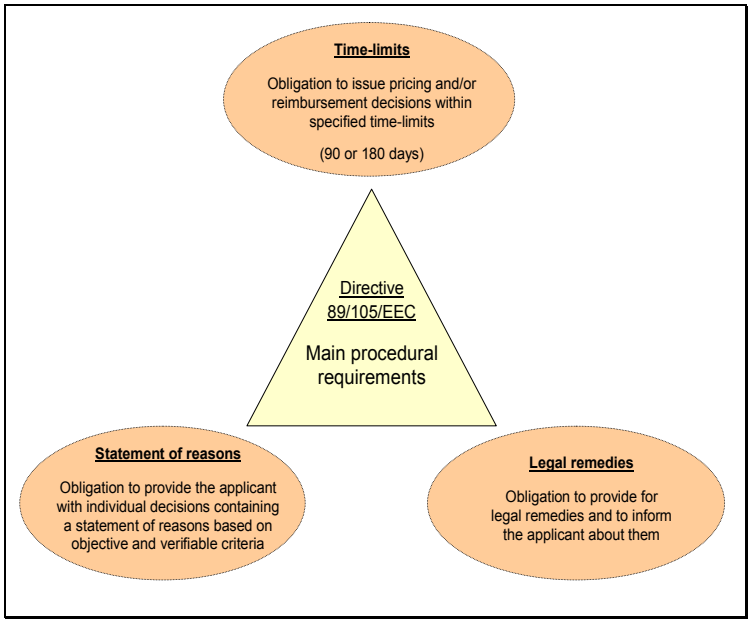
17 Case C-181/82 Roussel Laboratoria [1983] ECR 3849; Case 238/82 Duphar and Others [1984] ECR 523.

18 See, for example, Case C-249/88 Commission v Belgium [1991] ECR I-1275.

19 Communication from the Commission on the compatibility with Article 30 of the EEC Treaty [today Article 34 TFUE] of measures taken by Member States relating to price controls and reimbursement of medicinal products (OJ C.310, 4.12.1986, p. 7).

20 COM(86)765 final.

Figure 3: Main procedural requirements of Directive 89/105/EEC



It is important to underline that Directive 89/105/EEC concerns national procedures and decisions which typically intervene after the marketing authorisation stage. It does not interfere in any way with the marketing authorisations delivered by the competent authorities, nor address any aspect relating to the quality, safety and efficacy of medicines. Furthermore, in accordance with the provisions of the Treaty, Directive 89/105/EEC does not affect national policies on price setting and on the determination of social security schemes, except as far as it is necessary to ensure the transparency of procedures.[21] In other words, the directive does not regulate *what* the Member States can do with regard to the pricing and reimbursement of medicines, but only *how* they can do it.[22]

3.2. Problem identification

3.2.1. Evaluation of the existing instrument

As from the early 1990s, Directive 89/105/EEC played a key role in promoting the transparency of national pricing and reimbursement measures. Instead of just applying general principles set out by the Court of Justice in individual cases, Member States were required to transpose specific procedural requirements in their legislation and to implement them consistently. This helped to build up a basic culture of transparency in the competent national administrations. For instance, the pricing and reimbursement system developed in France after the entry into force of the directive incorporated the specific timelines for the decision-making process and defined more precise criteria for the inclusion of medicines in the reimbursement list. The main foundations of this system are still in place today. Similarly, in the context of the EU enlargement to Central and Eastern Europe, the new Member States worked in collaboration with the Commission in order to adapt their systems to the procedural

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21 Directive 89/105/EEC, 6th recital.

22 Opinion of Advocate General Trstenjak in joined cases C-352/07 to C-356/07, C-365/07 to C-367/07 and C-400/07, point 74.

obligations of the directive. This resulted in the overhaul of many pricing and reimbursement systems and in the establishment of new decision-making processes generally reflecting the obligations of the directive in terms of time-limits, reasoned decisions and appeal procedures.

The public consultation confirmed the positive effects of the directive on the operation of the pharmaceutical market. A large majority of respondents (including economic operators, public authorities and citizens or patients) underscored the benefits of the existing procedural rules on equal treatment between domestic and imported products, speed of pricing and reimbursement decisions and transparency of procedures – see Annex 1.

The general impact of the directive is therefore considered to be positive. Nevertheless, enforcement difficulties and challenges linked to the evolution of the pharmaceutical market have arisen. Annex 2 provides an overview of major developments in the pharmaceutical market in the last two decades. It shows that the pharmaceutical market has considerably changed, not only with the emergence of generic medicines but also with the development of increasingly innovative research-based products which provide new treatment options but are also a major cost driver for public governments. In response to the rising pharmaceutical expenditure, public authorities in the Member States have regularly devised new policies and established new procedures to control pharmaceutical expenditure. In this context, discrepancies have emerged between the enacting terms of the directive and the national measures it is meant to address.

The main problems and the drivers underlying them are described below. They are also summarised in the problem tree attached as Annex 4.

3.2.2. Delays in time to market medicinal products

Directive 89/105/EEC lays down specific time-limits for pricing and reimbursement decisions, which the national authorities are not entitled to exceed.[23] Pricing decisions, on the one hand, and reimbursement decisions, on the other hand, must be adopted within 90 days from the receipt of an application by the marketing authorisation holder. Combined procedures covering both pricing and reimbursement must lead to an individual decision issued to the applicant within 180 days.

Evidence presented in this section shows that the effective entry of originator medicines into the market often takes place beyond this timeframe. In practice, the availability of medicines in national markets depends on a number of factors, including the choices and commercial strategies of the marketing authorisation holders.[24] Nevertheless, pricing and reimbursement processes stretching beyond the time-limits laid down in the directive contribute to postponing the launch of innovative medicines to the market (section 3.2.2.1). Market access delays are also a cause for concern in the generic market. The Pharmaceutical sector inquiry indeed revealed that pricing and reimbursement procedures often unnecessarily delay the launch of generic medicines in European markets (section 3.2.2.2).

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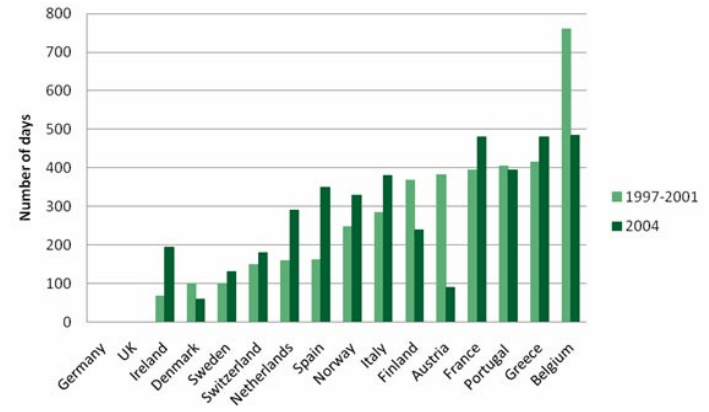
[23] See Case C-245/03 Merck, Sharp & Dohme [2005] ECR I-637 and Case C-296/03 Glaxosmithkline [2005] ECR I-669.

[24] After a marketing authorisation has been granted for a medicinal product, the marketing authorisation holder can decide if and when to place the said product on the market(s) in which the marketing authorisation is valid.

3.2.2.1. Market access delays for originator medicines

During the Pharmaceutical sector inquiry, stakeholders reported frequent delays in pricing and reimbursement decisions.[25] Industry representatives also deplored the excessive length of administrative procedures in some Member States in the context of the Pharmaceutical market monitoring study.[26] Similar concerns were raised in the framework of the public consultation. In particular, originator companies claim that national pricing and reimbursement decisions are often made or implemented outside the time-limits laid down by Directive 89/105/EEC. The available data confirm that the time-limits for pricing and reimbursement decisions are not always complied with. The example below illustrates the delays encountered in some countries between 2001 and 2004 (Figure 4). Although no compiled data is available for the post-enlargement period, there is evidence that recurrent delays have also been experienced in many EU-15 and new Member States after 2004. For instance, in the last five or six years, the Commission has received and investigated an important number of complaints pointing to repeated non-compliance with the time-limits of the directive in different countries. A more detailed description and analysis of pricing and reimbursement delays is provided in Annex 5.

Figure 4: Average number of days for pricing and reimbursement decisions – 2004 compared to 1997-2001



Source: 1997-2001 data from OECD (2008) Health Policy Studies Pharmaceutical Pricing Policies in a Global Market, p. 133. 2004 data from Pharmaceutical Industry Competitiveness Task Force, Competitiveness and Performance Indicators (2005), p. 42.

The main reasons for delays highlighted by Member States and stakeholders during the Pharmaceutical sector inquiry and the public consultation pertaining to this impact assessment include:

- The controversial use of the "stop the clock" mechanism foreseen in the directive, which allows Member States to suspend the procedure if the information supporting the application is considered inadequate;

- The necessity for Member States to carry out technically complex health technology assessments* or other types of pharmaco-economic evaluations* in order to assess the

[25] Commission Communication on the Pharmaceutical Sector Inquiry, Section 4.4; Staff Working Document, §1422 et seq.

[26] Pharmaceutical market monitoring study, Volume I, p. 83.

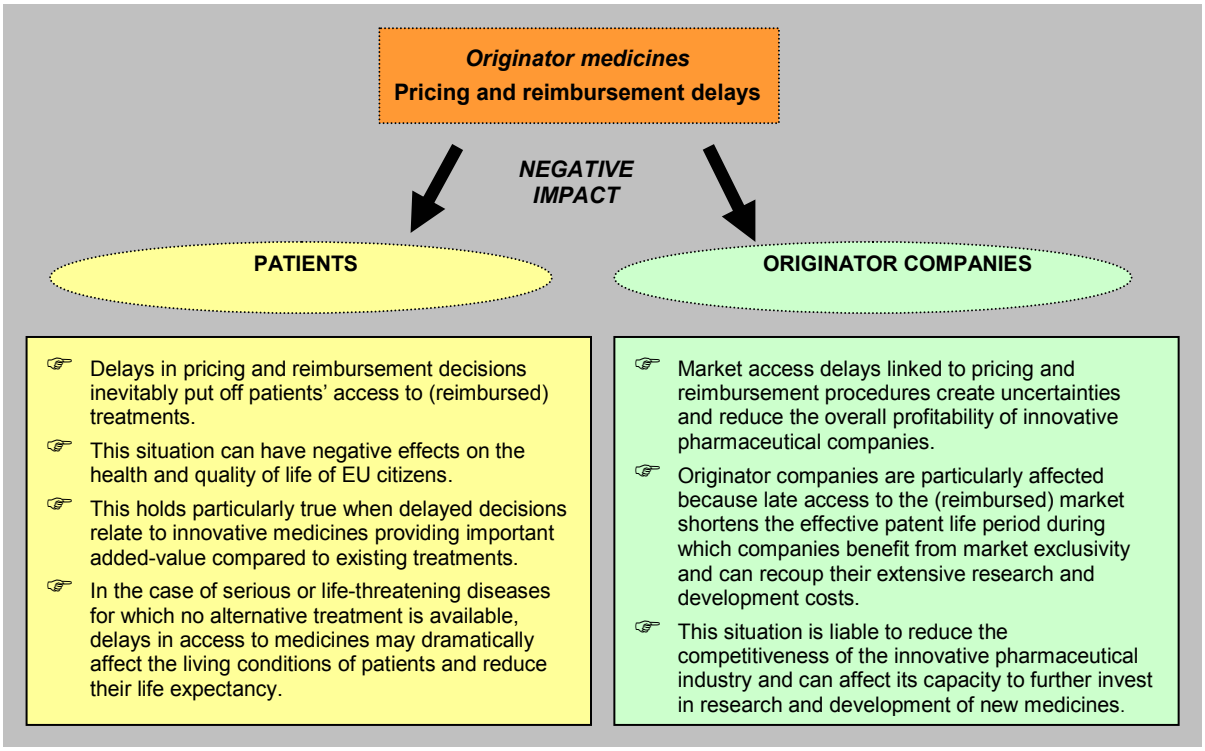
clinical and budgetary impact of new medicines. The rationale for such assessments and their benefits in ensuring the maintenance of cost-effective health systems are fully recognised and accepted by Member States. Nevertheless, the duration of these assessments is a cause for concern when they contribute to delay the final pricing and reimbursement decisions;

- Publication delays between the individual decision notified to the applicant and the actual entry into force of this decision upon publication (for instance in price or reimbursement lists). Such official publications are often necessary under national rules, both for generic and originator medicines, but the timeframe for publication is not always taken into consideration in the overall pricing and reimbursement procedures;

- The use of specific pricing and reimbursement techniques such as external reference pricing.*

In most national systems, authorised medicinal products cannot be marketed or dispensed to patients in the framework of the health insurance system before the competent national authorities have set their price and/or established their reimbursement status. Delayed pricing and reimbursement decisions therefore postpone market access or, at least, defer the availability of medicines under the national health system. Such delays mainly impact patients and research-based companies (figure 5).

Figure 5: Impact of pricing and reimbursement delays – Originator products



The increasing burden of medicines on public health budgets – and in particular the significant costs associated with highly innovative, research-based medicines – fully justifies the particular attention devoted by Member States to the evaluation and determination of their pricing and reimbursement status. At the same time, pricing and reimbursement decisions made outside the mandatory time-limits defined by Directive 89/105/EEC impede the smooth

functioning of the internal market to the detriment of European citizens and business operators. For the public authorities, delays in the pricing and reimbursement of originator medicines may not necessarily represent a budgetary gain for national healthcare budgets. For instance, the Pharmaceutical market monitoring study points out that *"the delay in access to (innovative) medicines can reduce the gains in total costs of treating a disease as a result of a new drug"*. Although this is by no means a general and systematic rule, the authors refer to several studies showing that the reduction in non-pharmaceutical spending which results from the introduction of a new medicine can be significantly higher than the cost induced by the prescription of that medicine.[27]

3.2.2.2. Market access delays for generic medicines

The conclusions of the Pharmaceutical sector inquiry pointed to delays regarding the entry of generic medicines into EU markets after the loss of exclusivity* of the originator products. The inquiry demonstrated that, on a weighed average basis, it takes more than seven months for generic medicines to become available after originator medicines have lost their exclusivity.[28] The Commission investigated the reasons for these delays and found that – beyond the launch strategies of generic firms and the practices sometimes used by originator companies to extend the commercial life of their medicines – regulatory factors also account for this situation. In particular, pricing and reimbursement procedures contribute to delaying the entry of generics on the market in a number of countries.

The time-limits of 90/180 days laid down in Directive 89/105/EEC apply equally to generic and originator medicines.[29] Figure 6 shows that a majority of EU countries issue their decisions as regards generic medicines within these time-limits. The European Generic Medicines Association (EGA) observed that generic companies wait on average 153 days after marketing authorisation to receive pricing and reimbursement status.[30]

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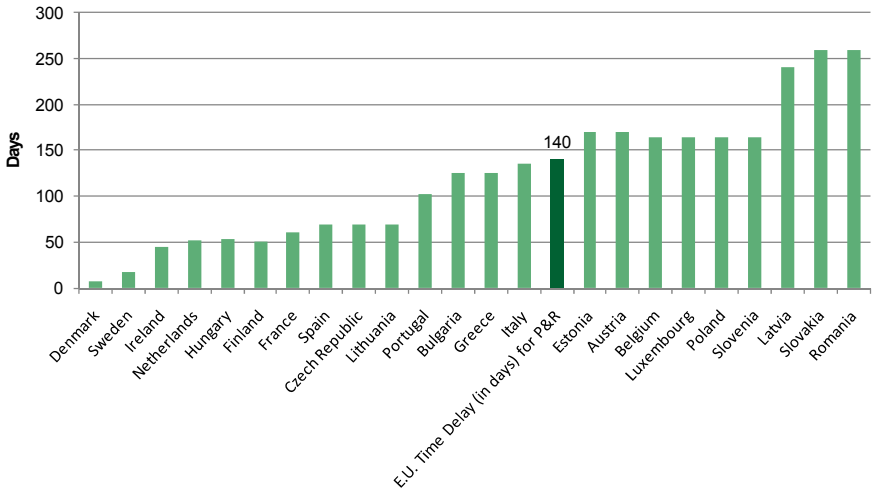
27 Pharmaceutical market monitoring study, Volume I, p. 92.

28 Commission Communication on the Pharmaceutical sector inquiry, Section 2.1.2; Staff Working Document, §§191-192.

29 Generic products represented a very small proportion of the market in the 1980s, which is probably the main reason why they were not distinguished from originator products. Nevertheless, generics today represent a significant share of the EU pharmaceutical market (nearly 50% of the market in volume).

30 European Generic Medicines Association (2009) How to increase patient access to generic medicines in the European Union.
http://www.egagenerics.com/doc/ega_increase-patient-access_update_072009.pdf

Figure 6 - Time delay (in days) for P&R approval for a generic medicine after granting of market authorisation (2005)



Source: EGA

However, the timeframe for pricing and reimbursement procedures with respect to generic products varies considerably across the EU, ranging from 14 to more than 270 days (table 1).

Table 1: Time delays by country for pricing and reimbursement approval

	AT	BE	BG	CZ	DK	ES	FR	IRL	IT	LV	L	NL	PL	PT	RO	SK	SI	ES	SE
Average time delay for price approval	80	90	90	90	14	90	75	45	135	120	30	-	180	21	90	120	15	75	30
Average time delay for reimbursement approval	180	120	30	90	14	90	75	45	135	120	180	45	180	90	180	150	180	75	30
Are P&R applications for generic medicines simultaneous?	Y	Y	N	Y	Y	N	Y	Y	Y		Y	Y	Y	N	N	N	Y	N	Y
Average time delay for P&R approval after MA	180	120	120	180	14	180	75	45	135	240	180	45	180	111	270	270	180	150	30

Source: EGA

When examining the duration of pricing and reimbursement procedures, an important distinction must be drawn between originator and generic medicines. The appraisal of originator products for the purpose of pricing and reimbursement is often a complex and time-consuming exercise due to the novelty and innovative character of these products. National authorities use sophisticated methodologies, such as health technology assessments*, to evaluate the added-value or the effectiveness of innovative medicines in view of determining their price and reimbursement conditions. However, pricing and reimbursement procedures for generic medicines should logically not require any new or detailed assessment since the characteristics of the product are already well known. In addition, when a generic company applies for the inclusion of its product in the health insurance system, the corresponding originator product usually benefits from reimbursement based on a higher price. In this respect, many European countries have adopted regulations whereby the maximum prices of generic medicines are set at a certain percentage below the reference originator product.[31]

[31] Analysis of differences and commonalities in pricing and reimbursement systems in Europe, p. 145.

Consequently, pricing and reimbursement processes for generic medicines could be much shorter than the maximum time-limit of 180 days set out in Directive 89/105/EEC. This is demonstrated by the minimal time delays observed in some countries that have adopted simplified pricing and reimbursement procedures for generics. It is the reason why the Commission, in its Communication on the Pharmaceutical sector inquiry, called on Member States to *"consider the introduction of national provisions granting automatic/immediate reimbursement status to generic medicinal products where the corresponding originator already benefits from reimbursement at a higher price".*[32]

Based on information gathered from stakeholders, the sector inquiry also reported specific regulatory approaches or administrative practices which unnecessarily prolong pricing and reimbursement procedures for generic medicines. All generic companies and representative organisations reiterated these problems during the stakeholder consultation.

Practices delaying generic pricing and reimbursement

- Additional evaluation of bioequivalence: one of the requirements defined by EU law to obtain a marketing authorisation for a generic medicine is for applicant companies to demonstrate the bioequivalence of their product with the reference (originator) medicinal product.[33] Bioequivalence is thus established during the marketing authorisation procedure, which usually precedes the application for pricing and reimbursement. However, it has been reported that, in some cases, the pricing and reimbursement authorities require additional data and proof of bioequivalence beyond the elements already assessed by marketing authorisation bodies. Such duplicate assessments of scientific evidence examined during the marketing authorisation process, even if limited to specific elements of safety or bioequivalence, necessarily slow down the pricing and reimbursement procedure and the effective launch of generic medicines. In addition, the sector inquiry stressed that these additional requirements provide a tool to originator companies to intervene before the pricing and reimbursement authorities and further delay the procedure.[34]
- Patent linkage*: EU law does not foresee any examination of the patent status of the reference product in order to grant a marketing authorisation to a generic medicine. Nevertheless, in some countries, patent linkage practices have been identified in the framework of pricing and reimbursement procedures. The sector inquiry highlighted cases in which the pricing and reimbursement authorities refused to issue pricing and reimbursement decisions unless the applicant could demonstrate that the generic product would not infringe valid patents. Originator companies were also said to intervene before the pricing and reimbursement authorities, or to initiate proceedings in national courts against these authorities, in order to stall the pricing and reimbursement procedures on account of an alleged patent violation.[35] Such interventions can relate to other specific rights under pharmaceutical law, such as the supplementary protection certificate, market exclusivity or data exclusivity.

Delays in establishing the pricing and reimbursement status of generic medicines have a significant impact on competition in the pharmaceutical market. Indeed, even after loss of exclusivity*, originator products continue to benefit from *de facto* exclusivity as long as no corresponding generic product has been launched on the market. This situation not only affects patients and generic companies but also national healthcare systems (figure 7).

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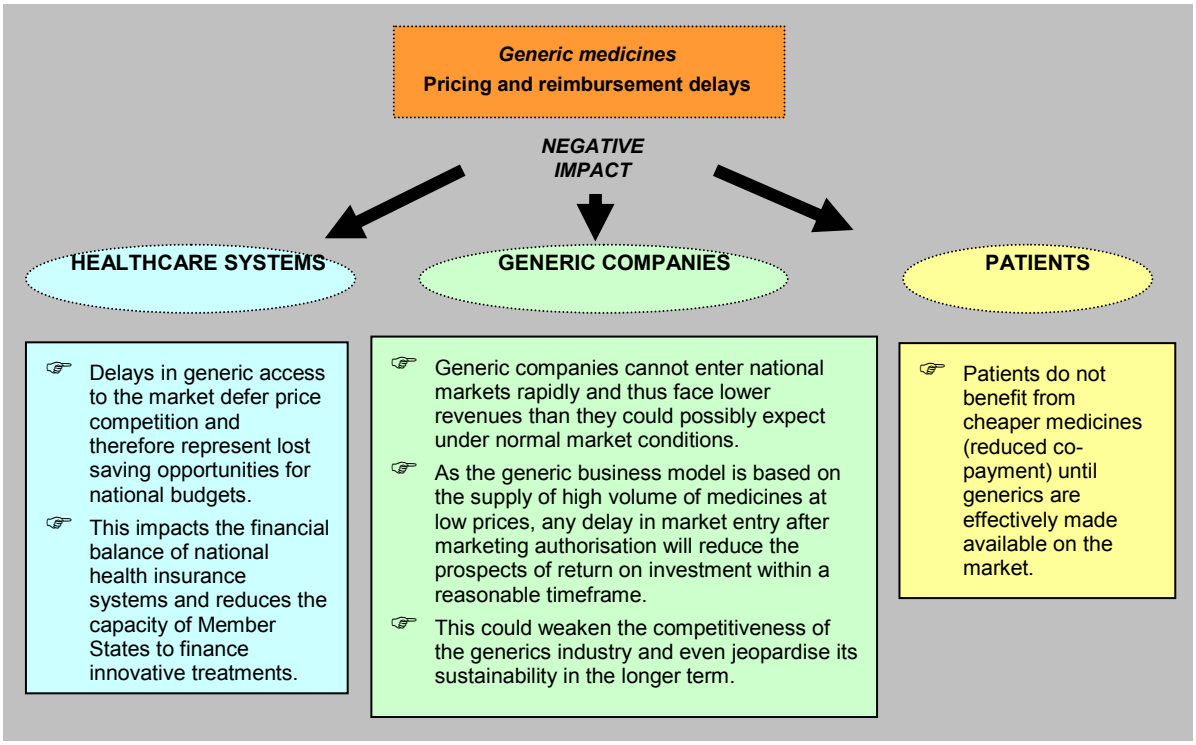
[32] Commission Communication on the Pharmaceutical Sector Inquiry, Section 4.4; Staff Working Document, §1434.

[33] Article 10 of Directive 2001/83/EC as amended.

[34] Commission Communication on the Pharmaceutical Sector Inquiry, Section 4.4; Staff Working Document, §1597.

[35] Commission Communication on the Pharmaceutical Sector Inquiry, Section 4.4; Staff Working Document, §446 et seq.

Figure 7: ***Impact of pricing and reimbursement delays – Generic products***



3.2.3. Adequacy and effectiveness of the directive in a changing context

Directive 89/105/EEC was adopted at the end of the 1980s in consideration of the market conditions and national policies which prevailed at the time. It was designed to address all measures enacted by Member States, whether laid down by law, regulation or administrative action, to control the pricing and reimbursement of medicines.[36] The provisions of the directive were drafted on the basis of the main procedural mechanisms established in those days by Member States to control public health expenditure on medicines (table 2).

Table 2: Main types of national measures described in Directive 89/105/EEC

Types of measures	⇨	Characteristics
Administrative price setting	⇨	Mechanisms to approve or modify the prices of medicines on the basis of individual applications by marketing authorisation holders
General or targeted price freezes	⇨	Freezing of pharmaceutical prices to avoid global increases in pharmaceutical expenditure
Positive and negative reimbursement lists	⇨	Listing mechanisms to determine which medicinal products should be included in – or excluded from – the scope of the health insurance system
Profit control systems	⇨	Mechanism which consists in setting maximum profit targets for pharmaceutical companies (only used in the United Kingdom to date).

[36] Directive 89/105/EEC, Article 1.

Even though the types of measures described in the directive are still frequently used, Member States have devised increasingly complex and detailed mechanisms to control pharmaceutical expenditure and promote the financial stability of their healthcare systems.[37] In practice, many of the national pricing and reimbursement procedures established by Member States differ from or go beyond the mechanisms specifically identified in the directive. This raises challenges in terms of legal interpretation, implementation and enforcement of the directive (section 3.2.3.1). Furthermore, due to the significant evolution of the pharmaceutical market, the relationship between the directive and some of the most innovative pricing and reimbursement policies has become unclear (section 3.2.3.2). Finally, the existing regulatory framework may not reflect the specificity of recent medical advances (section 3.2.3.3).

3.2.3.1. Issues of legal interpretation, implementation and enforcement

Directive 89/105/EEC has frequently given rise to interpretation debates, either in the context of infringement investigations by the European Commission or in the framework of cases submitted to the Court of Justice. Different factors explain the recurrence of legal interpretation issues:

(a) National pricing and reimbursement measures do not necessarily match the processes described in the directive

Since Member States are free to organise their health insurance systems in the way that best suits their needs and objectives, national pricing and reimbursement measures are often much more sophisticated than actually described in the provisions of the directive.

Examples:

- Article 6 of Directive 89/105/EEC lays down specific procedural obligations for the inclusion of medicines in a positive reimbursement list. Nevertheless, some Member States have established reimbursement systems comprising several lists or categories of reimbursement, with different reimbursement conditions attached to each category. This regularly triggers controversies as to how the provisions of the directive apply to such systems. In one of its judgements, the Court of Justice considered that marketing authorisation holders must be given the possibility to file an application for the inclusion of their medicinal products into any of the reimbursement categories (including the most favourable ones) and must receive a motivated decision on this application within 90/180 days.[38] Member States cannot circumvent their obligations under the directive by creating one reimbursement category which respects the requirements of the directive, while other reimbursement categories would not comply with these requirements.

- Some countries only operate one reimbursement list but, when deciding on the inclusion of a given medicine in their health insurance system, they also define the specific conditions of reimbursement of this product (for example, the amount or rate of reimbursement applicable to the product). In line with the case-law of the Court of Justice, the Commission has consistently argued that both the decision to include a product in the health insurance system and the specific conditions attached to its reimbursement must comply with the requirements of the directive – i.e. they should be motivated on the basis of objective and verifiable criteria defined in national legislation. Otherwise, the objectives of the directive could be easily circumvented since the competent authorities could grant symbolic reimbursement to some products and full reimbursement to others without explaining the reasons for such decisions. This interpretation has often been put into question by Member States in the framework of infringement investigations.

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[37] For an overview of pricing and reimbursement systems in EU countries, see the studies mentioned in footnotes 6 and 7, as well as ÖBIG (2009) Pharmaceutical Pricing and Reimbursement Information (PPRI) - http://ppri.oebig.at/index.aspx?Navigation=r%7C2-

[38] Case C-311/07 Commission v Austria [2008] ECR I-113.

Member States have also adopted general cost-control mechanisms that are not based on individual applications by marketing authorisation holders. This stands in contrast with the main provisions of the directive, which are built on the assumption that pricing and reimbursement processes are initiated with the introduction of administrative applications.

Examples:

- A majority of Member States have introduced so-called internal reference price systems* in view of containing pharmaceutical expenditure.[39] Such systems consist in establishing groups of medicines considered similar or therapeutically equivalent and defining a "reference price" (i.e. maximum reimbursement limit) for each of these groups. Under reference price systems, products are covered by health insurance up to the maximum limit set for the group to which they belong. The creation of reference groups or the inclusion of a specific product in an existing group usually has an impact on the level of reimbursement of all products in the group. Reference price systems are not mentioned as such in Directive 89/105/EEC, so that the extent and modalities of their coverage has been a regular subject of disagreement with Member States.

- Another cost-containment mechanism frequently used by Member States but not specifically addressed in Directive 89/105/EEC consists in defining maximum reimbursement budgets for individual pharmaceutical companies associated with so-called pay-back or claw-back mechanisms: if the reimbursement budget allocated to a company is exceeded, the company has to pay back to the health insurance authorities the excess payments received.[40] Different modalities of such systems exist across Europe. Their transparency requires clear criteria to be defined for the determination of the reimbursement budget allocated to each company and for the calculation of any over-expenditure. Nevertheless, the application of the directive to claw-back systems has been a contentious issue in bilateral discussions with the Member States.

In addition, the application of the directive to medicines used in hospital has regularly raised uncertainties due to the specific ways in which medicines for hospital use are purchased or included in health insurance systems. The directive covers "medicinal products for human use" within the meaning of EU law[41], including therefore medicines used in hospitals. However, controversies have occurred as to whether and how medicines for hospital use are subject to the requirements of the directive.

Examples:

- In some Member States, hospital lists or formularies are drawn up at national or regional level to determine which medicines may be purchased and used by hospitals in the framework of the health insurance system. Such formularies are equivalent to positive reimbursement lists and the Commission services have always considered that they are subject to the transparency obligations of the directive. The setting of maximum prices for hospital medicines, which is required by some countries, would also fall within the scope of the directive (even if hospitals may then be free to acquire these medicines at a lower price). However, the applicability of the directive in such cases has been questioned by some Member States.

- Tendering procedures are commonly used by hospitals or groups of hospitals to acquire the medicines they need at lower prices. Whether such procedures constitute national measures to control the prices of medicines (thus falling within the scope of the directive) is questionable: they are mainly purchasing methods used for the acquisition of goods by hospitals. In addition, when tendering procedures are carried out by public hospitals that are contracting authorities within the meaning of public procurement law, they are subject to specific public procurement rules. Nevertheless, the relationship between Directive 89/105/EEC and the purchase of medicines by hospitals has often been contentious issue.

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39 Analysis of differences and commonalities in pricing and reimbursement systems in Europe, p. 83.

40 *Ibid*, p. 105.

41 Directive 2001/83/EC (formerly Directive 65/65/EEC) as amended.

(b) Pharmaceutical cost-control policies affecting the internal market go beyond pricing and reimbursement measures

National measures regulating the pricing and/or the reimbursement of medicines are only one way to control pharmaceutical expenditure. Such measures are usually referred to as "supply-side" practices. Another way to limit spending is to manage the volume of medicinal products prescribed and dispensed to patients. All Member States therefore adopt measures to steer the decisions of the three main actors influencing the demand and utilisation of medicines, namely physicians (responsible for prescribing), pharmacists (responsible for dispensing) and patients (final consumers). Such measures are traditionally referred to as "demand-side" practices. Like supply-side measures, demand-side practices have the potential to disrupt the internal market: the conditions of prescription and delivery of a given medicinal product affect its level of consumption and may amount to a partial or total exclusion from the market.

Example:

☞ Many Member States have introduced rules or incentives for good prescribing practices by doctors in order to control the utilisation and consumption of medicines.[42] In a preliminary question referred to the Court of Justice, a national court in the UK enquired whether a scheme offering financial incentives to doctors to prescribe specifically-named medicines conflicts with EU legislation prohibiting the advertising of prescription medicines (Directive 2001/83/EC, as amended). In its judgement, the CJEU concluded that such measures do not constitute a form of advertising prohibited by EU law. However, it considered that a system of financial incentives to doctors to prescribe specifically-named medicines must comply with the provisions of Directive 89/105/EEC.[43] Pricing and reimbursement measures are therefore defined broadly by the Court: they cover all measures intended to promote the financial stability of the health insurance systems. The above-mentioned judgement indicates that the directive also applies to demand-side measures aimed at health professionals, which was not necessarily apparent from the text of the directive.

(c) Some provisions of the directive may be open to interpretation

The Commission's experience in the enforcement of the directive has shown that the wording of some of its provisions is not sufficiently clear or precise, thus allowing for divergent interpretations and impacting the effectiveness of the directive.

Examples:

☞ Key provisions of Directive 89/105/EEC provide that pricing and reimbursement decisions must be adopted and communicated to the applicant within 90/180 days. The Commission services have always considered that these time-limits apply not only to the adoption of the decisions but also to their effective entry into force. Otherwise, the directive would be deprived of its effectiveness as Member States could adopt and communicate decisions to the applicants within 90/180 days, while postponing their entry into force to a later date. However, this interpretation has been challenged by different Member States (in particular countries requiring the formal publication or adoption of general price/reimbursement lists before the individual decision communicated to the applicant can take legal effect).

☞ Article 4 requires that, in the event of a price freeze imposed by the competent authorities, the Member State concerned should carry out a review to ascertain whether the macro-economic conditions justify that the freeze be continued unchanged. The interpretation of the terms "macro-economic conditions" has given rise to controversies. In several recent judgements, the Court of Justice highlighted the margin of discretion which Member States enjoy in defining the elements to be taken into account as part of the examination of the macro-economic conditions.[44]

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42 *Ibid*, p. 116.

43 Case C-62/09 Association of the British Pharmaceutical Industry, *nyr*.

44 Cases C-352/07 Menarini [2009] ECR I- 2495, and C-471/07 AGIM, *nyr*.

In its role of guardian of EU law, the Commission has been enforcing compliance with Directive 89/105/EEC through individual infringement proceedings pursuant to Article 258 TFEU (formerly Article 226 EC). Several of these proceedings have resulted in judgements by the Court of Justice. National courts have also made a number of references to the Court in accordance with Article 263 TFEU (formerly Article 234 EC). The Court of Justice has therefore considered various cases relating to the legal interpretation of the directive and its implementation by Member States. A summary of this case-law is provided in Annex 6.

In its judgements, the Court followed a consistent line of interpretation relying on the general objectives and principles of the directive rather than merely on the wording of its provisions. The settled case-law provides that the directive must be interpreted in light of its objectives so as to ensure its effectiveness (*'effet utile'*). An extensive interpretation must prevail because the directive is linked to one of the fundamental freedoms of the European Union, namely the free movement of goods. In this context, the Court has consistently held that the directive applies to *any* national measure to control the pricing and reimbursement of medicinal products. The scope of the directive therefore extends beyond the measures specifically identified in its provisions: all national measures to control the pricing and reimbursement of medicines must comply with the procedural obligations laid down in the directive. The Court considers that any other interpretation would deprive European law of its effectiveness because Member States could easily circumvent the obligations of the directive and therefore compromise the realisation of its objectives.

The Commission relies on this broad interpretation when controlling the application of the directive by Member States. Nonetheless, in practice, the enforcement of the directive has always been a difficult task. The investigation procedures conducted by the Commission and the cases examined by the Court of Justice show that Member States tend to advocate a restrictive interpretation of the existing EU rules, at odds with that of the Court. National authorities regularly dismiss the application of the directive to their national pricing and reimbursement measures. In most of the legal investigations carried out by the Commission, they interpreted the directive in relation to the precise wording of its provisions rather than in light of its broad scope and general objectives. An argument frequently used by the competent national authorities is that the obligations of the directive do not apply to the specific pricing and reimbursement measures adopted in their country because such measures are not specifically addressed in any article of the directive. In some cases, Member States were willing to implement the directive but failed to see concretely how this should be done in the context of their specific pricing and reimbursement system.

A major implication of the Court's extensive interpretation of Directive 89/105/EEC is that the mere textual transposition of its provisions into national legislation does not guarantee the effective compliance of all pricing and reimbursement measures with the obligations of the directive. For example, even if parts of a national pricing and reimbursement system (i.e. those corresponding to the processes described in the directive) are in line with the requirements of the directive, EU legislation may be circumvented if other pricing and reimbursement measures (e.g. innovative or complex measures not mentioned as such in the directive) are not accompanied by similar procedural obligations. An adequate implementation of the directive therefore requires a case-by-case analysis of the national measures foreseen, as well as the introduction in national law of specific procedural requirements going beyond the actual transposition of the provisions of the directive.

In this regard, it should be noted that the directive includes an obligation for Member States to communicate to the European Commission the texts of national pricing and reimbursement

measures, as well as any amendments or modifications made to them.[45] Even though pricing and reimbursement systems are subject to frequent amendments in all EU countries, national authorities scarcely abide by their obligation of notification. It is also worth mentioning that the obligation of notification applies to national measures after their formal adoption. This means that potential incompatibilities with the directive or interpretation issues can only be detected at a late stage, usually on the basis of complaints from economic operators, unless the Member State concerned initiates dialogue with the Commission and the other Member States during the preparation of its national measures. In the Commission's experience, such preventive dialogue has taken place on very rare occasions.

3.2.3.2. Relationship with innovative pricing and reimbursement mechanisms

The broad interpretation of the provisions of Directive 89/105/EEC recognised by the Court of Justice aims to ensure the flexibility and adaptability of the EU legal framework in the context of diverse and evolving national policies. Nevertheless, in response to the evolution of pharmaceutical expenditure, Member States have developed alternative pricing and reimbursement mechanisms which fundamentally differ from the procedural approaches envisaged by the directive.

Examples of innovative pricing and reimbursement mechanisms

- Managed entry agreements*: in addition to their traditional pricing and reimbursement methods, some Member States have introduced innovative schemes aimed at facilitating access to new medicines by enabling their inclusion in health insurance systems under specific conditions. Instead of relying on administrative decisions, these schemes are based on the negotiation of contractual agreements between manufacturers and health insurance bodies or payers. These agreements are known under different names such as managed entry agreements, price-volume agreements, risk-sharing agreements, outcome or performance-based agreements, etc.[46] Managed entry agreements are implemented in several countries, for instance Estonia, Hungary, Germany, France, Italy, Lithuania or the United Kingdom. An overview of different managed entry agreements and of their characteristics is provided in Annex 7.
- Tendering by social security systems: several EU countries have introduced tendering procedures to determine the prices and reimbursement conditions of certain categories of medicinal products (mainly off-patent products). These procedures should be distinguished from tendering by hospitals: they are carried out by the health insurance institutions in view of determining, within a group of products considered as therapeutically equivalent, which specific medicine(s) will be covered by the health insurance system and at what price. Such tendering mechanisms have been used mainly in Germany and The Netherlands. A more detailed description of these innovative schemes is provided in Annex 8.

The mechanisms described above respond to a very different logic from the administrative decision-making procedures covered by Directive 89/105/EEC. They are also subject to specific rules such as legislation on public procurement and contract law. This results in uncertainty as regards the scope of the directive and its relationship with other relevant legal instruments. In particular, it is not always clear whether the principles of procedural transparency and timely access pursued by the directive apply in conjunction with, or are superseded by, the law applicable to public tenders or contractual agreements.

3.2.3.3. Adequacy to address medical developments

Scientific developments in the healthcare sector could create further challenges in the context of pricing and reimbursement decisions, with a potential impact on the internal market for

[45] Article 11.2 of Directive 89/105/EEC.

[46] In order to use consistent terminology, this report will use the term "managed entry agreements".

medicinal products. For instance, so-called "personalised medicines", linked to advanced screening technologies such as pharmaco-genomics, are reaching the European market and may become important therapeutic options in the future. These new therapeutic approaches use patient-specific information to ensure that patients will benefit from the most appropriate treatment. Personalised medicines recognise that the optimal treatment or prevention of a medical condition differs across individual patients as a result of genetic or environmental factors which some patient groups are more exposed to than others.

One of the characteristics of these targeted medicines is that they closely associate medicinal products with medical devices such as in-vitro diagnostic tests. Their use is dependent upon the availability of both the companion diagnostic and the medicine itself. In terms of pricing and reimbursement, this implies that both the companion diagnostic and the medicine must be priced and/or reimbursed in order to provide effective access to the treatment. Any disconnection between pricing/reimbursement decisions for the companion diagnostic and for the associated medicinal product is susceptible to create barriers to trade and market access delays. However, at present, many EU countries apply different processes to determine, on the one hand, the price and reimbursement status of medicines and, on the other hand, the inclusion of medical devices and in-vitro diagnostic tests in the health insurance system.

It is expected that personalised medicines will represent an increasing share of the pharmaceutical market in the coming years. Less than 10% of medicines in company portfolios can currently be considered as personalised medicines, but this may reach 50% by 2014 and even more than 80% in the oncology field.[47] In the United States, PwC projects that the market for personalised medicines will grow from US$ 225-232 billion in 2008 to US$344-452 billion in 2015. The core segment of the market – primarily diagnostic tests and targeted therapies – is estimated at $24 billion in 2008 and expected to grow by 10% annually to $42 billion by 2015.[48]

Consequently, the adequacy of the directive to address the emergence of personalised medicines requires examination in the context of the present review.

3.2.4. Transparency of pricing and reimbursement procedures for medical devices

In accordance with its Article 1, Directive 89/105/EEC applies to medicinal products as defined in Directive 2001/83/EC (formerly Directive 65/65/EEC). Other healthcare products, such as medical devices, are excluded from the scope of the directive. Nevertheless, medical devices within the meaning of EU law[49] can, similarly to medicinal products, be subject to price regulation and require decisions regarding their inclusion in the scope of national health insurance systems.

The medical devices market is very heterogeneous and differs substantially from the pharmaceutical market in terms market players, characteristics and variety of products and regulation. The medical devices sector is mainly composed of small companies (80% are

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47 Ministerial Industry Strategy Group (2009) Forum on Personalised Medicines: Summary of Discussions. http://www.mhra.gov.uk/home/groups/es-policy/documents/websiteresources/con065593.pdf

48 PriceWaterhouseCoppers (2009) The New Science of Personalised Medicines: Translating the Promise into Practice: http://www.pwc.com/us/en/healthcare/publications/personalized-medicine.html.

49 Article 1 of Directives 90/385/EEC, 93/42/EC and 98/79/EC.

SMEs). Unlike the pharmaceutical sector, it is characterised by extremely rapid innovation, with an average product lifetime and investment recovery period of approximately 18 months. There are also significant differences between medicines and medical devices in terms of price control and modalities of coverage by national health insurance systems. In particular, many medical devices are not reimbursed as such to the patients: they are instead covered by health insurance systems as part of the global health interventions practised by health professionals.

Annex 9 provides a brief overview of the structure and main characteristics of the medical devices market. It highlights the growing economic importance of medical devices in the EU and the significant increase in public expenditure on these products in recent years. Some pricing and reimbursement practices used by Member States with respect to medical devices are also described on the basis of selected case studies.

The functioning of the internal market in medical devices may be affected by national rules governing their prices or their inclusion in health insurance systems. From a legal perspective, Articles 34-36 TFEU relating to the free movement of goods apply to trade in medical devices. Beyond the general safeguards provided by the provisions of the Treaty, the more specific requirements of Directive 89/105/EEC currently do not apply to medical devices. In particular, when Member States determine the price and reimbursement status of medical devices by way of administrative procedures, they are not subject to any obligation to issue their decisions within specific time-limits.

During stakeholder discussions organised by DG Enterprise and Industry on the future of the medical devices sector (2009), participants stressed the impact of public funding systems on innovation dynamics and highlighted the necessity to examine ways to increase transparency in the pricing and reimbursement decisions pertaining to medical devices.[50] The relevance of Directive 89/105/EEC to medical devices should be examined in this context.

3.3. Subsidiarity

Directive 89/105/EEC is based on Article 114 TFEU (formerly Article 95 EC), which foresees the adoption of measures for the establishment and functioning of the internal market. The fundamental objective of the directive is to ensure that market operators can verify that national measures do not constitute barriers to trade prohibited by the Treaty. The directive has as its underlying principle the idea of minimum interference in the organisation by Member States of their domestic social security policies[51].

In accordance with the principle of subsidiarity, the EU should act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level. National pricing and reimbursement decisions have a clear transnational impact linked, in particular, to the potential disruption they might cause to the internal market in medicinal products. The proper functioning of the internal market therefore requires timely and transparent decisions regarding the pricing of medicinal products and their inclusion in the scope of health insurance systems.

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[50] http://ec.europa.eu/consumers/sectors/medical-devices/competitiveness/exploratory-process/index_en.htm

[51] Case C-245/03 Merck, Sharp & Dohme [2005] ECR I-637, point 27.

As described above, the existing regulatory framework raises uncertainty and implementation challenges due to the evolution of the pharmaceutical market and the concomitant development of national cost control policies over the past twenty years. Pricing systems and health insurance schemes are highly complex and specific to each country. The application of Directive 89/105/EEC may require specific legal reasoning depending on the characteristics of different pricing and reimbursement systems. Despite the broad legal interpretation provided by the Court of Justice, the notion of procedural transparency is understood differently in each Member State so that action by individual Member States would not provide sufficient guarantees of procedural transparency for market operators.

The Commission is fully aware of the existence of broader challenges linked to the fragmentation of pharmaceutical pricing and reimbursement systems in the EU. The power of Member States to regulate the prices of medicines and decide on their inclusion in social security systems inevitably results in price differences and variations in the public coverage of medicines across Europe. This creates discrepancies in the availability and affordability of medicinal products in the Member States and, therefore, inequalities in access to medicines for EU patients. In addition, the diversity of pricing and reimbursement systems has important repercussions on market dynamics, research and development (R&D) and the competitiveness of the pharmaceutical industry in Europe.

Nevertheless, these issues are inextricably linked to the exercise of national competences recognised by the EU Treaty. The responsibility of the Member States for the organisation and financing of their healthcare systems must be respected. This means that discrepancies within the EU can only be addressed by fostering voluntary cooperation between national authorities and the various actors of the pharmaceutical sector. The Commission has already undertaken several initiatives to this end, including the High Level Pharmaceutical Forum, the Process on Corporate Responsibility in the field of Pharmaceuticals and the collaboration in the field of health technology assessment* (see Section 3.3 below).

3.4. Baseline scenario: how the problem would evolve under present policies

The problems encountered today in terms of market access delays and reduced effectiveness of the EU regulatory framework mainly find their roots in the evolution of the pharmaceutical market and in the diversification of national pricing and reimbursement policies. These developments increasingly result in a mismatch between Directive 89/105/EEC and the national measures it is meant to address, thus generating ambiguity, legal uncertainty and implementation challenges.

As the guardian of EU law, the Commission has been seeking to ensure the enforcement of Directive 89/105/EEC and to facilitate its effective implementation by the Member States based on the case-law of the European Court of Justice. These efforts have essentially relied upon two instruments:

- First, bilateral dialogue with individual Member States during the investigation of complaints pointing to an incorrect implementation or application of the directive (infringement proceedings pursuant to Article 258 TFEU); and

- Second, regular multilateral dialogue with Member States in the framework of the consultative Committee established by Article 10 of the directive (Transparency Committee).

Bilateral dialogue in the framework of infringement investigations has facilitated the proper application of the directive in a number of concrete cases. In parallel, meetings of the Transparency Committee – held once to twice a year – have provided an open discussion platform enabling the Commission services to exchange views concerning the directive and its implementation. In this framework, the Commission has regularly presented the case-law of the Court of Justice and circulated working documents on the interpretation of the directive.

Nevertheless, the mere continuation of current policies would not solve the problems identified in section 2.3:

- *Delays in pricing and reimbursement decisions*: the Pharmaceutical sector inquiry and the comments received during the public consultation point to persistent delays in a number of Member States. In addition, unnecessary delays as regards generic medicines are bound to persist as long as some countries consider the time-limits of 90/180 days as an appropriate benchmark for the pricing and reimbursement of generic medicines.

- *Adequacy and effectiveness of the directive*: given the constant evolution of national pricing and reimbursement policies, the gap between the 'historical' provisions of the directive and increasingly innovative and complex national measures is likely to remain and even to further expand. Existing provisions are either ambiguous or outdated in light of the much broader range of instruments used nowadays by Member States to control pharmaceutical costs. The continued growth in pharmaceutical sales and consumption, on the one hand, and the steady increase in public expenditure on medicines, on the other hand, herald that new pricing and reimbursement methods will continue to be devised by Member States. The issues of legal interpretation and implementation presented in previous sections will therefore persist if no initiative is taken.

- *Inclusion of medical devices*: the opportunity and feasibility of extending the scope of the directive to medical devices would remain unaddressed under the current policy framework.

4. OBJECTIVES

4.1. Overall objective

The overarching objective of this initiative is to ensure the transparency of national measures intended to regulate the prices of medicinal products, to manage their consumption or to establish the conditions of their public funding. This goal shall be pursued with due regard for the responsibility of the Member States to adopt such measures and to determine their actual substance. This means that any form of interference with national approaches towards price setting and reimbursement (for instance, decisions to use health technology assessment*, external reference pricing*, public tendering, managed entry agreements*, etc.) shall be excluded.

The aim is limited to providing effective procedural safeguards in order to avoid obstacles to pharmaceutical trade prohibited by the provisions of the EU Treaty relating to the free movement of goods. EU policies should contribute to strengthening the internal market,

thereby improving the health of European citizens and the competitiveness of the pharmaceutical industry. The same general goal is pursued with respect to medical devices.

4.2. Specific and operational objectives

The specific objectives are closely linked to the issues and underlying causes identified in section 2. They are described in table 3.

Table 3: Specific and operational objectives

General policy objective
Ensure the transparency of national measures intended to regulate the prices of medicinal products, manage their consumption or establish the conditions of their public funding, whilst respecting the responsibility of the Member States to adopt such measures and freely determine their substance.

Issues	Specific objectives	Operational objectives
Delays in time to market medicinal products ➢ Market access delays for innovative medicines ➢ Market access delays for generic medicines	A. Ensure timely pricing and reimbursement decisions	*a) Ensure the effectiveness of the time-limits* Ensure that national procedures leading to pricing and reimbursement decisions, from the inception of the decision-making process to the effective entry into force of the decisions, respect specific time-limits. *b) Avoid unnecessary delays for generic medicines* Ensure that unnecessary hurdles to the swift adoption of pricing and reimbursement decisions are effectively removed. *c) Improve current market access delays for innovative medicines* Ensure that the timeframe for the pricing and reimbursement of innovative medicines is kept to a minimum
Effectiveness of the existing regulatory framework in a changing context ➢ Issues of legal interpretation, implementation and enforcement ➢ Relationship with innovative pricing & reimbursement policies ➢ Adequacy to address medical developments	B. Ensure the adequacy and effectiveness of the directive in light of national pricing and reimbursement systems and market evolution	*a) Clarify the scope of the directive* Ensure legal certainty regarding the scope of the directive and the national measures it addresses. In accordance with the case-law of the Court of Justice, any decision to regulate the prices of medicines, to manage their consumption or to establish the conditions of their public funding should comply with minimum procedural requirements (appropriate statement of reasons, decisions based on objective and verifiable criteria which do not discriminate against imported medicinal products, availability of legal remedies). *b) Ensure consistency between the transparency requirements of the directive and the current policy environment* Ensure legal clarity concerning the procedural rules applicable to innovative pricing and reimbursement measures. *c) Facilitate the effective implementation and enforcement of the directive* Ensure that mechanisms are in place to guarantee the effective implementation and enforcement of the procedural obligations laid down in Directive 89/105/EEC as interpreted by the Court.
Transparency of pricing and reimbursement measures for medical devices	C. Possible extension of the scope of the Transparency Directive to medical devices	*a) Necessity of an extension* Determine whether procedures governing the pricing and reimbursement of medical devices require specific transparency rules. *b) Feasibility of an extension* Determine if the minimum procedural requirements of the directive may be applied or adapted to the medical devices sector.

4.3. Consistency with other EU policies and horizontal objectives

The objectives pursued under the present initiative tie in with the Commission's long-standing policies to strengthen the internal market in view of fostering industrial competitiveness, innovation, economic growth and employment in the EU. The importance of the Single Market as a vehicle of Europe's economic and social progress has been recently recalled in the Monti Report "A new strategy for the single market at the service of Europe's economy and society"[52] and confirmed with the adoption of the Single Market Act.[53]

The review of Directive 89/105/EEC must be seen in the context of the Commission's efforts to generate favourable conditions for a competitive pharmaceutical market that provides safe, innovative and accessible medicines to European citizens. The 2008 Communication on "Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector"[54] outlined a comprehensive strategy to encourage the sustainable development of the pharmaceutical industry in Europe. An important objective of this strategy is to make further progress towards a single market in pharmaceuticals, in particular by ensuring affordable and timely access to treatments for European citizens. The Commission announced in Objective 3 of the Communication that the application of Directive 89/105/EEC would be enhanced to ensure genuinely transparent and speedy pricing and reimbursement decisions.

The initiative also relates to the Commission's competition policies following the Pharmaceutical sector inquiry carried out at the initiative of DG Competition in 2008-2009. The sector inquiry demonstrated the significant impact of pricing and reimbursement processes on product launches and competition in the pharmaceutical market. It concluded that the Commission might examine the potential need to review Directive 89/105/EEC in order to facilitate timely market access for generic medicines and therefore improve competition in off-patent markets*.

Although pricing, reimbursement and the challenges of access to medicines are essentially a national competence, the Commission has for several years been engaged in fostering EU cooperation on these issues. They were at the heart of the High Level Pharmaceutical Forum launched in 2005 in collaboration with a wide range of stakeholders[55]. The conclusions of the Forum, endorsed in 2008 by the EU Health Ministers and pharmaceutical stakeholders, include a series of recommendations to ensure that pricing and reimbursement policies achieve the common goals of timely and equitable access to medicines for European patients, control of pharmaceutical expenditure and reward for innovation.

More recently, Commission Vice-President Antonio Tajani initiated a broad stakeholder Process on Corporate Responsibility in the field of pharmaceuticals. A key objective of this initiative is to enhance collaboration among Member States and pharmaceutical stakeholders in view of improving access to medicines in Europe through a Platform on access to medicines in Europe.[56] The platform discusses a number of concrete projects intended to

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52 http://ec.europa.eu/bepa/pdf/monti_report_final_10_05_2010_en.pdf

53 COM(2011) 206 final.

54 COM(2008) 666 final

55 http://ec.europa.eu/pharmaforum/

56 http://ec.europa.eu/enterprise/sectors/healthcare/process_on_corporate_responsibility/access_to_medicines_in_europe/index_en.htm#Projects

contribute to a responsible environment for access and facilitate, within the current legal framework, the pricing and reimbursement of innovative treatments after their marketing authorisation. Finally, voluntary cooperation between Member States on health technology assessment* is being taken forward in the framework of the EUnetHTA Joint Action[57] and will be formalised through the implementation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.[58]

Concerning the international dimension, it is worth mentioning that Directive 89/105/EEC has positive ramifications for the EU's trade policy because it sets an example of how to establish and enforce minimum procedural requirements on public bodies engaged in decisions on pricing and reimbursement. As many emerging economies run public healthcare insurance programmes and European companies often criticise the non-transparent nature of decisions and procedures (which in their view tend to favour local manufacturers), reference to the existing European provisions has proven to be a good instrument to promote minimum standards in trade negotiations.

5. POLICY OPTIONS

This section explains why two extreme options – namely the full harmonisation of pricing and reimbursement measures and the repeal of the existing directive – have been excluded from the scope of this analysis.

It then sets out different policy options in order to achieve the *specific* objectives described in Section 3. The options are presented in three sets (A, B, C) that each correspond to a specific objective. Within these three sets, there are sub-options that correspond to particular *operational* objectives. The following table links specific/operational objectives and options. It should be noted that the options are not necessarily mutually exclusive: several of them may be considered complementary and can therefore be combined.

Issues	Specific objectives	Operational objectives	Options
Delays in time to market medicinal products ➢ Market access delays for innovative medicines ➢ Market access delays for generic medicines	A. Ensure timely pricing and reimbursement decisions		A.1 A.2
		a) Ensure the effectiveness of the time-limits	A.3/a, A.3/b and A.3/c
		b) Avoid unnecessary delays for generic medicines	A.4/a and A.4/b
		c) Improve current market access delays for innovative medicines	A.5

[57] http://www.eunethta.net/

[58] OJ L.88, 4.04.2011, p. 45. Article 15 of Directive 2011/24/EU provides for the creation of a voluntary network connecting national authorities or bodies responsible for health technology in order to support and facilitate cooperation and the exchange of scientific information on HTA among Member States.

Effectiveness of the existing regulatory framework in a changing context ➢ Issues of legal interpretation, implementation and enforcement ➢ Relationship with innovative pricing & reimbursement policies ➢ Adequacy to address medical developments	B. Ensure the adequacy and effectiveness of the directive in light of national pricing and reimbursement systems and market evolution	a) *Clarify the scope of the directive* b) *Ensure consistency between the transparency requirements of the directive and the current policy environment* c) *Facilitate the effective implementation and enforcement of the directive*	B.1 B.2 B.3/a and B.3/b B.3/a and B.3/b B.4
Transparency of pricing and reimbursement measures for medical devices	C. Possible extension of the scope of the Transparency Directive to medical devices	a) *Necessity of an extension* b) *Feasibility of an extension*	C1 and C2

5.1. General options discarded at an early stage

5.1.1. Harmonisation of national pricing and reimbursement measures

Directive 89/105/EEC was initially foreseen as a first step towards the harmonisation of different national pricing and reimbursement measures. The recitals of the directive referred to it as *"a first step towards the removal of these disparities"* and stated that *"the further harmonisation of such measures must take place progressively"*. As explained in Section 2.2, initiatives towards further harmonisation have proved unsuccessful and the Commission's efforts to propose more far-reaching legislation were eventually abandoned in 1992.

The present evaluation takes place in very different legal context than the one prevailing in the late 1980s-early 1990s. The Treaty on the European Community, signed in Maastricht in February 1992, created a subsidiary role for the European Community in the field of public health which only aimed at facilitating cooperation between Member States and complementing national policies. It provided that *"Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care"*. The Member States' responsibility for the determination of pharmaceutical prices and the inclusion of medicines in the scope of their health insurance system was therefore enshrined in the Treaty. The new Treaty on the Functioning of the European Union (Lisbon Treaty) made this competence even clearer: Article 168(7) provides that the responsibilities of the Member States "*shall include the management of health services and medical care and the allocation of the resources assigned to them."* (our underlining).

Consequently, the Commission does not have the legal competence to propose legislation harmonising national pricing and reimbursement measures within the European Union. Similarly, any regulatory proposal aiming to introduce a common European price for medicinal products or to harmonise pharmaceutical prices across the EU would infringe the powers of Member States under the current Treaties. The option of further harmonisation has therefore been discarded.

5.1.2. Deregulation: repeal of Directive 89/105/EEC

The option of deregulation through the mere repeal of Directive 89/105/EEC has also been discarded at an early stage. It would indeed weaken the procedural safeguards provided to pharmaceutical companies in view of avoiding discriminatory treatment between domestic and imported medicinal products. This would clearly represent a step backward in the operation of the internal market.

If the directive were repealed, the provisions of the Treaty concerning the free movement of goods (Articles 34-36 TFEU) and the related case-law of the Court of Justice would continue to apply to national pricing and reimbursement measures. However, the provisions of the Treaty are more general and less far-reaching in terms of procedural transparency than those of the directive. It is in fact the very reason why the EU legislator decided to codify and reinforce the judgements of the Court of Justice in secondary legislation. For instance, the obligation for Member States to deliver pricing and reimbursement decisions within mandatory time-limits is imposed by the directive but not expressed as such in the Treaty or in the case-law of the Court with regard to the free movement of goods.

The positive evaluation of the directive provided by stakeholders during the public consultation confirms that the repeal of the directive would not be a sensible option (see Section 3.2.1 and Annex 1).

5.2. Objective A: Ensure timely pricing and reimbursement decisions

5.2.1. Policy option A.1: No further action

In a "no policy change" scenario, the time-limits of 90/180 days for pricing and reimbursement decisions would continue to apply to originator and generic products alike. Timely market access for originators would therefore depend on the effective implementation of the time-limits by Member States and on their enforcement by competent jurisdictions. It may also be improved by pursuing EU cooperation in the field of HTA. Tackling the issue of unnecessary delays with respect to generic products would require action by individual Member States.

5.2.2. Policy option A.2: Soft law

An alternative option to the status quo would be to rely on soft law in order to promote timely pricing and reimbursement decisions in the Member States. This option would involve the exchange of best practices between national authorities.

As explained above, Member States enjoy a large margin of discretion in the definition of their national pricing and reimbursement policies. In this context, some Member States have established schemes enabling them to implement the obligations of Directive 89/105/EEC in an effective manner. In particular, several countries have managed to ensure the swift pricing and reimbursement of medicines or to implement shorter administrative procedures for generic medicines.

5.2.3. Policy option A.3: Revision of the directive to improve the enforcement of the time-limits

Three options may be envisaged to facilitate the enforcement of the time-limits with respect to both originator and generic medicines. Although the first two are mutually exclusive, they may be combined with option three which is based on a different stringency level.

(1) Option A.3/a: Financial penalties in case of non-compliance with the time-limits for the inclusion of medicines in the health insurance system

As explained in Section 2, pricing and reimbursement decisions issued by Member States beyond the time-limits prescribed by Directive 89/105/EEC can delay patients' access to innovative or cheaper medicines but also entail important financial losses for pharmaceutical companies. Any pricing and reimbursement decision made beyond the time-limits entails damages to the applicant company. On this basis, the directive would establish that the affected company may claim compensation for these damages in the competent national courts. National jurisdictions would remain competent to determine the type and amount of the financial compensation to be granted in light of the elements of the case (e.g. specific payment rates based on the duration of the delay).

(2) Option A.3/b: Automatic inclusion of individual products in the health insurance system after the expiration of the time-limits and until a decision is adopted

Directive 89/105/EEC provides that, in the framework of applications to set or increase the price of a medicine, the marketing authorisation holder is entitled to market the product at the price proposed if no decision is made by the competent authorities within 90 days (except in case of requests for additional information to the applicant). This mechanism currently does not apply to reimbursement decisions.[59] A possible option to ensure compliance with the time-limits would therefore consist in applying a similar mechanism of tacit/automatic inclusion into reimbursement until the decision takes place: in the absence of decision on the inclusion of a medicine in the scope of the health insurance system within 90 days (or 180 days for both pricing and reimbursement), the product would automatically benefit from reimbursement (or pricing and reimbursement) under the conditions requested in the application until the competent authorities issue their decision.

(3) Option A.3/c: Obligation to communicate and publish reports on pricing and reimbursement approval times

This option would consist in requiring the regular publication at national level (for instance once a year), and the official communication to the Commission, of detailed reports concerning the actual time taken by Member States for pricing and reimbursement decisions, including information on the use of the "stop the clock" period. It would mainly aim at benchmarking the performance of Member States in order to encourage compliance with the time-limits laid down in the directive.

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[59] This was recognised by the Court of Justice in Case C-245/03 Merck, Sharp & Dohme [2005] ECR I-637.

5.2.4. Policy option A.4: Revision of the directive to avoid unnecessary delays for generic medicines

Two main actions can be proposed to avoid unnecessary delays in pricing and reimbursement decisions (see Section 3.2.2.2). These options aim to address the different causes of delays, so that they could be applied in combination:

(1) Option A.4/a: Shorter time-limits for pricing and reimbursement decisions concerning generic medicinal products

This option would consist in significantly reducing the time-limits of 90/180 days as regards the pricing and reimbursement of generic medicines when the originator already benefits from reimbursement based on a higher price.

(2) Option A.4/b: Prohibit patent linkage* and the duplication of assessments carried out during the marketing authorisation phase

Under this option, the directive would clarify that intellectual property issues should not be a barrier to pricing and reimbursement applications and should not be considered in the context of pricing and reimbursement procedures (e.g. patent linkage), thereby ensuring consistency with EU rules on marketing authorisations. It would also rule out any re-assessment of elements already evaluated during the marketing authorisation phase (e.g. bioequivalence, safety aspects).

5.2.5. Policy option A.5: Shorter time-limits for pricing and reimbursement decisions concerning originator medicines

Some Member States manage to comply with the current time-limits, including for highly innovative and complex products, and sometimes even make decisions regarding originator products in a quicker way. This tends to demonstrate that there could be room for improving the speed of national procedures. This option would therefore reduce the time-limits of 90/180 days as regards the pricing and reimbursement of originator products in order to speed up market access for innovative products.

5.3. Objective B: Ensure the adequacy and effectiveness of the directive in a changing context

5.3.1. Policy option B.1: No further action

This option would consist in leaving the current legislative framework unchanged and refraining from taking any further EU initiative beyond the existing policies. Under this baseline scenario, the situation would continue to be framed only by the existing provisions of the directive, applied in conjunction with the obligations of the Treaty and the judgements of the Court of Justice. Issues of interpretation or legal uncertainty would continue to be addressed on a case-by-case basis or through horizontal, voluntary dialogue with the Member States. Solutions to the interpretation and implementation challenges stemming from the evolution of the market and current national policies would depend on the rulings of the Court of Justice and on the willingness of the Member States to apply the principles set out by the Court in the context of their individual pricing and reimbursement system.

5.3.2. Policy option B.2: Soft law

To facilitate the implementation of the directive in the current context, a relevant policy option would be to strengthen cooperation between the competent national authorities, still in the framework of the Transparency Committee but going beyond the activities undertaken so far. This scenario would not propose additional binding legal measures: the aim would be to achieve better understanding of national policies, improved knowledge of their relationship with Directive 89/105/EEC and consistent implementation of the existing procedural rules in concrete cases.

Despite the Commission's efforts to involve the Transparency Committee in the interpretation and implementation of the directive, this consultative body has never fully played the prominent role originally assigned to it to facilitate the concrete application of the EU transparency rules. Nevertheless, many of the uncertainties and challenges impeding the operation of the directive could be addressed through increased collaboration with the competent national authorities. This clearly requires a more focused and structured dialogue between the Commission and Member States, leading to the adoption of concrete tools facilitating both the interpretation and the effective implementation of the principles established by the directive.

The following actions would be envisaged under this option:

- Exchange of best practices between national authorities
- Interpretative Communication concerning the implementation of the directive
- Implementation guidelines by the Commission services

5.3.3. Policy option B.3: Revision of the directive to align its provisions with major developments in the pharmaceutical market

(1) Option B.3/a: Minimal revision of the directive to reflect the case-law of the European Court of Justice

Under this scenario, the directive would be amended to integrate the different elements of interpretation put forward in the judgements of the European Court of Justice. This approach would confirm the necessarily broad interpretation of the existing transparency rules and clarify a number of technical aspects examined by the Court such as the notion of positive list, the practical application of the time-limits and the obligations of the Member States when freezing or reducing the prices of medicines. The inclusion within the scope of the directive of 'demand-side measures' to control or promote the prescription of specific medicinal products would also be made clear in line with the latest judgement of the Court (see Section 3.2.3).

(2) Option B.3/b: Extensive revision of the directive to bring it into line with the current pharmaceutical environment

Beyond the codification of the case-law of the Court of Justice foreseen in Option B.3/A, this approach would seek to align the provisions of the directive with major developments in the pharmaceutical market (See Section 3.2.3). This approach would require an overall rewording of the provisions of the directive on the basis of general principles (rather than specific procedures) as well as a number of technical adaptations to ensure that even the most

sophisticated procedures not currently foreseen in the directive and not examined by the Court are addressed by its provisions (e.g. internal reference pricing*, claw back mechanisms, decision-making systems based on HTA assessments – please refer to the examples provided in Section 3.2.3.1).

The revision would also clarify the interface between the directive and innovative pricing and reimbursement mechanisms as described in Section 3.2.3.2. Tendering procedures by public authorities (including public hospitals) are regulated by public procurement legislation, which provides specific transparency rules. This *lex specialis* should therefore take precedence and exclude the concomitant application of the Directive 89/105/EEC. Similarly, managed entry agreements* are based on a voluntary contractual relationship between pharmaceutical companies and public authorities in order to ensure early access to innovative medicines. They are either subject to contract law (for private law contracts) or to administrative law (for public law contracts).

Finally, the directive could address the specific issues linked to the emergence of personalised medicines (see Section 3.2.3.3) by requiring that coordination takes place between the domestic pricing and reimbursement authorities responsible for the pricing and reimbursement of the medicine, on the one hand, and those responsible for the associated medical device, on the other hand. However, this approach requires a careful analysis of impacts, which is carried out in Section 6.2.

5.3.4. Policy option B.4: Notification of draft national measures to facilitate the enforcement of the directive

As explained above (Section 3.2.3.1), the current system of ex-post notification of the national measures adopted by Member States does not allow for an effective monitoring of the implementation of the directive. This option would therefore consist in introducing a system of notification of draft national measures in order to enable the Commission to examine national proposals falling within the scope of the directive prior to their adoption. This preventive tool would promote early dialogue and facilitate the early detection of potential incompatibilities with the obligations of the directive.

Such notification and consultation systems have been in place for a long time in order to facilitate the functioning of the internal market. In particular, Directive 98/34/EC[60] requires Member States to notify to the Commission any draft technical regulation concerning products and information society services before they are adopted in national law. Directive 98/34/EC has been a cornerstone of the internal market for goods for more than twenty-five years. Nevertheless, it does not apply to national measures regulating the price of medicinal products and their inclusion in the scope of health insurance systems. A specific pre-notification mechanism would therefore be established.

[60] OJ L. 204, 21.7.1998, p. 37.

5.4. Objective C: Possible extension of the scope of the directive to cover medical devices

5.4.1. Discarded policy option: extension of the directive to the medical devices market as a whole

As discussed in Section 3.2.4, both the nature and structure of the medical devices market intrinsically differ from those of the pharmaceutical market. From the perspective of price regulation and health insurance coverage, the market for medical devices can be divided into three main segments:

(a) Medical devices sold over the counter (OTC), which are neither covered by public health insurance, nor subject to price regulation.

(b) Medical devices financed as part of a global health intervention: these devices are covered by public health insurance systems in an indirect way, i.e. as part of the health services provided by health professionals (the medical intervention/service and the devices used in the context of this intervention are covered globally). The products falling within this segment are usually aimed for use by healthcare professionals. Their price is not directly regulated: they are mostly procured through public tendering or negotiated directly by hospitals.

(c) Medical devices subject to price regulation and/or inclusion into the reimbursement system: these devices are subject to a pricing and 'listing' mechanism in order to be financed from public funds. The products falling within this segment are usually supplied directly to the patients in the framework of the national health insurance system.

These segments are not mutually exclusive: the same medical device may fall within different categories depending on its intended use. Nevertheless, this typology indicates that an extension of Directive 89/105/EEC to cover the entire medical devices market would not be a viable and realistic option. Indeed, segment (a) is not relevant to the directive and segment (b) relies on procedures of health insurance coverage which are not related to the product as such (meaning that these procedures relate to the provision of services and cannot be addressed in the framework of legal instruments regulating the internal market for goods). Only the third segment of the market undergoes pricing and reimbursement processes similar to those applied in the pharmaceutical sector. In their replies to the public consultation, most Member States and representatives of the medical devices industry confirmed that only segment (c) of the market might be relevant in view of an extension of the procedural rules currently applicable to medicines. The option of extending the scope of the directive to cover the medical devices market as a whole was therefore discarded at an early stage.

5.4.2. Policy option C.1: No further action

Under this "no policy change scenario", medical devices would remain outside the scope of the directive. National measures regulating the pricing and reimbursement of medical devices would still be subject to the provisions of the Treaty concerning the free movement of goods (Articles 34-36 TFEU) as interpreted by the Court of Justice.

5.4.3. Policy option C.2: Partial extension of the directive to a specific segment of the medical devices market

This option would consist in applying the principles and provisions of the directive to a limited segment of the medical devices market, namely medical devices subject to pricing and listing procedures in view of their coverage by health insurance systems on a "per product" basis. This scenario would imply an extension of the scope of the directive to cover medical devices supplied directly to patients in the framework of public health insurance systems.

6. ANALYSIS AND COMPARISON OF OPTIONS

In accordance with the objectives of Commission impact assessments, this section analyses the likely impacts of the different policy options. Considering the merely procedural nature of Directive 89/105/EEC, and given the Commission's intent to preserve its present objectives, no environmental impact has been identified in relation to the options analysed. This section therefore examines the main impacts from an economic and social perspective.

6.1. Objective A: Ensure timely pricing and reimbursement decisions

6.1.1. Analysis of impacts

As regards Objective A, the anticipated effects of the different policy options mainly relate to:

- Competition in the pharmaceutical market
- Public health budgets
- Patients' health
- Legal certainty and business predictability
- Compliance costs for public administrations
- Legal compliance and enforcement

Policy option A.1 - No further action: as stated above, this option is very unlikely to provide any effective solution to the issues of delayed pricing and reimbursement decisions (in particular for originator medicines) and of unnecessary delays as regards generic medicines, unless Member States take action to avoid such delays on an individual basis. The main consequences of pricing and reimbursement delays on pharmaceutical stakeholders have been described in Section 3.2.2. A more detailed analysis is provided hereafter.

Several factors can explain market access delays for originator medicines. These include not only lengthy pricing and reimbursement procedures but also company launch strategies in different EU markets. Based on the available data, analysts and researchers have so far been unable to break down the costs of delayed launches according to their origin. Nevertheless, the Pharmaceutical market monitoring report examined the foregone revenues of originator companies linked to the delayed launch of their products following marketing authorisation. In an estimate based on a sample of products, the authors found that economic losses for

innovative pharmaceutical companies can vary from 35 to more than 100 million EUR (in terms of present value of cash flows) for a single medicine.[61] These losses were considered significant in light of the development costs of new medicines, which are estimated at approximately 1 billion EUR on average. Pricing and reimbursement delays and the resulting financial losses can be particularly detrimental to SMEs as the economic viability of these companies is often dependent upon the limited number of products they have developed. For instance, SMEs in the biotechnology sector often develop one single biotechnology product, so that their financial sustainability can depend exclusively on the timely launch of this product in EU markets.

As explained in Section 3.2.2.1, delayed decisions concerning the pricing and reimbursement of originator medicines will not necessarily represent a net budgetary gain for public health budgets. The reduction in non-pharmaceutical spending resulting from the introduction of a new medicine may indeed be higher than the cost induced by the prescription of that medicine, but this conclusion is far from absolute and always depends on the characteristics of the medicine concerned.

The Pharmaceutical market monitoring report also gives indications of the welfare losses suffered by patients due to delayed access to originator medicines:

Welfare losses suffered by patients[62]

One way of estimating this welfare effect is the use of quality-adjusted life years (QALY's) which put a monetary value on the increase in quantity and quality of life lived as a result of a medical intervention. It is based on the number of years of life that would be added by the medical intervention. Each year in perfect health is assigned the value of 1.0 down to a value of 0.0 for death. If the extra years would not be lived in full health, then the extra life-years are given a value between 0 and 1 to account for this. The monetary value attached to a QALY differs per country and the concept of a QALY is sometimes criticized because it is based on a utilitarian principle and it does not reflect important values such as equity and societal preferences. Additionally, the QALY estimates depend on the viewpoint by which they are approached. Different viewpoints such as from the side of patient groups, taxpayers, average citizens, or even epidemiologists and health economists frequently result in different QALY estimates.

In a recent Dutch study, it is estimated that in the benchmark scenario (with a QUALY equal to €50 000) that the welfare effect of having access to new innovative medicines was €1.7 billion in 2006 in the Netherlands. Since the average delay in the introduction of a medicine in the market after registration was 7 months in that year in the Netherlands, it is estimated that this delay resulted in 2006 to €970 million (=€1.7 billion *7/12) foregone welfare gains. In the case of their lower scenario (QUALY = €20 000) they estimated that there would be no foregone welfare gains and in the case of the upper scenario (QUALY = €80 000) they estimated €2 million in foregone welfare gains.

Although we can not extrapolate the Dutch result to the other EU Member States, the estimate of €970 million in one year (2006) in one country (the Netherlands) of foregone welfare gains as a result of the delay between market authorization and market access (in this case 7 months) gives a first indication of the considerable order of magnitude of the welfare effect for the EU as a whole which could be achieved if the earlier described delays would be shortened. One could even argue that the negative welfare effect caused by the delay is in reality even considerably higher because R&D costs are not immediately responsive to the length of the delay and thus could be seen as "sunk costs".

Looking at the delays in time to market generic medicines, again irrespective of their origin, the Pharmaceutical sector inquiry demonstrated, based on a sample of medicines analysed

[61] Pharmaceutical market monitoring study, Volume I, p. 88. The methodology used for the analysis is described in Annex 1.

[62] Abstract from the Pharmaceutical market monitoring study, Volume I, p. 91.

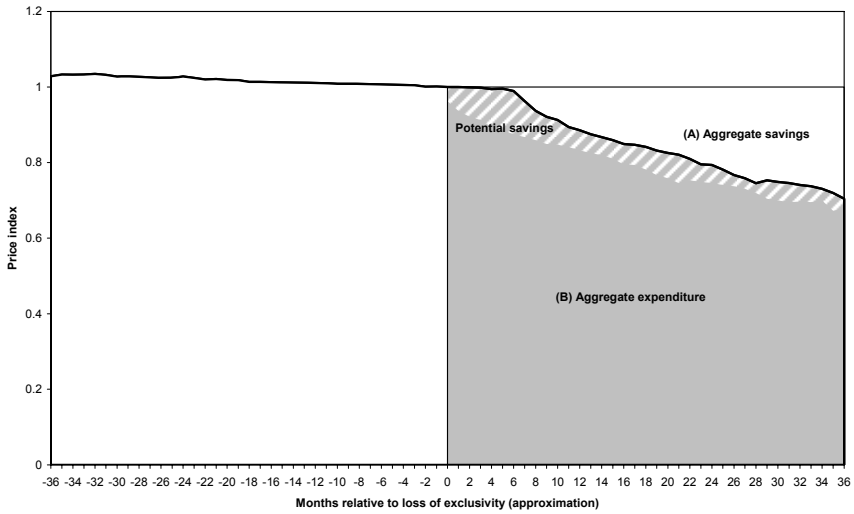
during the period 2000-2007, that it took more than seven months (on a weighed average basis) for generic entry to occur once originator medicines lost exclusivity*.[63] It concluded that "*savings due to generic entry could have been 20% higher than they actually were, if entry had taken place immediately following loss of exclusivity. According to the in-depth analysis of this sample, the aggregate expenditure amounting to about € 50 billion for the period after loss of exclusivity would have been about € 15 billion higher without generic entry (evaluated at constant volumes). However, additional savings of some € 3 billion could have been attained, had entry taken place immediately.*"[64]

Financial losses suffered by health insurance systems[65]

In order to appraise the impact of these potential savings, these savings should be compared with the aggregate expenditure and savings on medicines for originator and generic products, on the sample investigated. These figures can again be measured, for each INN and country pair for the period between the date of loss of exclusivity (LoE) and December 2007. By considering the price index before expiry (equal to 1) with the price index as it developed over time with an average time to entry of seven months, the aggregate savings derived over the period between LoE and December 2007 due to generic entry can be estimated at about € 15 billion (white area A in figure 8 below), at constant (preexpiry) volumes. The aggregate expenditure (value sales) in the period between LoE and 2007, net of these savings, is in the order of € 50 billion (grey area B, including shaded surface). Therefore, the € 3 billion in savings should be compared to a universe worth an approximate € 50 billion. Had entry been immediate following LoE, this expenditure could have been € 3 billion (or 5%) lower (indicated by the shaded surface). Compared to the actual savings of € 15 billion, it can be concluded that savings could have been 20% higher than they actually were.

Figure 8: Aggregate value sales, aggregate savings for generic entry after seven months following LoE and potential savings if entry were immediate

(approximation; sample: E75 list; expiries in 2000 – 2006; all INNs with entry; weighted by INN; month 0 = LoE; index = 1 for price six months before LoE)



Source: Pharmaceutical Sector Inquiry

63 Commission Communication on the Pharmaceutical sector inquiry, Section 2.1.2; Staff Working Document, §191 et seq.

64 Commission Communication on the Pharmaceutical sector inquiry, Section 2.1.2; Staff Working Document, §217.

65 Abstract from the Staff Working Document on the Pharmaceutical sector inquiry, §219.

Policy option A.2 – Soft law: a positive element of this approach is that it would enable flexible solutions concerning the implementation of the time-limits, based on concrete experience from the Member States and in line with the principle of subsidiarity. At the same time, EU cooperation and implementation guidelines are by definition non-binding and can only be effective if the competent authorities are willing to implement the technical solutions discussed to reduce delays in pricing and reimbursement procedures. This option may bring results if it builds upon the EUnetHTA collaboration to reinforce common HTA methodologies: optimising assessment methodologies may indeed reduce delays in pricing and reimbursement procedures for originator medicines. However, soft law instruments are unlikely to be sufficient to address the issue of unnecessary delays for generic medicines for two reasons:

- Firstly, the recommendations of the Pharmaceutical sector inquiry – which call on Member States to consider provisions that would grant pricing and reimbursement status to generic products automatically/immediately where the corresponding originator already benefits from such a status – have been followed up in a very limited number of Member States (for instance in Spain). Other Member States appear unwilling to implement the Commission's recommendations (despite their interest in doing so to reduce the burden of medicines on public health budgets) and consider that the time-limits for the pricing and reimbursement of generics should not be amended. In the framework of the public consultation, half of the responding national authorities and public health insurance bodies (8 out of 16) took the view the current time-limit of 180 days should be maintained with respect to generic medicines. These positions indicate that a reduction of processing times for generic medicines is unlikely to happen across the EU at the sole initiative of Member States.

- Secondly, the use of administrative practices delaying the pricing and reimbursement of generics, such as patent linkage*, finds its source in a legal grey zone at EU level. Although patent linkage is prohibited in the administrative proceedings leading to marketing authorisation, alleged breaches of intellectual property rights are regularly put forward by originator companies in the context of pricing and reimbursement procedures due to the lack of precise rules in that area. From this perspective, legally binding instruments could be more appropriate to achieve the objective of minimal delays for the pricing and reimbursement of generic medicines. Unsurprisingly, this regulatory approach is strongly opposed by originator companies but has been unanimously supported by the generic industry during the stakeholder consultation.

Policy option A.3 – Revision of the directive to improve the enforcement of the current time-limits

Option A.3/a – Financial penalties in case of non-compliance with the time-limits for the inclusion of medicines in the health insurance system: this option would secure the capacity of pharmaceutical companies to claim damages in the competent national courts and would provide an incentive for Member States to comply with the time-limits. The budgetary impact for the national authorities would be proportional to their capacity to ensure effective compliance with the time-limits. This approach would maintain the central role of national jurisdictions in assessing potential breaches of the time-limits, in line with the principle of subsidiarity.

Nevertheless, the effectiveness of this option would depend upon the willingness of pharmaceutical companies to enforce their rights. The slowness and the cost of legal

procedures (in particular for SMEs) often act as deterrents for economic operators to engage in judicial action, which might create a feeling of impunity within public authorities. This is reinforced by the fact that pharmaceutical companies often fear that legal action against public authorities may damage their longer term relationship with them. The effectiveness of this option would also depend on the level of the financial compensations granted by national jurisdictions: these should be sufficiently high to incentivise public authorities to respect the time-limits and, if need be, to convince companies to seek the enforcement of their rights in national courts.

Another element to consider in this option is the impact on patients. Sanctions imposed on Member States would not solve the problem of delayed access to medicines for patients in case of late pricing and reimbursement decisions. On the contrary, patients would still suffer from the delayed entry of medicines on the market and would also, as citizens and taxpayers, have to contribute to the payment of financial penalties imposed by national jurisdictions on the public authorities.

Option A.3/b - Automatic inclusion of individual products in the health insurance system after the expiration of the time-limits and until the decision is adopted: considering the difficulties encountered to ensure compliance with the time-limits for pricing and reimbursement decisions, this option would introduce an effective enforcement system with far-reaching consequences for all stakeholders.

- For public authorities, this option could have a significant but temporary impact on pharmaceutical budgets since the inclusion of medicines in the scope of their health insurance system would be legally imposed in case of unjustified delays beyond 90/180 days, at least until the expected decision is issued. The financial burden on public budgets would depend on the extent of the procedural delay. The capacity of Member States to make their own reimbursement decisions would be fully preserved as automatic inclusion may only intervene if no decision is issued within the time-limits. Several additional safeguards would also ensure the proportionality of this mechanism with the objective pursued. Firstly, the potential impact of this measure would be mitigated by the ability for Member States to trigger the "stop the clock" period should the information supporting an application be considered insufficient or inadequate. It is therefore anticipated that automatic inclusion would only intervene if the delays cannot be justified by the competent national authorities on the basis of objective reasons. In addition, the pricing and reimbursement process could be taken forward until the authorities reach a decision on the application. Secondly, a formal decision not to include the medicines concerned in the scope of the health insurance system, or to include them in less favourable reimbursement categories, would remain possible if pharmaco-economic evaluations* by the competent authorities eventually demonstrate that these products do not meet the reimbursement criteria defined in national law. This mechanism would act as a strong incentive for Member States to avoid delays in their pricing and reimbursement procedures. It may also require some national authorities to streamline or improve the efficiency of their health technology assessment procedures, which is one of the objectives pursued at EU level by the EUNetHTA Joint Action (see Section 4.3). Finally, should unjustified delays occur, experience shows that changes in the reimbursement status of a medicine are always delicate once patients have been granted access to the treatment funded by the social security system.

- For pharmaceutical companies, unjustified delays in pricing and reimbursement procedures would facilitate early market access and enable the rapid uptake of their

products by public health insurance systems. Taking as an example the product sample analysed by the authors of the Pharmaceutical market monitoring, lost profits within a range of 35 to 100 million EUR per product could be avoided (see the details presented under policy option A.1). This would guarantee a better return on investment for the product concerned, while contributing to future R&D activities and reinforcing the competitiveness of the pharmaceutical industry in Europe. This option would significantly enhance business predictability, although this impact may be mitigated by the capacity of Member States to stop the clock and to adopt a negative (or less favourable) decision at a later point in time. Increased predictability would be particularly important for SMEs, in particular in the biotechnology sector, to avoid that delays in pricing and reimbursement jeopardise the economic viability of companies. Nevertheless, this option may also reduce flexibility in pricing and reimbursement systems to the detriment of pharmaceutical companies: Member States may choose to issue negative reimbursement decisions within the time-limits, instead of taking more time for evaluation and possibly issuing a positive decision outside the prescribed time-limits.

- For patients, this option would ensure rapid access to medicines – in particular to innovative products – even if the competent pricing and reimbursement authorities do not issue their decision within the time-limits. This option would therefore be positive from the point of view of patients' health. However, unintended consequences cannot be excluded for patients as the competent national authorities may later decide that the product should not be included in the reimbursement list or should be included under less favourable conditions. This could interrupt access to the treatment, possibly after a short period of availability, and force patients to switch (or switch back) to alternative therapies.

Option A.3/c - Obligation to communicate and publish reports on pricing and reimbursement approval times: this option would establish the necessary conditions for a closer monitoring of the situation by the Commission, stakeholders and the national authorities themselves. The reports, rather than being a mere legal enforcement tool, would provide a basis for dialogue between stakeholders at national and EU level. From this perspective, positive effects regarding compliance with the time-limits should be expected for patients, industry and the competent national authorities. The Commission's experience with the Internal Market Scoreboard[66] indicates that benchmarking plays an emulating role towards the national authorities, thus generating better compliance with EU law. However, monitoring and benchmarking activities can only reach their objectives if the Member States accept to "play the game" by providing accurate statistics and if they are open to dialogue with the Commission and stakeholders so as to draw the lessons of any poor performance. This option should therefore be seen as complementary to the options examined above. In terms of impact on public authorities, the additional compliance costs stemming from reporting obligations are considered to be negligible as the necessary data should be readily available in the competent administrations and mandatory updates would take place at once a year.

Policy option A.4 – Revision of the directive to avoid unnecessary delays with respect to generic medicines

Option A.4/a – Shorter time-limits for pricing and reimbursement decisions concerning generic medicines: this option reflects the position expressed by the Commission in the

[66] http://ec.europa.eu/internal_market/score/index_en.htm

conclusions of the Pharmaceutical sector inquiry, according to which automatic/immediate reimbursement status should be granted to generic medicinal products where the corresponding originator already benefits from reimbursement at a higher price. Instead of relying on the Member States' willingness to take measures to this purpose, the approach would consist in reducing the time-limits of 90/180 days as regards the pricing and reimbursement of generic medicines.

Although the immediate pricing and reimbursement of generics may be desirable to reinforce competition in the off-patent market*, the public consultation showed that it cannot necessarily be implemented across the EU due to specific administrative and legal constraints in some Member States. For instance, many countries must publish their pricing and reimbursement decisions in their official journal before these can take effect. The public consultation invited the stakeholders concerned to express their point of view regarding the most appropriate time-limits for generic pricing and reimbursement decisions. As shown in Table 4, the question reveals a clear split between economic operators and public authorities: more than 80% of respondents from the generic industry advocate immediate pricing and reimbursement decisions, while nearly 60% of respondents representing public authorities and public health insurance bodies consider that a reduction of the current time-limits would be inadequate. Between these two extreme positions, the figures indicate that a 30-day time-limit would best reconcile the generic industry's objective of early market entry with the administrative constraints of the Member States.

Table 4: Time-limits considered appropriate for the swift pricing and reimbursement of generics

	Generic industry *(16 contributions)*	**Public authorities & public health insurers** *(17 contributions)*	**Patient organisations** *(3 contributions)*
0 days	**81,3%**	-	-
30 days	18,7%	23,5%	-
45 days	-	5,8%	-
60 days	-	11,8%	-
No change to current time-limits	-	**58,9%**	1
Reduction of time-limits (no timeframe specified)	-	-	2

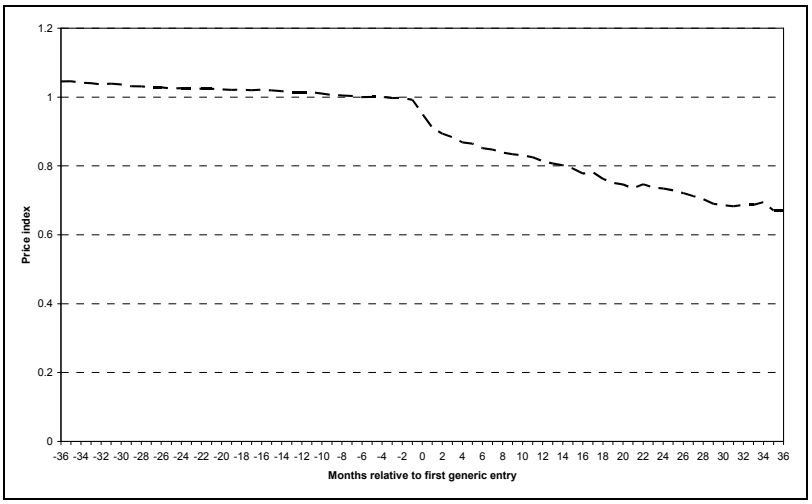
Source: Public consultation

A reduction of the time-limits to 30 days for generic medicinal products (covering both the pricing and reimbursement processes) would ensure earlier market access in a number of Member States and stimulate price competition in the off-patent market* within a reasonable timeframe after the loss of exclusivity* of originator products. This would bring significant benefits not only to the generic pharmaceutical industry, but also to patients and public health budgets. The Pharmaceutical sector inquiry indeed demonstrated that the prices of medicines substantially decline following the entry of generics on the market (Figure 9). On average, in the European Union, prices drop by approximately 20% during the first year after generic entry and roughly 25% in the second year. In some markets and for some medicines, the price decrease may be as high as 80-90%.[67]

[67] Commission Communication on the Pharmaceutical Sector Inquiry, Section 2.1.2; Staff Working Document, §212 et seq.

Figure 9: Development of average price index for INNs with generic entry

(sample: E75 list; all INNs with entry; weighted by INN; month 0 = entry; index = 1 for price six months before loss of exclusivity)



Source: Pharmaceutical Sector Inquiry

Consequently, a reduction of the overall time-limits from 180 to 30 days for generic medicines would reinforce competition in the off-patent market* and allow for significant reductions in the cost of medicines up to five months earlier than in the current situation. While these financial gains would partly accrue to patients (if they have to pay part of their pharmaceutical bill through co-payment*), they would mainly benefit the national health insurance systems. The extent of the financial savings for the public authorities would vary from country to country depending on the medicines at stake and on the attractiveness of national markets for generic manufacturers. However, an indication of the overall range of impact can be inferred from the conclusions of the Pharmaceutical sector inquiry.

The Commission indeed calculated that, for the period 2000-2007, potential savings of around 3 billion EUR[68] could have been obtained if generic market entry had taken place immediately after loss of exclusivity*, rather than with a 7-month delay on average. On this basis, any reduction in the duration of pricing and reimbursement procedures by one month would yield savings in the order of magnitude of 400 million EUR at EU level. Under the analytical framework of the Pharmaceutical sector inquiry, savings would have climbed up to 2 billion EUR if all EU countries had shortened their pricing and reimbursement procedures for generics from 180 to 30 days. This projection undoubtedly represents an overestimation because some countries already have delays much below 180 days. Nevertheless, some countries with high generic penetration rates still take more than 150 days on average for generic pricing and reimbursement procedures. There is no doubt that a reduction to 30 days of generic pricing and reimbursement procedures would generate substantial savings for their pharmaceutical budgets. Such savings may contribute to financing other treatments, including more expensive innovative medicines.

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[68] This figure is an estimate of the missed savings based on the list of 128 INNs considered in the sector inquiry (E75 list) in the 17 Member States for which observations were available. Each of these INNs expired at different times during the period 2000-2007. All calculations relate to the period between loss of exclusivity* and December 2007, a period which differs in length for each of the INNs and countries. Missed savings in the period 2000-2007 in relation to expiries from the period before 2000 are not taken into account. Nor are missed savings in relation to the list of INNs under consideration materialising after 2007.

The Member States which favour maintaining the 90/180-day time-limits for generic medicines consider that changes to their current procedures would entail a significant additional burden but do not provide any details concerning the exact nature and extent of this burden. Quite surprisingly, some of these countries (e.g. Sweden, UK) already apply procedures taking 30 days or less for generics. Nevertheless, in the framework of the public consultation, Member States did not report any specific legal obstacles which would prevent a reduction of the time-limits to 30 days in their country (the Belgian and Dutch authorities, however, mentioned that publication in the Official Journal may take up to 30 days in their country). In addition, the Pharmaceutical sector inquiry stressed that a mechanism granting automatic reimbursement to generic medicines if the reference product already benefits from reimbursement based on a higher price does not require any detailed assessment by the competent authorities[69]. This implies that a less stringent reduction of the time-limits to 30 days should not involve important technical investments or staff costs for the national authorities. The Member States which currently display the longest periods for the pricing and reimbursement of generic medicines (see Section 3.2.2.2) may bear more important costs than others. However, these costs would also depend on the current organisation of their administration and on potential efficiency gains in their national procedures. Furthermore, the additional burden on Member States would mainly consist in one-off compliance costs for amending existing systems. These should be considered proportionate as they are unlikely to offset the long-term, substantial savings that can be expected from earlier generic market entry.

Finally, it is self-evident that earlier generic entry due to shorter pricing and reimbursement procedures would impact the profits of originator companies by reducing their actual period of market monopoly. However, this negative short-term impact is also accompanied by positive effects in terms of R&D insofar as cost savings from generic medicines can free up resources to reimburse the development costs of originator products.

Policy option A.4/b – Prohibit patent linkage* and the duplication of assessments carried out in the marketing authorisation phase: in the Pharmaceutical sector inquiry, the Commission stressed that pricing and reimbursement procedures are bilateral proceedings between the applicant and the competent administration and recalled that the pricing and reimbursement authorities are not competent to assess patent, bioequivalence or safety issues.[70] This option would clarify these points in EU legislation in order to avoid any delays linked to the interference of intellectual property or safety issues with pricing and reimbursement procedures.

The Pharmaceutical sector inquiry demonstrated that claims of alleged patent infringements by originator companies and litigation against pricing and reimbursement bodies on such grounds can significantly delay pricing and reimbursement decisions for generic products.[71] The economic impacts of this option are therefore broadly similar to those outlined in the analysis of Option A.4/a. In fact, Options A.4/a and A.4/b tend to be complementary by targeting the causes of delays in the market entry of generics that are linked to pricing and reimbursement procedures.

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69 Staff Working Document on the Pharmaceutical sector inquiry, §1433.

70 Commission Communication on the Pharmaceutical Sector Inquiry, Section 4.4; Staff Working Document, §212 et seq.

71 Staff Working Document on the Pharmaceutical sector inquiry, Section 2.5.2.

One of the major consequences of Option A.4/b would be to provide legal clarity for Member States and economic operators as regards the necessity to keep a strict separation between pricing and reimbursement procedures and, on the one hand, intellectual property issues and, on the other hand, safety aspects already examined during the marketing authorisation process. While this separation is fully recognised by some Member States (for instance, it has been upheld by national jurisdictions in Sweden[72]), its implementation has proved more difficult in other Member States. Several examples of successful interventions by originator companies before pricing and reimbursement bodies on grounds of an alleged patent violation have been reported in the Pharmaceutical sector inquiry.[73] This option would therefore provide additional legal security for national authorities and increase business predictability for generic companies.

Option A.5 – Shorter time-limits for pricing and reimbursement decisions concerning originator medicines: the time-limits laid down in the current directive have been set to reflect a balance between three equally important factors:

- the need for Member States to assess the (added) value of medicines that may eventually be financed from public funds;
- the objective of market access for pharmaceutical companies in order to recoup their costs: R&D costs are particularly high for the research-based pharmaceutical industry and any delay in launching a product reduces the period of protection during which investments can be recouped and profits can be earned;
- the necessity for patients to have access as quickly as possible to the medicinal products authorised by the competent EU or national authorities.

Contributions to the public consultation highlight a fairly homogeneous support of stakeholders in favour of maintaining the time-limits of 90/180 days for originator products. More than 75% of all respondents consider that these time-limits are appropriate and this view is shared by 60% of the Member States (see Annex 1).

An extension of the time-limits beyond 90/180 days for originator medicines is advocated by some Member States or public health insurers to cater for the increasing complexity of assessing the (relative) value of new and usually expensive products. There is no doubt that such an extension would contribute to delay patients' access to medicines and therefore lead to welfare losses for EU citizens. It would also affect pharmaceutical companies by delaying their return on investment, with a potential negative impact on future research and on their capacity to innovate. On the contrary, a reduction of the time-limits would facilitate the quick entry of innovative medicines on the market to the benefit of pharmaceutical innovation and patients.

With this objective in mind, a reduction of the time-limits by a third (down to 60/120 days) was felt to be politically relevant. The exact point of balance between the three factors mentioned above is impossible to determine with precision as many parameters come into

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[72] Judgement of the Swedish Supreme Court, Case T 4705-07, 23 December 2008.

[73] Staff Working Document on the Pharmaceutical sector inquiry, Section 2.5.2.

play in the equation, such as the complexity of the medicines evaluated, the data available regarding their effectiveness, the initial R&D costs invested by the marketing authorisation holder, the seriousness of the conditions to be treated, etc.

The implementation of shorter time-limits would undoubtedly require improvements to national pricing and reimbursement systems in order to make them more effective, which would in turn entail compliance costs for Member States. These costs could not be quantified as they depend on the current set-up and effectiveness of each national system. The increasing complexity of innovative products and the uncertainties about their (relative) effectiveness in real-life conditions represent challenges for the public authorities. A significant increase in resources could therefore be required in some countries to meet reduced deadlines as there seems to be a correlation between the efficiency of national systems and the size of the budget allocated to pricing and reimbursement processes. However, shorter deadlines would mean earlier access to medicines for patients (unless there are unintended consequences with an increase in the number of negative decisions delivered within the time-limits) and thus positive welfare effects. As already mentioned, the costs induced by the earlier introduction of a new medicine financed from public funds can be much lower for the public authorities than the overall economic and health gains linked to the prescription of that medicine. In addition, EU legislation would act as a driver in helping Member States to identify administrative bottlenecks or weaknesses and improve the efficiency of their procedures.

6.1.2. Comparison of options

Table 5 compares the options for achieving Objective A in light of their main advantages and disadvantages.

Table 5: Objective A – Comparison of options to ensure timely pricing and reimbursement decisions

	Advantages/Benefits	Disadvantages/Costs
Option A.1: **Status quo (baseline scenario)**	° Member States' responsibility to address delays (subsidiarity).	° Some Member States are unwilling or unable to address the problem of delays on their own (possible administrative inertia). ° Persistence of delays for originator medicines: welfare losses suffered by patients (e.g. estimation 970 million EUR for one country in 2006), economic losses for originator industry (e.g. estimation 35-100 million EUR/product), reduction in R&D. ° Persistence of delays for generic medicines: lost savings for patients and pharmaceutical budgets (e.g estimation of savings 2000-2007 if generic entry had been immediately: 20% more savings, 3 billion EUR at EU level), economic losses for generic industry. ° Lack of effective enforcement tools at EU level.
Option A.2: **Soft Law**	° Flexible solutions to pricing and reimbursement delays based on concrete Member States' experience. ° Action is taken at the lowest possible level in accordance with the subsidiarity principle. ° Possibly effective to reduce assessment delays for originator products, for instance if builds upon results of the EUnetHTA Joint Action. ° Stronger basis for enforcement based on EU guidance	° Non-binding solutions to avoid pricing and reimbursement delays: success depends on Member States cooperation, lack of effective enforcement mechanisms. ° Difficulties in setting benchmarks due to disparities between national systems. ° Guidance unlikely to address the issue of unnecessary delays for generic medicines. ° Legal certainty will not significantly improve without binding rules.
Option A.3/a: **Financial penalties by national judges**	° Enforcement by national judge in line with the principle of subsidiarity. ° Incentive for Member States to comply with the time-limits (deterrent effect). ° Compensation of economic damage for pharmaceutical companies.	° Effectiveness depends on the willingness of economic operators to seek enforcement of their rights and on the level of sanctions decided by national judges. ° Problem of delayed access to medicines for patients not addressed. Patients pay twice due to delayed access and financial compensations paid by taxpayers' money.

Option A.3/b: **Automatic inclusion in reimbursement after expiration of the time-limits and until the decision is adopted**	° Effective enforcement of the time-limits. ° No unjustified delays, improved market access for companies, additional predictability (including for SMEs). ° Rapid access to medicines for patients. ° Stronger level of regulatory intervention but proportionate approach as Member States retain their decision-making powers.	° Potential impact on public health budgets, with safeguards available for Member states. ° Need to streamline or improve the efficiency of HTA procedures (objective supported by the EUNetHTA collaboration). ° Patients' expectations: difficult to exclude products from reimbursement once they are used by patients. ° Potential insecurity for patients and companies if the decision issued beyond the time-limits is negative.
Option A.3/c: **Benchmarking reports**	° Public pressure on Member States. ° Facilitates monitoring of application of the time-limits. ° Basis for dialogue with Member States.	° Only effective if Member States provide accurate data and are ready to draw lessons from poor performance. ° Additional compliance costs for public authorities, although very limited (staff for contact point).
Option A.4/a: **Shorter time-limits for generics**	° Earlier market access for generic products, earlier price competition in off-patent market*. ° Significant savings for public health budgets and possible savings for patients (if co-payment*). ° Encourages pursuit of innovation by originator industry by enhancing competition in off-patent markets*. ° Option strongly supported by the generic industry.	° Short-term losses for originator companies (earlier competition). ° One-off compliance costs for public authorities, but unlikely to offset long-term savings resulting from earlier price competition. ° Unequal support from Member States.
Option A.4/b: **Prohibition of patent linkage and duplication of assessments**	° Patent disputes are assessed by the competent bodies: legal clarity for Member States, business predictability for generic industry. ° Earlier market access for generic products, earlier price competition in off-patent market*. ° Significant savings for public health budgets and possible savings for patients (if ci-payment). ° Encourages pursuit of innovation by originator industry.	° Short-term losses for originator companies (earlier competition).
Option 5: **Shorter time-limits for originators**	° Earlier patient access to medicines and associated welfare gains. ° Earlier return on investment for pharmaceutical companies, with potentially positive effects on research and innovation.	° Compliance costs for public authorities due to the necessity to streamline and improve pricing and reimbursement procedures. ° Possible unintended effects: non-inclusion of medicinal products into reimbursement in order to respect the shorter time-limits imposed by the directive.

6.1.3. Preferred options

Despite the flexibility provided by soft law, legal certainty and effective enforcement are crucial to ensure timely pricing and reimbursement decisions. In addition, it is very unlikely that soft law (such as the adoption of an interpretative Communication and additional guidelines) would address an important aspect of the problem, namely unnecessary delays in pricing and reimbursement procedures for generic medicines. Consequently, regulatory measures seem preferable in order to achieve Objective A.

Comparison between options A.3/a and A.3/b shows that both would act as deterrents for Member States to make their reimbursement decisions beyond the time-limits. Preference should be given to the more effective of these two options with the least drawbacks: the second option (A.3/b) should better respond to these objectives because it is not conditional upon lengthy and costly judicial procedures as well as decisions by national judges and it enables patients to have effective access to the medicines (an objective which is not achieved by option A.3/a). While options A.3/b and A.3/c may be seen as alternative regulatory measures based on different levels of stringency, they could also be applied in conjunction in order to strengthen compliance with the time-limits to the best possible extent. In order to avoid unnecessary delays in the pricing and reimbursement of generics, options A.4/a and A.4/b are fully complementary insofar as they would address different causes to generic

delays. Although the implementation of shorter time-limits for generic products would contribute to earlier market access for generics, this objective would only remain partially met if safety or intellectual property issues continue to interfere with pricing and reimbursement processes. Conversely, the prohibition of patent linkage* and of safety reassessments would contribute to lifting important hurdles to early access but would not solve the issue of administrative slowness observed in several countries.

Compliance with the time-limits for originator medicines would, in itself, greatly improve market access and bring benefits to patients and the research-based pharmaceutical sector. It is nevertheless difficult to conclude on whether a reduction of these time-limits to 60/120 days would be advisable. It would involve important adjustment and compliance costs for Member States but could also promote efficiency in national systems at the service of public health and industrial dynamism.

Consequently, amendments to the directive are recommended on the basis of options A.3/b and A.3/c and A.4 (including sub-options a and b).

Table 6: Performance of options against key criteria – Objective A

Objective A: Ensure timely pricing and reimbursement decisions	Effectiveness	Efficiency = Effectiveness vs. burden/costs for Member States	Legal certainty	Enforcement
Option A.1: Status quo (baseline scenario)	-	-	-	-
Option A.2: Soft Law	±	+	±	±
Option A.3/a: Financial penalties by national judges	±	+	+	±
Option A.3/b: Automatic inclusion in reimbursement after expiry of the time-limits and until the decision is adopted	+ +	±	+	+
Option A.3/c: Benchmarking reports	+	+	+	±
Option A.4/a: Shorter time-limits for generics	+ +	+	+	×
Option A.4/b: Prohibition of patent linkage and duplication of assessments	+ +	+ +	+ +	×
Option 5: Shorter time-limits for originators	+	-	+	×
Performance levels: + + Very high + High ± Moderate - Negative × No impact □□□□ : Preferred options				

6.2. Objective B: Ensure the adequacy and effectiveness of the directive in a changing context

With respect to Objective B, the foreseen effects of the policy options mainly relate to:

– Legal certainty and business predictability

– Compliance costs for public administrations

– Legal compliance and enforcement

6.2.1. Analysis of impacts

Policy option B.1 – No further action: this option would have two major consequences on the operation of Directive 89/105/EEC. Firstly, it would maintain the discrepancy between the provisions of the existing directive and the significant developments observed in the pharmaceutical market, including the evolution of pricing and reimbursement policies. Secondly, the option would fail to address the issues of enforcement faced by the Commission due to the restrictive interpretation by Member States of the transparency obligations imposed by EU legislation. Consequently, the problems of legal interpretation, implementation and enforcement described in Section 3 would persist and may even worsen as national pricing and reimbursement policies continue to evolve. For economic operators, this would lead to increasing legal uncertainty and lack of business predictability. From a broader economic perspective, if the transparency objectives pursued by EU legislation cannot be adequately fulfilled, the internal market in medicinal products will not function in an optimal way: there can be no level playing field for companies and the principles of non-discrimination between foreign and domestic products may be jeopardised. Although the economic and social impacts of procedural transparency cannot be precisely measured, the status quo is detrimental to pharmaceutical companies in terms of sales, investment in R&D and employment, as well as to patients in terms of access to medicines, health and well-being.

Policy option B.2 – Soft Law: the public consultation showed that this approach is strongly advocated by the innovative pharmaceutical industry (originator companies) in order to avoid a complete reopening of the directive with the risk of a possible lowering by the legislator of the procedural safeguards it currently provides.

The advantage of soft law is that it can be developed to clarify specific legal issues whenever the need arises. This is undoubtedly a strong feature in the context of Directive 89/105/EEC because national pricing and reimbursement measures evolve on a permanent basis and EU legislation cannot be adapted at the same pace. A focus on soft law would enable to increase the clarity of the existing framework and to reinforce legal security for stakeholders, while ensuring that the interpretation of the directive follows the development of national policies and the evolution of the pharmaceutical market.

At the same time, experience in managing pharmaceutical rules at EU level shows that drafting specific guidelines is a lengthy process, which usually involves important investment from the Member States and stakeholders in the framework of consultation processes. In addition, due to their non-binding nature, open dialogue and informal guidance can only provide limited additional certainty for national authorities, economic operators and other interested parties. A Commission Communication and published guidelines could, nevertheless, be taken into account by the Court of Justice and national jurisdictions when they are requested to examine cases under the directive. The willingness of Member States to engage in a dialogue regarding the interpretation of the directive and to follow the guidelines established by the Commission would remain a decisive factor for the success of this option. There is therefore no assurance that soft law would effectively address the problems of interpretation and enforcement of the directive in the current policy context.

Policy option B.3/a – Minimal revision of the directive to reflect the case-law of the Court of Justice: the broad interpretation of the directive put forward by the Court, if integrated into its provisions, would facilitate the implementation of the directive by the Member States and the verification of Member States' compliance by the Commission. However, the specificity of the cases examined by the Court (by definition, all cases relate to

a particular national health insurance system) means that this option would not necessarily address the wide range of possible interpretation issues linked to the variety of pricing and reimbursement policies.

The Court of Justice has not had the opportunity to examine all the pricing and reimbursement mechanisms which may trigger interpretation challenges under the directive. For instance, the question of the relationship between the provisions of the directive and tendering procedures or managed entry agreements* has so far not been submitted to the Court. Consequently, this option might increase legal clarity and predictability for national authorities, economic operators and other stakeholders but only to a limited extent. The public consultation highlighted that stakeholders are divided over the idea of a revision of the directive to codify the case-law of the Court of Justice (see Annex 1). Exactly half of the responding public authorities take the view that the directive should be amended to this effect, while the other half does not consider it necessary. Although the generic industry largely favours a codification of the case-law, the originator industry appears reluctant to it. The originator industry's position reflects its strong preference for soft law initiatives rather than regulatory amendments to the existing framework.

Policy option B.3/b – Extensive revision of the directive to bring it into line with the current pharmaceutical environment: beyond the issues already addressed by the Court of Justice, this option would contribute to clarifying legal aspects of Directive 89/105/EEC which have been subject to divergent interpretation by stakeholders. The recurrent controversies regarding the types of national measures falling within the scope of the directive mainly find their origin in the construction of the directive, which specifically describes a limited number of pricing and reimbursement mechanisms. A rewording of the legal provisions to focus on general principles, rather than on specific types of national measures, would bring legal clarity and facilitate the implementation of the directive in the context of complex and evolving pricing and reimbursement measures.

The main impact of this approach would be to improve the effectiveness of the directive, with expected positive effects on the internal market since unjustified barriers to trade would be easier to detect and, therefore, to deter. These effects cannot be directly quantified in terms of economic or social gains. However, this option would clearly increase business predictability for pharmaceutical companies and improve legal certainty for all stakeholders. The public consultation showed that a large majority of national authorities (72%) and of generic companies (88%) support regulatory amendments to the directive in order to better reflect the current environment for pricing and reimbursement policies, while originator companies favour a soft law approach. Among the other stakeholders, 44% consider that a modification of the directive would be appropriate to reflect the evolution of national policies but 28% do not have any definite opinion on this issue. Importantly, a rewording of the directive to frame the transparency obligations along general principles, rather than existing national systems, would contribute to making the directive 'future proof' and capable of addressing future types of pricing and reimbursement procedures developed by Member States.

In accordance with the principle of better regulation, the present option would clarify that pricing and reimbursement mechanisms based on public tendering fall outside the scope of Directive 89/105/EEC because they are regulated by national and EU public procurement law.

Indeed, Directives 2004/18/EC[74] and 2007/66/EC[75]already aim at ensuring transparency, equality and non-discrimination in public procurement procedures. They notably provide for procedural rules on publication and notices, information to tenderers about the decisions made, justification of these decisions and judicial appeals. Consequently, with respect to public tendering procedures, the transparency objectives pursued by Directive 89/105/EEC are fulfilled by more specific legislation. In this respect, representatives of the pharmaceutical industry generally consider that EU and national public procurement law provides sufficient guarantees of procedural transparency (position shared by 80% of originator companies and 70% of generic companies). However, some stakeholders consider that these rules should be reinforced or adapted to the specificity of the pharmaceutical market.

Similarly, voluntary agreements concluded between pharmaceutical companies and public authorities are subject to specific bodies of legislation (contract law for private law contracts and administrative law for public law contracts). Annex 7 demonstrates that managed entry agreements* are still at an early stage of development in a very limited number of Member States. Only the future will tell if such agreements require more specific regulation in light of their particular characteristics and of the evolution of their role in the market. The exclusion of contractual agreements from the scope of the directive will, at this stage, play an important role in improving legal certainty and facilitating the application of the directive. It should also be recalled that public tendering and contractual agreements involving public authorities must comply with the rules of the EU Treaty relating to non-discrimination, equal treatment, competition and free movement.

Finally, the inclusion of new provisions to increase internal coordination of pricing and reimbursement procedures for products associating medicines with medical devices (in-vitro diagnostic tests) could contribute to avoiding market access delays linked to the separation of decision-making procedures for medical devices and medicines. Beyond potential benefits in terms of public health, this would establish a more favourable framework for economic operators with a positive medium to long-term impact on innovation and competitiveness in this promising segment of the market. Nevertheless, this impact is very difficult to quantify. Many pharmaceutical originator companies consider that the directive does not need to be amended to increase transparency in the pricing and reimbursement of personalised medicines but half of the SMEs operating in the medical devices sector (which are very active in developing companion diagnostic tests) take the view that Directive 89/105/EEC should play role in achieving an increased transparency in the pricing and reimbursement of personalised medicines.

As far as Member States are concerned, they are generally opposed (more than 75%) to the introduction of provisions aiming to facilitate collaboration between the authorities in charge of the pricing and reimbursement of medicines and those responsible for the pricing and reimbursement of the associated medical devices. In most EU countries, the procedures for medicines and associated devices fall under the responsibility of two different bodies (sometimes even at different administrative levels, i.e. national vs. regional). These bodies

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[74] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts (OJ L.134, 30.4.2004, p. 114).

[75] Directive 2007/66/EC of the European Parliament and of the Council of 11 December 2007 amending Council Directives 89/665/EEC and 92/13/EEC with regard to improving the effectiveness of review procedures concerning the award of public contracts (OJ L.335, 20.12.2007, p. 31).

generally issue two distinct decisions and, in most cases, no procedure is foreseen to ensure collaboration between the competent administrations. Consequently, provisions in favour of increased coordination of decisions as regards medicines associated with medical devices would require adjustments to the national procedures and create one-off compliance costs for most Member States. In addition, whether such provisions would comply with the principles of subsidiarity and proportionality is questionable as the directive would create new obligations which may be seen as interfering with the capacity of Member States to organise their health insurance system. This particular amendment to the directive will therefore not be retained.

Policy option B.4 – Notification of draft national measures to facilitate the enforcement of the directive: a system of information concerning the draft national measures proposed by Member States in the area of pricing and reimbursement (early notification) would facilitate preventive dialogue between stakeholders and the enforcement of Directive 89/105/EEC by the Commission. This approach would improve the effectiveness of the directive and therefore create additional legal security for economic operators, in line with the objective of the directive to enable the parties concerned to verify that the national measures do not constitute barriers to trade incompatible with the provisions of the Treaty. It would also ensure that the directive remains 'future proof' by facilitating the examination of any new and potentially innovative pricing and reimbursement measure proposed by a Member State at an early stage in the decision-making process.

It is anticipated that the highest share of financial costs relating to a notification procedure would fall upon the Commission (e.g. translation costs, cost of electronic infrastructure, staff costs for the operation of the system and the examination of draft national measures). However, this option would also require the establishment of a contact point in each Member State, with responsibility for notifying draft measures and liaising with the competent Commission services. The activities of this contact person would depend on the volume of national measures to be notified within a year. Assuming that coordination activities at national level require 0,5 person/day, estimated annual costs would be within a range of 30,000-60,000 EUR per year in staff costs for national authorities (depending on monthly gross salaries in each Member State).

In addition, the introduction of a notification system may impact the speed of adoption of national pricing and reimbursement measures. Since national reforms and new measures introduced by Member States usually aim at containing pharmaceutical costs, any delay in their adoption would entail financial costs to the national authorities in keeping with the expected budget impact of the measure foreseen. Such costs could be reduced to a minimum by providing for a short period of initial examination (e.g. three months).

6.2.2. Comparison of options

Table 7 compares the options for achieving Objective B in light of their main advantages and disadvantages.

Table 7: Comparison of options for Objective B – Ensure the adequacy and effectiveness of the directive in a changing context

	Advantages/Benefits	Disadvantages/Costs
Option B.1: **Status quo (baseline scenario)**	° Interpretation of the directive on a case-by-case basis or through informal, voluntary dialogue with the Member States.	° Gap between the provisions of the directive and the current pharmaceutical market/national policies will remain. ° Persistent issues of enforcement due to restrictive interpretation by Member States. ° Increasing legal uncertainty and lack of business predictability. ° No level playing field for companies, potential impact on competitiveness (reduced sales, innovation and employment). ° Potential impact on healthcare (reduced access to medicines for patients).
Option B.2: **Soft Law**	° Flexible solutions to interpretation and implementation issues based on concrete Member States' experience. Possibility to clarify specific legal issues when the need arises. ° EU guidance in line with the subsidiarity principle. ° Stronger basis for enforcement based on EU guidance. ° Option supported by innovative industry.	° Non-binding solutions to ensure the relevance off the directive to national policies, only effective if Member States are willing to implement them. ° Guidance unlikely to address persistent issues of enforcement if Member States continue to advocate a restrictive interpretation of the directive. ° Transparency and legal certainty unlikely to improve significantly without binding rules. ° Important resources required to draft guidelines (e.g. regular cooperation between the Commission and Member States).
Option B.3/a: **Minimal revision to reflect case-law**	° Actualisation of several provisions of the directive in line with the judgements of the Court. ° Implementation of the directive by Member States and verification of compliance by the Commission facilitated.	° Difficulty to amend regulatory framework over time. ° Variety of pricing and reimbursement policies and broad range of interpretation issues will not be addressed. ° Limited improvement in legal clarity and predictability (e.g. uncertainty regarding tendering procedures and managed entry agreements*). °
Option B.3/b: **Extensive revision to align with the current pharmaceutical environment**	° Improvement in legal clarity and effectiveness of the directive: unjustified barriers to trade more easily detected and deterred or sanctioned. Directive drafted on the basis of general principles (rather than existing procedures) will be more "future proof". ° Better regulation: clear delimitation between the directive and other relevant legal instruments (e.g. public procurement law, contract law).	° Difficulty to amend regulatory framework over time. ° Potential delays in pricing and reimbursement procedures relating to personalised medicines: difficult to address without interfering with the Member States' capacity to organise their health insurance system and lack of support in public consultation. Approach therefore discarded.
Option B.4: **Notification of draft national measures**	° Preventive dialogue and improved enforcement. ° Contributes to ensure that the directive remains 'future proof' by facilitating the examination of new and potentially innovative pricing and reimbursement measures	° Compliance costs for public authorities and risk of financial costs linked to delayed adoption of national legislation (no impact on individual decisions). ° Administrative costs for the Commission (translation, IT tools and staff costs)

6.2.3. Preferred options

A comparison of the expected impacts in relation to Objective B highlights that a difficult balance needs to be found in order to increase legal certainty while minimising the compliance burden on national authorities. Here again, the flexibility offered by soft law (option B.2) is a positive element but non-binding interpretations are unlikely to ensure that Directive 89/105/EEC is effectively implemented by Member States in the context of their changing policies. A minimal revision of the directive to reflect the case-law of the Court of Justice (option B.3/A) would not entail any additional burden on Member States, yet it would fail to provide an adequate level of certainty given the growing variety of pricing and reimbursement measures introduced by Member States. Only a more extensive revision of the

existing legal framework (option B.3/B) can ensure that the debates relating to the actual scope of the directive in the current pharmaceutical environment are effectively solved. Nevertheless, improving legal clarity will remain insufficient to ensure the effectiveness of the legal framework if the issue of enforcement is not solved concomitantly. For this reason, the proposed mechanism of notification of draft national measures by Member States appears to be a proportionate option, even though it would entail additional costs for the national authorities (option B.4).

Consequently, the adequacy and effectiveness of the transparency requirements would be best ensured through a revision of the directive based on options B.3/b and B.4.

Table 7: Performance of options against key criteria – Objective B

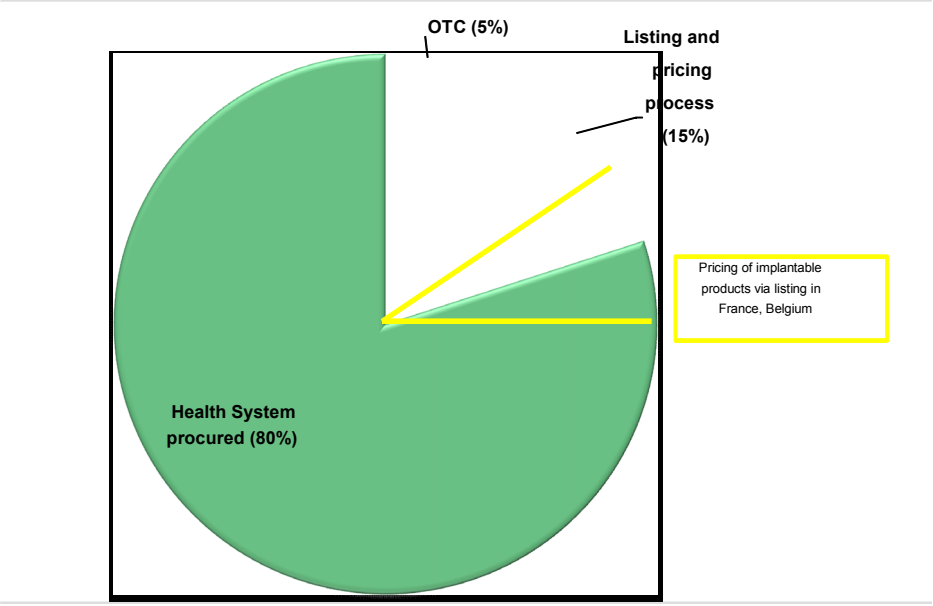
Objective B: Ensure the adequacy and effectiveness of the directive in a changing context	**Effectiveness**	**Efficiency = Effectiveness vs. burden/costs for Member States**	**Legal certainty**	**Enforcement**
Option B.1: Status quo (baseline scenario)	-	-	-	-
Option B.2: Soft Law	±	+	±	±
Option B.3/A: Minimal revision to reflect case-law	±	±	+	+
Option B.3/B: Extensive revision to align with the current pharmaceutical environment	+	+	+ +	±
Option B.4: Notification of draft national measures	+	±	+	+ +
Performance levels: + + Very high + High ± Moderate - Negative × No impact □□□□ : Preferred options				

6.3. Objective C: Possible extension of the scope of the directive to cover medical devices

6.3.1. Analysis of impacts

Policy option C.1 – No further action: analysis of the medical devices market demonstrates that keeping medical devices outside the scope of Directive 89/105/EEC would not fundamentally affect the general market situation in this sector. Indeed, as shown in Figure 10 approximately 85% of the medical devices market in the EU is not subject to price regulation and mechanisms of inclusion in health insurance systems. Roughly 80% of medical devices are purchased via public procurement/tendering processes and financed by public funds as part of the global health interventions practised by health professionals (category (b) as defined in Section 5.4.1). Another 5% of the market represents medical devices paid out-of-pocket by patients and therefore neither subject to price regulation, nor reimbursed (segment (a) as defined in Section 5.4.1).

Figure 10: Overview of pricing and reimbursement practices for medical devices in the EU



Source: EUCOMED

In their reply to the public consultation, the organisations representing the medical technology and diagnostics industry in Europe underscored that transparency issues in the medical devices sector should be addressed through reforms of the EU public procurement framework. This position reflects their contribution to the Commission's public consultation on public procurement in April 2011.

As regards the small segment of the market subject to price regulation and listing procedures, representatives of medical devices companies point to the fact that the transparency of procedures and the speed of pricing and reimbursement decisions vary from one Member State to another. However, many of them underline the necessity to preserve the specificity of the medical devices sector compared to the pharmaceutical market. From their perspective, Directive 89/105/EEC is not the appropriate instrument to address problems in the medical devices market, even if these relate to price determination and inclusion in health insurance systems. In this respect, several companies mentioned that such issues should be raised in the context of the on-going revision of the medical devices directives.[76] It should be noted, however, that these directives aim at regulating the placing on the market of medical devices and that pricing and reimbursement issues fall outside their scope.

Policy option C.2 – Partial extension of the directive to a specific segment of the medical devices market: as explained in Section 5.4.3, this option would consist in extending the scope of Directive 89/105/EEC only to medical devices subject to pricing and listing procedures in view of their inclusion in public health insurance systems. This would ensure early market access for these medical devices in all Member States by setting clear time-limits for pricing and listing decisions, with benefits for companies in terms of return on investment

[76] http://ec.europa.eu/consumers/sectors/medical-devices/documents/revision/index_en.htm

and for patients due to the swift access to health technologies. Bearing in mind that minimum transparency requirements already exist for the pricing and reimbursement of medical devices on the basis of Article 34-36 TFEU, the definition of more specific transparency requirements in secondary legislation would also bring additional legal certainty for all stakeholders by complementing the rules of the Treaty.

Nevertheless, during the public consultation, the medical devices industry expressed strong doubts that an extension of Directive 89/105/EEC would significantly contribute to improve the transparency of national pricing and reimbursement procedures for medical devices. Representative organisations and their member companies consider that such an extension, even if limited to the technically relevant part of the medical devices market, would neither be appropriate nor justified. The overall benefits for industry and patients would be limited since the transparency provisions would apply to a very small share of the overall medical devices market currently estimated at 15%. According to the industry, this share has been diminishing in recent years and is anticipated to further decrease in the future: due to growing constraints on national health budgets, medical devices supplied directly to the patients are more and more paid out of pocket (i.e. moved from segment (c) to segment (a) in our typology). The relevance of medical devices undergoing price regulation and listing is therefore diminishing, meaning that the directive would potentially cover an increasingly negligible part of the overall market.

The limited relevance of extending the directive to medical devices subject to price regulation and listing was equally highlighted by many of the contributing Member States, although other responding national administrations were either not opposed to such an extension or did not have any opinion on the issue. Several national authorities also mentioned the significant additional administrative burden linked to necessary adjustments to their national systems.

In addition, the partial extension of Directive 89/105/EEC to this specific segment of the medical devices market would be legally and technically difficult to implement due to the heterogeneity of national healthcare policies. Indeed, the individual medical devices which are subject to price regulation and listing differ from one Member State to another. For instance, Figure 9 shows that implantable products must undergo pricing and listing procedures in France and Belgium, whereas they are financed in the framework of global health interventions in other countries. Moreover, in a given country, the same medical device may be financed according to different rules depending on its intended use. This could lead to a situation where (a) the same medical device might be subject to the provisions of the directive in one Member State but not in another and (b) the same medical device might be subject to the provisions of the directive if it is sold directly to patients after a pricing and listing decision, but not if it is bought by hospitals via public procurement procedures. The extension of the directive would therefore create problems of legal classification and entail confusion as to which products are effectively covered by the directive in the different EU countries. This option would eventually increase market fragmentation, rather than improve transparency, due to the differentiated treatment of similar products depending on the national rules governing their pricing and reimbursement.

6.3.2. Comparison of options

Table 8 provides a comparative overview of the options analysed above.

Table 8: Comparison of options for Objective C: Possible extension of Directive 89/105/EEC to medical devices

	Advantages/Benefits	Disadvantages/Costs
Option C.1: **Status quo**	° Maintenance of regulatory delimitation between medicines and medical devices. Procedural transparency issues relating to medical devices can be addressed via other legal instruments (e.g. public procurement law, medical devices directives). ° Safeguards of the Treaty continue to apply (Articles 34-36 TFEU). ° Support for this option from both Member States and medical devices industry.	° Transparency of procedures for medical devices subject to price regulation and listing continues to vary across the EU.
Option C.2: **Limited extension to a specific segment of the medical devices market**	° Early market access for medical devices subject to price regulation and listing (specific time-limits). ° Quicker return on investment for companies marketing medical devices supplied directly to patients and swift patient access to these technologies. ° Additional legal certainty (transparency requirements more specific than in the Treaty).	° First time mix-up between regulation on medicines and medical devices. ° No major effect on internal market situation since 85% of the medical devices market is not subject to price regulation and mechanisms of inclusion in health insurance systems: extension would cover a negligible and decreasing share of the medical devices market (below 15%). ° Increased market fragmentation due to the differented treatment of similar products depending on the national rules governing their pricing and reimbursement. ° Additional burden/costs for some Member States.

6.3.3. Preferred option

The comparison between the above options indicates that the benefits of an extension of Directive 89/105/EEC to the small segment of the medical devices market subject to pricing and listing procedures would not counterbalance the drawbacks, in particular the legal and technical complexities of such an extension as well as the risk of further market fragmentation. This conclusion is reinforced by the fact that industry itself does not favour such an extension and considers that procedural transparency in the medical devices market would be better addressed in the framework of other regulatory instruments. The lack of support from the main interested parties for the inclusion of medical devices within the scope of the directive speaks in favour of the status quo.

Consequently, it is recommended to discard the idea of an extension of the directive to medical devices.

Table 9: Performance of options against key criteria – Objective C

Objective C: Possible extension of Directive 89/105/EEC to medical devices	**Effectiveness (impact on transparency of the market)**	**Efficiency = Effectiveness vs. burden/costs for Member States**	**Legal certainty**
Option C.1: **Status quo**	±	+	+
Option C.2: **Partial extension to a specific segment of the medical devices market**	±	-	-
Performance levels: + + Very high + High ± Moderate - Negative × No impact □□□□ : Preferred options			

6.4. Synergies between the preferred options

The above analysis addressed the impact of the different policy options in relation to each of the objectives pursued. It should also be pointed out that there are synergies between the favoured policy options in terms of effectiveness, legal certainty and improved enforcement of the directive. These synergies essentially lie in the mutually reinforcing legal effects of the options and can therefore not be quantified. Nevertheless, the qualitative interactions between the preferred options are highlighted below.

Firstly, several policy options have been retained to ensure timely pricing and reimbursement decisions. The cumulative implementation of these options will indeed increase their effectiveness in avoiding procedural delays. In particular, compliance with the time-limits will be improved more effectively if information procedures on the actual time taken by Member States for pricing and reimbursement decisions (option A.3/c) apply in conjunction with the more stringent option of temporary automatic inclusion into reimbursement (option A.3/c). Similarly, the objective of scrapping unnecessary delays in the pricing and reimbursement of generic products will be better achieved if shorter time-limits (option A.4/a) are combined with efforts to avoid any form of patent linkage* and re-assessments of bioequivalence/safety (Option A.4/b). The added value of this approach lies in the fact that the main causes of delays are addressed simultaneously through different regulatory provisions.

Secondly, the policy options aiming to improve the enforcement of the directive will be much more effective if the legal obligations to be enacted by Member States are clarified and adequately aligned with the current pharmaceutical market. There is no doubt that the absence of legal certainty contributes to the current interpretation controversies which, in turn, undermine the capacity to enforce the directive. The preferred options seek to increase legal certainty while at the same time strengthening enforcement tools. They should therefore be seen as two sides of the same coin: their combination constitutes the best possible way to improve the effectiveness of the directive and achieve its internal market objectives.

Thirdly, the proposal to maintain medical devices outside the scope of the directive will avoid confusion between different types of products. It will therefore allow putting emphasis on the implementation of the key objectives of this initiative, which primarily addresses medicinal products in accordance with the 'historical core' of the directive.

The main implications of the proposed set of policy options for each of the main stakeholders (Member States, originator companies, generic companies and patients) are summarised in Table 10.

Table 10: Preferred set of policy options – Key impacts on stakeholders

	Advantages/Benefits	Disadvantages/Costs
Member States	° Increased legal clarity and easier implementation of the procedural requirements. ° Potential cost savings linked to quicker pricing and reimbursement for generics. ° No interference of intellectual and industrial property rights with day-to-day pricing and reimbursement activities.	° Stronger enforcement instruments requiring more systematic compliance. Potential impact on public health budgets in case of non-compliance with the time-limits. ° Need to improve or streamline pricing and reimbursement processes (including expert assessments such as HTA). ° Shorter time-limits for generics may entail initial compliance costs if national procedures need to be adapted. ° Limited administrative costs linked to reporting obligations and notification of draft national measures.
Originator companies	° Increased legal clarity, stronger enforcement instruments and more 'future proof' legislation will: - bring additional business predictability; - improve market access; - improve competitiveness and foster innovation. ° Earlier competition with generics will encourage the pursuit of innovation.	° Automatic inclusion in case of non-compliance with the time-limits may have the side effect of encouraging Member States to issues negative decisions within the deadlines. ° Should automatic inclusion occur in practice, potential insecurity if the decision eventually issued by the competent authorities beyond the time-limits is negative.
Generic companies	° Increased legal clarity, stronger enforcement instruments and more 'future proof' legislation will: - bring additional business predictability; - improve market access; - improve competitiveness and foster innovation. ° Shorter time-limits for pricing and reimbursement decisions and clarification of the non-interference of safety and IPR issues with pricing and reimbursement procedures will ensure earlier market entry and more effective competition in off-patent markets.	° Should automatic inclusion occur in practice, potential insecurity if the decision eventually issued beyond the time-limits by the competent authorities is negative. Should automatic inclusion occur in practice, potential insecurity if the decision eventually issued by the competent authorities beyond the time-limits is negative.
Patients	° Access to medicines not hampered by delays in pricing and reimbursement decisions. ° Cost savings linked to earlier generic entry and price competition in off-patent markets (in case of co-payment).	° Should automatic inclusion occur in practice, potential insecurity or even health impact if the decision eventually issued beyond the time-limits by the competent authorities is negative and patients have to switch their treatment.

7. MONITORING AND EVALUATION

The proposal consists in a modification of the existing regulatory framework. Consequently, the implementation of the new rules in the legislation of the Member States, will be the first critical step to ensure the success of the initiative. The Transparency Committee will play a crucial role in this process as it provides an established forum of cooperation between the Commission and the Member States. The Committee will meet on a regular basis during the transposition phase to monitor and facilitate transposition by the Member States through the exchange information with and amongst the competent authorities. Bilateral expert meetings could also be held with these authorities as the need arises.

As already mentioned in this analysis, the transposition of the provisions of the directive is only one element in the application of the directive. The adequate implementation of the EU procedural rules also requires that Member States reflect the provisions of the directive in any new measure regulating the pricing and reimbursement of medicines. This implies a longer term monitoring of national legislation. The proposed pre-notification mechanism will serve this purpose by enabling preventive control and dialogue with the Member States. Similarly, the information system in relation to the actual timing for pricing and reimbursement

decisions in each Member State will provide a key instrument to determine whether the objective of timely pricing and reimbursement decisions is achieved. Finally, the actual operation of the new regulatory framework should be reviewed within a reasonable timeframe. It is proposed that:

- Member States should send a report to the Commission on the implementation of the amended directive within two years after the date of its adoption;
- The Commission should carry out an assessment of the implementation of the new regulatory framework within three years after the entry into force of the directive and take any additional initiatives deemed necessary on the basis of this assessment.

The core progress indicators and monitoring instruments which will be used to assess whether the new directive is meeting its objectives are presented in table 11.

Table 11: Progress indicators and monitoring instruments

Objectives	Progress indicators	Monitoring instruments
A. Timely pricing and reimbursement decisions: compliance with the time-limits	Observed timing for pricing and reimbursement decisions in the Member States	Annual mandatory reporting on the actual time taken for individual pricing and reimbursement decisions.
B. Adequacy and effectiveness: legal clarity and enforcement	a) Changes in national measures and compliance of notified drafts with the directive (compliance rate based on pre-notification system) b) Complaints filed and investigated by the Commission, Commission referrals to the Court of Justice of the European Union	Notification of draft national measures to the Commission Infringement statistics