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Amended proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

EXPLANATORY MEMORANDUM*

1. CONTEXT OF THE PROPOSAL

- **General context**

The legislation of the Union requires a marketing authorisation to be granted by the competent EU or national authorities before any medicinal product can be placed on the market.[1] The rules in force aim to safeguard public health by ensuring that the quality, safety and efficacy of medicines are properly evaluated before these can be made available to patients in the European Union. This legislative framework also intends to facilitate trade in medicines between Member States in accordance with the principle of free movement of goods.

Meanwhile, pursuant to Article 168(7) of the Treaty on the Functioning of the European Union, Member States are responsible for the organisation of their healthcare system and for the delivery of health services and medical care, including the allocation of resources assigned to them. In this framework, each Member State can take measures to manage the consumption of medicines, regulate their prices or establish the conditions of their public funding. A medicinal product authorised in accordance with EU legislation on the basis of its quality, safety and efficacy profile may therefore be subject to additional regulatory requirements at Member State level before it can be placed on the market or dispensed to patients under the public health insurance scheme. For instance, Member States usually evaluate the cost-effectiveness of authorised medicines, or their relative efficacy as well as the short- and long-term effectiveness compared to other products in the same therapeutic class, in order to determine their price, funding and utilisation in the framework of their health insurance system.

National measures to control the funding of medicines and manage their consumption in the framework of healthcare systems are susceptible to create barriers to trade as they affect the capacity of pharmaceutical companies to sell their products in domestic markets. The settled case-law of the Court of Justice of the European Union recognises the right of Member States to adopt such measures in view of promoting the financial stability of their health insurance system.[2] However, basic conditions of procedural transparency must be met to ensure their

*** N.B. Provisions which have been introduced in the proposal compared to the initial proposal are indicated in bold and underlined. Deleted provisions of the initial proposal are indicated in strikethrough.**

[1] See Directive 2001/83/EC of the European Parliament and the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L311, 28/11/2001, p. 67), as amended, and Regulation (EC) N°726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

[2] See, for instance, Case 181/82 Roussel Laboratoria [1983] ECR 3849; Case 238/82 Duphar and Others [1984] ECR 523; Case C-249/88 Commission v Belgium [1991] ECR I-1275.

compatibility with the rules of the Treaty relating to the Single Market. In particular, pricing and reimbursement measures must be free of discrimination against imported medicinal products and based on objective and verifiable criteria which are independent from the origin of the products.

Directive 89/105/EEC[3] codifies the minimum requirements set forth by the Court of Justice. It was adopted to enable market operators to verify that national measures regulating the pricing and reimbursement of medicines do not contravene the principle of free movement of goods. To this end, the Directive lays down a series of procedural requirements to ensure the transparency of pricing and reimbursement measures adopted by the Member States. These obligations include specific time limits for pricing and reimbursement decisions (90 days for pricing, 90 days for reimbursement or 180 days for combined pricing and reimbursement decisions). The Directive also requires the competent national authorities to provide a statement of reasons based on objective and verifiable criteria for each of their decisions and to provide appropriate legal remedies to the applicant companies.

- **Grounds for and objectives of the proposal**

Directive 89/105/EEC has never been amended since its adoption. Its provisions reflect the pharmaceutical market conditions which prevailed more than twenty years ago. However, these conditions have fundamentally changed, for instance with the emergence of generic medicines providing cheaper versions of existing products or the development of increasingly innovative (yet often expensive) research-based medicinal products. In parallel, the constant rise in public expenditure on pharmaceuticals in the last decades has encouraged Member States to devise more complex and innovative pricing and reimbursement systems over time.

Despite the historically positive impact of Directive 89/105/EEC on the internal market for medicines, there is evidence that it does not fully achieve its objectives in the present context:

– Firstly, a gap has emerged between the provisions of the Directive, which describe the main types of pricing and reimbursement procedures established in the 1980s, and the much wider range of cost-containment measures adopted nowadays by Member States. Despite the extensive interpretation of the Directive by the Court of Justice[4], the implementation of its provisions in national law and the effective enforcement of its principles, in particular by the Commission, have become particularly challenging. This situation not only results in legal uncertainties but also in a reduced transparency of national pricing and reimbursement measures, which negatively affects the smooth functioning of the internal market to the detriment of European patients and pharmaceutical companies.

– Secondly, the time limits for pricing and reimbursement decisions established by Directive 89/105/EEC are regularly exceeded by Member States. This leads to delays in the marketing of medicinal products, which in turn slows down the availability of

[3] 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 in the scope of national health insurance system (OJ N°40, 11.2.1989, p. 8).

[4] See Case C-424/99 Commission of the European Communities v Republic of Austria [2001] ECR 9285; Case C-229/00 Commission of the European Communities v Republic of Finland [2003] ECR 5727; Case C-317/05 Pohl-Boskamp [2006] ECR I-10611; Joined Cases C-352/07 to C-356/07, C-365/07 to C-367/07 and C-400/07 Menarini Industrie Farmaceutiche Riunite and Others, **[2009] ECR I-2495** ~~nyr;~~ Case C-62/09 Association of the British Pharmaceutical Industry v Medicines and Healthcare Products Regulatory Agency, **[2010] ECR I-3603** ~~nyr.~~

valuable treatments for patients. In 2009, the Commission's Competition Inquiry into the Pharmaceutical Sector[5] recalled that Member States should comply with these time limits. The inquiry also demonstrated that unnecessary delays in the pricing and reimbursement of generic medicines delay patients' access to cheaper medicines and increase the financial burden on Member States. The Commission therefore considered that pricing and reimbursement procedures should be shortened with respect to generic medicinal products. In addition, the sector inquiry showed that the interference of patent or safety related issues with pricing and reimbursement processes can significantly delay access to cheaper generic medicinal products.

The fundamental objectives and principles of Directive 89/105/EEC remain fully valid in the present context. Accordingly, this initiative aims at adapting the Directive to the current pharmaceutical environment while preserving its core foundations. The overall objective of the proposal is to clarify the procedural obligations incumbent upon Member State and to ensure the effectiveness of the Directive, both in avoiding delays in pricing and reimbursement decisions and in preventing barriers to pharmaceutical trade. This shall be done without affecting national social security policies, except as far as it is necessary to achieve the transparency of national procedures and the effectiveness of the internal market legislation.

2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENTS

- **Consultation of interested parties**

A public consultation on a possible revision of Directive 89/105/EEC was held from 28 March to 30 May 2011. In response to this consultation, the Commission received 102 contributions from a broad range of stakeholders including national authorities, public health insurers, individual companies and organisations representing the research-based pharmaceutical industry, the generic industry, 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 were also consulted through the Enterprise Europe Network.

A large majority of respondents recognised the positive impact of the Directive on the transparency of national procedures and the functioning of the internal market. However, many of them also pointed to its weak implementation by Member States and highlighted its shortcomings in terms of legal clarity and enforcement. Opinions differed as to the relevant actions which should be proposed by the Commission. For instance, the generic industry unanimously advocated a revision of the Directive, while research-based companies and their representative organisations favoured a soft law approach based on an interpretative Communication by the Commission.

The results of the public consultation are available at: http://ec.europa.eu/enterprise/sectors/healthcare/public-consultation/index_en.htm.

[5] Commission inquiry into the European pharmaceutical sector pursuant to Article 17 of Regulation 1/2003. The results of the inquiry are published 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.

Impact assessment

Responses to the public consultation were carefully considered during the impact assessment carried out by the Commission services. The impact assessment report identifies and assesses regulatory and non-regulatory options to achieve the overall objective of ensuring that adequate and effective transparency rules apply to the pricing and reimbursement measures adopted by Member States. The proposal to revise the Directive is based on the combination of options recommended in the framework of the impact assessment, namely:

– To ensure timely pricing and reimbursement decisions: options A.3/c (regular reports on pricing and reimbursement approval times), A.4/a (shorter time-limits for pricing and reimbursement decisions concerning generic medicinal products) and A.4/b (prohibition of patent linkage and re-assessment of safety features).

– To ensure the adequacy and effectiveness of the Directive in the current context: options B.3/b (extensive revision of the Directive to clarify its scope and wording) and B.4 (notification of draft national measures to facilitate enforcement).

The possible extension of the Directive to include medical devices was examined in the impact assessment but discarded due to the specificities of this market.

~~Furthermore, in spite of the difficulty to conclude on the overall cost-benefit balance of reducing the time limits with respect to originator medicines, a reduction from the current 90/180 days to 60/120 days is proposed in light of the positive impact it would have on the swift availability of innovative medicines to patients and on rewarding pharmaceutical innovation when medicines are approved for reimbursement. However, given the complexity of the health technology assessment (HTA) procedures, it was deemed necessary to find a more differentiated approach for the time limits; therefore, different time limits are proposed, depending on whether the medicinal products are subject to health technology assessment (90/180 days) or not (60/120 days).~~

The impact assessment report and its executive summary are available at: http://ec.europa.eu/governance/impact/ia_carried_out/cia_2012_en.htm.

3. LEGAL ELEMENTS OF THE PROPOSAL

- **Legal basis and subsidiarity**

The main objective of Directive 89/105/EEC is to facilitate the functioning of the internal market for medicinal products. The legal basis is therefore Article 114 of the Treaty on the Functioning of the European Union.

The existing Directive has as its underlying principle the idea of minimum interference in the organisation by Member States of their domestic social security policies.[6] This fundamental principle is maintained in the proposal. The proposed requirements to ensure timely and transparent decisions carefully balance the obligation to preserve the competences of Member States in the field of public health against the necessity to guarantee the effectiveness of the Directive in meeting its internal market objectives. In order to respect the responsibilities of the Member States under the Treaty, the proposal does not provide for the approximation of national pricing and reimbursement measures, nor does it restrain the ability of Member States to freely determine the prices of medicines and the conditions of their public funding on the basis of the criteria they choose. The impact assessment report explains in further detail

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

how the subsidiarity and proportionality principles have been taken into account in the proposal.

- **Overview of the main legal elements**

The proposal maintains the core principles of the existing Directive but also puts forward a comprehensive adaptation of its legal provisions based on the following key elements:

– Clarification of the scope of the Directive: the transparency requirements apply to all pricing and reimbursement measures understood in a broad sense, including "demand side" measures to control or promote the prescription of specific medicines. Nevertheless, measures involving public procurement and voluntary contractual agreements with individual companies are excluded from the scope of the Directive in order to avoid interference with other bodies of law.

– Comprehensive coverage of national measures and legal clarity: the provisions of the Directive are reworded in accordance with general principles (rather than on the basis of specific national procedures) and incorporate the case-law of the Court of Justice. Several key provisions are clarified and updated to avoid interpretation controversies. In particular, it is made clear that the time limits for pricing and reimbursement decisions include all procedural steps leading to the decision, including health technology assessments where applicable.

– Adaptation of the time limits for pricing and reimbursement decisions: the time limits applicable to generic medicines are reduced to **30/60** ~~15/30~~ days when the reference product has already been priced and included in the health insurance system. ~~The time limits applicable to all other medicinal products are reduced to 60/120 days. However, in cases where national authorities subject medicinal products to health technology assessment procedures in order to assess the relative efficacy or the short- and long-term effectiveness, as an integral part of their decision-making process, the time-limits shall be 90/180 days.~~

– Non-interference of patent and safety issues with pricing and reimbursement procedures: the proposal clarifies that intellectual property rights should not interfere with pricing and reimbursement procedures, as is already the case for marketing authorisation procedures. In addition, elements already assessed in the framework of the marketing authorisation process (quality, safety and efficacy, including bioequivalence) may not be reassessed in the framework of pricing and reimbursement procedures.

~~– Dialogue and enforcement tools: different instruments are put in place to facilitate dialogue on the implementation of the Directive and to ensure its effective enforcement (consultation on draft measures at national level and pre-notification to the Commission, the creation of a remedies procedure in case of non-compliance with the time-limits related to the inclusion of medicinal products in health insurance systems).~~

- **Repeal of Directive 89/105/EEC**

The amendments proposed to Directive 89/105/EEC are substantial and cover all major provisions currently in force. For the sake of legal clarity, and in accordance with the principle of better regulation, the adoption of the proposal will lead to the repeal of existing legislation. However, the effects of Article 10 of Directive 89/105/EEC shall be maintained.

No correlation table is foreseen as the existing EU legislation referring to Directive 89/105/EEC does so in a general way without pointing to specific provisions of the Directive.

4. BUDGETARY IMPLICATION ~~[WHERE NECESSARY]~~

The Commission's proposal has no impact on the European Union budget beyond what is already foreseen for the years to come in the Multiannual Financial Framework. The details of the financial resources are indicated in the Legislative Financial statement.

5. TRANSPOSITION

The notification of the Member States' transposition measures must be accompanied by correlation tables explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments. This is necessary due to:

- The complexity of the Directive, which does not touch upon the substance but only lays down minimum procedural requirements to ensure the transparency of the measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems.
- The complexity of the transposition process due to the difficulties related to the interpretation of the Directive. The application of a set of procedural rules to the complicated architecture of the pricing and reimbursement systems is not always easy and straightforward.
- The constant evolution of national measures on pricing and reimbursement in view of controlling pharmaceutical expenditure, which makes it difficult to monitor the implementation process.

Therefore, the obligation to communicate correlation tables will facilitate the implementation process.

6. ADDITIONAL INFORMATION

The proposed act concerns an EEA matter and should therefore extend to the European Economic Area.

The proposal for a Directive repealing the Council Directive 89/105/EEC was adopted by the Commission on 1 March 2012.

The European Economic and Social Committee Opinion was adopted on 12 July 2012.

Negotiations in the Council Working Party on Pharmaceuticals and Medical Devices proved to be difficult, given the politically sensitive nature of the file. Main concerns of the Member States were related to: the principle of subsidiarity; the remedies procedure (Article 8); the creation of a system of pre-notification of draft national measures to the Commission (Article 16); shortening of the time limits for taking decisions on pricing of medicines and their inclusion in the scope of health insurance systems (Articles 3, 4, 5, 7); the distinction between originator medicinal products subject to HTA and those not

subject to HTA (Articles 3, 7); the obligation to consult the interested parties (Article 15).

The European Parliament adopted its position in 1st reading on 6 February 2013 with 559 votes in favour, 54 against and 72 abstentions. The European Parliament put forward amendments which provide a pragmatic compromise: while maintaining the substance of the Commission proposal, they also take into consideration the concerns expressed by the Member States.

As the result of the vote in Plenary and taking into consideration the position of the Member States in the Council, the Commission decided to amend its Proposal. The amendments of the European Parliament voted in Plenary have been duly taken into account. The Commission accepted or accepted in principle a large number of the amendments: 50 were acceptable (16 as such and 34 acceptable in principle, even if, a few of them were acceptable only in part) and only 7 were unacceptable. These 7 amendments were unacceptable because they represented a step backwards compared to the existing Directive, because they would have introduced legal uncertainty, or they would have gone beyond EU competences.

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THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee,[7]

After consulting the European Data Protection Supervisor,

Acting in accordance with the ordinary legislative procedure,

Whereas:

(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 in the scope of national health insurance systems[8] was adopted so as to remove distortions to intra-Community trade in medicinal products.

(2) In order to take into account the evolution of the pharmaceutical market and of national policies to control public expenditure on ~~medicines~~ **medicinal products,** substantive changes are necessary to all major provisions of Directive 89/105/EEC. Therefore, in the interest of clarity, Directive 89/105/EEC should be replaced.

(3) Union legislation provides a harmonised framework for the authorisation of medicinal products for human use. According to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use,[9] medicinal products may be placed on the market in the Union only after they have received a marketing authorisation based on the evaluation of their quality, safety and efficacy.

(4) Member States have been confronted to a steady rise in pharmaceutical expenditure over the last decades, leading to the adoption of increasingly innovative and complex policies to manage the consumption of ~~medicines~~ **medicinal products** in the framework of their public health insurance systems. In particular, Member States' authorities have implemented a broad range of measures to control the prescription of **medicinal products** ~~es~~, to regulate their prices or to establish the conditions of their public funding. Such measures mainly aim at promoting public health **for all citizens**

[7] OJ C 299, 4.10.2012, p. 81.
[8] OJ L 40, 11.2.1989, p. 8.
[9] OJ L 311, 28.11.2001, p. 67.

by ensuring the availability of adequate supplies of medicinal products at reasonable costs, while ensuring the financial stability of public health insurance systems.

(5) Disparities in national measures may hinder or distort intra-Union trade in medicinal products and distort competition, thereby directly affecting the functioning of the internal market in medicinal products.

(6) In order to reduce the effects of the disparities on the internal market, national measures should comply with minimum procedural requirements enabling the parties concerned to verify that those measures do not constitute quantitative restrictions on imports or exports or measures having equivalent effect thereto. **Those minimum procedural requirements should also ensure legal certainty and transparency for all the parties involved in the process of pricing of medicinal products and inclusion in the health insurance systems, while promoting the production of medicinal products, accelerating the entry into the market of generic medicinal products and encouraging research and development of new medicinal products.** However, those requirements should not affect the policies of those Member States which rely primarily upon free competition to determine the price of medicinal products. They also should not affect national policies on price setting and on the determination of social security schemes, except as far as it is necessary to attain transparency within the meaning of this Directive and to ensure the functioning of the internal market.

(7) In order to ensure the effectiveness of the internal market in medicinal products, this Directive should apply to all medicinal products for human use within the meaning of Directive 2001/83/EC.

(8) Due to diversity of national measures managing the consumption of medicines, regulating their prices or establishing the conditions of their public funding it is necessary to clarify Directive 89/105/EEC. In particular this Directive should cover all types of measures devised by Member States and susceptible to impact the internal market. Since the adoption of Directive 89/105/EEC, the pricing and reimbursement procedures have evolved and have become more complex. While some Member States have interpreted the scope of Directive 89/105/EEC restrictively, the Court of Justice ruled that those pricing and reimbursement procedures fall within the scope of Directive 89/105/EEC given the objectives of that Directive and the need to ensure its effectiveness. Therefore, this Directive should reflect the developments in national pricing and reimbursement policies. Given that specific rules and procedures exist in the area of public procurement and voluntary contractual agreements, national measures involving public procurement and voluntary contractual agreements should be excluded from the scope of this Directive.

(9) **Competent authorities and marketing authorisation holders increasingly engage in voluntary contractual agreements to provide patients with access to innovative treatments. In particular, those agreements allow the inclusion of a medicinal product in the scope of the health insurance systems while at the same time addressing the evidentiary uncertainties relating to the relative efficacy and/or effectiveness of a specific medicinal product by monitoring the elements agreed upfront and for a defined period of time. The delay in defining the terms and conditions of such voluntary contractual agreements often exceeds the time limits set in this Directive and justifies the exclusion of such agreements from its scope. Those agreements should effectively facilitate or enable patients' access to innovative medicinal products, should remain voluntary and should not affect the**

right of the marketing authorisation holder to submit an application for the inclusion of a medicinal product in the health insurance system pursuant to this Directive.

(10) Any measure **taken by the Member State** to regulate, either directly or indirectly, the prices of medicinal products, as well as any measure to determine their coverage by public health insurance systems should be based on **transparent** objective and verifiable criteria that are independent from the origin of the product and should provide adequate legal remedies, including judicial remedies, **in accordance with national procedures,** to affected companies. These requirements should equally apply to national, regional or local measures to control or promote the prescription of specific medicinal products as such measures also determine their effective coverage by health insurance systems.

(11) **The Union's support for cooperation on health technology assessment (hereinafter "HTA") in accordance with Article 15 of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare[10] aims to optimise and coordinate HTA methodologies which should ultimately also reduce delays in pricing and reimbursement procedures of medicinal products for which Member States use HTA as part of their decision-making process. HTA includes, in particular, information on the relative efficacy as well as on the short-term and long-term effectiveness, where appropriate, of health technologies, also taking into account broader economic and social benefits or cost-effectiveness of the assessed medicinal product, in accordance with the methodology of the competent authorities. HTA is a multidisciplinary process that summarises information about the medical, social, economic and ethical aspects relating to the use of health technology in a systematic, transparent, unbiased and robust manner. Its aim is to contribute to the formulation of safe, effective, health policies that are patient-focused and that seek to achieve best value.**

(12) Applications to approve the price of a medicinal product or to determine its coverage by the health insurance system should not delay the placing on the market of that product beyond what is necessary. It is therefore desirable that this Directive sets out mandatory time limits within which national decisions should be made. In order to be effective, the prescribed time periods should run from the receipt of an application until the entry into force of the corresponding decision. They should include all expert evaluations, including health technology assessments where applicable, and all administrative steps required for the decision to be adopted and take legal effect.

(13) **In order to facilitate compliance with the time limits set in this Directive, it may be useful for applicants of a marketing authorisation to start informal negotiations for price approval or for inclusion of a medicinal product in the public health insurance systems already before the marketing authorisation is granted. To this end, Member States should have the possibility to allow such applicants to submit a request for informal negotiations for price approval of a medicinal product or for its inclusion in the health insurance systems after the scientific assessment is finalised by the Committee for Medicinal Products for Human Use or by the national competent authority in charge of the marketing authorisation procedure, as appropriate. In such cases the time limits for**

[10] OJ L88; 4.4.2011; p.45

decisions on the price of a medicinal product or its inclusion in the health insurance system should run from the formal application for pricing or inclusion in the health insurance systems after the granting of the marketing authorisation.

(14) The time-limits for the inclusion of medicinal products in the health insurance systems set out in Directive 89/105/EEC are mandatory as clarified by the case-law of the Court of Justice. Experience has shown that those time limits are not always respected and that there is need to ensure legal certainty and improve the procedural rules related to the inclusion of medicinal products in the scope of health insurance system. Therefore, an effective and rapid remedies procedure should be put in place.

(15) In its Communication "Executive Summary of the Pharmaceutical Sector Inquiry Report"[11] the Commission demonstrated that pricing and reimbursement procedures often unnecessarily delay the launch of generic **medicinal products** ~~medicines~~ in Union markets. Approving the price of generic medicinal products and their coverage by the health insurance system should not require any new or detailed assessment when the reference product has already been priced and included in the health insurance system. It is therefore appropriate to lay down shorter time limits for generic medicinal products in those cases. **Same conditions might apply where appropriate to biosimilar medicinal products.**

(16) The judicial remedies available in the Member States have played a limited role in ensuring compliance with the time limits due to the often lengthy procedures in national jurisdictions, which deter affected companies from initiating legal action. Therefore, effective mechanisms are necessary to **ensure swift infringement resolution besides the judicial proceedings if necessary so as to** control and enforce compliance with the time limits for pricing and reimbursement decisions. **To this end, Member States should have the possibility to designate an existing administrative body.**

(17) The quality, safety and efficacy of medicinal products, including the bioequivalence of generic **medicinal products or the biosimilarity of biosimilar** medicinal products with the reference product, are ascertained in the framework of marketing authorisation procedures. In the framework of pricing and reimbursement procedures, **the competent authorities** ~~Member States~~ should therefore not re-assess ~~the elements on which the marketing authorisation is based, including~~ the quality, safety, efficacy or bioequivalence **or biosimilarity** of the medicinal product **which have been already assessed during the marketing authorisation process. Similarly, in the case of orphan medicinal products, the competent authorities should not re-assess the criteria of the orphan designation. However, competent authorities should have full access to the data used by the authorities responsible for granting the marketing authorisation of a medicinal product as well as the possibility of using or generating additional relevant data for the purpose of assessing a medicinal product in the context of its inclusion in the scope of the public health insurance system.**

(18) **The non-reassessment of the elements on which the marketing authorisation is based within the framework of pricing and reimbursement procedures should not, however, prevent the competent authorities from requesting, accessing and using data generated during the marketing authorisation process for the purpose**

[11] COM(2009) 351 final.

of HTA. Data sharing between the competent authorities responsible for marketing authorisation and for pricing and reimbursement should be possible at national level if such sharing exists. The competent authorities should also be able to use available data or generate additional relevant data for health technology assessment purpose.

(19) In accordance with Directive 2001/83/EC, intellectual property rights do not provide a valid ground to refuse, suspend or revoke a marketing authorisation. By the same token, applications, decision-making procedures and decisions to regulate the prices of medicinal products or to determine their coverage by health insurance systems should be considered administrative procedures which, as such, are independent from the enforcement of intellectual property rights. The national authorities in charge of those procedures, when examining an application with respect to a generic **or biosimilar** medicinal product, should not request information concerning the patent status of the reference medicinal product and should not examine the validity of an alleged violation of intellectual property rights should the generic **or biosimilar** medicinal product be manufactured or placed on the market subsequently to their decision. Consequently, intellectual property issues should neither interfere with nor delay pricing and reimbursement procedures in the Member States.

(**20) The Commission and the Member States might investigate possibilities to co-operate in the view of setting up and maintaining price information database on medicinal products and relevant conditions so as to provide a Union-wide added value in terms of price transparency while respecting the Member States' competences in this field**.

(21) In order to ensure the transparency, integrity and independence of the decision-making process within the national competent authorities, the names of experts participating in the bodies responsible for pricing and reimbursement decisions, together with their declarations of interest and the procedural steps leading to pricing and reimbursement decisions should be disclosed to the public.

(22) Member States have frequently amended their health insurance schemes or adopted new measures falling within the scope of Directive 89/105/EEC. It is therefore necessary to establish **an** information **mechanism** ~~mechanisms~~ intended~~, on the one hand,~~ to ensure the consultation of **all** interested stakeholders **including civil society organisations, such as patient and consumer groups** ~~and, on the other hand, to facilitate preventive dialogue with the Commission as regards the application of this Directive.~~ Since the objective of the action to be taken, namely providing minimal transparency rules to ensure the functioning of the internal market, cannot be sufficiently achieved by the Member States, as the notion of transparency of national measures is understood and applied differently in each Member State, and can therefore, by reason of the scale of the action be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.

(23) In accordance with the Joint Political Declaration of Member States and the Commission on explanatory documents of 28 September 2011, Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition

instruments. With regard to this Directive, the legislator considers the transmission of such documents to be justified.

HAVE ADOPTED THIS DIRECTIVE:

Chapter I

Scope and definitions

Article 1

Subject matter and scope

1. Member States shall ensure that any national, regional or local measure, whether laid down by law, regulation or administrative action, to control the prices of medicinal products for human use or to determine the range of medicinal products covered by public health insurance systems, including the extent and conditions of their coverage, complies with the requirements of this Directive. **Member States shall also ensure that the national procedures related to the pricing of medicinal products and their inclusion in the health insurance systems are not duplicated at regional or local level in their respective territories.**

2. This Directive shall not apply to the following:

(a) voluntary contractual agreements **which are concluded between competent authorities and the marketing authorisation holder for a medicinal product, which is not mandatory nor represents the only possibility for the medicinal product to be included in the health insurance systems, and which aims to include a medicinal product under the scope of a health insurance system while monitoring elements are agreed upfront among both parties relating to the effectiveness and/or relative efficacy of the given medicinal product, with a view to enabling the effective provision of that medicine to patients under specific conditions and during an agreed period of time.**

~~concluded between public authorities and the holder of a marketing authorisation for a medicinal product that have as their object to enable the effective provision of this medicine to patients under specific conditions;~~

(b) national measures intended to determine the prices or the coverage of medicinal products by public health insurance systems which are subject to national or Union legislation on public procurement, in particular Council Directive 89/665/EEC,[12] Council Directive 92/13/EEC[13] and Directive 2004/18/EC of the European Parliament and of the Council.[14]

The provisions of this Directive shall apply to measures intended to determine which medicinal products may be included in contractual agreements or public procurement procedures. **In accordance with Union and national law regarding business**

[12] OJ L 395, 30.12.1989, p. 33.

[13] OJ L 76, 23.3.1992, p. 14.

[14] OJ L 134, 30.4.2004, p. 114.

confidentiality, information regarding the name of the medicinal product and the name of the marketing authorisation holder included in contractual agreements or public procurement procedures shall be made publicly available once those agreements or procedures are concluded.

3. Nothing in this Directive shall permit the placing on the market of a medicinal product which has not received marketing authorisation as provided for in Article 6 of Directive 2001/83/EC.

This Directive shall be without prejudice to the marketing authorisation relating to a medicinal product granted in accordance with the procedure referred to in Article 6 of Directive 2001/83/EC and Article 3 of Regulation (EC) No 726/2004 of the European Parliament and of the Council. [15]

Article 2

Definitions

For the purposes of this Directive, the following definitions apply:

(1) "medicinal product" means a medicinal product as defined in Article 1 of Directive 2001/83/EC;

(2) "reference medicinal product" means a reference medicinal product as defined in point (a) of Article 10(2) of Directive 2001/83/EC;

(3) "generic medicinal product" means a generic medicinal product as defined in point (b) of Article 10(2) of Directive 2001/83/EC;

(4) "biosimilar medicinal product" means biological medicinal product which is similar to a reference biological medicinal product;

(5) "health technology" means a health technology as defined in point (l) of Article 3 of Directive 2011/24/EU of the European Parliament and of the Council[16];

(6) "health technology assessment" means an assessment **which as a minimum includes** ~~of~~ **the assessment of** the relative efficacy or of the short- and long-term effectiveness of the medicinal product compared to other health technologies **or interventions** in use for treating the associated condition.

[15] OJ L 136, 30.4.2004, p. 1.

[16] OJ L 88, 4.4.2011, p. 45.

Chapter II

Pricing of medicinal products

Article 3

Price approval

1. Paragraphs 2 to 9 shall apply if the marketing of a medicinal product is permitted only after the competent authorities of the Member State concerned have approved the price of the product.

2. Member States shall ensure that an application to approve the price of the product can be introduced by the marketing authorisation holder at any point in time. **The competent authorities shall provide the applicant with an official acknowledgement of receipt of the formal application for pricing within 10 days of its receipt.**

   Member States may provide the possibility to the applicant of a marketing authorisation to submit a request for informal negotiations on price approval when the Committee for Medicinal Products for Human Use established by Article 5 of Regulation (EC) No 726/2004 or the national competent authority has issued an opinion in favour of the granting of a marketing authorisation for the medicinal product concerned.

3. Member States shall ensure that a decision on the price which may be charged for the medicinal product concerned is adopted and communicated to the applicant within ~~60~~ **90** days of the receipt of an application submitted, in accordance with the requirements laid down in the Member State concerned, by the holder of a marketing authorisation. ~~However, with respect to medicinal products for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days.~~ With respect to generic medicinal products, that time limit shall be **30** ~~15~~ days, provided that the price of the reference medicinal product has been approved by the competent authorities.

   Where Member States decide to include health technology assessment as part of their decision-making process on the pricing of medicinal products, such assessment shall be carried out within the time limits set out in the first subparagraph.

4. Member States shall establish in detail the particulars and documents to be submitted by the applicant.

5. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of the detailed additional information required and take their final decision within **90** ~~60~~ days of receipt of this additional information. ~~However, with respect to medicines for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days.~~ With respect to generic medicinal products, that time limit shall be **30**~~15~~ days, provided that the price of the reference medicinal product has been approved by the competent authorities. Member States shall not request any additional information which is not explicitly required under national legislation or administrative guidelines.

6. In the absence of a decision within the relevant time limit set out in paragraphs 3 and 5, the applicant shall be entitled to market the product at the price proposed.

7. If the competent authorities decide not to permit the marketing of the medicinal product concerned at the price proposed by the applicant, the decision shall contain a statement of reasons based on objective and verifiable criteria, including any evaluation, expert opinion or recommendation on which it is based. The applicant shall be informed of all remedies available, including judicial remedies, and of the time limits for applying for such remedies.

8. Member States shall publish in an appropriate publication and communicate to the Commission the criteria which the competent authorities must take into account when approving the prices of medicinal products. **Member States shall make publicly available the information on those criteria and decision-making bodies at national or regional level.**

9. If the competent authorities decide to reduce the price of a specific named medicinal product on their own initiative, the decision shall contain a statement of reasons based on objective and verifiable criteria, including any evaluation, expert opinion or recommendation on which it is based. The decision shall be communicated to the holder of the marketing authorisation, who shall be informed of all remedies available, including judicial remedies, and of the time limits for applying for such remedies. **The decision and summary of the statement of reasons shall be made publicly available by the competent authorities without delay, after deletion of any information of a commercially confidential nature.**

Article 4

Price increase

1. Without prejudice to Article 5, paragraphs (2) to (6) shall apply if an increase in the price of a medicinal product is permitted only after prior approval has been obtained from the competent authorities.

2. Member States shall ensure that an application to increase the price of the product can be submitted by the marketing authorisation holder **in accordance with national law** at any point in time. The competent authorities shall provide the applicant with an official acknowledgement of receipt **of the application within 10 days of its receipt.**

3. Member States shall ensure that a decision **to approve or reject** ~~on~~ an application submitted in accordance with the requirements laid down in the Member State concerned, by a marketing authorisation holder to increase the price of a medicinal product is adopted and communicated to the applicant within **90** ~~60~~ days of its receipt.

   In case of an exceptional number of applications, the time limit set out in this paragraph may be extended once only for a further 60 days. The applicant shall be notified of such an extension before the expiry of the time limit set out in this paragraph.

4. Member States shall establish in detail the particulars and documents to be submitted by the applicant.

The applicant shall furnish the competent authorities with adequate information, including details of those events intervening since the price of the medicinal product was last determined which in his opinion justify the price increase requested. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of the detailed additional information required and take their final decision within **90** ~~60~~ days of receipt of this additional information. Member States shall not request any additional information which is not explicitly required under national legislation or administrative guidelines.

5. In the absence of a decision within the relevant time limit referred to in paragraphs 3 and 4, the applicant shall be entitled to apply the price increase requested.

6. If the competent authorities decide not to permit the whole or part of the price increase requested, the decision shall contain a statement of reasons based on objective and verifiable criteria and the applicant shall be informed of all remedies available, including judicial remedies, and of the time limits for applying for such remedies.

Article 5

Price freeze and price reduction

1. In the event of a price freeze or price reduction imposed on all medicinal products or on certain categories of medicinal products by the competent authorities of a Member State, that Member State shall publish a statement of reasons for its decision based on objective and verifiable criteria, including, if applicable, a justification of the categories of products subject to the price freeze or price reduction. **Once a year Member States shall assess whether the price freeze or the price reduction is still justified taking into account the macro-economic conditions and adopt necessary changes where appropriate.**

2. Marketing authorisation holders may apply for a derogation from a price freeze or price reduction if this is justified by particular reasons. The application shall contain an adequate statement of reasons. Member States shall ensure that applications for a derogation can be introduced by the marketing authorisation holder at any point in time. The competent authorities shall provide the applicant with an official acknowledgement of receipt **of the formal application for inclusion of the medicinal product in the health insurance system within 10 days of its receipt.**

3. Member States shall ensure that a reasoned decision on an application referred to in paragraph 2 is adopted and communicated to the applicant within **90** ~~60~~ days of the receipt of the application. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of the detailed additional information required and take their final decision within **90** ~~60~~ days of receipt of this additional information. If the derogation is granted, the competent authorities shall forthwith publish an announcement of the price increase allowed.

If there is an exceptional number of applications, the relevant time limit set out in paragraph 3 may be extended once only for a further 60 days. The applicant shall be notified of such extension before the expiry of the time limit set out in paragraph 3.

Article 6

Controls on profits

Where a Member State adopts a system of direct or indirect controls on the profitability of persons responsible for placing medicinal products on the market, the Member State concerned shall publish the following information in an appropriate publication and communicate it to the Commission:

(a) the method or methods used in the Member State concerned to define profitability: return on sales and/or return on capital;

(b) the range of target profit currently permitted to persons responsible for placing medicinal products on the market in the Member State concerned;

(c) the criteria according to which target rates of profit are accorded to an individual responsible for placing medicinal products on the market, together with the criteria according to which they will be allowed to retain profits above their targets in the Member State concerned;

(d) the maximum percentage profit which any person responsible for placing medicinal products on the market is allowed to retain above his target in the Member State concerned.

The information referred to in the first subparagraph shall be updated once a year or when significant changes are made.

Where, in addition to operating a system of direct or indirect controls on profits, a Member State operates a system of controls on the prices of certain types of medicinal products which are excluded from the scope of the profit control scheme, Articles 3, 4 and 5 shall, where relevant, apply to such price controls. However, those Articles shall not apply where the normal operation of a system of direct or indirect controls on profits results exceptionally in a price being fixed for an individual medicinal product.

Chapter III

Coverage of medicinal products by public health insurance systems

Article 7

Inclusion of medicinal products in health insurance systems

1. Paragraphs 2 to **8** ~~9~~ shall apply if a medicinal product is covered by the public health insurance system only after the competent authorities have decided to include the medicinal product concerned in the scope of that system.

2. Member States shall ensure that an application to include a medicinal product in the scope of the public health insurance system can be introduced by the marketing authorisation holder at any point in time. **The competent authorities shall provide the applicant with an official acknowledgement of receipt of the application within 10 days of its receipt.**

Member States may also provide the possibility to the applicant of a marketing authorisation to submit a request for informal negotiations on inclusion of a medicinal product in the scope of the public health insurance systems when the Committee for Medicinal Products for Human Use established by Article 5 of Regulation (EC) No 726/2004 or the national competent authority has issued an

opinion in favour of the granting of a marketing authorisation for the medicinal product concerned.

3. If the public health insurance system comprises several schemes or categories of coverage, the marketing authorisation holder shall be entitled to apply for the inclusion of its product in the scheme or category of its choice. Member States shall establish in detail the particulars and documents to be submitted by the applicant.

4. Member States shall ensure that a decision on an application to include a medicinal product in the scope of the public health insurance system, submitted by the marketing authorisation holder in accordance with the requirements laid down in the Member State concerned, is adopted and communicated to the applicant within **90** ~~60~~ days of its receipt. ~~However, with respect to medicinal products for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days.~~ With respect to generic medicinal products, that time limit shall be ~~15~~ **30** days, provided that the reference medicinal product has already been included in the public health insurance system.

Where Member States decide to include health technology assessment as part of their decision-making process on the pricing of medicinal products, such assessment shall be carried out within the time limits set out in the first subparagraph.

5. If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of the detailed additional information required and take their final decision within **90** ~~60~~ days of receipt of the additional information. ~~However, with respect to medicinal products for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90 days.~~ With respect to generic medicinal products, that time limit shall be ~~15~~ **30** days, provided that the reference medicinal product has already been included in the public health insurance system. Member States shall not request any additional information which is not explicitly required under national legislation or administrative guidelines.

6. Irrespective of the organisation of their internal procedures, Member States shall ensure that the overall period of time taken by the inclusion procedure set out in paragraph 5 of this Article and the price approval procedure set out in Article 3 does not exceed ~~120~~ **180** days. ~~However, with respect to the medicinal products for which Member States use health technology assessment as part of their decision-making process, the time limit shall not exceed 180 days.~~ With respect to generic medicinal products, that time limit shall not exceed ~~30~~ **60** days, provided that the reference medicinal product has already been included in the public health insurance system. Those time-limits may be extended in accordance with paragraph 5 of this Article or Article 3(5).

7. Any decision not to include a medicinal product within the scope of the public health insurance system shall contain a statement of reasons based upon objective and verifiable criteria. Any decision to include a medicinal product within the scope of the public health insurance system shall contain a statement of reasons justifying the decision, including the extent and conditions of the product's coverage, on the basis of objective and verifiable criteria.

The decisions referred to in this paragraph shall also include any evaluation, expert opinion or recommendation on which they are based. The applicant shall be informed

of all remedies available, including judicial remedies, and the remedies procedure set out Article 8, of the time limits for applying for such remedies.

8. Member States shall publish in an appropriate publication and communicate to the Commission the criteria which the competent authorities must take into account when deciding whether or not to include medicinal products within the scope of the public health insurance system. **Member States shall make publicly available the information on those criteria and decision-making bodies at national or regional level.**

Article 8

Remedies procedure in case of non-compliance with the time limits related to the inclusion of medicinal products in health insurance systems

1. Member States shall ensure that effective and rapid remedies procedures are available to the applicant in case of non-compliance with the time limits set out in Article 7 and are in accordance with their national law.

2. For the purposes of the remedies procedures referred in paragraph 1, Member States may designate a body and entrust it with the powers to take, at the earliest opportunity and by way of interlocutory procedures, interim measures with the aim of correcting the alleged infringement or preventing further damage to the interests concerned.

3. The body in charge of the remedies procedures shall be independent of the competent authorities in charge of controlling the prices of medicinal products or in charge of determining the range of medicinal products covered by health insurance systems.

4. ~~Member States shall ensure that effective and rapid remedies are available to the applicant in case of non-compliance with the time limits set in Article 7.~~

5. ~~For the purposes of the remedies procedure Member States shall designate a body and entrust it with the powers to:~~

~~(a) take, at the earliest opportunity and by way of interlocutory procedures, interim measures with the aim of correcting the alleged infringement or preventing further damage to the interests concerned;~~

~~(b) award damages to the applicant in case of non-compliance with time limits set in Article 7 where damages are claimed, unless the competent authority may prove that the delay is not imputable to it;~~

~~(c) impose a penalty payment, calculated by day of delay.~~

~~For the purposes of point (c), the penalty payment shall be calculated depending on the seriousness of the infringement, its duration, the need to ensure that the penalty itself is a deterrent to further infringements.~~

~~Member States may provide that the body referred to in the first subparagraph may take into account the probable consequences of potential measures taken under the present paragraph for all interests likely to be harmed, as well as the public interest, and may decide not to take such measures when their negative consequences could exceed their benefits.~~

~~6. A decision not to grant interim measure shall not prejudice any other claim of the applicant seeking such measures.~~

~~7. Member States shall ensure that decisions taken by bodies responsible for remedies procedures can be effectively enforced.~~

~~8. The body referred to in paragraph 2 shall be independent of the competent authorities in charge of controlling the prices of medicinal products for human use or in charge of determining the range of medicinal products covered by health insurance systems.~~

~~9. The body referred to in paragraph 2 shall state reasons for its decision. Furthermore, where that body is not judicial in character, provision must be made to guarantee procedures whereby any allegedly illegal measure taken by the independent body or any alleged defect in the exercise of powers conferred on it can be subject to judicial review or review by another body which is a court or tribunal within the meaning of Article 267 of the Treaty on the Functioning of the European Union and independent of both the competent authority and the body referred to in paragraph 2.~~

~~The members of the body referred to in paragraph 2 shall be appointed and leave office under the same conditions as members of the judiciary as regards the authority responsible for their appointment, their period of office, and their removal. At least the president of that body shall have the same legal and professional qualifications as members of the judiciary. That body shall take its decisions following a procedure in which both sides are heard, and these decisions shall, by means determined by each Member State, be legally binding.~~

Article 9

Exclusion of medicinal products from health insurance systems

1. Any decision to exclude a medicinal product from the scope of the public health insurance system, or to modify the extent or the conditions of coverage of the product concerned, shall contain a statement of reasons based on objective and verifiable criteria. Such decisions shall include any evaluation, expert opinion or recommendation on which they are based. The applicant shall be informed of all remedies available, including judicial remedies, and of the time limits for applying for such remedies.

2. Any decision to exclude a category of medicinal products from the scope of the public health insurance system, or to modify the extent or the conditions of coverage of the category concerned, shall contain a statement of reasons based on objective and verifiable criteria ~~and be published in an appropriate publication.~~

3. **Any decision to exclude a medicinal product or a category of medicinal products from the scope of the public health insurance system shall be made publicly available, together with a summary of the statement of reasons, after deletion of any information of a commercially confidential nature.**

Article 10

Classification of medicinal products in view of their inclusion in health insurance systems

1. Paragraphs 2, 3 and 4 shall apply where medicinal products are grouped or classified according to therapeutic or other criteria for the purpose of their inclusion within the scope of the public health insurance system.

2. Member States shall publish in an appropriate publication and communicate to the Commission the objective and verifiable criteria according to which medicinal products are classified in view of their inclusion in the public health insurance system.

3. For the medicinal products subject to such grouping or classification, Member States shall publish in an appropriate publication and communicate to the Commission the methodologies used to determine the extent or conditions of their inclusion in the public health insurance system.

4. At the request of the holder of a marketing authorisation, the competent authorities shall specify the objective data on the basis of which they have determined the arrangements of coverage for their medicinal product, in application of the criteria and methodologies referred to in paragraphs 2 and 3. In such a case, the competent authorities shall also inform the marketing authorisation holder of all remedies available, including judicial remedies, and of the time limits for applying for such remedies.

Article 11

Measures to control or promote the prescription of specific medicinal products

1. Paragraphs 2, 3 and 4 shall apply where a Member State adopts measures intended to control or promote the prescription of specific named medicinal products.

2. Measures referred to in paragraph 1 shall be based on objective and verifiable criteria.

3. Measures referred to in paragraph 1, including any evaluation, expert opinion or recommendation on which they are based, shall be published in an appropriate publication **and made available to the public.**

4. At the request of the holder of a marketing authorisation whose interests or legal position are affected by the measures referred to in paragraph 1, the competent authorities shall specify the objective data and criteria on the basis of which these measures have been taken with respect to its medicinal product. In such a case, the competent authorities shall also inform the marketing authorisation holder of all remedies available, including judicial remedies, and of the time limits for applying for such remedies.

Chapter IV

Specific requirements

Article 12

Effectiveness of the time limits

1. The time limits laid down in Articles 3, 4, 5 and 7 shall be construed as the period between the receipt of an application or additional information, as the case may be, and the effective entry into force of the corresponding decision. All expert evaluations and administrative steps necessary for taking the decision and bringing it into effect shall be carried out within the prescribed time limits.

2. If the decision making process involves negotiations between the marketing authorisation holder and the competent authority, provided that it is agreed by both parties, the time limits laid down in Articles 3, 4, 5 and 7 shall be suspended from the time the competent authority communicates its proposals to the marketing authorisation holder until the competent authority receives the response to its proposals from the marketing authorisation holder. Member States shall make available to the public the practical modalities for such suspension.

Article 13

Additional proof of quality, safety, efficacy or bioequivalence

1. In the framework of pricing and reimbursement decisions, Member States shall not re-assess ~~the elements on which the marketing authorisation is based, including the~~ **the** quality, safety, efficacy, ~~or~~ bioequivalence, **biosimilarity** of the medicinal product **or the criteria for orphan designation, which have already been assessed during the marketing authorisation procedure.**

2. Paragraph 1 shall be without prejudice to the right of the competent authorities to request and have full access to data generated during the marketing authorisation process for the purpose of health technology assessment, so that they can assess the relative efficacy as well as the short- and long-term effectiveness, where appropriate, of a medicinal product.

3. The competent authorities shall also be able to use the available data or generate additional relevant data for the purpose of health technology assessment.

Article 14

Non interference of intellectual property rights

1. Applications, decision-making procedures and decisions to regulate the prices of medicinal products in accordance with Article 3 or to determine their inclusion within the scope of public health insurance systems in accordance with Articles 7 and 9 shall be considered by Member States as administrative procedures which, as such, are independent from the enforcement of intellectual property rights.

2. The protection of intellectual property rights shall not be a valid ground to refuse, suspend or revoke decisions relating to the price of a medicinal product or its inclusion within the public health insurance system.

3. Paragraphs 1 and 2 shall apply without prejudice to the Union and national legislation relating to the protection of intellectual property.

Chapter V

Transparency mechanisms

Article 15

Consultation of interested parties

Where a Member State intends to adopt or amend any **legislative** measure falling within the scope of this Directive, it shall give **civil society organisations, including patient and consumer groups, and other** interested parties, the opportunity to comment on the draft measure within a reasonable period. The competent authorities shall publish the rules applicable to consultations. The results of consultations shall be made publicly available, with the exception of confidential information in accordance with Union and national legislation regarding business confidentiality.

Article 16

Transparency of decision-making bodies and prices

1. Member States shall ensure that the competent authorities controlling the prices of medicinal products or determining the coverage of medicinal products by public health insurance systems make publicly available a regularly updated list of the members of their decision-making bodies, together with their declarations of interest.

2. Paragraph 1 shall also apply to the body referred to in Article 8(2).

~~*Article 16*~~

~~*Notification of draft national measures*~~

~~1. Where Member States intend to adopt or amend any measure falling within the scope of this Directive, they shall immediately communicate to the Commission the draft measure envisaged, together with the reasoning on which the measure is based.~~

~~2. Where appropriate, Member States shall simultaneously communicate the texts of the basic legislative or regulatory provisions principally and directly concerned, if knowledge of such texts is necessary to assess the implications of the measure proposed.~~

~~3. Member States shall communicate the draft measure referred to in paragraph 1 again if they make changes to the draft that have the effect of significantly altering its~~

~~scope or substance, or shortening the timetable originally envisaged for implementation.~~

~~4. The Commission may send its observations to the Member State which has communicated the draft measure within three months.~~

~~The observations of the Commission shall be taken into account as far as possible by the Member State concerned, in particular if the observations indicate that the draft measure may be incompatible with Union law.~~

~~5. When the Member State concerned definitively adopts the draft measure, it shall communicate the final text to the Commission without delay. If observations have been made by the Commission in accordance with paragraph 4, this communication shall be accompanied by a report on the actions taken in response to the observations of the Commission.~~

Article 17

Report on the implementation of the time limits

1. By 31 January of […] [*insert a date - the year following the date referred to in the first subparagraph of Article 18(1)*], and by 31 January ~~and 1 July~~ of every year thereafter, Member States shall communicate to the Commission and publish in an appropriate publication a detailed report providing the following information:

   (a) the number of applications received in accordance with Articles 3, 4 and 7 during the preceding year;

   (b) the amount of time taken to issue a decision on each of the applications received in accordance with Articles 3, 4, and 7.

   (c) an analysis of the main reasons for delays, if any, together with recommendations to bring decision-making processes into line with the time limits laid down in this Directive.

   For the purposes of point (a) of the first subparagraph, a distinction shall be made between generic medicinal products subject to shorter time limits in accordance with Articles 3, 4 and 7 and other medicinal products.

   For the purposes of point (b) of the first subparagraph, any suspension of the procedure to request additional information to the applicant shall be reported with a clear indication of the duration of the suspension and the detailed reasons for the suspension.

2. The Commission shall publish every **year** ~~six months~~ a report on the information submitted by Member States according to paragraph 1.

Chapter VI

Final provisions

Article 18

Transposition

1. Member States shall adopt and publish, by [*last day of the 12th month following publication of this Directive in the Official journal of the European Union*] at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

   They shall apply those provisions from [the day after the date set out in the first subparagraph.].

   When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 19

Report on the implementation of this Directive

1. Member States shall send a report to the Commission on the implementation of this Directive by [*insert date - within two years after the date referred to in the second subparagraph of Article 18(1)*] and every three years thereafter.

2. By [*insert date - within three years after the date referred to in the second subparagraph of Article 18(1)*], the Commission shall submit a report to the European Parliament and the Council on the implementation of this Directive. The report may be accompanied by any appropriate proposals.

Article 20

Repeal

Directive 89/105/EEC is repealed from [the date set out in the second subparagraph of Article 18(1)].

The effects of Article 10 of Directive 89/105/EEC shall be maintained.

References to the repealed Directive shall be construed as references to this Directive.

Article 21

Entry into force and application

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

~~Article 16 shall apply from [insert the date - date set out in the second subparagraph of Article 18(1)].~~

Article 22

Addressees

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

1.2. Policy area(s) concerned in the ABM/ABB structure

1.3. Nature of the proposal/initiative

1.4. Objective(s)

1.5. Grounds for the proposal/initiative

1.6. Duration and financial impact

1.7. Management method(s) envisaged

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

2.2. Management and control system

2.3. Measures to prevent fraud and irregularities

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

3.2. Estimated impact on expenditure

3.2.1. Summary of estimated impact on expenditure

3.2.2. Estimated impact on operational appropriations

3.2.3. Estimated impact on appropriations of an administrative nature

3.2.4. Compatibility with the current multiannual financial framework

3.2.5. Third-party participation in financing

3.3. Estimated impact on revenue

LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

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 (Repealing Directive 89/105/EEC)

1.2. Policy area(s) concerned in the ABM/ABB structure[17]

Title 02 – Enterprise

1.3. Nature of the proposal/initiative

☒ The proposal/initiative relates to **the extension of an existing action**

1.4. Objectives

1.4.1. The Commission's multiannual strategic objective(s) targeted by the proposal/initiative

1a. Competitiveness for growth and employment

1.4.2. Specific objective(s) and ABM/ABB activity(ies) concerned

Specific objective No.1.

To continually develop existing internal market *acquis* and propose new legislative or non-legislative action whenever appropriate

ABM/ABB activity(ies) concerned

Chapter 02 03: Internal market for goods and sectoral policies

1.4.3. Expected result(s) and impact

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

The proposal provides for a comprehensive update of Directive 89/105/EEC in view of ensuring the transparency of national measures regulating the prices of medicinal products for human use and their inclusion in the scope of social security systems. The existing directive has become outdated and difficult to enforce due to the evolution of the pharmaceutical market in the last twenty years and to the multiplication of national measures to contain growing pharmaceutical costs. The proposal aims at avoiding barriers to the free movement of goods prohibited by the EU Treaty, while respecting the responsibilities of the Member States for the organisation of their health insurance systems. The initiative is expected to:
- Improve legal clarity and certainty for all interested parties;
- Provide a level playing field for pharmaceutical companies operating in Europe;
- Facilitate the enforcement of the procedural obligations incumbent upon Member States.

1.4.4. Indicators of results and impact

Specify the indicators for monitoring implementation of the proposal/initiative.

[17] ABM: Activity-Based Management – ABB: Activity-Based Budgeting.

The proposal consists in a directive to be transposed into national legislation by the Member States. The first indicator will therefore be the actual transposition rate by the end of the transposition deadline. Budget is earmarked in order to ensure the verification of transposition by Member States.

Effective implementation will be monitored as a second step. The key objectives pursued by the proposal consist in a) guaranteeing that national pricing and reimbursement decisions are made within specific time-limits and b) ensuring the effectiveness of minimal transparency rules for national pricing and reimbursement measures. Results will be measured against the following indicators:

1/ Actual timing for pricing and reimbursement decisions in the Member States (monitoring instrument: mandatory annual reporting by Member States).

2/ Number of non-compliance cases identified in the Member States (monitoring instruments: ~~mandatory notification of draft national measures by national authorities and~~ statistics of infringement procedures).

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term

The text of the proposal essentially requires Member States to ensure that:

1/ Pricing and reimbursement decisions are made within ~~60/120~~ **90/180** days. ~~However, with respect to medicines for which Member States use health technology assessment as part of their decision-making process, the time-limit shall be 90/180 days.~~ Furthermore, the timeframe is reduced to **30/60** ~~15/30~~ days with respect to generic medicinal products.

2/ Any measure intended to regulate the prices of medicines, to manage their consumption or to determine their reimbursement status is adopted in a transparent manner on the basis of objective and verifiable criteria.

3/ Effective judicial remedies are available to affected pharmaceutical companies.

1.5.2. Added value of EU involvement

National pricing and reimbursement measures have a clear transnational impact linked, in particular, to the potential disruption they might cause to the internal market for medicinal products. The proper functioning of the internal market therefore requires timely and transparent decisions to be made by Member States. The notion of procedural transparency is understood differently across the EU so that action by individual Member States would not provide sufficient guarantees of transparency for economic operators.

1.5.3. Lessons learned from similar experiences in the past

In the last twenty years, Directive 89/105/EEC has played a key role in promoting the transparency of national pricing and reimbursement measures. However, experience in managing the directive has shown that:

1/ National pricing and reimbursement policies evolve at a quick pace, so that the requirements of the directive should be based on general principles rather than on the description of specific types of measures.

2/ The effective monitoring of national legislation in this field of competence belonging essentially to the Member States requires stronger information and enforcement mechanisms.

1.5.4. Coherence and possible synergy with other relevant instruments

The proposal must be seen in the context of the Commission's efforts to reinforce the internal market and to generate favourable conditions for a competitive pharmaceutical industry that provides safe, innovative and accessible medicines to European citizens. It relates to a number of recent or on-going initiatives, in particular:

1/ The Commission Communication on a renewed vision for the pharmaceutical sector (2008), which announced that the application of Directive 89/105/EEC would be enhanced to ensure genuinely transparent and speedy pricing and reimbursement decisions.

2/ The Commission's Pharmaceutical Sector Inquiry (2008-2009), which 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.

3/ The political initiatives to foster cooperation between Member States on pricing and reimbursement challenges, in particular the High Level Pharmaceutical Forum (2005-2008) and the Process on Corporate Responsibility in the Field of Pharmaceuticals launched by the European Commission in 2010.

4/ Voluntary cooperation between Member States on health technology assessments currently take forward in the framework of the EUNetHTA Joint Action and to be formalised through the implementation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.

1.6. Duration and financial impact

☒ Proposal/initiative of **unlimited duration**

– Depending on progress with the legislative process, implementation is envisaged to begin in 2014 (adoption by Council and Parliament) with a deadline for transposition by Member States in 2015.

1.7. Management mode(s) envisaged[18]

☒ **Centralised direct management** by the Commission

Comments

Member States will be responsible for implementing the provisions of the directive. The Commission's role will mainly consist in:

-Facilitating and verifying the transposition of the Directive. Budget impact: administrative expenditure (missions, conferences, etc.) and expert support (verification of transposition).
- Facilitating the implementation of the Directive in the context of the Committee created according to Article 10 of Directive 89/105/EEC and composed of national representatives and chaired by the Commission services. Budget impact: administrative expenditure for the organisation of the Committee.

[18] Details of management modes and references to the Financial Regulation may be found on the BudgWeb site: http://www.cc.cec/budg/man/budgmanag/budgmanag_en.html.

~~- Checking the compliance with the provisions of the Directive of draft national measures notified to the Commission. Budget impact: this activity involves the mobilisation of additional human resources, external translation work as well as the development of specific IT tools for communication with Member States.~~

- The financial resources required will be met by the existing resources (internal market line) which are already assigned to the management of the actions and/or by redeployment within the DG.

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

The proposal requires Member States to communicate to the Commission:

1/ The criteria they use to approve the prices of medicines and to decide whether or not to include medicinal products within the scope of the public health insurance system. Any amendment to these criteria should be reported as well.

2/ Specific information on the effective timing for their pricing and reimbursement decisions (frequency: every **year** ~~six months~~)

~~/ Any draft proposal falling within the scope of the Directive (permanent verification of compliance and early dialogue).~~

3/ A report on the implementation of the Directive within two years following transposition.

The information communicated will be assessed by the Commission and, if necessary, discussed with the Member States for appropriate follow-up.

2.2. Management and control system

2.2.1. Risk(s) identified

The main risks in managing the proposed legislation relate to the following three phases:

- Initial transposition in national laws;
- Compliance of any new national measure falling within the scope of the Directive;
- Effective implementation of the procedural requirements laid down in national law.

2.2.2. Control method(s) envisaged

The control methods envisaged are described in detail in the Transposition and Implementation Plan (TIP). They mainly consist in:

- The provision of technical expertise by the Commission during the transposition phase;
- The adoption of interpretative guidelines by the Commission, in cooperation with the Member States, to clarify implementation issues, if any;
~~- The verification of compliance of draft national measures by the Commission;~~
- The review of national implementation reports, the drafting by the Commission of an implementation report and possible follow-up measures.

2.3. Measures to prevent fraud and irregularities

This initiative does not involve any particular risk of fraud as it only lays down procedural requirements to be followed by Member States in their pharmaceutical pricing and reimbursement policies. The Commission will ensure the overall management of the regulatory framework through administrative involvement, subject to the Commission's internal control standards.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing expenditure budget lines*

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number [Description……...…….]	Diff./non-diff. (19)	from EFTA[20] countries	from candidate countries[21]	from third countries	within the meaning of Article 18(1)(aa) of the Financial Regulation
Heading 1	02.03.01 – Operation and development of the internal market, particularly in the fields of notification, certification and sectoral aproximation	Diff	YES	NO	NO	NO
Heading 1	02.01.04.01 – Operation and development of the internal market, particularly in the fields of notification, certification and sectoral approximation --- Expenditure on administrative management	Non-Diff	YES	NO	NO	NO

* Financial headings and budget lines will need to be adapted to the new legal basis to be adopted under the financial perspectives 2014-2020.

19 Diff. = Differentiated appropriations / Non-diff. = Non-Differentiated Appropriations.

20 EFTA: European Free Trade Association.

21 Candidate countries and, where applicable, potential candidate countries from the Western Balkans.

3.2. Estimated impact on expenditure

3.2.1. Summary of estimated impact on expenditure

EUR million (to 3 decimal places)

Heading of multiannual financial framework:	1	1.a Competitiveness for growth and employment

DG: ENTERPRISE			Year **N = 2014**	Year **N+1= 2015**	Year **N+2 = 2016**	Year **N+3 = 2017**	Year **N+4 = 2018**	….. Action continued …..		**TOTAL**
• Operational appropriations										
02.03.01 – Operation and development of the internal market, particularly in the fields of notification, certification and sectoral approximation	Commitments	(1)	0,645	0,735	0,585	0,585	0,585	0,585	0,585	…
	Payments	(2)	0,150	0,500	0,500	0,500	0,500	0,500	0,500	
Appropriations of an administrative nature financed from the envelope for specific programmes[22]										
02.010401 – Operation and development of the internal market, particularly in the fields of notification, certification and sectoral approximation — Expenditure on administrative management		(3)	0,050				0,200			
TOTAL appropriations for DG ENTERPRISE	Commitments	=1+1a +3	0,700	0,735	0,585	0,585	0,785	0,585	0,585	...
	Payments	=2+2a +3	0,150	0,500	0,500	0,500	0,700	0,500	0,500	

[22] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former "BA" lines), indirect research, direct research.

• TOTAL operational appropriations	Commitments	(4)	0,645	0,735	0,585	0,585	0,585	0,585	0,585	
	Payments	(5)	0,150	0,500	0,500	0,500	0,500	0,500	0,500	
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)	0,050				0,200			
TOTAL appropriations under HEADING 1 of the multiannual financial framework	Commitments	=4+ 6	0,700	0,735	0,585	0,585	0,785	0,585	0,585	
	Payments	=5+ 6	0,200	0,500	0,500	0,500	0,700	0,500	0,500	

Heading of multiannual financial framework:	**5**	" Administrative expenditure "

EUR million (to 3 decimal places)

		Year **N = 2014**	Year **N+1 = 2015**	Year **N+2 = 2016**	Year **N+3 = 2017**	Year **N+4 = 2018**	….. Action continued …..	**TOTAL**
DG: ENTERPRISE								
• Human resources		0,159	0,508	0,508	0,508	0,508	0,508	0,508	…
• Other administrative expenditure		0,050	0,050	0,050	0,050	0,050	0,050	0,050	
TOTAL DG ENTERPRISE	Appropriations	0,209	0,558	0,558	0,558	0,558	0,558	0,558	…

TOTAL appropriations under HEADING 5 of the multiannual financial framework	(Total commitments = Total payments)	0,209	0,558	0,558	0,558	0,558	0,558	0,558	

EUR million (to 3 decimal places)

		Year **N = 2014**	Year **N+1 = 2015**	Year **N+2 = 2016**	Year **N+3 = 2017**	Year **N+4 =2018**	….. Action continued …..		**TOTAL**
TOTAL appropriations under HEADINGS 1 to 5 of the multiannual financial framework	Commitments	0,859	1,293	1,143	1,143	1,093	1,093	1,093	
	Payments	0,409	1,058	1,058	1,058	1,258	1,008	1,008	

Note: The financial resources required will be met by the existing resources (internal market line) which are already assigned to the management of the actions and/or by redeployment within the DG.

3.2.2. Estimated impact on operational appropriations

– ☒ The proposal/initiative requires the use of operational appropriations, as explained below:

Commitment appropriations in EUR million (to 3 decimal places)

Indicate objectives and outputs ⇩			Year **N=2014**		Year **N+1=2015**		Year **N+2=2016**		Year **N+3=2017**		….. Action continued …..						**TOTAL**	
	OUTPUTS																	
	Type of output[23]	Average cost of the output	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Total number of outputs	Total cost
SPECIFIC OBJECTIVE : To continually develop existing internal market acquis and propose new legislative or non-legislative action whenever appropriate																		
Translation	(A)	0,495	1	0,495	1	0,495	1	0,495	1	0,495	1	0,495	1	0,495	1	0,495		…
IT database	(B)	0,15	1	0,15	0,6	0,09	0,6	0,09	0,6	0,09	0,6	0,09	0,6	0,09	0,6	0,09		…

[23] Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.). (A) = translation work, (B) = IT support, (C)= Services – Verification of transposition.

Transposition	(C)	0,15	0		1	0,15	0		0		0		0		0			0,15
Sub-total for specific objective N°1																		
TOTAL COST			2	0,645	2,6	0,735	1,6	0,585	1,6	0,585	1,6	0,585	1,6	0,585	1,6	0,585		…

3.2.3. Estimated impact on appropriations of an administrative nature

3.2.3.1. Summary

– ☒ The proposal/initiative requires the use of administrative appropriations, as explained below.

EUR million (to 3 decimal places)

	Year **N =2014**	Year **N+1 = 2015**	Year **N+2 = 2016**	Year **N+3 = 2017**	Year **N+4 = 2018**	….. Action continued …..	**TOTAL**
HEADING 5 of the multiannual financial framework							
Human resources	0,159	0,508	0,508	0,508	0,508	0,508	0,508 …
Other administrative expenditure	0,050	0,050	0,050	0,050	0,050	0,050	0,050
Subtotal HEADING 5 of the multiannual financial framework	0,209	0,558	0,558	0,558	0,558	0,558	0,558 …
Outside HEADING 5[24] of the multiannual financial framework							
Human resources							
Other expenditure of an administrative nature	0,050				0,200		
Subtotal outside HEADING 5 of the multiannual financial framework	0,050						
TOTAL	0,259	0,558	0,558	0,558	0,758	0,558	0,558 …

3.2.3.2. Estimated requirements of human resources

– ☒ The proposal/initiative requires the use of human resources, as explained below:

Estimate to be expressed in full amounts (or at most to one decimal place)

	Year **N= 2014**	Year **N+1= 2015**	Year **N+2= 2016**	Year **N+3= 2017**	….. Action continued …..

[24] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former "BA" lines), indirect research, direct research.

• Establishment plan posts (officials and temporary agents)								
02 01 01 01 (Headquarters and Commission's Representation Offices)		0,159	0,508	0,508	0,508	0,508	0,508	…
XX 01 01 02 (Delegations)								
XX 01 05 01 (Indirect research)								
10 01 05 01 (Direct research)								
• External personnel (in Full Time Equivalent unit: FTE)[25]								
XX 01 02 01 (CA, INT, SNE from the "global envelope")								
XX 01 02 02 (CA, INT, JED, LA and SNE in the delegations)								
XX 01 04 ***yy*** [26]	- at Headquarters[27]							
	- in delegations							
XX 01 05 02 (CA, INT, SNE - Indirect research)								
10 01 05 02 (CA, INT, SNE - Direct research)								
Other budget lines (specify)								
TOTAL		**0,159**	**0,508**	**0,508**	**0,508**	**0,508**	**0,508**	**…**

XX is the policy area or budget title concerned.

The human resources required will be met by staff from the DG who are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

Description of tasks to be carried out:

Officials and temporary agents	Overall management of the Directive (coordination with Member States, organisation of consultative committee, legal interpretation, infringement procedures, etc.), assessment of draft national measures notified to the Commission, secretarial and administrative support.
External personnel	--

[25] CA= Contract Agent; INT= agency staff ("*Intérimaire")*; JED= "*Jeune Expert en Délégation"* (Young Experts in Delegations); LA= Local Agent; SNE= Seconded National Expert.

[26] Under the ceiling for external personnel from operational appropriations (former "BA" lines).

[27] Essentially for Structural Funds, European Agricultural Fund for Rural Development (EAFRD) and European Fisheries Fund (EFF).

3.2.4. Compatibility with the current multiannual financial framework

– ☒ Proposal/initiative is compatible the current multiannual financial framework.

– Financial headings and budget lines will need to be adapted to the new legal basis to be adopted under the financial perspectives 2014-2020

– ☐ Proposal/initiative will entail reprogramming of the relevant heading in the multiannual financial framework.

Note: Financial headings and budget lines will need to be adapted to the new legal basis to be adopted under the financial perspectives 2014-2020.

3.2.5. Third-party contributions

– ☒ The proposal/initiative does not provide for co-financing by third parties

3.3. Estimated impact on revenue

– ☒ Proposal/initiative has no financial impact on revenue