



***European Commission
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 the public health insurance system
COM(2012) 84***

***Position of the
European Social Insurance Platform (ESIP)***

07 September 2012

About the *European Social Insurance Platform (ESIP)*

The *European Social Insurance Platform (ESIP)* represents over 40 national social security organisation in 15 EU Members States and Switzerland, active in the field of health insurance, pensions, family benefits, occupational safety and accident insurance and unemployment insurance. The aims of ESIP and its members are to preserve high-profile social security for Europe; to reinforce solidarity-based social insurance systems and to maintain European social protection quality. ESIP builds strategic alliances for developing common positions to influence the European decision-making process and is a consultation forum for the European institutions and other multinational bodies active in the field of social security.

Statement regarding positions submitted by ESIP: *ESIP members support this position in so far as the subject matter lies within their field of competence. ESIP's positions are not legally binding on its members.*

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***European Commission proposal for
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Executive Summary

The aim of the social health insurers, represented by ESIP, is to ensure an equal access to high quality healthcare for all. This aim is supported by national pricing and reimbursement measures that are designed to ensure the adequate supply of effective medicines at reasonable cost.

The European Commission proposal which is the subject of this paper, if unchanged, would 1) undermine the capacity of Member States' pricing and reimbursement authorities to comply with their public health mission and 2) add undue administrative and financial burdens on public healthcare systems that would threaten their sustainability and patients' access to safe and effective medicines. ESIP's position is that the proposal in its present form is unfit as a basis for the legislative procedure and should be reconsidered by the Commission.

We identify the following key measures in the Commission proposal which must be changed:

1. While reduced **time limits** for generic medicinal products can be foreseen and supported, a reasonable time of **60 days** is required for price negotiations and for assessment of the relative safety, efficacy and effectiveness of the medicine in the context of the health insurance scheme. The increasing complexity of originator products, however, requires increasingly complex evaluation and demands that the current time limits of a total of **180 days** are maintained for all non-generic medicines.
2. While adequate data usually exists for generic medicines at the time of application for pricing and reimbursement, the data available for originator

medicinal products is frequently very limited; therefore **access to the data used for marketing authorisation is essential**.

3. Member States need to retain a level of flexibility in determining what **additional information** is required in order to rapidly respond to unexpected situations and avoid unnecessary delays in processing applications.
4. The legal basis of **Article 8 (remedies procedures)** is questionable. Further, its provisions serve to add complexity and redundancy to existing national provisions, and will lead to substantial additional administrative and financial burdens on the public authorities. The impact of its measures on Member States public health systems, patients and industry are likely to be negative or very negative. Article 8 should be deleted.
5. The **notification of draft national measures** would undermine a Member State's ability to react quickly to a new situation which threatens the stability of its healthcare system. In addition to the additional administrative burden, one might argue that these provisions interfere with a Member State's right to organise its healthcare system (article 5 TEU) and the principle of subsidiarity.
6. The right of **appeal against demand-side measures** is on the one hand unjustified since they do not affect the inclusion of other medicines in the scope of the health insurance system and secondly, since all competitors would be entitled to appeal it would lead to a legal and administrative nightmare. Article 11(4) should be deleted.
7. It is important to be able to define **criteria for the refusal of a renewed application** for pricing and reimbursement. Such specific measures including those that define the inclusion of a product in a specific scheme or category of coverage should be left to national law.

Background

Council Directive 89/105/EEC relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of the national health insurance system (the Transparency Directive) was introduced to promote the free movement of medicinal products in the EU in accordance with the Treaty of the European Economic Community. The European Commission has considered that Directive 89/105/EEC should to be updated to reflect recent developments in the structure of the pharmaceutical market and the introduction of new types of pricing and reimbursement policies by Member States aimed at controlling rising public expenditure on medicines.

Following the Pharmaceutical sector enquiry of 2008-2009¹, the European Commission carried out a public consultation in Spring 2011² with a view to the possible revision of the Directive. The overall view expressed by the principal stakeholders (national authorities, public health insurers, pharmaceutical industry (generic and originator), medical devices industry) was one of satisfaction with the current Directive. However, it showed an interest from the generic industry to review some of the provisions in view of their particular sector e.g. shorter time limits for pricing and reimbursement decisions for generic medicines.

Despite the feedback from the public consultation, the European Commission has decided to make substantive changes to all major provisions of the Directive such that it proposes to replace Directive 89/105/EEC with a new Directive as published on 1 March 2012 (COM[2012] 84). The content of this proposal is the subject of this ESIP position.

Introduction

In its proposal COM(2012) 84 of 1 March 2012 for a new Directive relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of the national health insurance system the European Commission has chosen to make sweeping changes to Directive 89/105/EEC, which it is intended to replace. In doing so it fails to take fair account of the results of the public consultation of 2011 and shows a lack of understanding of pricing and reimbursement procedures. More importantly, it goes far beyond its original remit of promoting free movement of goods (Article 114, TFEU) through improved *transparency* of national pricing and reimbursement measures. The proposal introduces new demands and penalties on Member States' pricing and reimbursement authorities, which in view of the current economic crisis would have significant and potentially dire consequences for the sustainability of (already threatened) public healthcare systems and consequently patients' equitable access to safe and effective medicines. In ESIP's view the proposal in its present form is unfit as a basis for the legislative procedure and should be reconsidered by the Commission.

¹ Report on the Pharmaceutical sector enquiry of 2008-2009:

http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf

² Summary of responses to the public consultation on the possible revision of council directive 89/105/eec: http://ec.europa.eu/enterprise/sectors/healthcare/public-consultation/contributions_received/summay_of_public_consultations_final_en.pdf

The aim of public health insurers represented by ESIP is to ensure an equal access to high quality healthcare for all. The pricing and reimbursement measures developed and introduced by Member States' healthcare systems provide the means for ensuring that health insurers reimburse those medicines which have a real added value and for making those medicines equally accessible to the patients.

In this paper we identify key issues in the European Commission proposal that jeopardize or constitute a barrier to achieving these public health goals and offer suggestions to better meet these objectives as well as those of the Directive.

Key issues:

1. Undermining the competent bodies' capacity to comply with their missions

A number of measures proposed by the European Commission show a clear lack of understanding of both the nature and complexity of pricing and reimbursement procedures in the Member States.

a. Time limits (articles 3, 4, 5, 7):

Generic medicinal products

In the public consultation in 2011, there was a clear call from the generic industry to shorten the timelines for pricing and reimbursement decisions. The possibility of shortening the time limits was also supported by some public authorities and health insurers including ESIP. Speeding up the decision-making process and reducing delays to market for generics is clearly in the interest of both health insurers and patients. In this context, ESIP welcomes the proposed measures to eliminate interference from originator companies in pricing and reimbursement decision-making procedures as regards questions of intellectual property rights (article 14), as highlighted in the sector enquiry. Having said that *the time limits proposed for pricing (15 days) and reimbursement (15 days) decisions are too short.*

Even for generics a reasonable time is required for price negotiations with the industry and for the assessment or reassessment of the relative safety, efficacy and effectiveness of the medicine in the context of the health insurance scheme, in particular in cases of e.g. a modified formulation (delivery method) or therapeutic indication, compared to the reference product. In our view, ***a time limit of a total of 60 days for pricing and reimbursement decisions (30 days + 30 days) would be reasonable***, although this would still require some adaptation in some Member States as regards e.g. the timing of the official publication of decisions.

Other medicinal products

In contrast to the case for generic products, the public consultation indicated that the large majority of national authorities and nearly all contributors from the originator industry shared the view that the current time limits of 90 days plus 90 days (a total of 180 days) were appropriate for originator products. This indicates a mutual understanding of the complexity and importance of the

decision making process based on a thorough assessment of the relative (therapeutic) effectiveness and in some cases cost effectiveness of a new innovative medicine. In cases of unmet medical need, accelerated procedures are available in most Member States.

The introduction of increasingly complex and innovative research based products (advanced therapies, personalised medicines) since adoption of the Transparency Directive in 1989 have called for increasingly sophisticated and time-consuming assessment procedures, including HTA. This has undoubtedly been a contributing factor to some Member States failing to comply with the existing timelines. Therefore, to reduce the time limits for pricing and reimbursement decisions for originator medicinal products makes no sense and could indeed be counterproductive in the overall context of the proposal since Member States authorities may be inclined to give an early negative decision (less risky from a societal point of view) rather than risk being penalized for non-compliance. This would have negative consequences for both the industry and patients.

In ESIP's view the proposal to introduce dual timelines for non-generic medicinal products is arbitrary and only serves to introduce another level of complexity. It depends on reaching agreement on a definition of HTA³ and its interpretation. In effect this will be different in each Member State. Therefore, ***ESIP proposes to remove the dual timelines for originator medicinal products***, which would also eliminate the need for including a definition of HTA (article 2(5)). ***We propose that the time limit for these products remains at 180 days.***

Furthermore, in exceptional cases requiring extremely complex assessment procedures (personalised medicine, advanced therapy, etc.), it should be foreseen to include the possibility that the pricing and reimbursement body can put forward a case to extend these time limits based on objective and verifiable criteria.

b. Additional proof of quality, safety, efficacy or bioequivalence (article 13)

The sector enquiry revealed that the marketing strategies of some originator pharmaceutical companies have included campaigns that put into question the quality, safety, efficacy or bioequivalence of competitor generic medicines entering the market. Article 13, which specifically forbids the Member States from reassessing these elements on which the marketing authorisation is based, might be seen as an attempt to eliminate the impact of such strategies on the pricing and reimbursement decision-making procedures for generic

³ EUnetHTA defines *health technology assessment* (HTA) as —"a multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe effective, health policies that are patient focused and seek to achieve best value". As pricing and reimbursement systems are highly complex, heterogeneous and specific to each Member States, even this definition might generate a variety of interpretations.

medicines. However, as it stands this article applies to *all* medicinal products and could be interpreted as preventing Member States authorities from using the same data or requesting further data that enables them to perform their evaluation of the relative risk-benefit / relative effectiveness of the product as compared to other therapies included in their health system. This assessment is valid for both generic and originator medicines. Further, particularly as regards originator medicines, the data available at the time of application for pricing and reimbursement is frequently very limited, therefore access to the data used for marketing authorisation is essential and this should be clear. Last but not least, access to this information avoids duplication of effort by both the Member State authorities and the industry alike.

Therefore, ***we propose to delete Article 13; otherwise it should be reworded as follows: “Proof of quality, safety, efficacy or bioequivalence. In the framework of pricing and reimbursement decisions, Member States shall not aim to re-assess the absolute elements (quality, safety, efficacy or bioequivalence) on which the marketing authorisation is based. However, Member States shall be guaranteed full access to the data used by the marketing authorisation authority in assessing these elements, with a view to evaluating the relative safety, efficacy and effectiveness of the medicine in the context of the health insurance scheme.***

c. Additional information (Articles 3, 4 and 7)

Articles 3, 4 and 7 state that: *Member States shall not request any additional information which is not explicitly required under national legislation or administrative guidelines.* This implies that the public authorities will be obliged to publish in advance exhaustive lists of all possible information that may be required to cover every possible case. This is neither beneficial to the applicant nor practical, particularly in view of the developing market in increasingly complex innovative medicinal products; these products are likely to demand new types of information. Member States need to retain a level of flexibility in determining what additional information is required in order to rapidly respond to unexpected situations and avoid unnecessary delays in processing applications. Therefore, ***ESIP calls to strike the above sentence in Articles 3, 4 and 7.***

Notwithstanding the above, it might be considered if a public listing of generic categories of information might be beneficial to applicants and a feasible alternative for Member States authorities.

2. Jeopardizing the sustainability of public health systems and adding administrative burden

Further measures can only be considered to add undue complexity / redundancy to already existing national systems, increase the administrative and financial burden of public authorities and threaten the sustainability of public health systems to the detriment of patients and industry alike.

a. Remedies procedure in case of non-compliance with the time limits (Article 8)

Article 8 foresees that Member States shall designate a body, independent from the competent authorities for pricing and reimbursement that will be responsible for taking interim measures, awarding damages to the applicant and imposing penalty payments in case of non-compliance with the time limits related to the inclusion of medicinal products in health insurance systems. This article, taken in its entirety, imposes measures with such far reaching (financial and administrative) impact on Member States public health insurance systems that they cannot be considered proportional to the goal of facilitating the functioning of the internal market for medicinal products; as such the article brings into question the legal basis of the directive (Article 114, TFEU).

Remedies procedures, including judicial remedies via national and regional courts, already exist in Member States⁴. The obligation to designate a new *essentially* judicial body and accompanying new procedures in every Member State, in our view, violates the subsidiarity principle and will add undue administrative burden and cost to the public authorities.

Further, contrary to the findings of the public consultation, the European Commission has attempted to define appropriate sanctions in the directive in the specific terms of awarding damages to the applicant and penalty payments (Article 8(b) and 8(c)). These provisions have the potential to undermine the sustainability of the public health insurance systems and consequently patients' access to medicines.

The objective of this Directive should not be to redirect public (health) funds to support the financial interests of the investors of pharmaceutical companies but rather to support public health interests. Combined with the reduced time limits proposed under article 7, Member States' authorities may choose to deliver a negative decision regarding the inclusion of a medicinal product within the scope of the public health insurance system in order to avoid penalties and sanctions. This could lead to appeal proceedings and greater delays to market.

The legal basis of Article 8 is questionable. Its provisions serve to add complexity and redundancy to existing national provisions, and will lead to substantial additional administrative and financial burdens on the public authorities. The impact of its measures on Member States public health systems, patients and industry are likely to be negative or very negative. Therefore Article 8 should be deleted.

b. Notification of draft national measures (article 16)

Article 16 requires that Member States refer any draft national measures (new or amended) that fall within the scope of this Directive to the European Commission along with the reasons for these measures; any significant

⁴ For example, the Conseil d'Etat in France

changes to these drafts should also be communicated. The Member States should then wait up to three months for the observations of the European Commission which it should take into account as far as possible in the final text. The adopted measures should then be communicated to the European Commission along with a report on the actions taken in response to the Commission's observations. This highly bureaucratic process would totally undermine a Member State's ability to react quickly to a new situation which threatens the stability of its healthcare system. In addition to the undoubted additional administrative burden that the provisions of this article would impose, one might argue that these provisions interfere with a Member State's right to organise its healthcare system (article 5 TEU) and the principle of subsidiarity.

We therefore consider that Article 16 needs to be completely reviewed or deleted.

c. Demand side measures (article 11)

Demand side measures as described in article 11 are a legitimate development in Member States' national pricing and reimbursement policies that are aimed at promoting public health by ensuring the availability of adequate supplies of medicinal products at reasonable cost, while ensuring the financial stability of public health insurance systems. This was the conclusion of the European Court of Justice in Case C-62/09, provided that these measures comply with the Transparency Directive i.e. they are based on objective and verifiable criteria and are published in an appropriate publication. To this extent, ESIP supports the measures outlined in Article 11. However, the additional requirement that on the request of one or more market authorisation holders, whose interests are affected by the measures, competent authorities need to specify the objective data and criteria on the basis of which these measures have been taken with respect to their individual medicinal product(s) would involve unlimited and unnecessary additional administrative burden. More importantly, we consider that the right of appeal against such measures is on the one hand unjustified since they do not affect the inclusion of other medicines in the scope of the health insurance system and secondly, since all competitors would be entitled to appeal it would lead to a legal and administrative nightmare. Therefore, ***Article 11(4) should be deleted.***

Further, it should be specifically excluded under Article 11 that marketing authorisation holders can request that such demand side measures be applied to their products.

d. Application by a marketing authorisation holder at any point in time (Articles 3, 4, 5 and 7)

Articles 3, 4, 5 and 7 state that Member States should ensure that an application to approve/increase the price, for a derogation from a price freeze/reduction or 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. In each of these cases, it is likely that the administrative burden on the public authority will be significantly increased due

to repeated applications following a negative decision even if the circumstances have not changed. Therefore, ***it is important to be able to define criteria for the refusal of a renewed application.*** In our opinion, such ***specific measures including those that define the inclusion of a product in a specific scheme or category of coverage should be left to national law.***