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

2012/0035(COD) - 01/03/2012 - Legislative proposal

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

PROPOSED ACT: Directive of the European Parliament and of the Council.

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 national health insurance systems was adopted so as to remove distortions to intra-Community trade in medicinal products. 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**:

(1) 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, 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.

(2) 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 valuable treatments for patients.

In order to take into account the evolution of the pharmaceutical market and of national policies to control public expenditure on medicines, 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**. The fundamental objectives and principles of Directive 89/105/EEC remain fully valid in the present context.

IMPACT ASSESSMENT: 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.

LEGAL BASIS: Article 114 of the Treaty on the Functioning of the European Union (TFEU).

CONTENT: 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.

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 **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).

BUDGETARY IMPLICATION: 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. Total appropriations under headings 1 to 5 of the multiannual financial framework are estimated at EUR 0.859 million (2014); EUR 1.293 million (2015); EUR 1.143 million (2016-2017); EUR 1.093 (2018 action continued).