

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) - 18/03/2013 - Amended legislative proposal for reconsultation

The Commission presents an amended proposal for the Directive 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. **The European Parliament will be consulted again on this proposal.**

Background: the Commission presented its initial legislative proposal on 1st March 2012 (*please refer to the summary of the same date*). **Negotiations in the Council Working Party on Pharmaceuticals and Medical Devices proved to be difficult.** The main concerns of Member States were related to: (i) the principle of subsidiarity; (ii) the remedies procedure; (iii) the creation of a system of pre-notification of draft national measures to the Commission; (iv) the shortening of the time limits for taking decisions on pricing of medicines and their inclusion in the scope of health insurance systems; (v) the distinction between originator medicinal products subject to health technology assessment (HTA) and those not subject to HTA; (vi) the obligation to consult the interested parties.

As the result of the European Parliament's position in 1st reading on 6 February 2013 (*please refer to the summary of that date*) and taking into consideration the position of Member States in the Council, the Commission decided to amend its proposal.

It took into account the amendments of the European Parliament voted in plenary: 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.

The main amendments to the initial proposal are as follows:

Minimum procedural requirements: these should **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.

Definitions: the amended proposal inserted a definition for **“biosimilar medicinal product”** which means a biological medicinal product that is similar to a reference biological medicinal product.

The concept of **“health technology assessment”** is clarified: it means an assessment which as a minimum includes 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.

Price approval: a decision on the price which may be charged for the medicinal product concerned is adopted and communicated to the applicant within **90 days** (rather than 60 days as stated in the initial proposal) of the receipt of an application submitted. With respect to generic medicinal products, that time limit shall be **30 days** (15 days in the initial proposal), 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 these time limits.

Price increase: a decision to approve or reject on an application to increase the price of a medicinal product must be adopted and communicated to the applicant within **90 days of its receipt**.

Price freeze and 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.

Inclusion of medicinal products in health insurance systems: the amended proposal states that a decision must be adopted and communicated to the applicant within **90 days** of its receipt. With respect to **generic medicinal products, that time limit shall be 30 days**, provided that the reference medicinal product has already been included in the public health insurance system.

Irrespective of the organisation of their internal procedures, Member States shall ensure that **the overall period of time taken by the inclusion procedure and the price approval procedure does not exceed 180 days**. With respect to **generic medicinal products, that time limit shall not exceed 60 days**, provided that the reference medicinal product has already been included in the public health insurance system.

Furthermore, information on information on 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 must be made public, as must information regarding decision-making bodies at national or regional level.

Additional proof of quality, safety, efficacy or bioequivalence: 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 quality, safety, efficacy, or bioequivalence, or biosimilarity of the medicinal product** or the criteria for **orphan designation** which have already been assessed during the marketing authorisation procedure.

Consultation of interested parties: where a Member State intends to adopt or amend any legislative measure falling within the scope of the 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.