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) - 06/02/2013 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 559 votes to 54, with 72 abstentions, a legislative resolution on the 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.

Parliament adopted its position at first reading under the ordinary legislative procedure. Its amendments are as follows:

Scope: this Directive may not call into question a marketing authorisation relating to a medicinal product granted in accordance with the procedure referred to in Directive 2001/83/EC.

Definitions: Parliament defines a "**voluntary contractual agreement**" as an agreement concluded between public authorities and the marketing authorisation holder for a medicinal product which is neither mandatory nor required by law, nor the only alternative to being included in the national pricing and reimbursement scheme to ensure that agreements are not used as a loophole to avoid the applicability of the Directive. A "**biosimilar medicinal product**" means a similar biological medicinal product approved in accordance with Directive 2001/83/EC. "**Health technology assessment**" (HTA) means an assessment which **as a minimum** includes the relative efficacy or the short- and long-term effectiveness of the medicinal product compared to other health technologies or interventions in use for treating the associated condition.

Criteria underlying decisions regulating prices of medicinal products: Parliament introduces a new recital requiring that the criteria underlying any decision directly or indirectly regulating the prices of medicinal products, as well as any measure determining the extent to which they shall be covered by public health insurance systems, include the **assessment of unmet medical needs, clinical and societal benefits and innovation**. Such criteria should also include the **protection of the most vulnerable groups** of the population.

These criteria, as well as the information concerning the decision-making bodies at national or regional level, should be made publicly available.

Deadlines: Parliament proposes extending a number of the deadlines in the Commission's proposal. Member States shall ensure that a decision on the price which may be charged for a medicinal product concerned is adopted and communicated to the applicant within **90 days** of the receipt of an application submitted. With respect to **generic medicinal products,** that time limit shall be **30** days, provided that the reference medicinal product has been approved by the competent authorities. Where appropriate, Member States shall use **health technology assessment** as part of their decision-making process on the pricing of medicinal products.

In regard to a decision on the inclusion of a medicinal product in the scope of the public health insurance scheme, a decision shall 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.

Mediation and remedies procedures: Parliament amended the Commission's proposal requiring Member States to ensure that effective and rapid mediation or remedies procedures are available to the applicant in case of **unjustified delays** or non-compliance with the time limits set in the Directive, and in accordance with their **national law**.

Transparency of decision-making bodies and prices: 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. These authorities shall also publish and communicate to the Commission, at least once a year, a **complete list** of the medicinal products covered by their public health insurance systems and the prices which have been set during the relevant period. 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.

Report: Parliament considers that a **yearly report** collecting Member States' data and information would be more appropriate than a six-monthly report, as proposed by the Commission, in order to allow an accurate overview and relevant trends analysis on the implementation of time limits.