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

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The Committee on the Environment, Public Health and Food Safety adopted the report by Antonyia PARVANOVA (ALDE, BG) 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.

It recommends that the European Parliament's position at first reading, under the ordinary legislative procedure, should amend the Commission's proposal as follows:

Legal base: Members consider that because this proposal deals specifically with the free movement of medicinal products and the pricing thereof (**a matter that falls within the competence of Member States in the field of public health)**, Article 168 of the TFEU should therefore be added to the legal basis.

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: Members define 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.

Innovative treatments: competent authorities and marketing authorisation holders increasingly engage in contractual agreements to provide patients with access to innovative treatments by including a medicinal product in the scope of public health insurance systems whilst monitoring elements agreed upfront and for a defined period of time in order, in particular, to address evidentiary uncertainties relating to the effectiveness and/or relative efficacy or the appropriate use of a specific medicinal product.

Criteria underlying decisions regulating prices of medicinal products: 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, should 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.

Members consider that in the framework of pricing and reimbursement decisions, the competent authorities responsible for these decisions should not reassess the essential elements on which the marketing authorisation is based, including the quality, safety, efficacy, bioequivalence or biosimilarity of the medicinal product.

Time-periods: the Committee extended a number of the deadlines in the Commission's proposal. For example, 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 **90 days** (60 days in Commission proposal) of the receipt of an application submitted. Members recommended a **60-day time limit to decide on the pricing and reimbursement of generic medicines**.

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: Members consider 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.