Brussels, 25 April 2013
Letter to the CoRePers

Proposal for a new directive on transparency measures regulating the prices of medicinal products and their inclusion in the scope of public health insurance systems.

On the 26th April 2013, the Council working party "Pharmaceuticals and Medical devices" will gather to consider the European Commission's amended proposal on the directive on transparency measures regulating medicines' prices, published the 20th March 2013.
Even though, the initial proposal has been slightly modified, the amended version is of no added value to European citizens. On the contrary, it threatens national health systems and their sustainability, as well as the mandate of health technology assessment (HTA) bodies[1].

Legislative background

According to the European Commission, the changes to the pharmaceutical market' structure require an update of the current directive on the transparency of prices[2]. Therefore, on 1st March 2012, the European Commission published a new legislative proposal for a directive on the transparency of prices.
Even though the proposed directive has similar goals to the current legislation, it introduces numerous changes that could endanger Member States' health systems and their sustainability. In addition, the proposal goes far beyond the European Commission's mandate, breaching the subsidiarity principle.

On February 6th, the final report of the "Environment, Public Health and Food Safety" parliamentary committee, reviewing the legislative proposal, was adopted in plenary by the European Parliament.

On March 20th, the European Commission published an amended version of its proposal.

The amended version has been slightly improved.

The Medicines in Europe Forum (MIEF) and the International Association of Mutualities (AIM) and the International Society of Drug Bulletins (ISDB) acknowledge the efforts of the Members of the European Parliament and the European Commission to improve the initial legislative proposal.

The European Commission upholds the current timelines for procedures of price-setting and reimbursement eligibility.

The European Commission has accepted to uphold the current timelines for procedure of price-setting and reimbursement eligibility (articles 3 paragraph 3 and 5; 4 paragraph 3 and 4 and article 7 paragraph 4 and 5 of the amended proposal).

[1] The drug regulatory agencies assess the efficacy, safety and quality of a new medicine in absolute terms, on the basis of the information delivered during the application for marketing authorization. This data is selected by the pharmaceutical company. In most cases, human clinical trials have been designed to show that the medicine is as effective as existing treatments (non-inferiority trials). The scientific assessment carried out by HTA bodies (i.e. the French Haute Autorité de Santé (HAS), the German IQWIG and the NICE in the UK) compares the added therapeutic value of the new medicine compared to existing treatments, as well as their added economic value.

[2] Directive 89/105/CEE CEE 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"*

The current timelines are compatible with the complex procedures for price-setting and reimbursement eligibility and with the results of the public consultation held in 2011 (75% of answers considered that the current time limits were appropriate[3]).

Nevertheless, the Commission's amended proposal still threatens the structure and quality of Member States' health systems.

1. **Member States cannot reassess essential elements of the marketing authorisation.**

The European Commission opposes the reassessment of essential elements of marketing authorisation by Member States (recital 17 and article 13 of the amended proposal).
This would force Member States to base their price and reimbursement decisions solely upon the review carried out during the marketing authorisation procedure. Since the European Medicines Agency does not show a degree of independence or transparency equivalent to many national agencies[4], this provision does not guarantee that the level of safety currently offered to European citizens can be maintained.
MIEF, AIM and ISDB invite Council members to jointly delete recital 17 and article 13.

2. **Contractual agreements are excluded from the directive's scope.**

The European Commission favours the exclusion of contractual agreements from the scope of the directive (recital 9 and article 1 paragraph 2 subparagraph 1 point a).
MIEF and AIM and ISDB strongly oppose such agreements that are detrimental to public health and allow insufficiently evaluated medicines to be used by Europeans citizens (conditional prices). In order to reduce their impact on public health and on the sustainability of public finance, agreements should be included in the scope of the directive. This inclusion would also require competent authorities and marketing authorisation holders to settle agreements more transparently.
MIEF, AIM and ISDB invite Council members to jointly suppress recital 9 and article 1 paragraph 2 subparagraph 1 point a.

3. **The manufacturer can impose its price and price increase when timelines are not met.**

The European Commission has introduced a mechanism whereby the manufacturer can decide unilaterally on a price and on a price increase when time limits are not respected by the competent authorities (article 3 paragraph 6 and article 4 paragraph 5). This procedure would *de facto* be imposed on Member States.
These provisions challenge Member State's prerogative on their own decisions on price-setting and therefore breach the subsidiarity principle. Moreover, they could strongly question the sustainability of public finances.
MIEF, AIM and ISDB invite Council members to jointly delete article 3 paragraph 6 and article 4 paragraph 5.

4. **Member States are requested to provide grounds for their decisions to use a specific medicinal product or medicinal product category (through prescribing guidelines).**

The European Commission has introduced a cost containment policy into the scope of the directive (article 11 of the amended proposal).
This provision goes far beyond the Commission's mandate. Actually, Member States have, and should keep their own authority on decisions regarding cost containment policies.
MIEF, AIM and ISDB invite Council members to jointly delete Article 11 in full.

[3] See http://ec.europa.eu/enterprise/sectors/healthcare/public-consultation/index_en.htm

[4] Both in 2008 and again in 2010, the Commission's Internal Audit Service found that the European Agency was guilty of widespread breaches of its obligations in relation to supervising the independence and quality of expert appraisal (sources: the Commission's 2008 audit report and 2010 follow-up report). The European Parliament has stated that it has "*serious concerns*" about "*the inability of the European Medicines Agency to control its conflicts of interest ».* The European Ombudsman has sentenced the European Agency on several occasions for its breaches of transparency, especially on data relating to drug monitoring (failure to adhere to Regulation (EC) 1049/2001).

5. The stop clock procedure is to be agreed upon by both parties.

The European Commission has introduced a stop clock mechanism during negotiations between the marketing authorisation holder and the competent authority, to be agreed upon by both parties (article 12 paragraph 2 of the amended proposal).

MIEF and AIM and ISDB support a clock stop mechanism. However, competent authorities should be the only party allowed to stop the clock. Otherwise, marketing authorisation holders that would not agree to the decision to stop would then be able to impose their prices, arguing that time limits had not been respected (see article 3 paragraph 6 and article 4 paragraph 5).

Moreover, it is important to underline that at the level of the European Medicines Agency, during the marketing authorisation procedures the Committee for medicinal products for Human Use (CHMP) is the only party with the power to stop or not to the clock, when they decide that further information is needed.

MIEF, AIM and ISDB call for the agreement by both parties to be removed from Article 12 paragraph 2. We invite Council members to propose a common position in order to support a clock stop mechanism exclusive to competent authorities.

6. Judiciary remedies when deadlines are not met.

The European Commission has introduced judiciary remedies as a measure to prevent non-compliance with timelines (Article 8 of the amended proposal). By imposing a strict and repressive control, the European Commission goes far beyond its mandate. Moreover, such judiciary procedures already exist at national level.

MIEF and AIM, and ISDB invite Council members to jointly delete article 8 in full.

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About Us

The Association Internationale de la Mutualité (AIM) is a grouping of autonomous health insurance and social protection bodies operating according to the principles of solidarity and non-profit-making orientation. Currently, AIM's membership consists of 42 national federations representing 25 countries. In Europe, they provide social coverage against sickness and other risks to more than 160 million people. AIM strives via its network to make an active contribution to the preservation and improvement of access to health care for everyone. More info: www.aim-mutual.org.
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MiEF. Medicines in Europe Forum (MiEF), launched in March 2002, covers 12 European Member States. It includes more than 70 member organizations representing the four key players on the health field, i.e. patients groups, family and consumer bodies, social security systems, and health professionals. Such a grouping is unique in the history of the EU, and it certainly reflects the important stakes and expectations regarding European medicines policy. Admittedly, medicines are no simple consumer goods, and the Union represents an opportunity for European citizens when it comes to guarantees of efficacy, safety and pricing.
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The International Society of Drug Bulletins (ISDB), founded in 1986, is a worldwide Network of bulletins and journals on drugs and therapeutics that are financially and intellectually independent of pharmaceutical industry. Currently ISDB has around 80 members in 41 countries around the world. More info: www.isdbweb.org. Contact: press@isdbweb.org.