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Joint policy briefing

Proposal for a new Directive on the transparency of measures regulating the prices of medicinal products: the European Commission oversteps its role

With its proposed revision of Directive 89/105/EC, the European Commission is endangering the organisation of Member States' health systems and their health technology assessment (HTA) procedures.

Summary:

- The European Commission claims to obtain “*faster access to medicines for patients*”¹ by revisiting Directive 89/105/EC known as the “*Directive on the transparency of prices*”².
- However, the new Directive proposal does not meet patients’ interests, as it is solely driven by **pharmaceutical competitiveness, to the detriment of public health**. For new medicines, shortening review deadlines for reimbursement applications and for price-setting practices is likely to **weaken assessment quality** and undermine decision-making.
- The **European Commission is going well beyond its remit** by proposing **disproportionate sanctions** when deadlines are not met by competent authorities. The **approach** taken by the Commission is **unbalanced**: stringent requirements are made to Member States (i.e. to deliver exhaustive supporting evidence to companies and to the EU Commission for decisions involving delisting, price drops or freezes) while pharmaceutical companies are granted “rights” such as to ask for price increases at any time.
- The *Association Internationale de la Mutualité* (AIM), the *Medicines in Europe Forum* (MiEF) and the *International Society of Drug Bulletins* (ISDB) call on Member States and Members of the European Parliament (MEPs) to require the European Commission to **refocus its proposals towards measures that would really speed up access to health products that actually meet patients’ needs**. For instance, **require that the added therapeutic value of a new product is demonstrated** and substantiated when applying for a marketing authorisation. That **would prompt the collection of relevant data, which would in turn facilitate both medical and economic assessments, thus reducing time burdens**.

¹- European Commission – press release dated 1st March 2012 MEMO/12/148

²- “[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](http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/transpadir_finalprop01032012_en.pdf) repealing Council Directive 89/105/EEC” COM(2012) 84 final - 2012/0035 (COD); Brussels, 1.3.2012.
http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/transpadir_finalprop01032012_en.pdf: 39 pages.

1- Reminder: the goals of the initial Directive on the transparency of measures regulating the prices of medicinal products (Directive 89/105/EC)

Directive 89/105/EC of 21st December 1988 governs the transparency of measures that regulate price-setting of medicinal products for human use, as well as their inclusion within the scope of national health insurance systems. Its goal is to avoid any discriminatory effect due to national price-control mechanisms and reimbursement purposes, in order to improve the functioning of the internal market.

It sets out three major requirements:

- Decisions must be taken within a precise time limit (90/180 days);
- Notice of these decisions must be given to the applicant and they must contain a statement of grounds based upon objective, verifiable criteria;
- Decisions must be subject to legal recourse at national level.

In any case, **Directive 89/105/EC does not regulate what Member States can or cannot do as to price-setting and reimbursement**. It foresees **minimal interference** by the European Commission in Member States' social protection structures and policies, leaving them considerable room for manoeuvre.

2- Proposal for a new Directive on the transparency of prices: pharmaceutical competitiveness above all

In order to increase the competitiveness of the pharmaceutical sector, the European Commission's Directorate-General for Enterprise and Industry has, for many years, been pursuing a **strategy of deregulation at European level**, often to the detriment of public health³.

With its new proposal for a directive on the transparency of measures regulating the prices of medicinal products, the European Commission **tackles the national level**. Its aim is to create "*a more predictable environment with greater transparency for pharmaceutical companies, thus improving their competitiveness*"¹. However, with this Directive proposal, the Commission is not only overstepping its own prerogatives, but also endangering both the quality of the medical and economic assessments carried out by the Member States, as well as the long-term sustainability of their health systems.

Company competitiveness overrides subsidiarity. The new Directive proposal **fails to respect the Member States' areas of competence on health** as set out in the Treaties⁴.

Furthermore, **the need for an intervention by the Union has not been demonstrated** since the Commission has failed to identify obstacles to trade due to national price-setting and reimbursement eligibility procedures⁵. **The means proposed in the new directive are not proportionate to its stated goal which is to foster faster access to medicines for patients⁶:**

³- For example, in 2008, the pharmaceutical package was notably made up of proposals on "information"-to-patients aimed at introducing direct-to-consumer advertising (DTCA) of prescription medicines. The communication from the Commission on the pharmaceutical package of 10th December 2008 had already clearly set out its goals: "*Genuinely transparent and speedy pricing and reimbursement decisions should be made possible by enhancing the application of the Transparency Directive*" (Communication from the European Commission, Safe, Innovative and Accessible Medicines: a renewed vision for the pharmaceutical sector", COM(2008) 666 final).

⁴- The Commission is supposed to carry out its work ensuring that "*Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them*" (article 168 paragraph 7 of the Treaty on the Functioning of the Union).

And the Treaty on the European Union (article 5) enshrines the principle of subsidiarity as one of the fundamental principles of the Union. "*§3: Under the principle of subsidiarity, in areas which do not fall within its exclusive competence, the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, (...) but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level (...)*".

⁵- This new transparency Directive proposal is based upon article 114 of the Treaty on the Functioning of the European Union (TFEU) in relation to the adoption of measures for the harmonisation of the legislative, regulatory or administrative provisions of the Member States "*whose goal is the establishment and functioning of the internal market*". Nevertheless, the case law shows that recourse to this legal basis can only be justified when it can be shown that there are obstacles to trade, which is not the case here. Furthermore, article 114 of the TFEU is not the expression of a general jurisdiction to regulate the internal market.

⁶- According to the case law of the Court, in order to establish whether a provision of Community law complies with the principle of proportionality, it is important to check whether the means proposed are suitable for achieving the stated goal and whether they do not

- Measures are already available to grant those patients who have reached a therapeutic "dead end" with access to new medicines, even before a marketing authorisation has been obtained (compassionate use);
- The impact assessment did not include an analysis of the time lapsed between marketing authorisation and product commercialisation. It is unclear whether delays are due to the time taken to examine applications for reimbursement eligibility or to price negotiation or rather due to the commercial strategy adopted by the marketing authorisation holder^{7,8}.

The European Commission goes far beyond its prerogatives. Several proposals go far beyond the Commission's prerogatives and constitute breaches of subsidiarity:

- **Prohibiting Member States to reassess "the elements on which the marketing authorisation is based" (including efficacy and safety data) (article 13)**, preventing them from properly carrying out their health technology assessments (HTA) which help to ensure patient safety (for more details, read below);
- **Implementing different mechanisms to enable supervision of Member States by the EU Commission:** early stage supervision of any intended national measures on pricing or reimbursement (article 16); validation of national criteria used to set prices and classification for reimbursement (article 3 point 8; article 7 point 8; article 10);
- **Requesting Member States to provide considerable grounds for each of its decisions on prices and (de)listing, "including any evaluation, expert opinion or recommendation on which it is based" (article 3 point 7 and point 9; article 4 point 6; article 5 point 1 and 3; article 7 point 7; article 9)**, as well as for their decisions to promote the use of certain products (cost containment policies) through prescribing guidelines (article 11);
- **Requesting Member States to consider companies' requests for reimbursement, for increase in prices, or in order to benefit from exceptions in the event of a price drop at any given time (article 3 point 2; article 4 point 2; article 5 point 2; article 7 point 2);**
- **Foreseeing that the price demanded by the pharmaceutical company is automatically accepted if there is no response by the Member State within the relevant time limit (article 3 point 6; article 4 point 5);**
- **Imposing penalties on Member States payable to pharmaceutical companies when deadlines are unmet** (payments for each day's delay "where damages are claimed" (article 8 point 2 (b) and (c));
- **Requiring the establishment of a national judicial authority** responsible for ruling on penalties for delay (article 8).

► **Member States have - and must retain - supreme authority about their decisions on whether or not to include a medicine on their reimbursement lists, and also on pricing⁹. Here, breaching the subsidiarity principle, the Commission is introducing mechanisms whereby the manufacturer would decide unilaterally on a price that could then *de facto* be imposed upon Member States.**

go beyond what is necessary. In this case, the Commission has only listed nine judgements of the Court for breach of Directive 89-105/EEC.

⁷- The common practice of using prices observed in a sample of European countries to set the price on the national market (a practice known as external referencing), triggers marketing authorisation holders to sequence the marketing of their products, which first enter the market in countries where prices are higher. Commercialisation times are thus lengthened in countries that use external referencing, as well as in the countries have lower prices.

⁸- The impact report uses the WAIT index which measures the gap between the marketing authorisation and the marketing declaration, "without making any distinction between what relates to administrative procedures and what relates to decisions made by the holder of the marketing authorisation." (Competitiveness of the EU Market and Industry for Pharmaceuticals Volume I: Welfare Implications of Regulation Final report, by ECORYS). The decisions made by the holder of a marketing authorisation may have to do with marketing strategy: deferred launch of the product, sequencing of marketing, agreements between the generic producer and the branded manufacturer, amongst others.

⁹- The European Commission's working group dedicated to evaluations of impact assessments has itself pointed out that the impact assessment accompanying this Directive is not detailed or transparent enough, especially with regard to the impact which the proposed measures would have on the Member States at national level

(http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/opinion_impact_assessment_part1_en.pdf).

Company competitiveness over public health: moving towards the neutralisation of national health technology assessment (HTA) bodies?

Two provisions could have damaging effects on the quality of medical and economic assessment:

- Prohibiting Member States to reassess “*the elements on which the marketing authorisation is based*” (including efficacy and safety data) (*article 13*);
- Imposing shorter timelines for review of reimbursement eligibility and price-setting (*article 3 point 3*).

Prohibiting Member States to reassess “the elements on which the marketing authorisation is based”. Article 13 specifies “*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 of the medicinal product*”.

Not having to reassess the bioequivalence of a medicine is worthwhile to avoid an unjustified delay before a generic enters the market. But disabling any assessment of efficacy and safety data for new medicines will force Member States to base their price and reimbursement decisions solely upon the review carried out during the marketing authorisation procedure (handled by the European Medicines Agency (EMA) for the centralised procedure). Since the European Medicines Agency does not show a degree of independence or transparency equivalent to that of many national agencies¹⁰, **this provision does not guarantee that the level of safety currently offered to many European citizens can be maintained.**

Furthermore, this provision is based on a **lack of recognition of the distinctive roles played by authorities granting marketing authorisations and health technology assessment (HTA) bodies**¹¹. HTA bodies produce comparative assessments of various therapeutic strategies (new medicines versus existing treatments) and cost effectiveness assessments. These important missions are explicitly excluded from the remit of both national and European medicines agencies. HTA bodies need therefore to be able to use not only the **data presented at the time of the marketing authorisation application but also any other data which the marketing authorisation holder has failed to reveal or not wished to supply**, including any negative trial results¹² and results of trials or studies that were completed after the granting of the marketing authorisation. HTA bodies also need to assess any data about other available treatments to which the new medicine can be compared published in scientific literature, from drug regulatory authorities worldwide and from pharmacovigilance centres. **Article 13 endangers the scientific work carried out by health technology assessment bodies**¹³.

Shorter review periods for applications for reimbursement and price. In May 2011, the European Commission held a public consultation on a possible revision of the Directive on transparency of prices. Published in August 2011, the summary of consultation **responses indicated that more than 75% of respondents considered the current times taken to examine applications to be reasonable**¹⁴, albeit **difficult to adhere to.**

¹⁰- 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*”; so much so that, in May 2012, it refused to discharge the European Agency’s budget for 2010 and 2011. 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).

¹¹- The medicines drug regulatory agencies assess the efficacy, safety and quality of a new medicine in **absolute terms**, on the basis of the data presented at the time of the application for marketing authorisation which includes the data selected by the firm applying for the marketing authorisation. In most cases, the clinical trials on humans have only 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 **therapeutic added value** of the new medicine compared to existing treatments, and sometimes their economic added value.

¹²- Publication bias is a well-known practice which, for pharmaceutical firms for instance, can consist of a tendency not to publish any studies whose results are negative (ref. Prescrire Editorial Staff “From “publication bias” to disinformation” *Prescrire International* 2009 ; 18 (104) : 244).

¹³- In France, the work of the Haute Autorité de Santé (HAS) and the political will to only reimburse medicines whose therapeutic progress is proven, as enacted in the medicines legislation of late 2011, would be seriously compromised.

¹⁴- According to Directive 89/105/EC, the **time limits for examining applications** for eligibility for reimbursement and to negotiate prices are currently 90 days for inclusion in the health insurance system and 90 days for the price; the “clock stop” mechanism, in other words the requesting of additional elements by the assessing authorities and the supplying of these elements by the industrial companies, is not incorporated into the time limit.

Nevertheless, in its proposal for a new Directive on the transparency of prices, the Commission has made two provisions which could compromise the ability of competent national authorities to produce quality assessments:

- the **shortening of review times for applications** for reimbursement eligibility and price: from 180 to 120 days for “conventional” medicines;
- **restrictive and inflexible procedures**: the supporting evidence required to examine applications will have to be specified through an overall positive list, which will not be amended or adapted qualitatively on a case-by-case basis (*article 3 point 4; article 4 point 4; article 7 point 3*). If clinical trials outcomes submitted by a marketing authorisation holder do not provide answers to the clinical questions that are relevant for patients, how to proceed then to produce quality health technologies assessments?

► **The Commission’s goal is to accelerate the entry of new medicines onto the market. Introducing shorter deadlines for generic medicines (from 180 to 30 days) is a positive measure, since it would allow quicker market entrance. However, when the current examination times are already considered too short for new medicines, shorter deadlines for applications’ review, conjugated with restrictive and inflexible procedures for evidence to be submitted, threatens assessments’ quality. The risk for HTA bodies is to overlook essential data during the assessment process, thus making decisions based on incomplete evidence.**

► **By shortening time periods and preventing data from being reassessed, one is lead to question whether the aim is not to neutralise the health technology assessment (HTA) bodies, which role is crucial to protect both citizens’ health and health systems’ sustainability. Depriving Member States from their ability to independently and comparatively assess new medicines represents the hijacking of their sovereignty on their own health systems.**

3- The EU Commission needs to redress its proposal for a new Directive proposal on the transparency of prices

As it currently stands, the Commission’s new Directive proposal is of no added value for European citizens. On the contrary, it is likely to endanger the whole health technology assessment procedures carried out by Member States. The implementation of this proposal would amount to the European Commission overstepping its jurisdiction, infringing both the principles of subsidiarity and proportionality.

The *Association Internationale de la Mutualité* (AIM), the *Medicines in Europe Forum* (MiEF) and the *International Society of Drug Bulletins* (ISDB) call on Member States and Members of the European Parliament (MEPs) to require the European Commission to **refocus its proposals towards measures that would really speed up access to health products meeting patients’ needs**. For instance, demanding **that the added therapeutic value of a new product is to be demonstrated** and substantiated when applying for a marketing authorisation. In order to be able to show a therapeutic progress, marketing authorisation holders would have to conduct **comparative trials**¹⁵. That **would prompt the collection of relevant data, which in turn would facilitate both medical and economic assessment, thus reducing time burdens.**

AIM

Medicines in Europe Forum

ISDB

¹⁵- Comparative trials would make it possible to compare the new medicine to a reference treatment. Currently, clinical trials often compare a new drug to a placebo, or to an unsuitable comparator (demonstration of the “non-inferiority” of the new medicine).

AIM. 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 41 national federations representing 29 countries. In Europe, they provide social coverage against sickness and other risks to more than 150 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. Contacts: blandise.cassou-mounat@aim-mutual.org; rita.kessler@aim-mutual.org.

MiEF. The Medicines in Europe Forum (MiEF) was launched in March 2002 and reaches 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 European Union and is testament of the importance of European medicines policy. Admittedly, medicines are no mere consumer goods, and the Union represents an opportunity for European citizens to seek further guarantees of efficacy, safety and pricing. Contact: pierrechirac@aol.com.

ISDB. 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.