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Frau Mag. Barbara PRAMMER
Präsidentin des Nationalrates
Dr.-Karl-Renner-Ring 3
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Dear President,

The Commission would like to thank the Nationalrat for its reasoned Opinion 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 {COM (2012) 84 final}.

According to Article 168(7) TFEU health care falls within the competence of Member States:

> *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.*

In its case-law[1] *the Court of Justice ruled that "Community law does not detract from the power of the Member States to organise their social security systems (Case 238/82 Duphar and Others [1984] ECR 523, paragraph 16, Case C-70/95 Sodemare and Others [1997] ECR I-3395, paragraph 27, and Case C-158/96 Kohll [1998] ECR I-1931, paragraph 17). [...] Nevertheless, the Member States must comply with Community law when exercising that power."*[2] *Therefore, internal market rules, amongst others, need to be constantly observed.*

National measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems could create barriers to trade within the EU. For example, the exclusion of a medicinal product from reimbursement in a given country could result in its exclusion from a national market as doctors would be less likely to prescribe it. By making the sales of imported products impossible or more difficult than those of domestic products, pricing and reimbursement measures may be used by Member States to protect their national industry.

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[1] Case C-157/99 *B.S.M. Geraets-Smits and Stichting Ziekenfonds VGZ* [2001] ECR I-5473, paras. 44-46
[2] Ibid.

In its landmark judgements Roussel[3] and Duphar,[4] the Court of Justice established that the measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems must satisfy certain conditions in order to be compatible with the rules of the Treaty. In particular, they should be free of discrimination against imported medicinal products and they must be based on objective and verifiable criteria that are independent of the origin of the products.

Council Directive 89/105/EEC[5] is a codification of the Roussel and Duphar case-law. It is an internal market instrument designed to facilitate the free movement of medicines. It lays down a general procedural framework to ensure the transparency of measures regulating the pricing and reimbursement of medicinal products.

But it also raises uncertainty and implementation challenges due to the evolution of the pharmaceutical market and the concomitant development of national cost control policies over the past twenty years. Pricing systems and health insurance schemes are highly complex and specific to each country. Despite the legal interpretation provided by the Court of Justice, some procedural transparency provisions based on the current directive have given rise to different interpretations in Member States, so that action by national competent authorities does not provide sufficient guarantees of procedural transparency and legal security for market operators.

The Commission's new proposal keeps the spirit of the existing directive - a minimal procedural approach without prejudice to the competence of Member States for organising their pricing and reimbursement systems, as regards the substance of the decisions they take.

The Commission would welcome more information on the method of calculation by the Austrian Federation of Social Insurance Institutions of the impact of the proposed reduction of time limits for negotiation of adequate prices, resulting in losses of up to EUR 3.2 million per year for public health care systems. Indeed, the Commission proposal makes the distinction between originator and generic medicinal products, precisely because an earlier entry on the market of generics would achieve significant savings for public health systems.

The reduction of time limits for generic medicinal products is a follow-up to the Commission's Competition Inquiry into the Pharmaceutical Sector[6] which pointed to delays regarding the entry of generic medicines into EU markets after the loss of exclusivity[7] of the originator products. The Pharmaceutical Sector Inquiry demonstrated,

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[3] Case C-181/82 *Roussel Laboratoria* [1983] ECR 3849

[4] Case 238/82 *Duphar and others* [1984] ECR 523

[5] Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems [1989] OJ L40/8

[6] Commission Communication on the Pharmaceutical Sector Inquiry, COM(2009)351; Staff Working Document, SEC(2009)952

[7] Loss of exclusivity" ("LoE") is defined in Commission Communication on the Pharmaceutical Sector Inquiry, COM (2009)351 and Staff Working Document, SEC(2009)952 as comprising two forms of protection: (1) protection through patents (possibly extended by the so-called Supplementary Protection Certificate "SPC"*) and (2) protection through marketing and data exclusivity

based on a sample of medicines analysed during the period 2000-2007, that it took more than seven months (on a weighed average basis) for generic entry to occur once originator medicines lost exclusivity.[8] *It concluded that "savings due to generic entry could have been 20% higher than they actually were, if entry had taken place immediately following loss of exclusivity. According to the in-depth analysis of this sample, the aggregate expenditure amounting to about € 50 billion for the period after loss of exclusivity would have been about € 15 billion higher without generic entry (evaluated at constant volumes). However, additional savings of some € 3 billion could have been attained, had entry taken place immediately."*[9]

Moreover, the proposed time limit for originators which are subject to HTA (health technology assessment) remains unchanged and the definition of HTA provided in this proposal is broad, which would allow for the application of the longer time limits (90/90 days) in a large number of cases.

Another aspect to be taken into account when evaluating the overall impact on costs for the health systems, as identified in the Pharmaceutical market monitoring study, is that "the delay in access to (innovative) medicines can reduce the gains in total costs of treating a disease as a result of a new drug". The authors of this study refer to several studies showing that the reduction in non-pharmaceutical spending which results from the introduction of a new medicine can be significantly higher than the cost induced by the prescription of that medicine.[10]

As a matter of fact, the reduction of the period for originator medicinal products from 180 to 120 days would only apply to cases not covered by a HTA.

The Nationalrat is of the opinion that delays in the inclusion of medicinal products in the scope of national health insurance systems are in many cases due to incomplete information submitted by the applicants. The Commission would like to draw your attention to the fact that incomplete information submitted by the applicant should have no influence on time limits since the current directive already contains a "stop-the-clock" procedure in the following terms: "If the information supporting the application is inadequate, the competent authorities shall forthwith notify the applicant of what detailed additional information is required and take their final decision within 90 days of receipt of this additional information."[11]

With regard to the proposed remedies procedure, the Nationalrat condiders it to be to the unilateral advantage for the pharmaceutical industry.

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[8] Commission Communication on the Pharmaceutical Sector Inquiry, COM (2009)351, Section 2.1.2; Staff Working Document, SEC(2009)952 §191 et seq.

[9] Commission Communication on the Pharmaceutical Sector Inquiry, Section 2.1.2; Staff Working Document, §217.

[10] Competitiveness of the EU Market and Industry for Pharmaceuticals Volume I: Welfare Implications of Regulation, p. 92, available at:
http://ec.europa.eu/enterprise/sectors/healthcare/competitiveness/monitoring/index_en.htm

[11] Articles 2(1), 3(1), 4(1), 6(1) of Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems [1989] OJ L40/8

The Commission would like to underline that it would apply only to cases of non-compliance with the time limits set for decisions on the inclusion in the scope of health insurance systems, and thus increase the effectiveness of the directive in that respect.

The Commission proposal seeks to ensure full respect for the right to an effective remedy and to a fair hearing, in accordance with the first and second subparagraphs of Article 47 of the Charter of Fundamental Rights of the European Union and does not bring any additional advantage to the pharmaceutical industry. The principle of state liability has been recognized by the Court of Justice in its jurisprudence.[12]

The reason why the Commission put forward such provision is that the enforcement of the directive has proved to be a difficult task. This provision would provide more legal security for pharmaceutical companies, when claiming damages in the competent national courts, and would provide an incentive for Member States to comply with the time limits.

However, the proposal contains a safeguard clause according to which the competent national body may take into consideration the consequences of the potential measures for all interests likely to be harmed and for the public interest and may decide not to take such measures when their negative consequences could exceed the benefits.

With regard to the legal basis, the Commission would like to stress that it should be determined according to the main object of the act:[13] *the key objective of the proposal is to ensure that there are no restrictions to trade. To this end, the proposal lays down a series of transparency requirements, which must be complied with by all national measures on pricing and reimbursement.*

In cases where different objectives are pursued by a single legislative measure, the Court of Justice ruled that it is important to determine the centre of gravity of the measure.[14] *The aim of the proposal is to facilitate the functioning of the internal market for medicinal products for which Article 114 TFEU is the appropriate legal basis. Article 168(7) TFEU cannot be used as an operational legal basis, while Article 168 could be used as a legal basis for specific types of measures provided in paragraph 4 or for cooperation measures.*

The Nationalrat also considers that Articles 11, 13, 15 and 16 are to be regarded as an inadmissible interference with the constitutional autonomy of the Member States.

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[12] Cases C-6&9/90 *Francovich and Bonifaci v. Italy* [1991] ECR I-5357; Case C-221/89 *The Queen v Secretary of State for Transport, ex parte Factortame Ltd and others* [1991] ECR I-3905; Case C-46 &48/93 *Brasserie du Pêcheur SA v. Germany* [1996] ECR I-1029

[13] Case C-377/98 *Netherlands v. Parliament and Council* [2001] ECR I-7079; Case C-491/01 *British American Tobacco* [2002] ECR I-11453; Joined Cases C-465/00, C-138/01 & C-139/01, *Österreichischer Rundfunk* [2003] ECR I-4989; Case C-101/01 *Bodil Lindqvist*, [2003] ECR I-12971; Case C-434/02 *Arnold André* [2004] ECR I-11825; Case C-210/03 *Swedish Match* [2004] ECR I-11893; Joined Cases C-154 & 155/04 *Alliance for Natural Health* [2005] ECR I-6451; Case C-66/04 *United Kingdom v. Parliament and Council* [2005] ECR I-10553; Case C-436/03, *Parliament v. Council* [2006] ECR I-3733; Case C-217/04 *United Kingdom v. Parliament and Council* [2006] ECR I-3771

[14] Case C-376/98 *Federal Republic of Germany v European Parliament and Council of the European Union* [2000] ECR I-08419

From the Commission's point of view, Article 11 represents a codification of the case-law of the Court of Justice[15] *where the Court ruled that that public authorities are allowed to offer financial incentives to doctors to prescribe specific named medicines belonging to the same therapeutic class but they should comply with the provisions of Directive 89/105/EEC: national measures which are addressed to doctors must be transparent and must be based on objective and non-discriminatory criteria.*

Article 13 only prohibits pricing and reimbursement authorities to re-evaluate elements already assessed during the marketing authorisation procedure. Since the quality, safety, efficacy or bioequivalence of medicinal products has already been assessed once during the process of marketing authorisation, the competent authorities in charge of pricing and reimbursement should not re-assess these elements and should not call into question the evaluation made by the competent authorities during the marketing authorisation procedure . This is also a follow-up to the Commission's Competition Inquiry into the Pharmaceutical Sector where it was determined that re-evaluations trigger delays, in particular for generics.

With regard to Article 15, in an environment where prices are fixed it is important to ensure that the affected parties would have the right to be consulted, without prejudice to the outcome of the proposed legislation.

With Article 16, the Commission hopes to enter in an early dialogue with Member States, with the objective of ensuring better regulation. Though in line with the philosophy of Directive 98/34/EC,[16] *this provision would impose a less stringent obligation on Member States than Directive 98/34/EC (which can lead in some circumstances to the binding postponement of the adoption of the national measures), since no suspending effect would result from the reaction of the Commission on the national draft. At the same time it would allow to identify potential problems from the onset, instead of discussing them ex post, thus leading to less administrative burden and to more timely and effective administrative cooperation between the national authorities and the Commission.*

Finally, the Commission does not share the Nationalrat's view that Article 14 affects intellectual property rights or the right to a fair trial. It tackles the problem of patent-linkage which is instrumental in delaying access to the market for generic medicines and creating distortions of competition detrimental to patients and public health budgets.

EU law does not foresee any examination of the patent status of the reference product in order to grant a marketing authorisation to a generic medicine. From the Commission's point of view, there is no reason why the price and reimbursement decisions should rely on such an examination. The Pharmaceutical Sector Inquiry highlighted cases in which the pricing and reimbursement authorities refused to issue pricing and reimbursement decisions unless the applicant could demonstrate that the generic product would not infringe valid patents. Originator companies were intervening before the pricing and reimbursement authorities, or initiating proceedings in national courts against these

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[15] Case C-62/09 *Association of the British Pharmaceutical Industry v Medicines and Healthcare Products Regulatory Agency*, nyr

[16] Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations [1998] OJ L 204/37

authorities, in order to stall the pricing and reimbursement procedures on account of an alleged intellectual property rights violation.[17]*. The proposed article is meant to prevent such practices.*

Article 14 aims to ensure that protection of intellectual property rights shall not be a valid ground to refuse, suspend or revoke decisions relating to the price of a medicinal product or its inclusion within the public health insurance system. On the other hand, paragraph 3 of Article 14 would provide that the status of the intellectual property rights, or the right to enforce the intellectual property rights are not affected. It states that: "Paragraphs 1 and 2 shall apply without prejudice to the Union and national legislation relating to the protection of intellectual property." In other words, pricing and reimbursement are only administrative procedures and are independent from the enforcement of intellectual property rights. In the case of an infringement of intellectual property rights, this should be addressed by the competent national courts, which are the only jurisdictions with the power to decide whether there is an infringement of the intellectual property rights. In accordance with the conclusions of the Pharmaceutical Sector Inquiry, the pricing and reimbursement authorities cannot and should not play any role in the assessment or enforcement of intellectual property rights.

I hope that these clarifications address the concerns expressed by the Nationalrat and I look forward to continuing our political dialogue in the future.

Yours faithfully,

Maroš Šefčovič
Vice-President

[17] Commission Communication on the Pharmaceutical Sector Inquiry, COM (2009)351, Section 4.4; Staff Working Document, SEC(2009)952, §446 et seq.