EUROPEAN COMMISSION

Brussels, 6. 11. 2012
C(2012) 7502 *final*

Dear President,

The Commission would like to thank the Chambre des Députés 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}.

In accordance with the principle of subsidiarity, the EU should act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level. National pricing and reimbursement decisions have a clear transnational impact linked, in particular, to the potential disruption they might cause to the internal market in medicinal products within the EU.

The existing regulatory framework set up by Directive 89/105/EEC 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 proposal maintains the spirit of the existing directive: i.e. minimal procedural requirements without prejudice to the competence of Member States for organising their pricing and reimbursement systems.

The Commission is convinced that potential new administrative costs have to be weighed against expected benefits.

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In this case, an earlier entry on the market of generics would achieve significant savings for public health budgets. The reduction of time limits for generic medicinal products is a follow-up to the Commission's Competition Inquiry into the Pharmaceutical Sector [1] which pointed to delays regarding the entry of generic medicines into EU markets after the loss of exclusivity[2] of the originator products. The Pharmaceutical Sector Inquiry demonstrated, based on a sample of medicines analysed during the period 2000-2007, that it took more than seven months (on a weighted average basis) for generic entry to occur once originator medicines lost exclusivity.[3] 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."[4]

On the other hand, the proposed time limit for originators which are subject to HTA (health technology assessment) remains unchanged. As a consequence, the proposal would not entail additional administrative burden compared to the current situation. Moreover, the definition of HTA provided in this proposal is broad, which would lead to the application of the longer time limits (90/90 days) in a large number of cases. A reduction of the time limit for originator medicinal products from 180 to 120 days would only apply whenever the more complex procedure of a HTA would not be applicable.

The Commission would also like to recall that the obligation to publish and communicate the decision criteria, as well as the obligation to respect the time-limits prescribed are cornerstones of the existing directive, meant to guarantee procedural transparency and thereby legal security for market operators.

As for the obligation to consult the industry before the introduction of any new pricing or reimbursement measure, the Commission believes that, in an environment where prices are fixed, it is important that the affected parties are consulted, without prejudice to the outcome of the proposed legislation.

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

[2] *"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.*

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

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

With regard to the notification of draft national measures, the Commission aims at entering in an early dialogue with Member States, in line with the overarching principle of better regulation. The proposed procedure mirrors the logic of Directive 98/34/EC.[5] *However, it would provide 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. Potential problems could be identified ex ante and prevented, resulting in a reduction of administrative burden and in a more timely and effective administrative cooperation between the national authorities and the Commission.*

The Commission has observed shortcomings in the functioning of the existing directive as regards specifically the duration of some decisions concerning the inclusion of medicinal products in the health insurance systems. The proposed enhancement of the remedies procedure is meant to increase the effectiveness of the directive only in this aspect.

This proposal seeks to ensure the effective implementation of the right to a 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. It is not designed to advantage the pharmaceutical industry but to apply a fundamental principle. The principle of state liability has been recognized by the Court of Justice in its jurisprudence.[6]

Indeed, the enforcement of the present directive under this aspect prooved problematic in several cases. The proposed provision would provide more legal security by securing the capacity of pharmaceutical companies to claim damages in the competent national courts and would provide an incentive for Member States to comply with the time limits. The budgetary impact for the national authorities would be proportional to their capacity to ensure effective compliance with the time limits. This approach would maintain the central role of national jurisdictions in assessing potential breaches of the time limits, in accordance with national rules and procedures, in line with the principle of subsidiarity.

Moreover, the proposal contains an explicit safeguard clause according to which the competent national body may decide not to take such measures when their negative consequences could exceed the benefits, in line with the principle of proportionality.
Finally, the Commission would like to draw your attention to the fact that in case incomplete information is submitted by the applicant, additional information can be requested by national authorities according to the proposal (Articles 3.5, 4.4, 5.3, 7.5). The authorisation procedure should start only once adequate (i.e. complete) information has been submitted by the applicant to the competent authority.

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[5] *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

[6] 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

I hope that these clarifications address the concerns expressed by the Chambre des Députés and I look forward to continuing our dialogue on these issues.

Yours faithfully,

Maroš Šefčovič
Vice-President