EUROPEAN COMMISSION

Brussels, 20.02.2013
C(2013) 712 *final*

Mr Milan ŠTĚCH
President of the Senát
Valdštejnské naměstí 17/4
CZ – 118 01 PRAHA 1

Dear President,

The Commission would like to thank the Senát for its 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}and apologises for the delay in replying.

National measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems are susceptible to create barriers to trade within EU insofar as they affect the capacity of pharmaceutical companies to sell their products in domestic markets. By way of example, the exclusion of a medicinal product from reimbursement in a given country could result de facto in its exclusion from the national market because the product is unlikely to be prescribed by doctors and used by patients. Pricing and reimbursement measures may thus provide an opportunity for Member States to protect their national industry by making the sales of imported products impossible or more difficult than that of domestic products.

The Commission is convinced that the proposed directive does not touch upon the substance of pricing and reimbursement and that the spirit of the existing directive was maintained: minimal procedural approach preserving the competence of Member States for the organisation of their health insurance system and pricing/reimbursement decisions.

For instance, as to the creation of an independent institution monitoring adherence to the time limits concerning the inclusion of drugs into health insurance systems, the proposed remedies procedure is similar to the one set in Directive 2007/66.[1] *The body referred to*

---

[1] Directive 2007/66/EC of the European Parliament and of the Council of 11 December 2007 amending Council Directives 89/665/EEC and 92/13/EEC with regard to improving the effectiveness of review procedures concerning the award of public contracts Text with EEA relevance [2007] OJ L/335/31

in Article 8 of the proposal could be a newly created one or an existent body as well (i.e. national courts). The only condition required by the proposal is to be independent of the competent authorities in charge of controlling the prices of medicinal products for human use or in charge of determining the range of medicinal products covered by health insurance systems.

Based on the shortcomings observed in the functioning of the existing directive as regards specifically the duration of some decision concerning the inclusion of medicinal products in the health insurance systems, the remedies procedure is meant to increase the effectiveness of the directive; they would apply only in case of non-compliance with the time limits set for decisions on the inclusion in the scope of health insurance systems.

The reason why the Commission puts forward such provision is that the enforcement of the directive has always been a difficult task. This 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 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 (in line with the principle of proportionality).

As to the obligation for notifying the national draft measures, it has been put forward as it was felt necessary to enter in an early dialogue with Member States that would ensure better regulation. This procedure follows the philosophy of Directive 98/34.[2] *However, this provision would provide a much less stringent obligation on Member States than Directive 98/34, since no binding effect would result from the reaction of the Commission on the national draft, and would at the same time permit to prevent potential problems ex ante, 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.*

Therefore, this mechanism does not have any impact on those provisions which fully comply with EU law. It aims only at ensuring ex-ante that potential conflicts with EU law would be solved.

With regard to the Senát's comments related to the reduction of time limits, the Commission would like to highlight that the time limits for originator medicinal products has been maintained (180 days) provided that the complex procedure of a Health Technology Assessment would be applicable.

---

[2] 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

Furthermore, due to the evolution of the pharmaceutical market and due to the different nature of originator and generic medicinal products, the Commission felt necessary to distinguish between the regime applied to these two categories of products. The appraisal of originator products for the purpose of pricing and reimbursement is often a complex and time-consuming exercise due to the novelty and innovative character of these products. However, pricing and reimbursement procedures for generic medicines should logically not require any new or detailed assessment since the characteristics of the product are already well known. Therefore, a different treatment for generics and originators is necessary, in compliace with the principle of proportionality.

The reduction of time limits for generic medicinal products is a follow-up to the Commission's Competition Inquiry into the Pharmaceutical Sector[3] which pointed to delays regarding the entry of generic medicines into EU markets after the loss of exclusivity 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 weighed average basis) for generic entry to occur once originator medicines lost exclusivity.[4] 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"[5].

Therefore, faster access to generic medicinal products would achieve significant savings for public health budgets which the Commission believes would outweigh the administrative costs.

According to the proposal, the time limit for originators which are subject to HTA (health technology assessment) would remain unchanged. Therefore, there is no additional burden compared to the existent situation. Moreover, the definition of HTA provided in this proposal is broad and this would lead to the application of the longer time limits (90/90 days) in a large number of cases.

Furthermore, as pointed out in the Pharmaceutical market monitoring study, "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 refer to several studies showing that the reduction in non-pharmaceutical spending which results from the introduction of a new

---

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

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

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

medicine can be significantly higher than the cost induced by the prescription of that medicine[6].

The proposed reduction of the period 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 distinction between procedures with and without such assessment would respond to a need to provide for a different treatment to different situations, in line again with the principle of proportionality.

Finally, as regards the length of the administrative proceedings, the Commission would like to draw the Senát's attention to the fact that the current directive, as well as the new proposal, contain the possibility to stop-the-clock: 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. Therefore, in case more information is required, the time would start to run from 0 from the moment the additional information is received.

I hope that these explanations serve to clarify the points raised by the Senát and look forward to continuing our political dialogue in the future.

Yours faithfully,

Maroš Šefčovič
Vice-President

---

[6] 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