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M. Jean-Pierre BEL
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Dear President,

The Commission would like to thank the Sénat 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.

The Commission is convinced that this proposal maintains the spirit of the existing Council Directive 89/105/EEC[1]. It is an internal market instrument designed to facilitate the free movement of medicines, applying a minimal procedural approach without prejudice to the competence of Member States for organising their pricing and reimbursement systems

The Sénat is particularly concerned by the proposed reduction of the time limits for taking decisions on pricing and reimbursement of medicinal products, as it could affect the quality of the Haute autorité de Santé (HAS) evaluation, the good administration of the healthcare system, and the patients' interests.

The Sénat also considers that the reduction of the time limits could increase administrative spending, which is not desirable in the present economic context. The Commission would like to highlight the Pharmaceutical market monitoring study of 2009, according to which "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 medicine can be significantly higher than the cost induced by the prescription of that medicine.[2]

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[1] *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*

[2] *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

But more specifically, the distinction between procedures with and without health technology assessment (HTA), respectively of 180 and 120 days, mirrors the need to provide for a different treatment to different situations.

The Commission fully acknowledges the necessity for Member States to carry out technically complex health technology assessments or other types of pharmaco-economic evaluations in order to assess the clinical and budgetary impact of new medicines. The current time limits for taking decisions on pricing and reimbursement of medicinal products within HTA would be maintained. Moreover, the definition of HTA in the Commission proposal is broad and would lead to the application of longer time limits (90/90 days) in a large number of cases.

A different treatment for generics responds to the fact that 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.

Earlier entry on the market of generics would achieve significant savings for public health budgets. The proposed 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[4] 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.[5] 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."[6]

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

[4] *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.*

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

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

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

Yours faithfully,

Maroš Šefčovič
Vice-President