EUROPEAN COMMISSION
IMPACT ASSESSMENT BOARD

Brussels,
D(2011)

Opinion

Title

DG ENTR - Impact Assessment on: Proposal for a Directive of the European Parliament and of the Council on the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of the national health insurance systems

(draft version of 2 August 2011)

(A) Context

Council Directive 89/105/EEC (Transparency Directive) lays down a series of procedural requirements applicable to any national measure regulating the prices of medicines and their inclusion in the scope of health insurance systems. Its overall objective is to enable market operators to verify that national measures do not create barriers to trade incompatible with the provisions of the Treaty governing the free movement of goods. This impact assessment accompanies a proposal for the review of the Transparency Directive.

(B) Overall assessment

The report provides a comprehensive and sufficiently clear analysis overall, although certain issues should be explained in a more detailed and transparent fashion. Firstly, the report should better explain to what extent the policy options anticipate the evolution of pharmaceutical markets and of national pricing and reimbursement procedures. Secondly, the report should improve the assessment of impacts of the combined preferred policy options and should discuss in greater detail the impacts on national authorities. Some of the assumptions underlying the analysis should also be clarified. Finally, the report should improve the monitoring and evaluation arrangements by defining core progress indicators.

(C) Main recommendations for improvements

(1) Enhance the presentation of policy options. The report should better explain to what extent the policy options will be 'future proof' and be able to take into account the evolution of pharmaceutical markets and of national pricing and reimbursement policies. In this context, it should recognise the potential benefit of health technology assessments for cost-effective health systems. The report should also clearly indicate that marketing authorisation procedures for drugs are out of scope of the Transparency Directive.

(2) Strengthen the assessment of impacts. The report should improve the assessment of combined preferred policy options. It should clearly indicate all the expected costs and benefits associated with the preferred options, and should explain how each group of stakeholders will be affected by the set of preferred options. The impacts on national authorities in terms of administrative costs should also be discussed in greater depth. The report should indicate which Member States are likely to face the most substantial costs as a result of the proposed changes to the Transparency Directive, including via a better identification of impacts associated with the suggested shortened procedures for generics. The report should be clearer about the implications that the preferred policy options will have on the use of health technology assessments by the Member States as well as on their internal resources.

(3) Clarify the broader policy context and the assumptions underlying the analysis. The report should include a brief description of broad macro health expenditure trends and explain how pharmaceuticals influence these trends using available reports (e.g. Economic Policy Committee and Social Protection Committee reports). This should include a more balanced presentation of the effects of innovative drugs. The report should also explain the assumptions used to estimate the economic losses for innovative pharmaceutical companies (estimated to vary from 35 to 100 million EUR for a single medicine). The assumption 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 should also be further discussed.

(4) Improve the monitoring and evaluation arrangements by defining core progress indicators for the key objectives, which would enable verification of the extent to which the policy is achieving its objectives.

Some more technical comments have been transmitted directly to the author DG and are expected to be incorporated in the final version of the impact assessment report.

(D) Procedure and presentation

All procedural elements appear to be respected.

(E) IAB scrutiny process	
Reference number	2011/ENTR/005
External expertise used	No
Date of Board Meeting	7 September 2011