EUROPEAN COMMISSION
Impact Assessment Board

Brussels,
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Opinion

Title

DG TAXUD - Impact Assessment on an EU initiative on a Regulation amending Regulation (EC)111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

(draft version of 29 February 2012)

(A) Context

Drug precursors are chemicals produced for a licit purpose (e.g. for use in a wide variety of legitimate industrial processes such as the synthesis of plastics, pharmaceuticals, cosmetics etc.), which can be misused in the illegal drug production. A specific regulatory framework has been set up - both at international level and in the EU - to prevent the diversion of drug precursors to illicit drug production. The Commission's Report COM(2009)709 underlined the weaknesses in the existing control system of trade in drug precursors both within the Union, and between the Union and third countries. This IA addresses the recommendations that relate to the extra-EU trade, and assesses possible amendments of Regulation (EC) No 111/2005. The report focuses in particular on the trade of medical products containing ephedrine and pseudoephedrine, as these chemical substances are increasingly used by drug traffickers for the illicit manufacture of methamphetamines. The possible revision of Regulation (EC) No 273/2004 on intra-EU trade is the subject of a separate IA conducted by DG ENTR.

(B) Overall assessment

The report provides an adequate and proportionate analysis but should be further improved on a number of aspects. First, it should strengthen the problem definition and clearly present the scope of the proposal. Second, the report should provide a more developed baseline scenario, including the present powers of the Member States' customs and police authorities as well as their existing drugs legislation. Third, the report should reformulate the options in order to focus on their substance rather than their legal character, and it should also consider a sixth option which would ban ephedrine and pseudoephedrine altogether. Finally, the analysis of the impacts should be strengthened, and the options should also be compared on the basis of efficiency and effectiveness criteria.

(C) Main recommendations for improvements

(1) Strengthen the analysis of the problem. The report should provide a succinct description of the medicinal products which would be affected by this initiative, and give an indication of the size of the relevant markets in the EU. It should explain how these medicines are diverted into the production and distribution chain for methamphetamines. It should clearly state why much of the available information on Member State actions and the interests of stakeholders is so sensitive that is has to be kept entirely confidential. Where possible the report should include summary information from evaluation reports, without explicit naming of specific companies or Member States. The scope of the problem to be tackled by the proposal should be better explained, i.e. the need to close a loophole in current EU legislation to create the possibility for police and customs authorities to intervene effectively. The report should make more extensive use of the UNODC World Drug Report 2011, in order to provide background evidence on the overall problem and its scope. It should also better differentiate between the production of methamphetamines which is a regional problem within the EU, and the transit of drugs and drugs precursors through the EU which affects the whole Union. Finally, stakeholders' views should be better presented and analysed, including those of the industry which appear to favour the status quo. The report should also provide more insight into the reasons behind the disagreement among Member States on the desired approach.

(2) Improve the baseline scenario. The report should explicitly outline how the problem is expected to evolve should the EU take no further action to reinforce the control powers of police and customs authorities. The necessity and added value of the EU intervention should be more clearly demonstrated, and the report should present the arguments with which the UN is currently urging the EU to intervene. The report should explain why the new tariff code for medicinal products will only be applicable as from 1 January 2017. Similarly, the new tariff codes that the European Commission is implementing should be better described, their role explained and their entry into force specified. The current legal and enforcement arrangements in the Member States should be summarised in the main text as part of the baseline, with more detailed information in an Annex.

(3) Provide a clearer presentation of the options. The report should redesign the options, according to their substance rather than their legal format. It should also better indicate the cumulative nature of options 3, 4 and 5. In addition, the report should consider a sixth option which would consist in banning medicines containing ephedrine or pseudoephedrine altogether, and the implications of such a ban should be thoroughly assessed. Discarded options should be explicitly presented, and the report should justify why they have not been considered further.

(4) Strengthen the impact analysis and the comparison of the options. The report should analyse the impacts on SMEs and international trade in a systematic manner. It should also address the issue of compliance costs for industry. The report should attempt to differentiate the impact analysis for different kinds of firms (pharmaceutical companies, drug stores, trade firms). Moreover, the purpose and impact of the pre-export notifications (PEN system), as presented in Option 4, should be better explained. Similarly, the report should better analyse the administrative burden on industry for each option, not only focusing on the cost of obtaining a licence. The report should base its comparison of options on a more detailed analysis of their expected costs and benefits. It should compare the options on the basis of more criteria than the administrative burden on authorities, especially their expected effectiveness and efficiency.

(5) Improve the presentation of stakeholders' views and clarify monitoring and evaluation arrangements. References to stakeholders' input should be made more systematically throughout the report, especially in the problem definition and the presentation of the options. The report should clarify to what extent views differed between Member States. It should indicate more clearly how stakeholders' opinions have been taken into account, including of social interest groups where relevant. In addition, the report should provide more developed monitoring and evaluation arrangements, including a set of concrete progress indicators that are clearly linked to the preferred option.

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

The report should better justify why no public consultation was carried out. The executive summary should be modified in line with the recommendations concerning the main report.

(E) IAB scrutiny process	
Reference number	2011/TAXUD/006
External expertise used	No
Date of IAB meeting	29 February 2012