EUROPEAN COMMISSION
Impact Assessment Board

Brussels,
D(2013)

Opinion

Title **DG SANCO – Impact Assessment on detailed rules for the safety features of medicinal products for human use, and its verification**

(draft version of 2 August 2013)*

(A) Context

In order to reduce the presence of falsified medicines in the EU, Directive 2011/62/EU amending the "Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products" introduced two safety features: (i) a unique identifier (a number placed on a carrier/barcode, to identify an individual pack); and (ii) an anti-tampering device. Article 54a(2) stipulates that the Commission has to adopt a delegated act setting out the characteristics and technical specifications of the unique identifier, the modalities for the verification of the safety features and the establishment and management of the repository system containing the unique identifiers. In this context, the report examines how to introduce an effective authentication system while avoiding unnecessary costs for manufacturers of medicinal products, wholesale distributors and pharmacies/retailers.

(B) Overall opinion: NEGATIVE

The report should be significantly improved in a number of important respects. It also appears incomplete, and should therefore clarify what exactly the requirements stemming from the Directive 2011/62/EU are, and to what extent it provides scope for excluding or including specific medicines, such as generics or over-the-counter medicines. In particular, the report should explain the application of the exclusion criteria and on the basis of which analysis/evidence the list of exemptions (i.e. white/black list) will be established. It should also better demonstrate the need to prevent circulation of falsified medicines at the wholesale level. The report should present options addressing recalls and returns separately, and clarify how the options would work in practice (such as the protection of commercially sensitive data or the envisaged risk-based verifications by wholesalers). It should better assess impacts on different actors and patients and present the underlying calculations more clearly. Finally, the report should provide more detailed feedback on the views of different categories of stakeholders.

Given the nature of these concerns, the IAB requests DG SANCO to submit a revised version of the IA report on which it will issue a new opinion.

* Note that this opinion concerns a draft impact assessment report which may differ from the one adopted

(C) Main recommendations for improvements

(1) Better present the policy context. The report should clarify the difference between falsified and counterfeit medicines and indicate the extent to which the wider problem of falsified medicines is being addressed by this initiative. In doing so, it should provide more insights (and additional evidence, if available) into the increasing trend of falsification and the prevalence of falsified medicines (i) across the legal vs illegal supply chain, (ii) in originator vs generic medicines, and (iii) within prescription vs over-the-counter medicines. The report should also provide more detail on the role and relative importance of intra-EU trade, and the various actors in the supply chain (such as originator and generics companies, parallel importers or other points of dispense). In doing so, it should, where relevant, better reference the information and analysis provided in the preceding impact assessment accompanying the proposal for the Directive (COM(2008)668).

(2) Clarify the scope of the initiative. The report should clarify what the requirements stemming from the Directive 2011/62/EU are. First of all, it should clarify to what extent Directive 2011/62/EU provides scope for excluding or including specific medicines or groups of medicines, such as generics or over-the-counter medicines. In particular, the report should recall the exclusion criteria as defined in the Directive and substantiate the claim that exclusions concern only a small part of medicines. It should explain in particular how these criteria will be applied and by whom and, consequently, how and on the basis of which analysis/evidence the list of exemptions (i.e. white/black list) will be established and to what extent the list of exemption may affect the effectiveness of the proposed measures. Secondly, it should clarify that the envisaged harmonisation of batch numbers and expiry dates goes beyond the necessary minimum of introducing the unique identifier and explain why this initiative is thought to offer a good opportunity for increasing the efficiency of recalls and returns and thereby ensuring savings for the industry. Thirdly, the report should recall the link between the anti-tampering device and the unique identifier, and better explain what exactly the envisaged delegated act would stipulate on the former one. Finally, it should clarify if the Directive allows for excluding wholesalers from the verification obligations or not.

(3) Present the underlying drivers in more depth. The report should better describe the challenges related to the current use of coding systems, data carriers, verification throughout the supply chain as well as data repositories. For example, it should assess in more depth and better demonstrate with concrete evidence, the need to verify medicines by wholesale distributors, namely as regards the entry points of falsified medicines and the negative consequence related to their circulation in the supply chain. The report should also provide more information on the pilot projects run at European and national level, as well as the solutions envisaged or implemented in other markets such as the U.S.

(4) Better present and explain the options. Subject to further clarification of the scope of the initiative, the report should better present the choices that still need to be made. In doing so, it should clearly distinguish options going beyond the requirements of the Directive, i.e. including the harmonisation of additional product information, and explain why more alternatives have not been considered (e.g. the possibility to have additional verifications if the system does not prove to work, as proposed by some stakeholders). Furthermore, the report should better explain the content of the options and how they would work in practice. In particular, it should: (i) clarify which data will be stored in the repository system and explain how exactly the protection of commercially sensitive and personal data will be ensured; (ii) illustrate how the interoperability of repositories would work in practice; and (iii) explain the likelihood of the envisaged risk-based verifications

(e.g. it would seem that products are not obtained from the "genuine" manufacturers rather frequently).

(5) Better assess the impacts. The report should assess impacts in a more balanced and objective manner, namely by better explaining the relative importance of economic and social benefits related to the (reduction of) falsification and by comparing them to the increased efficiency of recall and return procedures (which seem to be relatively more important but also come at greater costs). It should further discuss what the expected disproportionate economic impact on generics companies, parallel importers or short-line wholesalers could mean in practice, particularly as regards their profitability and ability to remain on the market. Consequently, the likely impacts on competition and upon the prices of medicines should be explicitly assessed. As regards health care professionals, the report should clarify if the compliance costs are expected to be significant or not (and corroborate this by the corresponding views). In addition, it should indicate the expected impact on national control authorities and, more generally, on individual Member States. The report should more clearly explain what is included in the cost estimates (e.g. packaging, changes to production lines, setting up and operation of the repository etc.) and better present the underlying calculations, for example by clearly distinguishing between one-off and recurring costs. Finally, it should present the overall costs of the preferred option for a unique identifier separately from the cost estimates for an anti-tampering device.

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

In order to make the text accessible for non-expert readers, the report should include a glossary with definitions of key concepts. The underlying sources of data should be more systematically referenced, including the external support study. The report should report on stakeholder views in a more accurate and neutral manner, by better differentiating between the views of different categories of stakeholders, especially in the problem, options and impacts sections.

(E) IAB scrutiny process	
Reference number	2014/SANCO/002
External expertise used	No
Date of IAB meeting	18 September 2013