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**

(resubmitted draft version of 29 November 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: POSITIVE

While the report has been significantly improved along the lines of the recommendations in the Board's first opinion, it would benefit from further work in a number of respects. Firstly, while the report better explains the prevalence of falsified medicines, it should provide more insight into their likely points of entry in the legal supply chain. Secondly, it should clarify if any non-prescription medicines would have to bear the safety features. Thirdly, the report should present the cost estimates with a higher degree of caution and should clarify which operators would benefit most from the envisaged savings. Finally, in the absence of product-specific data, the report should assess the impact on the competitiveness of originators and generics in a more nuanced manner.

(C) Main recommendations for improvements

(1) Improve the problem definition. While the report provides more detail on the prevalence of falsified medicines and the role of various actors in the legal supply chain, it should provide more insight into the likely points of entry of falsified medicines into the legal supply chain. This could be done, for example, by providing anecdotal example(s)

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

that would illustrate how the traffickers can penetrate the legal supply chain in practice (for example when the product is being returned to a wholesaler). Furthermore, while the report recalls the exclusion criteria mentioned in Directive 2011/62/EU and explains how they would be applied, it still needs to clarify: (i) the role (of the number) of SMEs in establishing the lists (as referred to in the report); and (ii) if there are any non-prescription medicines that would have to bear the safety features (given that the key factor is the presence of incidents of falsification, while there seems to be none so far according to the report). In order to reinforce the argumentation that the initiative is a good opportunity to go beyond the requirements of the Directive (namely as regards the coding structure and carrier), the assessment of the inefficiencies related to recalls and returns should be presented as problems rather than impacts only.

(2) Better assess the impacts. While the report assesses impacts in a more comprehensive manner, it should still present the cost estimates with a higher degree of caution (including the fact that the cost per operator does not reflect the number of production/manufacturing lines). It should also explain the assumptions that stand behind the statement that "costs of the unique identifiers are the same across the EU". The report should clarify which operators (i.e. innovators, generics or parallel importers) would benefit most from the envisaged savings related to the replacement of national coding systems, reduction in falsified medicines and higher efficiency of recalls and returns. In this context, it should clarify if the benefits of reducing counterfeit medicines of approximately EUR 3 mio/year refer to legal supply chain only or also illicit sales. Finally, in the absence of data such as profit margins or price sensitivity of demand, and given that some stakeholder(s) argued that some generics manufacturers (many SMEs) may be forced to leave the market, the report should revisit the conclusion that the competitiveness of originators and generics would be equally affected by the implementation of the unique identifier.

(D) Procedure and presentation

The executive summary should include a table presenting the overall costs of the preferred option for a unique identifier. The executive summary sheet should respect the required length. The report should not refer to investment costs as "administrative" ones.

(E) IAB scrutiny process	
Reference number	2014/SANCO/002
External expertise used	No
Date of IAB meeting	Written procedure An earlier version of this report was submitted to the IAB in August 2013, for which the Board issued an opinion on 20 September 2013