Response to Commission consultation on a legal proposal to combat counterfeit medicines

Introduction and general remarks

Novartis is a global healthcare company which business divisions ranging from innovative pharmaceutical products, generics, over-the-counter medication to vaccines. Novartis is therefore uniquely placed to provide the European Commission with a balanced and comprehensive view how protection against counterfeits can be reconciled with a business-friendly regulatory environment.

In general, Novartis supports measures such as consumer education and strict (no-fault) liability for the whole distribution chain. Novartis advocates a balanced approach whereby the effectiveness of the measures are balanced against the additional costs for the industry.

All members of the distribution chain, including wholesalers and pharmacists, should be under a unambiguous no-fault liability for counterfeit products as well as defects occurring during the distribution. Such a liability would provide additional incentives for all distributors to implement the safeguards. It would allow the cheapest-cost-avoiders to carry responsibility while letting marketing forces continue the search for better solutions against counterfeit products.

Proposed measures 4.1.1 (clarify responsibilities for all parties in distribution chain) and 4.1.2 (tightening rules on inspection):

Novartis strongly supports the proposed measures which in Novartis opinion will improve patient safety considerably.

Proposed measures 4.1.3 (sealing), 4.1.4 (centrally accessible record - possibility of tracing batches) and 4.1.5 (mass serialization for pack tracing)

Novartis agrees with the Commission's proposal to apply the requirements on the basis of a risk-based approach.

Novartis considers that over-the-counter (OTC) products and generics are generally less at risk because of the different sale prices, profit margins and general attractiveness for counterfeiters. As counterfeiters in particularly are still largely (but not exclusively) concentrating on so-called "life-style" products, an obligation imposed on non-prescription (OTC) products and all generics would be disproportionate.

Similarly, Novartis would suggest that vaccine products are less at risk because of the very different distribution systems which largely reduce the risk of counterfeits entering the legitimate distribution chain.

However, we would suggest that the Commission is provided with the mandate and a legal mechanism to monitor the situation and to suggest changes to the EU's policy approach. The Commission can thus suggest which products or types of products should be considered to be particularly at risk.

Non-prescription medicines should at this stage be considered to be at low risk and thus exempted from the proposed requirements.

Proposal 4.2 (Import/Export/Transit Requirements)

Novartis supports these measures.

Proposal 4.3.1 (mandatory notification for manufacturers) and 4.3.2 (enhancing audit and enforceability of GMP)

Novartis does not believe that these measures will significantly improve patient safety. On the other hand, these measures will certainly increase the administrative burden for companies. Novartis would therefore be in favour of a risk-based approach. At the same time, the Commission should more closely evaluate the effectiveness of these measures.

Proposal 4.3.3 (enhancing GMP inspections)

Novartis supports these measures.