
Recommendations for health authorities on criteria for risk assessment and prioritization of cases of unregistered/unlicensed, substandard and falsified medical products

Executive summary¹

1. Risk assessment is a process of assessing the potential severity of a risk event, based on the premise that not all of such events are equally important. The results of a risk assessment should be used to establish an importance ranking of alerts, notifications and reports received by regulatory authorities, based on the identification of cases with greater potential to cause damage to public health. Ranking the events based on their significance helps decision-makers in regulatory authorities to better understand where resources may be most needed, to reduce the timeframe to initiate actions and to establish a protocol of actions according to the severity of the case, in order to protect patients' health and safety. **This prioritization is especially important where the number of alerts, notifications and reports received by the regulatory authority exceed its capacity to act immediately in all cases.**
2. The use of a well-defined and simple procedure/tool to perform a risk assessment is desirable in order to obtain standardized and reliable results. The full document describes elements and criteria that may be considered in order to conduct a rapid risk assessment and prioritization of events involving unregistered/unlicensed, substandard and falsified medical products. It is a reference that regulatory authorities can customize or that they can use to create their own risk analysis and management procedure/tool, considering their regional/national reality.
3. The recommendation is that regulatory authorities always consider cases of falsified medical products as presenting a high risk, and investigate them immediately. Hence, a risk assessment tool to indicate priority levels is especially useful for the analysis of cases involving unregistered/unlicensed and substandard medical products.
4. Each regulatory authority should identify and select, based on its experience and data available, the factors to be considered for risk assessment. The full document suggests that the evaluation should include, at least to some degree, the following factors: severity of defect/non-compliance, potential clinical consequences, whether or not the product is of high potency or low therapeutic index, and the route of administration and place of action. In addition, other factors might be relevant in the action plan developed by regulatory authorities to define the next steps for a specific case. Such factors

¹ The full document has been made available on the MedNet collaborative platform.

include the following: the probable place of the deviation; the exposed population; the frequency of occurrence; market turnover and expiration date; whether or not the product is the single medical product on the market or used in national/international health care programmes; and the degree of detectability of defect/non-compliance. The full document advocates that the factors contribute in differing proportions to the “final risk” of a given case.

5. The full document proposes a model risk classification and prioritization matrix to be customized and used by regulatory authorities. This matrix indicates that regulatory authorities should: (1) identify “risk factors”; (2) establish “importance levels” for each risk factor; (3) define different categories for each risk factor, considering the severity of the case and impacts on the patient’s health and safety; and (4) establish prioritization groups that show the severity and importance of the case for public health. Prioritization will support decision-making in respect of which case to act upon first, what to do and in what timeframe, based on activities pre-defined by each regulatory authority.

6. The full document contains annexed materials to support Member States in the establishment of their own procedures/tools to perform the risk assessment and prioritization of cases. Appendix I presents a catalogue of examples of quality defects in products, for illustrative purposes, and Appendix II presents practical examples of the use of the suggested matrix, for a fictional national context and fictional cases.

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