
Problem statement identifying the range of issues that facilitate the sale and supply of substandard and falsified medical products through the internet both nationally and across borders

Executive summary

1. This executive summary relates to prioritized activity H of the Member State mechanism: to identify and develop appropriate strategies to understand and address the distribution or supply of substandard and falsified medical (SF) products via the internet. This activity is led by Colombia. This summary has been produced in response to action (b): to provide a problem statement identifying the range of issues that facilitate the sale and supply of substandard and falsified medical products through the internet both nationally and across borders.

2. The increased accessibility of products via the internet has contributed to the expansion of SF medical products,¹ including the distribution, supply and sale of SF medical products through online pharmacies, e-commerce sites, social networks or virtual commercial platforms in general. Given that more people are buying medical products through the internet, the working group sought to better define the problem, identifying the range of issues that facilitate the sale and supply of SF medical products through the internet, both nationally and across borders.

3. To better understand the current regulatory landscape of this issue, a survey was disseminated across the Member State mechanism. A total of 28 Member States from all WHO regions provided responses. It should be noted that although the survey results are not globally representative, the summary of issues below provides useful indicators on the scope of the problem.

4. The following 12 issues were identified as facilitating the distribution, supply and sale of SF medical products via the internet:

- (a) absence of specific regulation for the distribution, supply and sale of medical products through the internet, and to address the marketing of SF medical products via the internet;
- (b) low level of health education related to the purchase of medical products online;

¹ For the purposes of the executive summary and full document and the scope of the working group, it was established that medical products include medicines (with and without a prescription), vaccines, in vitro diagnostic products and unregistered or unlicensed products (such as dietary supplements that have pharmaceutical components).

- (c) difficulty in identifying website data related to the sale of SF medical products;
- (d) limited actions are possible when the person responsible for the website is outside the scope of jurisdiction depending on the geographical location;
- (e) limited understanding of and weak collaboration with the stakeholders of the virtual distribution structure of SF medical products and the private sector in the fight against illegality in the trade of medical products via the internet;
- (f) lack of criminal authority over the agents of the virtual distribution structure of SF medical products and over those responsible for the sale, distribution and commercialization of SF products;
- (g) limited national and international cooperation and weak collaboration with other public entities for joint operations and investigations;
- (h) absence in some national health agencies of specific groups working on the topic of SF medical products;
- (i) limited experience of some national health agencies in the approach to be taken in carrying out decisive actions to mitigate the distribution, supply and sale of SF medical products;
- (j) lack of funding or budget to implement actions carried out by national health agencies against the distribution, supply and sale of SF medical products via the internet;
- (k) lack of rational use and provision of medical products via the internet;
- (l) difficulties in obtaining data on the problem.

5. To address these issues, it is necessary to implement a comprehensive model that includes, inter alia, the following variables.

- (a) Take a health agency-driven approach, including actions and strategies mostly related to regulation that can be carried out by public authorities.
- (b) Integrate a focus on the private sector, including the actions that can be carried out by such stakeholders (such as postal traffic agencies, airlines, logistics companies), understanding that their collaboration is necessary, and that coordination with them is key for the detection, surveillance and control over the distribution, supply and sale of SF medical products.
- (c) Ensure a consumer focus, with all actions aimed at preventing the consumption of these products and increasing health education.
- (d) Strengthen regulation and the capacities of public authorities, while coordinating with the relevant stakeholders, including the private sector, and educating consumers. Only thus will the chain of distribution of these products be tackled in conjunction with addressing the demand and supply.

- (e) Given the global nature of the problem, scenarios, networks and intersectoral working groups should involve all the interested parties (such as health agencies, police/customs authorities, agents of the virtual distribution structure, manufacturing and distribution companies, associations of health professionals, international organizations).
- (f) Foster dialogue between countries to support the design, implementation and adoption of commonly agreed instruments to fight the distribution, supply and sale of SF medical products in addition to sharing best practices and experiences of countries that already have such strategies in place.
- (g) Promote cooperation among the stakeholders and fill technical, legal, and resource gaps. Strengthening the capacities of a given country to tackle such gaps can also benefit others.
- (h) Generate awareness among public authorities and national health agencies so that joint, interagency work is strengthened. Such awareness should start by acknowledging the seriousness of the problem, as well as the need to address it in the most effective, articulated and unified fashion.

6. The full document¹ provides more substantive information on the above issues, including the survey results, to provide support to Member States in their preliminary understanding of this multifaceted issue. Due to the international dimension of the problem, it will be necessary to understand and share best practices and experiences of Member States that already have regulation and strategies in place, including coordination and collaboration with the relevant public and private stakeholders. Such dialogue would support the design, implementation and adoption of commonly agreed actions and strategies to prevent, detect and respond to the risk of SF medical products reaching consumers.

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¹ The full document is in the process of being finalized. Once available, it will be shared with Member States via the MedNet platform (<https://mednet-communities.net/sf>).