
Identification of reporting barriers faced by national focal points of the Global Focal Point Network and possible solutions

Executive summary linked to Activity B

1. The list of prioritized activities to implement the workplan of the Member State mechanism for the period 2022–2023 includes Activity B to develop, expand and maintain global networks of stakeholders to facilitate cooperation and collaboration.¹ This activity is led by Eritrea. The present executive summary has been produced in the light of the work of Working Group B, which, under Action (1) of its remit, has focused on identifying (a) reporting barriers faced by national focal points of the Global Focal Point Network in respect of the WHO Global Surveillance and Monitoring System for substandard and falsified medical products (GSMS) and (b) possible solutions.

BACKGROUND

2. The objective of GSMS is to work with Member States to improve the quantity, quality and analysis of accurate data concerning substandard and falsified medical products, and to use the data to prevent, detect and respond to those products. In 2020, the GSMS upgrade provided an opportunity to revise the data architecture and internal processes for handling the incidents that are received and managed by the technical team. The portal allows national focal points to report incidents and to search for reported substandard and falsified medical products using resources such as the database.

3. To understand better the current use of GSMS and the reporting barriers faced by national focal points, Working Group B developed a questionnaire and an interview protocol that were used for a two-phase study. The first phase of the study (quantitative approach) consisted of a global questionnaire, sent to all Member States, to identify the main barriers and possible solutions. The second phase of the study (qualitative approach) included in-depth interviews to explore further the possible solutions.

4. Once finalized, the full document, which provides more substantive information on the issues involved, including the full results of the study, will be made available to Member States via a shared platform.

Phase I: questionnaire

5. All Member States were invited to participate in the questionnaire, and a total of 76 (39.2%) responded.

¹ See Annex 2 to document A/MSM/10/11 Rev.1.

6. Respondents were first provided with a list of reporting barriers to consider; they were then asked to select one or more options as relevant and rank their importance on a four-point scale (highly impactful, somewhat impactful, not impactful, do not know). Although all the barriers were recognized by respondents, their perceived importance differed in and among all WHO regions. At a global level, the top five barriers were identified as:

- (a) unavailability of investigation mechanisms for suspected substandard and falsified medical products;
- (b) staff workload;
- (c) untrained national focal points;
- (d) inadequate/insufficient coordination among regulatory pillars; and
- (e) immaturity of the system in terms of the scope and diversity of reportable incidents.

7. Respondents were subsequently questioned about their perceptions of specific solutions to overcome the identified reporting barriers. They were provided with a list of possible solutions and asked to identify relevant facilitators and rank their importance on a four-point scale (highest, high, medium, low), variations in which were evident at a regional level. At a global level, the top five identified possible solutions were:

- (a) organize regular trainings for new and existing national focal points;
- (b) develop clear guidance documents on reporting substandard and falsified medical products to GSMS;
- (c) support countries to train their health workers in respect of combating substandard and falsified medical products;
- (d) organize regular meetings among national focal points; and
- (e) develop standardized tools for investigating substandard and falsified medical products.

8. Of the 76 Member States that responded, a total of 62 (81.6%) expressed an interest in participating in an in-depth interview (Phase II).

9. The results of the questionnaire may help to identify reporting barriers and possible solutions, and they highlight the importance of further investigating disparities in reporting capacities to understand why, even when incidents of substandard and falsified medical products are confirmed, Member States do not always report them to GSMS.

Phase II: interviews

10. Of the 62 Member States that expressed an interest in participating in an interview, a total of 44 (71.0%) were invited to take part, of which 14 (31.8%) responded positively. The definitive version of the interview protocol consisted of eight questions. Questions and prompts for the interview were developed to bring forth context and experiences of perceived barriers and possible solutions to substantiate, inform and provide answers.

11. An inductive quality analysis approach was used to identify relevant quotes and themes in respect of reporting barriers. A list of nine key themes was identified, and the most prominent quotes that emerged from the interviews were:

- (a) legal framework/structure;
- (b) delays in receiving results or information and fragmentation during investigation;
- (c) insufficient guidance and terminology;
- (d) untrained national focal points;
- (e) connectivity (GSMS access and internet issues); and
- (f) workload.

12. The same approach was used to identify relevant quotes and themes in respect of possible solutions to the reporting barriers. A list of 11 key themes was identified, and the most prominent quotes that emerged during the interviews were:

- (a) improve national capacity or resources in respect of processes supporting timely reporting;
- (b) provide training for national focal points;
- (c) increase advocacy and awareness;
- (d) increase collaboration;
- (e) reach consensus about processes and terminology used; and
- (f) develop guidance on how to use GSMS to report substandard and falsified medical products.

13. Understanding the possible solutions for the identified reporting barriers may help the Member State mechanism to adopt, advance and deliver solutions that have a predictable impact and consider the specific needs, experiences and context of all Member States across all WHO regions.

ACTION BY THE MEMBER STATE MECHANISM

14. The mechanism is invited to note the executive summary. In its discussions, it is further invited to provide comments and guidance in respect of the following questions:

- should disparities in reporting capacities be investigated further to understand why, even when incidents of substandard and falsified medical products are confirmed, Member States do not always report them to GSMS?
- what measures can be taken to enhance collaboration and communication between Member States and GSMS to facilitate the more efficient reporting and tracking of substandard and falsified medical products?
- what solutions could be adopted for the identified reporting barriers while considering the specific needs, experiences and context of all Member States across all WHO regions?

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