World Health Organization

TENTH MEETING OF THE MEMBER STATE MECHANISM ON SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS
Provisional agenda item 4(H)

A/MSM/10/10
7 October 2021

Develop guidance on strategies to enable national/regional regulatory authorities to address the distribution or supply of substandard and falsified medical products via the internet

Report on Activity H

Executive summary

1. This report relates to prioritized activity H of the Member State mechanism on substandard and falsified medical products: Identify and develop appropriate strategies to understand and address the distribution or supply of substandard and falsified medical products via the internet.[1] It summarizes the guidance produced in response to action (d): Develop guidance on strategies to enable national/regional regulatory authorities to address the distribution or supply of substandard and falsified medical products via the internet.[2]

2. There has been an observed increase in the online distribution and supply of medical products in almost all WHO regions since the beginning of the coronavirus disease (COVID-19) pandemic.[3] All States are vulnerable where there are deficits in infrastructure and weak regulatory systems to counter online distribution and supply. This extends the risk of consumer accessibility to substandard and falsified (SF) medical products. The guidance has been developed to support national/regional regulatory authorities (NRRA) in building their strategies to address this public health challenge.

3. A working group under the leadership of Colombia provided a problem statement to the eighth meeting of the Member State Mechanism, and a survey was conducted in 2019 and 2020 and repeated in 2021. The Internet Survey Report was completed in 2021, and a summary of it will be considered by this meeting.[4] The guidance on strategies has been developed using the Internet Survey Report 2021. The report and the guidance document are available on the MedNet platform.

4. The guidance acknowledges that States may be at different stages of development to address the online supply of SF medical products. It seeks to identify the most impactful strategic areas that will

[1] Agreed list of Prioritized Activities to implement the Workplan of the Member State Mechanism for the period 2020–2021. Agreed 25 October 2019. A/MSM/8/4. Accessed at A_MSM8_4-en-6-8.pdf (who.int).

[2] For the purposes of this guidance the term internet expanded to include social media and e-commerce platforms. The term substandard and falsified (SF) will be used without the additions of unlicensed/unauthorized medical products. Legitimate registered online pharmacies are referred to where applicable in the guidance document, but not in this summary.

[3] Internet Survey Report 2021 (Identify experiences, best practices and/or regulation of the distribution or supply of medical products via the internet to prevent and reduce the risk of substandard and falsified medical products reaching consumers).

[4] See document A/MSM/10/9.

support the NRRA to begin to exert control over this issue. It addresses the basic requirements to put an effective strategy in place.

A strategic approach to prevention, detection, and response to the online distribution and supply of SF medical products

Prevention

5. Strategic approaches have better outcomes when they prevent the risks arising from the online supply of SF medical products. Significant strategic focus may be placed in this area to exert control and avoid the necessity to react continually through detection and response following limited success in prevention. Prevention should be the primary area in which the NRRA aims to operate, and in the shortest possible time-frame.

Detection

6. Detection may be considered reactive when it follows product profiling or information received. It may be considered proactive when it seeks out SF medical products through inspections and other processes. Detection is preferable to response, as the immediate risk is halted. For many States, the entry points at ports and crossings act as a funnel, facilitating opportunities to detect SF medical product movement. While detection may contribute to other actions that can focus on the supply line disruption, it may only impact at a point in time and it relies on responses through follow-up actions. Without detection, many opportunities for an appropriate response may not be possible. Detection will remain an important factor in addressing SF medical products supplied online.

Response

7. Response actions vary and are wide in potential scope as they require the NRRA's reaction to events arising, usually outside of its control. Reaction, while necessary, is the most inefficient approach to addressing the online supply of SF medical products. Due to the prevalence of SF medical products supplied online it may become normalized as an everyday expectation. NRRAs need to continually challenge this normalization otherwise it raises a risk of accepting the public health risk as something that is managed, rather than moving to the prevention stage of eliminating or reducing the risk to below a given level. Response needs to be effective, prioritized, and not just routine. Every effort should be made to eliminate the need to respond and instead to exert control for most regulatory actions against SF medical products to focus on prevention. Response will continue to be the dominant activity in States, in particular those with undeveloped or deficits in strategies in this area.

8. The guidance highlights the need to focus on preventive actions within the strategy. This is where resources should operate for maximum effect. Until NRRAs move events back to the prevention stage, most resources will continue to be allocated for response actions. This is indicated in the guidance by the focus on actions that require attention. NRRAs should recognize that opportunities for positive media and other exposure for perceived successes against the online supply of SF medical products will arise from response actions. There are few credits provided or acknowledgement expressed when prevention is effective. This is a short-term gain that does not satisfy strategic goals. Short-term gain is the product of outputs but does little to achieve outcomes. Balancing prevention, detection and response in the strategy is important, as the primary focus moves from response to prevention. NRRAs should be realistic in recognizing that most likely this will not happen during the period of the first strategic plan for addressing the online supply of medical products, and instead will stretch over several strategic periods.

9. The prevention, detection and response phases form a continuous circle of events where one phase prevails or predominates over the others. As strategic actions may fall into any of the three phases depending on circumstances, the guidance follows the structure below without segregating prevention, detection and response.

Developing a strategic approach

10. A basic consideration and a challenge to strategic development is in not taking account of the wider policy field in which the NRRA must operate. Failure to consider this would create an artificial and isolated focus that is destined to fail due to lack of necessary support from officials who may not be directly involved in the strategy formulation or implementation. The NRRA may not have total responsibility or control in the area of online supply as other State agencies have their own remit that impact any NRRA strategy in this field. Strategic planning cannot perform effectively in isolation from other State authorities who have a remit in the areas of communications, criminal justice, revenue, and relating to the regulation of supply lines, at a minimum.

11. Cooperation, collaboration and communication with other authorities are mainstays of the successful development and implementation of strategic approaches and are equally important in addressing SF medical products from the public health perspective. Such efforts will also necessarily involve private sector actors who are involved, whether wittingly or unwittingly, in facilitating the online supply of SF medical products. They should also be seen as part of the solution. While most sectors will cooperate, some will be resistant even to communicate with the NRRA. While express carriers, postal services and the payment industry are readily identifiable potential partners, there should be some consideration to the inclusion of logistics companies at a minimum as their support, rather than absence of support, can contribute positively towards preventing and detecting online supplies that present risks to public health.

12. Cooperation and collaboration may be perceived by some NRRAs as a burden. Areas for collaboration may include the identification and handling of SF medical products, their analysis, risk assessment and the need for their destruction. The actions of other authorities against the online supply of SF medical products should be seen as their active support for and contribution to the protection of public health. It is unlikely that most NRRAs will ever have the resources to do the work conducted, or potentially to be conducted, on their behalf by the other authorities working in cooperation with them. The consequence for the NRRA of not working in cooperation with other authorities is to passively permit those SF medical products to continue to be supplied online.

13. Much may be achieved from the support of other States through the active sharing of information and cooperation with them. This can extend to assisting with the development of strategies and advising on the best mechanisms for their implementation to achieve the optimum benefit for public health in the State. It is also noted that those more advanced NRRAs may achieve a mutual benefit from this approach. NRRAs being supported may develop their ability to prevent and detect SF medical products in the online distribution line being transported through their State to the supporting State. Any offer of support must also respect the differences in States' regulatory frameworks and other arrangements, taking into account that a one-size-for-all approach does not work.

14. The guidance considers the strategic planning focus to ensure that development and achievement is contained to avoid planning overreach beyond what was intended and that might threaten the plan itself. Having good regulation[1] is key to supporting the NRRA's strategy in this area, and the guidance

[1] Delivering Quality-Assured medical Products for All 2019–2023: WHO's five-year plan to help build effective and efficient regulatory systems (WHO/MVP/RHT/2019.01). Geneva: World Health Organization; 2019. Accessed at WHO_ActionPlanWeb.pdf.

document provides some advice to ensure that the basis for planning exists and that implementation goals are focused and achievable. Achieving something different than intended by the strategic goals, even if it may be valuable in itself, is a failure to achieve the goals of the strategy. The strategic approach must therefore avoid mission creep beyond the NRRA's legal powers and remit.

15. In addition, the NRRA must ensure that the strategy has political and policy support, otherwise it will not be resourced, sustainable or successful if it reaches the implementation stage. Communicating effectively that the proposed strategy has public value in that it has the necessary political support and the required resources, and that it can be carried out by the NRRA, will ensure that it will be sustainable during crises when decisions may be made on suspending or deferring implementation of some strategic programmes. These issues, and others, are addressed in the guidance document through the process of identifying the strategic planning focus, proposing five sample strategic goals, and identifying sub-strategy activity focus areas that are needed for the strategy to be implemented effectively and successful in achieving outcomes. The strategy has to have enabling support to achieve the outcome desired, namely the protection of public health.

16. Prioritization of strategic approaches by NRRAs, in a logical and incremental way, is the key to the successful implementation and achievement of strategic goals addressing the online distribution and supply of SF medical products from the public health perspective. NRRAs will usually have more challenges than resources to face the online supply of SF medical products.

What the guidance includes

Strategic planning focus

17. Strategic planning focus should, at a minimum, include consideration of regulatory oversight support requirements, confidence-building measures capable of enabling coordinated activities, actions to bring about supply reduction outcomes for online sales of SF medical products, and obtaining the support and cooperation of the consuming public through behaviour change towards demand reduction.

Setting strategic goals

18. Sample strategic goals are identified to cover the remit of the NRRA to achieve outcomes. The five sample strategic goals are as follows.

(a) Bring the online market of distribution and supply of SF medical products into the NRRA remit to enable effective regulatory oversight to apply.

(b) Establish confidence building measures and mechanisms for the NRRA, and other relevant and supporting authorities, to achieve a coordinated approach to prevent, detect, and respond to the online distribution and supply of SF medical products

(c) Reduce the availability of SF medical products through online distribution or supply to the market

(d) Increase the awareness at all levels of the risks to safe and regulated online supply of medical products to attain demand reductions.

(e) Achieve a quality online regulated service of distribution and supply of medical products.

Sub-strategy activity focus areas

19. The activity focus areas that are essential to the successful implementation of strategic goals are discussed under each heading. These cover

(a) Regulation

(b) Surveillance

(c) Regulatory inquiry and investigations

(d) Cooperation and communication

(e) Training

(f) Public awareness raising

(g) Resourcing

20. A summary of selected areas for consideration in strategic goals in the WHO regions identified by the Internet Survey Report 2021 is provided in the guidance document to facilitate a view of regional deficits that may require attention and consideration for inclusion in strategic goals.

21. The Internet Survey Report 2021 and full guidance document on strategies are available on the MedNet platform: https://mednet-communities.net/sf/library.[1]

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[1] The MedNet community for substandard and falsified medical products is accessible only by Member States participating in the Member State mechanism on substandard and falsified medical products.