World Health Organization

TENTH MEETING OF THE MEMBER STATE MECHANISM ON SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS
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Promote shared understanding among Member States from a public health perspective regarding medical products in transit

Information note by the Secretariat on activity G

BACKGROUND

1. At its eighth meeting in 2019, the Member State mechanism on substandard and falsified medical products agreed a list of prioritized activities to implement its workplan for the period 2020–2021.[1] Prioritized activity G, currently led by the Secretariat, aims to promote shared understanding among Member States from a public health perspective regarding medical products in transit. This document provides an update on the progress made in this regard.

2. At its ninth meeting in 2020, the Member State mechanism agreed that the Secretariat would develop an information note on the current situation regarding medical products in transit within the public health domain, and that the questionnaire previously disseminated to Member States would be recirculated to the Global Focal Point Network and the responses used to draft this information note. Member States also discussed the need to better define the application of the information resulting from the analysis of the questionnaire responses.

3. The Member State mechanism agreed that a working group should be established to support activity G. Working group members were identified and consulted on the scope of this activity by the Secretariat.

4. When the Member State mechanism discussed activity G in 2018, it noted that medicines transiting through third countries were intercepted for several reasons. In cases where interception is required, it must be legal, justified and proportionate since delays could have a negative impact on public health. Until the questionnaire responses had been analysed, the extent to which national and regional regulatory authorities focused on medicines in transit issues was unknown.

QUESTIONNAIRE

5. The questionnaire circulated in 2019 and again in 2020 sought to ascertain from a public health perspective the current experience and views of Member States regarding medicines being imported, exported and imported for export and transiting through their territories, with the responses being used

[1] Document A/MSM/8/4.

to develop shared understanding among Member States of the issues surrounding medicines in transit. For analysis purposes, the 2019 and 2020 survey responses were collated and reported on in July 2021.

6. As not all Member States responded to the questionnaire, the survey outcomes may apply in a more general way for those States. The survey analysis provides Member States with indicators to assist them in taking a strategic approach to oversight arrangements so as to prevent the unauthorized entry into their territories of medicines in transit.

Survey outcomes

7. The survey analysis revealed that national and regional regulatory authority oversight on medicines is primarily focused on imports entering the internal market, followed by medicines intended for export. Medicines in transit are given low priority in comparison and are not subject to any intervention.

8. There is a reportedly high level of training provided to customs and border authorities on medicines issues. There is an equivalent attendance by or presence of national and regional regulatory authorities at customs and border authority facilities located at crossing points and ports, and a very high level of cooperation reported between the parties.

9. The reasons given for carrying out stops and checks or detention of medicines in transit revealed that the combined substandard and falsified medicines categories were greater than those for other products. This illustrates a level of awareness by customs and border authorities of the importance of public health, particularly in terms of halting the transit of substandard and falsified medicines.

10. The level of interaction reported between customs and border authorities and national and regional regulatory authorities may account for these findings. The degree of cooperation and liaison between the authorities may be providing Member States with some degree of confidence that the current levels of border surveillance on medicines from a public health perspective at crossings points and ports are effective or not warranting of diverting resources.

11. A slim majority of Member States recommended that a single point of contact should be established within the national and regional regulatory authorities to address issues relating to medicines in transit. Such an approach was not supported by earlier survey responses on the level of regulatory oversight given to medicines transiting through the territory.

12. One explanation for this shift in approach could be related to concerns, albeit not expressed, that the extent of national regulatory oversight activities on medicines in transit may be connected to the reported delays that result in shortages or stock-outs at health facilities in some destination countries. The proposal, if implemented, could facilitate greater national and regional regulatory authority coordination and avoid such delays.

FUTURE APPROACHES

13. As illustrated by the survey results, a significant number of Member States have found that close cooperation and strong working relationships with customs and border authorities have been of considerable benefit when tackling medicines in transit. Where not already the case, national and regional regulatory authorities may consider adopting this or a similar approach, with a view to formalizing their working arrangements as trust builds between the parties.

National and regional regulatory authority oversight: customs suspensive regimes and free-trade zones

14. Customs suspensive regimes involve goods being imported and placed in suspense from a customs perspective, pending their onward movement into the internal market once cleared by customs or their transit out of the country. This type of customs regime is primarily connected to national internal revenue arrangements. Customs also have a law enforcement mandate to ensure that no criminal activity is engaged in regarding the goods under this regime. Such goods are normally kept in facilities known as bonded warehouses or other similar facilities.

15. National and regional regulatory authorities should be vigilant that their approach to medicines in transit does not imply that they wish to take ownership of the goods in transit system since that matter falls under the remit of the customs authorities.

16. National and regional regulatory authorities may be required to monitor compliance with best practice for medical products in bonded warehouses. Following research and informal discussions with the World Customs Organization, it has been found that customs authorities on the whole recognize the need for national and regional regulatory authorities to conduct inspections on such medical products. This work is best conducted by close cooperation between the respective national and regional regulatory authorities and the customs authorities to avoid any conflicts in supervisory authority over goods subject to customs suspensive regimes. Where medical products need to be detained for good reason, the customs authorities will take charge of the process and work with the national and regional regulatory authorities on further action. Goods in the suspensive regime should not alter from the time they enter it to the time they leave it. This is in line with the public health approach of not interfering with the product integrity of medicines in transit from manufacturers and distributors to their intended destination.

17. Free-trade zones and similar facilities exist to promote trade and exports among Member States and attract certain economic benefits for operators working in those areas. Customs authorities have little, if any, role to play.

18. Free-trade zones are normally exempt from or have a reduced regulatory burden from a trade perspective. That does not mean however that regulatory oversight powers cannot be granted to national and regional regulatory authorities to ensure compliance with good manufacturing practices and good distribution practice in such zones. Where such powers are given, it ensures that no manufacturing or distribution activities related to medical products are conducted that may result in substandard and falsified medical products being distributed into the internal market or forwarded to other countries.

19. Following the responses received from the questionnaire, additional research, and informal discussions with the United Nations Office on Drugs and Crime concerning the transnational trafficking of medical products, activities such as repackaging and relabelling of medicines are understood to take place in free-trade zones. Medicines are also reported to transit through such zones.

20. National and regional regulatory authorities may wish to seek greater access to free-trade zones and bonded warehouses for regulatory oversight purposes in cases where they have grounds to believe that regulated activities are occurring. This is to ensure compliance with good manufacturing practices and good distribution practice, including for medicines in temporary storage pending onward movement, so as to prevent any unauthorized entry into the internal market and avoid any unlicensed/unauthorized interference with medicines imported for export and those in transit.

21. The level of regulation and compliance required for medical products in such facilities is an internal State decision.

Delays involving medicines in transit

22. To tackle reported delays of medical products in transit reaching their intended markets in other States, national and regional regulatory authorities may choose to support customs processing in the respective countries of transit by providing access to their own licence/authorization holder listings, either via hyperlink to the relevant national and regional regulatory authority licensing database or via periodic listing updates to customs authorities. Such an approach may assist customs authorities in identifying trusted and regulated traders and logistics companies for document processing and tracking efficiency.[1]

23. The levels of delay involving medicines in transit reported in the survey were low. Delays of such limited magnitude may not warrant further examination in advance of implementing other measures and subsequently determining their impact. In cases where a decision is taken to identify the cause of delays attributed to medicines in transit, action should first be taken to determine the correlations in the following situations.

(a) Between Member States:

- with a greater degree of oversight over medicines in transit; and
- those where delays occur causing shortages or stock-outs at health facilities in the countries of destination.

(b) Between Member States:

- with some level of national and regional regulatory authority presence in customs facilities including some cross-training between both parties and with a higher detection level of substandard and falsified medical products; and
- those with lower levels of delay involving medicines in transit.

CONCLUSIONS

24. Technical advice, support and cooperation by the national and regional regulatory authorities with the customs and border authorities appears to work for those Member States engaging in such activities. Other Member States may benefit in recognizing and replicating those activities. Cooperation and coordination between Member States in this manner may assist in a holistic approach to identifying and reducing potential obstacles to regulatory oversight of medical products in transit.

25. Delays involving medicines in transit do occur. However, such issues do not appear to be a high priority for Member States. Instead, they focus more on imports intended for the internal market. Port and crossing point surveillance is conducted by customs and border authorities with the active technical assistance of the national and regional regulatory authorities.

[1] The Single Window system operated by many customs authorities allows parties involved in trade and transport to lodge standardized information and documents with a single entry point to fulfil all import, export, and transit-related regulatory requirements. See https://tfig.unece.org/contents/single-window-for-trade.htm (accessed 27 September 2021).

26. In respect of substandard and falsified medical products, the remit of WHO, the Member State mechanism and national and regional regulatory authorities is to protect public health. While other intergovernmental organizations may have different responsibilities relating to substandard and falsified medical products, all share the same objective of preventing the risk of harm to consumers from such medical products. That is no less true in relation to transit issues that fall within the competence of the World Customs Organization and national customs and border control authorities. Transit issues can have an adverse impact on public health, whether in the country of destination when the timely arrival of medical products is delayed, or in countries of transit when medicines in transit infiltrate the internal market.

27. The responses to the 2019 and 2020 questionnaires illustrate the importance placed by Member States on the cooperative relationship between the national and regional regulatory authorities and the customs and border authorities. Any shortcomings in this regard may be corrected to strengthen international cooperation to ensure that medicines in transit reach their country of destination and that substandard and falsified medicines are subject to the appropriate oversight wherever they are detected.

NEXT STEPS

28. National and regional regulatory authorities are invited to continue, or if not already doing so, to commence support for and cooperation with customs and border authorities in order to facilitate:

(a) efficient movement of legitimate imports, imports for exports, and medical products in transit;

(b) prevention of the unauthorized entry into the internal market of medical products in transit, those in bonded warehouses and other similar facilities subject to customs suspensive regimes; and

(c) prevention and detection of and effective response to substandard and falsified medical products entering the territory of Member States, either via the internal market or passing through in transit.

29. Resolving issues focused on access and regulatory oversight of medical products in free-trade zones can be achieved by internal national arrangements, preferably including enabling regulations and accompanied by formalized agreements.

30. In the event that the application of the measures identified in this document does not lead to a reduction in delays involving medicines in transit, Member States may wish to consider conducting further inquiries in accordance with the steps identified in paragraph 23 above.

31. Prioritized activity G set out to achieve the objective of promoting shared understanding among Member States from a public health perspective regarding medical products in transit. Following the progress made in this area, Member States are invited to consider that this objective has been achieved.

32. The full information note containing the Member State survey on medical products in transit is available on the MedNet platform.[1]

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[1] https://mednet-communities.net/sf/library (accessed 24 September 2021). Please note: 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.