

## **Discussion paper – medicines in transit**

### **INTRODUCTION**

1. This discussion paper relates to prioritized activity G of the Member State mechanism workplan for 2018–2019: “Promote shared understanding among Member States from a public health perspective regarding medical products in transit”.<sup>1</sup> This activity is currently led by the Secretariat and this document provides an update on progress.

### **BACKGROUND**

2. Some Member States have pointed out that the interception of medicines by customs authorities in a third Member State through which the medical products are transiting, on the basis of the infringement of intellectual property legislation alone, may unnecessarily obstruct access to medicines and negatively impact public health.

3. The Sixty-fifth World Health Assembly, in resolution WHA65.19 (2012), established the Member State mechanism on substandard/spurious/false-labelled/falsified and counterfeit medical products for international collaboration among Member States, from a public health perspective, excluding trade and intellectual property considerations.<sup>2</sup>

4. This discussion paper considers the issue of medicines in transit from a public health perspective. However, this issue is closely linked to the area of intellectual property rights and to the mandate of national customs authorities. For the purpose of a common understanding, the definitions of substandard, falsified and unregistered/unlicensed medical products recently agreed by the mechanism are included as Annex 1, together with a set of definitions relating to commonly used intellectual property terms.

5. It is recognized that WHO is not the competent authority in relation to the enforcement of intellectual property rights. It is also recognized that well established international and domestic legislation, treaties and conventions exist that specifically deal with this broad and complex topic. Intellectual property legislation is in place for valid reasons and a careful balance needs to be struck between the protection of intellectual property rights and the protection of public health. This document is not intended to affect intellectual property legislation, and it is not derived from a detailed examination of such legislation.

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<sup>1</sup> [http://apps.who.int/gb/sf/pdf\\_files/MSM6/A\\_MSM6\\_4-en.pdf](http://apps.who.int/gb/sf/pdf_files/MSM6/A_MSM6_4-en.pdf), Annex 2 (accessed 6 November 2018).

<sup>2</sup> [http://www.who.int/medicines/services/counterfeit/mechanism/WHA65.19\\_extract.pdf?ua=1](http://www.who.int/medicines/services/counterfeit/mechanism/WHA65.19_extract.pdf?ua=1) (accessed 6 November 2018).

6. Substandard, falsified and unregistered/unlicensed medical products as defined by WHO have the potential to endanger the health of patients. It is recognized that part of the function of national customs authorities is to protect the health and safety of their populations. In some circumstances the interception of medical products in transit may therefore be justified on a public health basis.

7. Customs authorities use risk indicators on a range of commodities. These indicators are not publicly available but are contained in the WCO Customs Risk Management Compendium (Volume 2), which is available to all members of the World Customs Organization (WCO). It is these indicators that influence the likelihood of intervention by customs authorities.

## **SECRETARIAT ACTIVITIES**

8. The Secretariat has carried out a review of existing literature and held discussions with WCO representatives and with a legal expert involved in World Trade Organization tribunals on this issue.

9. The topic of medicines in transit was discussed at meetings of the Steering Committee of the Member State mechanism in March and September 2017. Following guidance from the Steering Committee, the Secretariat developed and circulated a pilot questionnaire to national medicines regulatory authorities at a recent regional workshop in Africa.

10. The questionnaire included five basic questions relating specifically to transit and was part of a larger set of questions concerning substandard, falsified and unregistered/unlicensed medical products in the region. It was circulated to the 38 Member States in attendance, 26 of whom responded to the transit questions.

11. The questions together with a brief summary of the responses are attached as Annex 2.

## **NEXT STEPS**

12. From the pilot questionnaire, the issue of medicines in transit was generally regarded by national medicines regulatory authorities as an issue primarily for customs authorities, and knowledge of the issue was very limited. Almost a third of Member States did not respond to the questions on transit. Where more than one response was received from a Member State, the responses were sometimes contradictory. Consideration could be given to developing the questionnaire or extending it to other regions, however there is a high likelihood of a similarly limited response.

13. Following research and discussions with WCO, the Secretariat has identified two topics that may merit further study: different transit arrangements used by customs authorities for landlocked countries; and the regulatory oversight of activities within free-trade zones in relation to medicines.

14. The Secretariat proposes that the Member State mechanism focus its discussions on these two topics, make recommendations on how to take forward this prioritized activity and identify a Member State to lead the activity.

## ANNEX 1

**DEFINITIONS****Substandard Medical Product<sup>1</sup>**

*Also called “out of specification”, these are authorized medical products that fail to meet either their quality standards or their specifications, or both.*

**Unregistered/Unlicensed Medical Product<sup>1</sup>**

*Medical products that have not undergone evaluation and/or approval by the national/regional regulatory authority (NRRRA) for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.*

These medical products may or may not have obtained the relevant authorization from the national/regional regulatory authority of its geographical origin.

**Falsified Medical Products<sup>1</sup>**

*Medical products that deliberately/fraudulently misrepresent their identity, composition or source.*

Any consideration related to intellectual property rights does not fall within this definition.

Such deliberate/fraudulent misrepresentation refers to any substitution, adulteration, reproduction of an authorized medical product or the manufacture of a medical product that is not an authorized product.

“Identity” shall refer to the name, labelling or packaging or to documents that support the authenticity of an authorized medical product.

“Composition” shall refer to any ingredient or component of the medical product in accordance with applicable specifications authorized/recognized by NRRRA.

“Source” shall refer to the identification, including name and address, of the marketing authorization holder, manufacturer, importer, exporter, distributor or retailer, as applicable. Medical products should not be considered as falsified solely on the grounds that they are unauthorized for marketing in any given country.

**Trademark<sup>2</sup>**

A trademark is a sign capable of distinguishing the goods or services of one enterprise from those of other enterprises. Trademarks are protected by intellectual property rights.

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<sup>1</sup> [http://apps.who.int/gb/sf/pdf\\_files/MSM5/A\\_MS5\\_7-en.pdf](http://apps.who.int/gb/sf/pdf_files/MSM5/A_MS5_7-en.pdf) (accessed 6 November 2018).

<sup>2</sup> <http://www.wipo.int/trademarks/en/> (accessed 6 November 2018).

**Trademark Counterfeit Goods<sup>1</sup>**

Goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation.

**Patent<sup>2</sup>**

A patent is an exclusive right granted for an invention. In other words, a patent is an exclusive right to a product or a process that generally provides a new way of doing something, or offers a new technical solution to a problem. To get a patent, technical information about the invention must be disclosed to the public in a patent application.

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<sup>1</sup> Article 51 Trade Related Aspects of Intellectual Property Rights.

<sup>2</sup> [http://www.wipo.int/patents/en/faq\\_patents.html](http://www.wipo.int/patents/en/faq_patents.html) (accessed 6 November 2018).

## ANNEX 2

## QUESTIONNAIRE ON TRANSIT AND ANALYSIS OF RESPONSES FROM NATIONAL MEDICINES REGULATORY AUTHORITIES

### Questions

1. Do medicines transit through your country to another country?
2. What is the main port of entry?
3. Is the national medicines regulatory authority (NMRA) or Customs allowed to stop and inspect medicines in transit?
4. Is the regulatory authority informed of medicines transiting from your port of entry to another country?
5. Has the inspection of medicines in transit ever led to unnecessary delays in medicines being released to other countries?

### Responses

Thirty-eight (38) Member States of the African Region attended a regional workshop on substandard, falsified and unregistered/unlicensed medical products in April 2018. A questionnaire was circulated in relation to substandard, falsified and unregistered/unlicensed medical products, of which five questions related specifically to transit issues.

Twenty-six (26) Member States responded to all or some of the transit questions, the results of which are shown in the table below. Where more than one response was received from a Member State the nominated focal point response from the officially nominated focal point was accepted.

**Table. Responses to transit questionnaire<sup>1</sup>**

Question	Number of Member States who responded “yes”	Number of Member States who responded “no”	Number of Member States who responded “unknown”
Do medicines transit through your country to another country?	15	4	7
Can the NMRA or customs stop and inspect medicines in transit?	17	5	4
Is the NMRA informed of medicines transiting from your port of entry to another country?	9	11	5
Has the inspection of medicines in transit ever led to unnecessary delays in medicines being released to other countries?	4	6	15

<sup>1</sup> Responses to one question were country-specific and are not included in the table.