



## **Substandard/spurious/falsely-labelled/ falsified/counterfeit medical products**

### **Report by the Director-General**

The Director-General has the honour to transmit to the Executive Board at its 138th session the report of the fourth meeting of the Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products (see Annex), which met in Geneva on 19 and 20 November 2015.<sup>1</sup>

---

<sup>1</sup> The goal, objectives, and terms of reference for this meeting were approved by the Sixty-fifth World Health Assembly in resolution WHA65.19 (2012), and are provided in the Annex to the resolution.

## ANNEX

### **REPORT OF THE FOURTH MEETING OF THE MEMBER STATE MECHANISM ON SUBSTANDARD/SPURIOUS/FALSELY-LABELLED/FALSIFIED/ COUNTERFEIT MEDICAL PRODUCTS**

1. The fourth meeting of the Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products was held in Geneva on 19 and 20 November 2015 and was chaired by Dr Rassoul Dinarvand of the Islamic Republic of Iran with the following Vice-Chairpersons: Mr Aina Ayodele on behalf of Dr Paul Botwev Orhii of Nigeria; Dr Ndeye Dome Fall on behalf of Dr Amadou Mactar Dieye of Senegal; Ms Lou Valdez of the United States of America; Mr Maximiliano Derecho on behalf of Ambassador Alberto D'Alotto of Argentina; Dr Mariam Saeed on behalf of Dr Fareha Bugti of Pakistan; Mr Alastair Jeffrey of the United Kingdom of Great Britain and Northern Ireland; Ambassador Carole Lanteri of Monaco; Mr Rolliansyah Soemirat of Indonesia; Dr V.G. Somani of India; and Ms Ruth Lee of Singapore.<sup>1</sup> The session was attended by 50 Member States and one regional economic integration organization.
2. The Secretariat provided an update on activities and the budget to implement the workplan, and on the WHO global surveillance and monitoring project. In view of the significant budget shortfall, Member States encouraged the Secretariat to do more to advocate for funding to support the activities of the Member State mechanism within the context of the Programme budget 2016–2017, and suggested that all Member States to consider providing support.
3. The Secretariat provided clarifications on the WHO global surveillance and monitoring project and agreed to post the terms of reference on the MedNet collaborative platform, before the next meeting of the Steering Committee. The mechanism was informed that the Secretariat will be developing a manual to be used in training activities, detailing the workings of the system and its interaction with other regional reporting mechanisms.
4. An opportunity was provided for Member States to present updates on national and regional activities.
5. Updates on implementation of the workplan and agreed list of prioritized activities for 2014–2015 were provided by Member States leading the implementation of activities and the Secretariat, as follows.

#### **Activity A**

6. An informal working group on Activity A was convened by Brazil on 17 November 2015. The meeting provided comments on the discussion document entitled “Framework/Guideline on developing a national plan for preventing, detecting and responding to SSFFC medical products.”
7. With respect to other elements of the mandate of Activity A, Member States were invited to submit training materials concerning the prevention, detection and response to SSFFC medical

---

<sup>1</sup> The Vice-Chairperson of China, Dr Gao Wen, was unable to attend.

products to the Secretariat through the MedNet platform. The Member State mechanism agreed that the mandate for Activity A would be extended by one year in order to complete the work.

### **Activity B**

8. The United Kingdom of Great Britain and Northern Ireland presented the draft terms of reference for the Global Focal Point Network for substandard/spurious/falsely-labelled/falsified/counterfeit medical products, as contained in document A/MSM/4/2. Amendments were provided to the document and it was approved by the Member State mechanism (see Appendix 1 for the text as amended). The Member State mechanism agreed that under the mandate for Activity B, the Secretariat would continue to work with Member States to formalize and expand the network into 2016.

### **Activity C**

9. An informal working group on Activity C was convened by Argentina on 16 November 2015. The meeting finalized document A/MSM/4/3 entitled “Existing technologies and ‘track and trace’ models in use and to be developed by Member States,” which was accepted by the fourth Meeting of the Member State mechanism and is attached, as amended, at Appendix 2. It was agreed that the table contained in the Annex to document A/MSM/4/3, providing details on experiences in countries, would be updated periodically and made available on the MedNet platform.

10. With reference to other elements of the mandate of Activity C, Member States were encouraged to share their experiences in using authentication and detection technologies and methodologies. It was agreed that the mandate for Activity C would be extended by one year in order to complete the work.

### **Activity D**

11. The Secretariat presented a review of WHO’s work on the issue of access to quality, safe, efficacious and affordable medical products, as contained in document A/MSM/4/5. It was agreed that the Secretariat would submit to the Steering Committee at its meeting in March 2016 a concept note and proposed budget for further work on element 8C.

### **Activity E**

12. The United Kingdom of Great Britain and Northern Ireland presented a proposal for implementing activity E to create a working group comprising technical communication experts from Member States and national and regional regulatory authorities in order to develop and leverage existing recommendations for effective risk communication and recommendations for awareness campaigns on SSFFC medical products and related actions, activities and behaviours, as contained in document A/MSM/4/5. It was agreed that information on the group’s remit, scope and objectives, as well as on the draft comprehensive project plan would be posted on the MedNet platform in advance of the Steering Committee meeting in March 2016 for consideration by the Steering Committee.

### **Activity F**

13. The Secretariat provided an update on the proposal for a study on the public health and socioeconomic impact of on SSFFC medical products, as outlined in document A/MSM/4/6. It was agreed that comments provided during the discussion would be taken into consideration in further developing the report, and that the following timelines would be adhered to.

- (1) The first draft of the report will be submitted to the Steering Committee by the end of February and Steering Committee members will have a period of three weeks to provide comments.
- (2) A second draft of the report will be submitted to the Steering Committee at its meeting in March 2016. The second draft will also be circulated to all Member States, who will have a period of two months to provide comments on the report.
- (3) The final draft will be submitted to the fifth meeting of the Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products.

## Activity G

14. The Secretariat presented an estimation of annual costs of the prioritized activities for year 2016. In response to concerns expressed by Member States about the lack of funds, the Secretariat indicated that efforts would be made to take forward the implementation of activities within existing resources and to secure additional resources. The Secretariat agreed to update the Steering Committee in March 2016. The Secretariat agreed to explore ways of reflecting in-kind contributions.

15. The Member State mechanism agreed that the list of prioritized activities for 2016–2017 would include the activities contained on the list of prioritized activities for 2014–2015 that had not been completed, as well as the following activities.

- i. The Secretariat would submit to the Steering Committee at its meeting in March 2016 a concept note and proposed budget for a study to increase the understanding and knowledge of the links between accessibility and affordability and their impact on the emergence of SSFFC medical products and recommendations to minimize their impact, as a follow-up to implementation of Activity D.
- ii. A Member State mechanism working group of experts from national and regional regulatory agencies would work on refining the working definitions. The modalities of the working group and budget implications, along with an update on the existing working definitions, would be submitted to the Steering Committee by the Secretariat at its meeting in March 2016.

16. The mechanism reviewed the outcome of the informal technical discussion on element 5(b) of the workplan on the identification of activities and behaviours that fall outside the mandate of mechanism, which was convened by India on 17 November 2015. It was agreed that while consensus had not been reached on the document, whose text was reproduced for the deliberations of the Member State mechanism,<sup>1</sup> discussions had been useful and would resume at a future point in time. The document is attached at Appendix 3. It was proposed that the issue of transit be considered by the Steering Committee for the agenda of the fifth meeting of the Member State mechanism on substandard/spurious/ falsely-labelled/falsified/counterfeit (SSFFC) medical products.

---

<sup>1</sup> Document A/MSM/4/7.

17. The Member State mechanism discussed the analysis provided by the Secretariat in document A/MSM/4/8 on WHO's participation in the global steering committee for quality assurance for health products. The Member State mechanism decided that the Secretariat could continue to observe on a provisional basis meetings of the global steering committee for quality assurance for health products. The Member State mechanism requested the Secretariat to share relevant information on issues discussed in those meetings. Furthermore the Member State mechanism requested the Secretariat to provide a report to the fifth meeting of the mechanism on the global steering committee, including inter alia documents and information on its nature, legal status, governance and participants, in response to questions and comments presented during the Steering Committee meeting and Member State mechanism.

18. The Secretariat provided an update on WHO's work on regulatory system strengthening for medical products and Member States emphasized the importance of ensuring that technical outputs of the Member State mechanism are incorporated, as appropriate, in other WHO work streams aiming to facilitate regulatory system strengthening.

19. The Secretariat outlined its proposed process for the review of the Member State mechanism in 2017, as contained in document A/MSM/4/9. There was agreement that the review process should be led by the Secretariat's Office for Evaluation and Learning, and that further details on the review, including on the questionnaire, would be provided to the Steering Committee at its meeting in March 2016.

20. The Member State mechanism decided that the term of office of the current Chair be extended to the end of the fifth meeting of the Member State mechanism in 2016.

21. The terms of the current vice-chairpersons and Chair will expire at the closure of the fifth meeting of the Member State mechanism. In addition, the Member State mechanism decided to amend Appendix 1 of document A66/22 on the structure, governance and funding of the Member State mechanism to reflect decision WHA66(10) (2013) that foresees that the chairmanship of the Member State mechanism rotates among the regions in alphabetical order. The new composition of the Steering Committee will start at the end of the fifth meeting of the Member State mechanism. It was also confirmed that subsequent terms of office of the Chair and Vice-Chairpersons will expire at the end of every second regular session of the Member State mechanism.

22. The Member State mechanism decided that its fifth meeting would be held in October or November 2016. Furthermore, the Member State mechanism considered but did not reach consensus on a proposal to include on the agenda of the fifth meeting of the Member State mechanism a panel discussion of national regulatory authorities. It was decided that the proposal may be discussed at a future meeting of the Steering Committee.

## Appendix 1

# **Create a focal point network for the exchange of information and consultation at large among Member States and establish an ongoing virtual exchange forum**

## **Terms of reference for the Global Focal Point Network for substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products**

### **Report by the Secretariat<sup>1</sup>**

1. The establishment of a global network of focal points for the exchange of information and consultation at large among Member States, and establish an ongoing virtual exchange forum was agreed and prioritized by the Member State mechanism at its third meeting held in October 2014.<sup>2</sup>
2. Recognizing the global nature of the manufacture, distribution and sale of medical products, the Member State mechanism has identified the need for a global network of focal points within WHO Member States to improve the flow and exchange of information from a public health perspective in a safe, secure and efficient environment. The creation of such a network has the potential to improve reporting and alerting of SSFFC medical products, learn from the experience of other Member States and provide access to a reliable source of information in a timely and efficient way.
3. This draft document is intended to provide a basis for discussion in setting the terms of reference for a focal point network relating to SSFFC medical products. It recognizes that networks exist in many regions and subregions and does not attempt to replace any of those networks but rather endeavours to ensure global coordination, consistency and possible integration in approach. The WHO global surveillance and monitoring system for SSFFC medical products has established focal points within national regulatory authorities within over 90 Member States, and these terms of reference would apply to those focal points. This document sets out to formalize the terms of reference for the existing focal points within the WHO global surveillance and monitoring system for SSFFC medical products.
4. Whilst the Member State mechanism has chosen to use the term “focal points” this is interchangeable with the term “single point of contact” currently used in some regions. It is important

---

<sup>1</sup> The terms of reference below are based on the original draft prepared by Switzerland, United Kingdom of Great Britain and Northern Ireland and the Secretariat. They take account of comments received from Member States.

<sup>2</sup> See document A/MSM/3/3 Annex 3.

that the focal point is situated in existing national and regional medicines regulatory authorities in order to avoid duplication and build synergies. Whilst the National focal point can be a specific group or department within the national medicines regulatory authority, Member States are encouraged to nominate specific personnel within that group or department as focal points, and that those nominated are appropriate for the role, have access to the relevant information and have the support of their senior management to share information in a timely way with the network.

5. The intention of creating this network is to ensure that enquiries and information concerning SSFFC medical products are channelled through to the most appropriate office within national medicines regulatory authorities, and that office is responsible for receiving, communicating and responding to SSFFC-related matters.

6. It is for Member States to identify and nominate the most appropriate office and person(s) within the national medicines regulatory authority to receive, communicate and respond to enquiries relating to SSFFC medical products based on their regulatory and administrative structures.

7. The terms of reference for a nominated national focal point for SSFFC medical products are as follows:

(a) The national focal point should be situated within the national medicine regulatory authority, and acts on behalf of that authority.

(b) To serve as the national focal point representative, Member States are encouraged to nominate a specific member of staff, and where possible a deputy within the national medicines regulatory authority, and their contact details including office address, telephone number and email address provided to the WHO Member State mechanism secretariat. Generic email addresses are acceptable, but the names of the nominated focal points should be notified to the WHO Secretariat. It is the responsibility of national medicine regulatory authorities to inform the WHO Secretariat of any changes in personnel or contact details. The designated focal point is to act only on behalf of its national medicines regulatory authority and not in his/her personal capacity.

(c) With the provision of the contact details to the WHO Secretariat the nominee agrees to the disclosing of his/her contact details to the other National focal points within the network. The WHO Secretariat will regularly circulate and update the list with contact details to all nominated focal points. The list will be treated as strictly confidential by all nominees.

(d) National medicines regulatory authorities are encouraged to nominate those officials who have the necessary training, expertise or experience for the role as focal point.

(e) The nominated focal point should be empowered to closely cooperate with the quality control laboratories, national pharmacovigilance centres, national poisons centres and other relevant government entities to ensure that suspected SSFFC medical products are identified and responded to quickly and proportionately.

(f) The nominated national focal point should be trained on the use of the WHO global surveillance and monitoring system for the reporting of SSFFC medical products, and in compliance with their own Member State laws and regulations concerning disclosure of information pertinent to the WHO surveillance and monitoring system.

(g) The nominated focal point under the direction of the national medicine regulatory authority should be empowered to receive and respond appropriately to all national, regional and global medical product alerts.

(h) Where national systems exist for patient reporting of suspected SSFFC medical products, close cooperation between the national focal point and such systems should be established to ensure that suspected SSFFC medical products are responded to quickly and proportionately.

(i) Nominated focal points should be trained in the use of an electronic platform to be created and administered by WHO Secretariat to enable secure communication with their counterparts from other Member States. All communications under the focal point network should be routed through this online platform.

8. The WHO Secretariat will retain and maintain the list of nominated focal points and administer the secure online platform.

9. The national medicines regulatory authority is encouraged to engage with all relevant stakeholders in preventing, detecting and responding to SSFFC medical products for example, health care providers, law enforcement and the private sector.

10. The Secretariat should ensure transparency in its activities with the focal point network and such activities should be reported to the Member State mechanism through the Steering Committee. WHO Secretariat shall ensure that training and other activities with the focal point network shall be free from conflict of interest.



## Appendix 2

**EXISTING TECHNOLOGIES AND “TRACK AND TRACE”  
MODELS IN USE AND TO BE DEVELOPED  
BY MEMBER STATES**

**Draft document submitted by Argentina**

**TABLE OF CONTENTS**

I. INTRODUCTION.....	10
II. SCOPE OF “TRACK AND TRACE” SYSTEMS.....	10
III. BENEFITS OF TRACK AND TRACE SYSTEMS AT THE LEVEL OF THE UNIT OF SALE (SECONDARY PACKAGING).....	12
IV. CRITICAL POINTS.....	13
1. Standards.....	13
2. Type of system.....	15
3. Product identification.....	16
4. Database.....	20
5. Products involved .....	22
6. Challenges to take into account .....	23
V. EXPERIENCES IN COUNTRIES.....	24
VI. LESSONS LEARNT .....	24

## I. INTRODUCTION

1. Over the last years, the implementation of medical products<sup>1</sup> traceability systems and mechanisms has been identified by National and/or Regional Regulatory Authorities (hereinafter NRRA), as a useful and efficient tool to fight against the falsification and illicit distribution of medical products.

2. At global level, some Member States have issued traceability regulations that are currently implemented or on the way to being implemented; whereas, others are assessing various implementation alternatives or otherwise have not approached the topic.

3. This type of initiative is considered relevant and a priority for countries. At the III Plenary Meeting of the Member States Mechanism on Substandard, Spurious, Falsified, Falsely labelled, Counterfeit (hereinafter SSFFC<sup>2</sup>) Medical Products, it was decided to establish a Working Group comprised of Member States experts to assess and report on “track and trace” technologies, methodologies and models currently in use or under development, and analyse their advantages and disadvantages.

4. It is worth mentioning that the national experiences described throughout the text are only illustrative, non-exhaustive and based on the information provided by countries, their official websites and/or bibliographic references, the sources of which were not verified, and, therefore, are subject to change and/or rectification, as appropriate, with no other purpose than that of serving as a reference to Member States NRRA. This document aims to be a “live document” which is updated on a periodic basis and in agreement with advances and new implementations by Member States.

## II. SCOPE OF “TRACK AND TRACE” SYSTEMS

5. The term “traceability” is usually defined as the ability to identify the origin and the various stages of consumption goods production and distribution processes. The term “track and trace” is also used when describing traceability, which also includes the ability to track where a product is at any given time within the distribution system. Within this framework, for some years, medical product manufacturers have been implementing “traceability” within the manufacturing production process, whereby each stage, from raw material procurement to finished products, can be known.

6. This traceability typically is carried out on a batch/lot basis. In terms of medical products distribution, it is supplemented with the identification of the manufacturing batch or serial number on the primary/immediate and secondary/outer packaging which, in some cases, is recorded on the commercial documentation that accompanies the product. However, batch/lot level traceability does not provide unequivocal identification of individual units of said batches in the distribution system.

---

<sup>1</sup> For the purpose of this document, the term “medical products” will be used in accordance with paragraph 3 of document A/SSFFC/WG/5, which refers to “medicines, vaccines and in-vitro diagnostics” and footnote 1, “This may also include medical devices at an appropriate time in the future”.

<sup>2</sup> For the purpose of this document, SSFFC will be used in accordance with reference to the footnote in Resolution WHA65.19: “The Member State mechanism shall use the term ‘substandard/spurious/falsely-labelled/falsified/counterfeit medical products’ until a definition has been endorsed by the governing bodies of WHO”, and the current document will not prejudice any further negotiation in relation to the definition within the MSM on SSFFC medical products.

7. In this line, a traceability system may have different scopes. Thus, traceability can be based on a product batch, on clustered units (tertiary packaging), on units of sale (secondary/outer packaging), primary/immediate packaging and/or on doses.

8. The scope of a traceability system typically depends on the legislation that authorizes such a system. In addition, different scopes of the requirements under the system may vary depending on the reason such a system was implemented (for example, combating SSFFC or preventing reimbursement fraud, or a combination of both).

9. The advantage of a batch-based traceability system relies on the possibility of tracing a complete manufactured batch in case of a market recall or, simply, in the face of an alert about an allegedly SSFFC medical product. On the other hand, its disadvantage is that the units within each batch are not differentiated or individualized and, therefore, individual units cannot be traced because tracing can only be performed on a batch-to-batch basis.

10. As regards the track and trace systems based on units clustered in tertiary packaging, the main objective is to reduce logistics costs and time, both in terms of receipt and dispatch of goods to wholesalers. The finished product pack and/or pallet is serialized and logistic processes are performed by reading the data carriers (e.g. bar code, radio-frequency identification (RFID) tag, etc) on the clusters, which relate to the information of the individual products contained therein, and therefore, opening the tertiary packaging is unnecessary. This type is more specific than batch-based traceability but unequivocal identification of each of the units within a tertiary packaging would not be available.

11. Individual serialization of medical products on their secondary/outer packaging allows unequivocal identification of each unit as sold to the public. In turn, this allows for the possibility of rebuilding the distribution chain of each individual unit.

12. The identification on the primary packaging provides most advantages at hospital level, where unit doses are administered; nevertheless, its disadvantages are considerable and related mostly to increased implementation complexity and higher costs in the serialization process (at industry level) as well as a need for more human resources and equipment in healthcare centres for capturing said serialization.

13. Regardless of the other alternatives, this document will focus on the track and trace systems applied on secondary/outer packaging currently available and those in the implementation phase.

Scope	Advantages	Disadvantages
<b>Batch level</b>	<ul style="list-style-type: none"> <li>– Possibility of tracking a complete manufactured batch.</li> </ul>	<ul style="list-style-type: none"> <li>– Batches usually involve a large number of units.</li> <li>– Units within each batch are not differentiated or individualized.</li> </ul>
<b>Tertiary level (Pallet and/or pack)</b>	<ul style="list-style-type: none"> <li>– Bulk reading of a cluster of units.</li> <li>– Information more specific than at batch level.</li> <li>– Reduces logistics costs and time at wholesaler level.</li> </ul>	<ul style="list-style-type: none"> <li>– Units within the tertiary packaging are not necessarily identified unequivocally on an individual basis.</li> </ul>
<b>Secondary or outer packaging (unit of sale)</b>	<ul style="list-style-type: none"> <li>– Unequivocal identification of each unit as sold to the public.</li> <li>– Enables the reconstruction of the distribution chain of each unit.</li> </ul>	<ul style="list-style-type: none"> <li>– Increased implementation complexity.</li> </ul>

Scope	Advantages	Disadvantages
<b>Primary or immediate packaging (unit of dispensation)</b>	<ul style="list-style-type: none"> <li>– Greater advantage at hospital level.</li> <li>– Possibility of identifying unequivocally doses administered to patients.</li> </ul>	<ul style="list-style-type: none"> <li>– Increased implementation costs and complexity in serialization process.</li> <li>– Need for availability of more human resources and equipment in healthcare centres.</li> <li>– No comparative advantages as to the rest of the supply chain.</li> </ul>

### III BENEFITS OF TRACK AND TRACE SYSTEMS AT THE LEVEL OF THE UNIT OF SALE (SECONDARY PACKAGING)

14. Track and trace systems, at any of their stages, present substantial advantages at healthcare level and can constitute a first step for NRRA towards a full serialization at the level of the primary/immediate packaging or doses of medical products.

15. Bearing in mind the degree of progress of available track and trace systems, today's globalized world proves right the convenience of having tools to move forward on a unit-of-sale based traceability system of medical products. Accordingly, this document will focus mainly on the advantages and disadvantages of this type of system, the challenges to be faced and the lessons learnt.

16. The adoption of a unit-of-sale-based traceability system for medical products brings about a series of advantages, namely:

- It helps to ensure that authorized medical products circulate only in the legal supply chain;
- It provides safety to patients who use medical products, by reducing the risks associated with SSFFC medical products, such as intoxications, adverse effects, increased number of hospitalization days, lack of response to treatment, need for alternative treatments, and even death;
- It prevents the entry and circulation of stolen and smuggled products into the legal supply chain;
- It prevents the distribution and/or dispensation of expired, prohibited or recalled products;
- It helps to ensure free medical products samples are delivered to their intended recipients;
- It favours efficient, fast and safe market recalls;
- It enables the collection of pharmacoepidemiological data and development of specific strategies based on such information;
- It favours an efficient supplies management at all health system levels;
- It contributes to reducing the expenditure on health stemming from inappropriate or unnecessary procedures such as the procurement of SSFFC medical products and the cost burden placed on the health system as a consequence of their administration.

17. All in all, the implementation of a unit-based traceability system contributes to strengthening NRRA's capacities and the efficient detection of SSFFC medical products and their removal from the market for further distribution or human consumption, thereby reducing public health expenditure and securing increased healthcare equity. Notwithstanding track and trace systems are one of many tools to prevent, detect and control SSFFC medical products, they may have some limitations and challenges (see Section IV).

#### **IV. CRITICAL POINTS**

18. The implementation of a National Traceability System for medical products entails the need to adopt a definition about certain critical points that are to be taken into consideration and which may be classified as follows:

1. Use of global or local identification and serialization standards
2. System model to be used
3. Identification of products
4. Database: holding and access to information
5. Products involved

19. When considering these points, in all cases it is advisable to look at the costs of implementing a Traceability System for both the NRRA and the agents involved in the supply chain. These costs vary from country to country and, therefore, a generalization cannot be made at a global level.

##### **1. Standards**

20. In a globalized world, multinational manufacturers tend to specialize their production of medical products, with a view to clustering the production of various types of products at a manufacturing plant and then distributing products with a single and uniform packaging which fulfils the regulations of every country they are marketed in.

21. This is the reason why products that reach the points of dispensation in countries with little domestic production and a relatively low market volume in comparative terms, are most likely to be imports that have been manufactured in a foreign plant, in accordance with the trend mentioned, packaged in uniform materials.

22. In order to build an interconnected world which is cost-effective in terms of health, the pharmaceutical industry could be more motivated to implement traceability measures by means of adopting a single set of global or international identification and serialization standards.

23. On the other hand, the existence and possibility of using domestic/regional identification and serialization standards are related to the regulations of each region or country.

24. Global identification and serialization standards already exist and their adoption should require only a ruling that governs them and the adaptation of relevant domestic procedures. Conversely, domestic standards may already exist or not, depending on the country in question, and in cases where

no standards have been set, they should be established and generated in accordance with the definition of the domestic identification model.

25. Lastly, a third alternative could be pointed out, which involves the adoption of international standards adapted to suit the reality and requirements inherent to each country; that is to say the adoption of “mixed standards”.

26. At international level, even though their models are still being defined, the USA and the European Union usually stand among those NRRA considering the adoption of international standards. For its part, China, which has already developed and implemented a model, stands as a current reference for the adoption of domestic standards.

27. Argentina and Brazil, both of which hold models regulated by rulings, can be mentioned as examples of mixed standard adoption. In Argentina, global GS1 standards (Global Trade Item Number (GTIN) and series number) are used to identify products. Physical locations are identified by means of global standards for the first steps of the chain (Global Location number (GLN) for manufacturers and distributors) and local standards (CUFE – acronym in Spanish which stands for “Establishment Physical Location Code”) are used to identify pharmacies and healthcare centres. In Brazil, regulations require product identification to be carried out in accordance with a domestic standard rather than a global standard. However, the supply chain sector has made the option for the use of both domestic and GS1 Standards in product identification.

Standards	Advantages	Disadvantages
<b>Global or international</b>	<ul style="list-style-type: none"> <li>– Homogeneity in multinational companies’ production.</li> <li>– Possibility of information interchangeability at world level.</li> <li>– Existence of standards already set.</li> <li>– Easier implementation in countries with large volumes of imported products.</li> <li>– Possible cost-cutting at domestic level.</li> </ul>	<ul style="list-style-type: none"> <li>– Need for useful information at national level to be adapted to standard parameters.</li> </ul>
<b>Domestic</b>	<ul style="list-style-type: none"> <li>– Established according to the needs and reality of each country.</li> </ul>	<ul style="list-style-type: none"> <li>– Need to define standards.</li> <li>– Arrangement of codes exclusive for the country.</li> <li>– Possible cost increase at domestic level.</li> <li>– Information interchangeability among countries subject to compatibility.</li> </ul>
<b>Mixed</b>	<ul style="list-style-type: none"> <li>– Leverage of international standards while adapted to the circumstances in and needs of the country.</li> </ul>	<ul style="list-style-type: none"> <li>– Will depend on the definitions adopted.</li> </ul>

## 2. Type of system

28. NRRA will be responsible for defining the type of system to be used based on their own needs and the existence of fully regulated legal supply chains for the distribution, storage and dispensation of medical products.

29. “Point of dispensing check” systems exempt agents at the middle of the legal supply chain (wholesalers) from providing information, and the marketing authorization/registration holder is required to identify it unequivocally and share said information through a database. Prior to the dispensation in pharmacies or healthcare centres, the serial code on the package of medical products is validated by comparing it with the code provided by the product registration holder.

30. The disadvantage of said systems is that SSFFC medical products can circulate for months, as the detection will occur at the time of dispensation and such detection is subject to the effective validation of the product at the point of dispensation.

31. Another system alternative is that called “Full Track and Trace” or “Full Pedigree” whereby the registration holder is required to identify the product unequivocally, and both the registration holder and all the agents at the middle of the supply chain are required to enter information on the logistics of products into the database up to the point the product reaches the patient. The advantage of this model relies on detecting in real time medical products irregularities and ensuring an effective and undelayed recall, while favouring an enhanced inventory management and contributing to the company’s quality assurance. Likewise, it provides visibility of the whole product supply chain, which may be useful to conduct epidemiologic studies and adopt focused healthcare measures. However, these models are more complex and involve a larger number of stakeholders in the supply chain who, in some cases, will need to allocate human resources to enhance the operation of the system. In turn, for wholesaler distributors, the need of entering logistic movements of products into the system may result in a slowdown, more or less stressed, of order receipt and preparation processes.

32. From both models, intermediate measures could be chosen such as the Point of dispensing check with random risk-based checks at wholesalers, or else, strategies differentiated per product type or agent characterization.

33. Turkey and Argentina are examples of countries adopting a Full Track and Trace system. For its part, the European Union is currently assessing the implementation of a “Point of dispensing check” system or/and an “end-to-end” system for all medical products marketed in the countries which are members of the European Union, with the possibility of risk-based controls at wholesaler level.

34. Lastly, the National Traceability System for implantable medical devices, which was approved at the beginning of 2014 in Argentina, stands as an example of a mixed system which only encompasses middle level stakeholders of the supply chain when they are licensed as “distributors”.

System	Advantages	Disadvantages
<b>Point of dispensing check</b>	<ul style="list-style-type: none"> <li>– Easier implementation (lesser number of stakeholders involved).</li> </ul>	<ul style="list-style-type: none"> <li>– SSFFC medical products are only detected at the point of dispensation, which is subject to an effective validation of the dispensing agent.</li> </ul>
<b>Full Track and Trace</b>	<ul style="list-style-type: none"> <li>– Visibility of the whole product supply chain.</li> <li>– Real time detection of irregularities.</li> <li>– More effective recalls.</li> <li>– Enhanced inventory management.</li> <li>– Possibility of conducting epidemiological studies and adopting focused health-related measures in any step of the supply chain.</li> </ul>	<ul style="list-style-type: none"> <li>– More complex implementation (higher number of agents involved).</li> <li>– Possible logistic processes slowdown.</li> </ul>
<b>Mixed</b>	<ul style="list-style-type: none"> <li>– Better response to the circumstances in and needs of the country.</li> </ul>	<ul style="list-style-type: none"> <li>– Will depend on the definitions adopted.</li> </ul>

### 3. Product identification

35. In order to establish a unit-based traceability of medical products, it becomes essential to identify products unequivocally for them to be distinguishable individually.

36. To such an end, the basis on which data products will be identified should be defined first. It is therefore essential to use a series or serial code, in accordance with the standard used. Said code may be numeric, consecutive or randomized, or even alphanumeric, in both cases with a fixed or variable extension.

37. It is recommended that such serial code be associated with a specific product code which identifies its commercial form. This will enable the obtainment of statistical data of serial sets for a same product. In all cases, the association of the product code and the serial code must be unique and must only be used once.

38. Additionally, systems may require the optional or compulsory coding of other relevant product data, such as batch number, manufacturing date, expiration date, product registration number, product identification for social security or health plans purposes, etc. However, the data for each unique unit that are not included in the product identification may be entered in the database.

39. The data concerning the batch and expiration date are usually pointed out as the most relevant. Including the batch data in the database (whether available or not on the data carrier) will enable products to be tracked more efficiently for market recall purposes. Moreover, the expiry identification will enhance prevention of the delivery of expired products to patients and inventory management, therefore avoiding losses due to expiration.

40. Regardless of the minimum data established as compulsory, it is advisable to accept the inclusion of additional data that may be useful for the stakeholders' management model.



41. The product data that is defined should be encoded into a data carrier which enables automated reading of the data. There are various technologies available for such purpose. The NRRA may determine that the data carrier uses a predefined specific technology, or else, may allow agents responsible for encoding the data to decide on which technology to use. This option has the advantage of enabling the use of technologies which have been previously agreed upon by the stakeholders, and which are cost neutral for them. However, it may mean that different technologies are required for an automated data reading throughout the legal supply chain.

42. The technologies known so far are linear bar coding, two-dimensional bar coding or data matrix and radio-frequency identification (RFID) tags. These technologies serve as options for data carriers where specific information can be stored or encoded.

43. Linear bar coding is widely used by industries in general, and readers are usually used in the value chain for this type of technology. Its main disadvantage is that larger data carriers are required in order to enter more information and it is difficult to place such a data carrier on small pharmaceutical containers.

44. On the other hand, the two-dimensional barcode data carrier allows for more information or data to be encoded into a relatively small space, with a better reading capacity compared to linear barcode. However, automatic data-reading equipment for this technology may not be available within the supply chain yet.

45. Unlike the technologies mentioned above, RFID devices are not an optical technology but rather, they contain information which is sent to the reader through transmission of a signal at a certain radio-frequency. In the past, some unreliability was raised about the use of RFID devices and the use is not widespread. Yet, their great advantage stems from the possibility of massive captures of data from multiple RFID tags in seconds with no need for an individual capture of each tag. This reduces series capture time, both for product receipt and dispatch. Therefore, their comparative advantage impacts the management of large volume logistics. Usually, the cost of putting RFID tags on products is considered higher than that of the other technologies, even though it may result in global cost cuts when assessing the logistics costs of reading data carriers individually when there are large numbers of products. Unfortunately, as RFID tags are devices, they cannot be printed serially and it is recommended that they be placed inside the secondary/outer packaging of products to reduce the incidence of problems caused by unintentional hits to the tag.

46. Regardless of the technology chosen, in all cases it may be required that all the information encoded on the data carrier also be in a language readable by the human eye. In turn, data carriers may be directly printed out on the medical product packaging (not for RFID) or, otherwise, labels may be affixed (usually, individual cost per data carrier may probably be higher as compared to the possibility of printing on the line). In both cases, it must be ensured that the data carrier reaches the patient unchanged, that its reading capacity is maintained throughout its shelf-life and that it cannot be removed without evidence on the packaging being left or placed on another unit. In addition, it is advisable to adopt tamper-evident packaging measures.

47. On the other hand, more than one technology could be used at the same time. The use of dual technology, RFID and Data Matrix codes may bring benefits by taking into account the advantages they both offer. Should the information contained in the RFID device be required to be printed in human readable language on the product, the additional printing of a Data Matrix code has a negligible additional cost.

48. It is important to stress that additional data carrier-related requirements, such as specific labels, serial number generation by the regulatory authority, label sizes or the definition of colour or material type will make the implementation more complex.

49. By the way of example of these definitions, it could be stated that the Turkish traceability system requires the use of Data Matrix technology with information coding in accordance with the GS1 international standard for the GTIN, and the serial code, batch number and expiration date.

50. On the contrary, Argentina implemented a flexible system whereby the product registration holder is allowed to choose the technology freely, in order to facilitate implementation by leveraging private existing resources with various technologies. The information to be included in the data carrier is to be adjusted to global GS1 standard and product registration holders are to check the quality of coding and reading consistency before releasing serialized products, so as to avoid subsequent errors in the supply chain. The data carrier can be placed on labels or printed out on the production line. Mandatory data to be included are GTIN and series code (other data are optional) and, regardless of the technology used, the information always must be readable to the human eye. Series numbers are generated by product registration holders.

Identification	Advantages	Disadvantages
<b>Only series</b>	<ul style="list-style-type: none"> <li>– Inescapable.</li> <li>– Additional data associated to the product may be recorded in databases.</li> </ul>	<ul style="list-style-type: none"> <li>– It must be assured that no repetition of series numbers occur among the various stakeholders.</li> <li>– Information cannot be sorted out by product type and/or commercial form; nor can statistical assessments be made.</li> </ul>
<b>Product code and series code</b>	<ul style="list-style-type: none"> <li>– Allows information to be sorted out by product type and/or commercial form and statistical assessments can be made.</li> <li>– Additional data associated to the product can be recorded in the databases.</li> </ul>	<ul style="list-style-type: none"> <li>– Product codes are to be defined or codes used in international standards should be adopted.</li> </ul>
<b>Additional data (e.g. batch number, expiration date, etc.)</b>	<ul style="list-style-type: none"> <li>– May be optional or mandatory.</li> <li>– Allow tracking of products with common specific characteristics.</li> <li>– Possible usefulness for stakeholders' management models.</li> </ul>	<ul style="list-style-type: none"> <li>– Possible need for larger space on packaging as more information is included.</li> <li>– It may lead to the use of a given technology.</li> </ul>
<b>Free technology</b>	<ul style="list-style-type: none"> <li>– Allows the use of technologies already owned by stakeholders.</li> <li>– Cost-neutral implementation for stakeholders.</li> <li>– Facilitates short-term implementation.</li> </ul>	<ul style="list-style-type: none"> <li>– Need for different technologies for automated data reading.</li> </ul>

Identification	Advantages	Disadvantages
<b>Linear bar coding</b>	<ul style="list-style-type: none"> <li>– Widely used.</li> <li>– The chain usually uses reading equipment.</li> <li>– Possibility of printing on the production line.</li> </ul>	<ul style="list-style-type: none"> <li>– Data carrier size increases as more information is added.</li> <li>– Difficulty to place the data carrier on small pharmaceutical containers.</li> <li>– Individual and direct reading by optical means.</li> </ul>
<b>Data Matrix</b>	<ul style="list-style-type: none"> <li>– Allows the storage of a large amount of information in a small space.</li> <li>– Enhanced reading capacity.</li> <li>– Possibility of printing out on the production line.</li> </ul>	<ul style="list-style-type: none"> <li>– The chain may not have available automatic data reading equipment yet.</li> <li>– Individual and direct reading by optical means.</li> </ul>
<b>RFID</b>	<ul style="list-style-type: none"> <li>– Allows massive captures of data in seconds with no need for individual capture from each data carrier.</li> <li>– Reduced reading time.</li> <li>– Comparative advantage for the management of large logistic volumes.</li> <li>– Global logistics cost cuts.</li> </ul>	<ul style="list-style-type: none"> <li>– Use is not widespread.</li> <li>– Individual cost per data carrier, probably higher as compared to the possibility of printing on the line offered by other technologies.</li> <li>– Factors may adversely affect readability. The chain may still not have available automatic data reading equipment.</li> <li>– Printing on the production line is not available (it is a device).</li> <li>– It is recommendable that it be placed within the secondary packaging.</li> </ul>
<b>Dual technology (Data Matrix + RFID)</b>	<ul style="list-style-type: none"> <li>– Leverage of advantages from both technologies according to the steps of the chain.</li> <li>– Should the information contained in the RFID device be required to be printed in human readable language on the product, additional printing of a Data Matrix code has a negligible additional cost.</li> </ul>	<ul style="list-style-type: none"> <li>– Individual cost per data carrier, probably higher as compared to the possibility of printing on the production line offered by other technologies.</li> </ul>



Figure 1: Linear barcode example



Figure 2: 2D Data Matrix barcode example

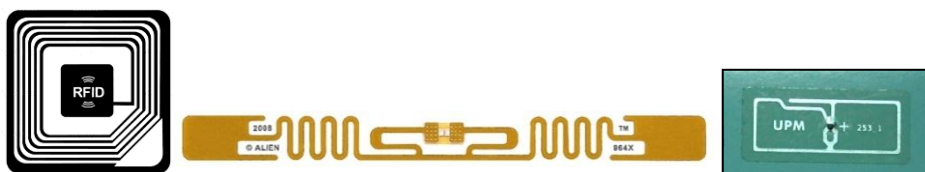


Figure 3: Examples of RFID tags

#### 4. Database

51. It is of paramount importance to state clearly that, in all cases, the database must allow the comparison of the information provided by each stakeholder against the information provided by the marketing authorization/registration holder, thereby ensuring that the series has been generated and released to market legitimately. In the case of Full Track and Trace models, also it must allow the validation of the information regarding receipt and dispatch by each of the members in the supply chain.

52. The database should ensure availability throughout the whole time products involved are distributed. In most countries, if not all of them, this will imply 365 days a year, 24 hours a day. In turn, it will need information technology measures that ensure protection against piracy, with the proper validation of the system, a timely response to stakeholders involved in the transactions, capacity to receive a large number of transactions simultaneously, data confidentiality and restricted access according to pre-established user profiles.

53. With respect to holding the database, some options are usually considered, namely:

- A database held by the NRRA where complete information from all stakeholders is gathered. It allows said authority to access data relating to product location, batch release, number of products manufactured and imported, dispensation of products,

pharmacovigilance, pharmacoepidemiological studies, etc. The health authority is required to have available technical capacity and adequate support.

- Outsourcing of IT development, technical maintenance and support to specialized companies with exclusive management of information centralized in the database by the NRRA. This option allows alternative methods when NRRA lacks the IT capability (not specialized in such matters) yet they may be expected to have such capabilities by leveraging the expertise of specialized companies engaged in performing this type of development. In general, this type of outsourcing must be contracted by the way of tender in the countries, and agreements must be entered into to ensure the contract validity, with stringent clauses regarding data confidentiality and safety.
- A database held by the industry (association of companies that clusters all the holders of product registrations) containing centralized information. In this case, if the regulatory authority wishes to access the information, it must request access to the industry sector. This model may raise some questioning in terms of formal and material legality from the rest of the stakeholders in the supply chain, since the first step in the chain would collect sensitive information from the rest of the steps. There may be legislation in place that grants the NRRA access to the information held by industry and the system is under the supervision of the NRRA.
- Individual databases held by each product registration holder which gather the information from all the stakeholders related to the products whose registration they hold. This option is similar to the previous one but information is stored in a fragmented way.

54. As an example, it can be mentioned that in Turkey, the development, maintenance and support of the IT base was put out to tender to a specialized company and the database is managed by the health authority. Argentina adopted a similar model which differs in that the technological development was commissioned to a government body with technical and technological capacity already installed by means of an inter-institutional cooperation agreement.

Database held by	Advantages	Disadvantages
<b>Health Authority</b>	<ul style="list-style-type: none"> <li>– Real time availability of the information relevant for various purposes.</li> </ul>	<ul style="list-style-type: none"> <li>– Requires adequate technical and support capacities at the health authority.</li> </ul>
<b>Development outsourcing + management by the health authority</b>	<ul style="list-style-type: none"> <li>– Leverage of the expertise of dedicated and specialized companies.</li> <li>– Real time availability of the information relevant for various purposes.</li> </ul>	<ul style="list-style-type: none"> <li>– Contracting usually is put out to tender in which technical aspects are to be defined.</li> <li>– Agreements are to be entered into to ensure information continuity and supply.</li> <li>– Need for setting stringent clauses concerning data confidentiality and safety.</li> </ul>

Database held by	Advantages	Disadvantages
<b>Pharmaceutical industry (corporate sector)</b>	<ul style="list-style-type: none"> <li>– Easier implementation.</li> <li>– Lesser resistance by product registration holders.</li> <li>– Where the law exists, access and supervision is granted to the NRRA.</li> </ul>	<ul style="list-style-type: none"> <li>– Access by regulatory authority only upon request.</li> <li>– Problems of access to the information of companies that stop operating.</li> <li>– Concerns may be raised about the management of sensitive information by third parties.</li> </ul>
<b>Pharmaceutical industry (individual firms)</b>	<ul style="list-style-type: none"> <li>– Easier implementation.</li> <li>– Lesser resistance by product registration holders.</li> <li>– Where the law exists, access and supervision is granted to the NRRA</li> </ul>	<ul style="list-style-type: none"> <li>– Access by regulatory authority only upon request.</li> <li>– Problems of access to the information of companies that stop operating.</li> <li>– Possible questioning as to sensitive information management by third parties.</li> <li>– Fragmented information.</li> <li>– Possible system compatibility problems for stakeholders who are to enter information in more than one database.</li> </ul>

## 5. Products involved

55. Even when it is desirable to conceive a traceability system for all medical products, in the mid and short-term, better results may be obtained through a gradual implementation with pre-established and reasonable timeframes which allow the industry sector to adapt their plants and procedures as necessary in order to fulfil regulations.

56. The larger the volume of products involved, the more complex a traceability system implementation is. Therefore, the main problems that are to be countered with this type of system should be previously assessed within the framework of the national/regional situation, for example SSFFC medical products.

57. The products that will be involved are to be defined. For instance, medical products with more SSFFC cases detected can be included, as well as those indicated for more critical pathologies, all prescription products, controlled substances, those pharmacovigilance-intensive ones, products bearing a risk management plan, high-cost products, all medicines, etc.

58. Prior to scope definition, it is advisable that communication channels and joint work with various stakeholders be established in order to lay down consensual implementation strategies.

59. Turkey stands as the example of a system that encompasses all prescription drugs, and has set a five-year term for implementation. For its part, Argentina established the model would be implemented gradually, in order that it would be operational in the shortest possible time. First, the system in Argentina targeted products with a high incidence of adulteration and fraud on financiers, those with a high cost, those indicated for cancer, HIV, haemophilia treatments and those of other special pathologies. This definition was assessed and discussed for more than one year before the regulation was issued. Some years after that first listing was released, other vigilance-intensive

products, antibiotics, anti-Parkinsonian and anti-depressant products as well as psychotropic, narcotic and abuse substances were included.

Scope	Advantages	Disadvantages
<b>All products</b>	<ul style="list-style-type: none"> <li>– More information and visibility of the distribution chain of all products.</li> </ul>	<ul style="list-style-type: none"> <li>– More complex implementation.</li> <li>– Need for longer deadlines.</li> <li>– Costs possibly higher.</li> <li>– Increased slowdown of production and logistics processes.</li> </ul>
<b>Gradual implementation</b>	<ul style="list-style-type: none"> <li>– Focus on products considered critical or more significant.</li> <li>– Easier implementation in the short or mid-term.</li> <li>– Lower implementation cost.</li> <li>– Lower negative incidence on production and logistics processes.</li> </ul>	<ul style="list-style-type: none"> <li>– Information limited to the products involved.</li> </ul>

## 6. Challenges to take into account

60. Regardless of previous impact assessment that may be made, operational problems are likely to occur during system implementation, which NRRA should be prepared to face and solve.

61. The inclusion of a large number of products may result in the need for companies to add traceability data carriers in an automated manner. To this end, certainly, companies will have to add new technologies, change production lines and validate them. Even though desirable, this may cause delays in improving production lines, slowdowns in production processes, and the need for adopting corrective measures to remedy inconveniences and maintain plant productivity.

62. On the other hand, the application of the data carrier will require product packaging with contrasted colours which enable code reading and sufficient space available to include data carriers without affecting the mandatory text required by regulations. Thus, companies may need to redesign product packaging.

63. Consideration should be given to the integrity and security of the data carrier and ensure that the appropriate materials are used so that the data carrier cannot be tampered with or altered throughout the whole chain. For instance, fast dry ink should be used, and the varnish usually used on cardboard should not be applied to the code printing area.

64. Additionally, account should be taken of the fact that as the volume of serialized products increases, receipt and dispatch time delays may occur at wholesaler distributors.

65. Access to safe, quality, efficacious and affordable medical products needs to be taken into account when developing and implementing the appropriate track and trace system.

## **V. EXPERIENCES IN COUNTRIES**

66. In order to survey the status and experiences of the countries in the region, they are kindly invited to fill in the annexed survey matrix. The updated version of this matrix will be made available on the WHO MedNet platform.

67. (See table).

68. Mexico and Switzerland had informed they do not have a track and trace system in place yet. Australia had informed they are yet to adopt a track and trace system through regulations, but they do have national IT systems and databases configured to interface with the global standards for products identification.

## **VI. LESSONS LEARNT**

69. The implementation of a traceability system based on unit of sale (secondary/outer packaging) is an objective to be attained and entails an enormous effort for stakeholders and NRRA as new technologies are to be adopted which enable substantial enhancement in patients' access to safe and efficacious products. The primary objective of stakeholders should be health-based and be to protect patients. This will enable understanding of the problem and the need for implementation regardless of economic implications.

70. The inclusion of numerous stakeholders from different geographies and with technological interaction, presents challenges that need to be addressed by inclusive policies that bring NRRA closer to stakeholders, allow them to learn from each other and to change roles in order to obtain maximum benefits through constant feedback.

71. Reasonable timeframes are to be considered when working, taking into account the globalization of the pharmaceutical industry, and without forgetting that each Member State has its own specific circumstances and needs, when the moment comes to define a traceability system of their own.



TABLE: EXPERIENCES IN COUNTRIES

Country	Argentina	Brazil	China	Colombia	India	Iran <sup>1</sup>	Philippines	Turkey <sup>2</sup>	USA	EU
<b>Primary objective of the NTS</b>	Combat against SSFFC, safety of the supply chain, improvement of recall procedures, prevention of reimbursement fraud	Traceability, combat SSFFC medical products in the supply chain, improvement of recall procedures	Traceability, tackle SSFFC, safety of the supply chain	Tackle the SSFFC problem with the purpose of guaranteeing public health	To authenticate the genuineness of medical products for sale or distribution in the country as well as for export	Combat against SSFFC Supervision and management of financial support (prevention of fraud in reimbursement and subsidies etc.) Shortage management Improve safety of the supply chain.	–	(a) tackle the SSFFC problem (b) safety of the legal supply chain (c) improvement of recall processes (d) market controlling-surveillance	Improve supply chain security from SSFFC products	Prevent the entry into the legal supply chain of falsified medicinal products
<b>Regulated</b>	Yes (Reg. MS 435/11 and regulations supplementary thereto)	Yes (RDC 54/2013; IN 6/2014 and supplementary regulations to be issued)	Yes	Decree 2078 of 2012 and law 1762 of 2015	Yes (DGFT Notice No. 13 of 2015 dated 22 May 2015).	Yes Public Law to Combat the Smuggling of Commodities and Currency, National Security Council Letter	Yes (It was issued a regulation adopting the Unique Global Product Identification Number)	Yes	Yes (Public Law 113-54, Title II, Drug Supply Chain Security Act) of 2013	Yes (Directive 2001/83/EC sets out basic principles)
<b>Date of implementation (established or estimated)</b>	First stage: December 15th, 2011	December 2016	Mandatory from December, 2015	First stage(new regulation): 2016	DGFT Notice is already in effect from 1 October 2015. The draft amendment to the Drugs and Cosmetics Act 2015 is under consideration.	Primary stage 2008 Second stage 2014	30th June, 2015	January, 2010	November 2013–2023	Estimated by 2019

Country	Argentina	Brazil	China	Colombia	India	Iran <sup>1</sup>	Philippines	Turkey <sup>2</sup>	USA	EU
<b>Standards</b>	Global and domestic	Global and specific requirements for product identification	Domestic	To be defined	Global	Global and domestic	No restrictions	Global	Global and domestic	Global and domestic
<b>Type of system</b>	Full Track and Trace	Full Track and Trace	Full Track and Trace	Currently, Point of dispensing check system but moving to Full Track and Trace system	Full track and trace under the proposed amendment to the Drugs and Cosmetics Act 2015	Currently, Authentication Control (AC) and gradually adding Full Track and Trace system (TTAC)	Not identified yet	Full Track and Trace	Resembles full because all members in supply chain involved	Point of dispensing check and risk based checks by wholesalers.
<b>Data Carrier</b>	Free (linear barcode, 2D and RFID) on secondary packaging	2D Data Matrix	Linear barcode (Code 128)	Moving to 2D Data Matrix on outer packaging	1 or 2D bar coding	2 Separate UIDs : First: 16 numeric Second: 2D Data Matrix	Barcode, QR code or any equivalent ID system may be used	2D Data Matrix	2D Data Matrix	2D Data Matrix
<b>Information in Data Carrier</b>	GTIN and series (Optional data allowed, e.g. batch and expiration date) Mandatory batch and expiration date in 2D Data Matrix and RFID tags	Unique Medicine Identifier – IUM (product registration number, serial number, batch number and expiration date)	20 digit Electronic Drug Monitoring Codes (EDMC: Pharmaceutical product code, National Drug Code, sequential number and randomized number), preassigned by China Food and Drug Administration (CFDA)	GTIN, series, expiration date and batch number	GTIN, series, expiration date and batch number	GTIN, 20-digit serial number (including company prefix), expiration date and lot number	Establishment (company) ID number and product ID number (GTIN). Also a unique ID number specific for batch	GTIN, series, expiration date and batch number	Standardized numerical identifier (National Drug Code) and serial number, lot number, expiration date (compatible with GS1 standards)	– unique serial number – product code – batch number – expiry date – possibility to add a national reimbursement number

Country	Argentina	Brazil	China	Colombia	India	Iran <sup>1</sup>	Philippines	Turkey <sup>2</sup>	USA	EU
<b>Database</b>	Within the NRA, with centralized information. Development and technological support provided by another government body	To be defined	Within the NRA (CFDA), with centralized information	Within the Ministry of Health and Social Protection	Central Government portal for track and trace – Drugs authentication and verification application (DAVA)	Supervision and management by IFDA through a special portal that designed and operated by outsourced company	Not yet in place	Within the NRA, with centralized information	To be defined	Defined but not yet in place
<b>Scope</b>	Gradual (1) Reg. 3683/11: high cost products (HIV, cancer, AHF) (2) Reg. 1831/12: more massive products, antibiotics, anti-hypertensive, anti-Parkinsonian, etc.) (3) Reg. 247/13: drugs of abuse (4) Reg. 963/15: high-cost and critical products offered through the internet	All medicines	All medicines	Gradual Around 75 medicines to be included in the first stage	All medicines defined in the Drugs and Cosmetics Act	Gradual 2008: expensive imported medicines 2009: All imported Medicines 2010: Imported Dietary Supplements 2011: Imported, Cosmetics and Hygienic products 2012: Imported Medical devices and Foods 2015: Domestic pharmaceutical products	–	(a) prescription medicines (b) non-prescription medicines (c) some medical food supplements	Human prescription drugs in finished dosage form, as defined in section 581(13) which excludes certain products	Human prescription medicinal products (with few exceptions) and identified over the counter medicinal products considered at risk

Country	Argentina	Brazil	China	Colombia	India	Iran <sup>1</sup>	Philippines	Turkey <sup>2</sup>	USA	EU
<b>Observations</b>	In the body of the document	–	Application of data carriers in packaging flaps not allowed Helper codes allowed in flaps	–	–	The system includes all IFDA supervised stuffs and generally used two UID's	–	A new application successfully implemented. The application is available for both Android and iOS-based smart phones. Everybody who downloads the application could easily use the application. The application is used to check if the medicine is authorized in Turkey or not. It is also open for public use.	–	Mixed system (developed by stakeholders, supervised by NRRRA with full access and with immediate notification of suspect products)
<b>Challenges identified</b>	Hospital packaging, inclusion of more products, maintaining daily distribution, optimizing financing models	System is being implemented Evaluation of challenges not yet final	–	–	–	Multiple stakeholder groups with varying level of capability – law and regulation requirements and support	–	–	– Multiple stakeholder groups with varying level of capability – Complexity of law and requirement Phased in approach lot level tracing first. Required to develop new system for unit level by 2023.	Developing and managing the huge repository (database) connected to thousands of stakeholders and the need for an immediate response after verification of a product

<sup>1</sup>. Column for Iran added after the meeting.

<sup>2</sup>. Additions made according to email received from Turkey on 20 November 2015.

## Appendix 3

**Actions, activities and behaviours that fall outside the mandate of the Member State mechanism [and separated from the list of actions, activities and behaviours that result in SSFFC medical products] [as they][[and] do not result in a public health risk]**

Objective 4 of the MSM's terms of reference as reflected in Element 5 of the workplan mandated the mechanism to identify a list of actions, activities and behaviours that result in SSFFC medical products being prevented and controlled due to the health risk they present to the population and also identify those that fall outside the mandate of the mechanism and separate them from the aforementioned list.

Annex I of document A/MSM/2/6 lists the actions, activities and behaviours that result in SSFFC medical products. The list set out below is a non-exhaustive list of actions, activities and behaviours that fall outside the mandate of the MSM and they should be separated from the actions, activities and behaviours that result in SSFFC medical products. This list could be subject to revisions and adjustments in the future.

[The rationale behind this exercise is to ensure that unauthorized actions, activities and behaviours and medical products will face regulatory actions; whereas authorized actions, activities and behaviours and medical products not posing health risks will not face unjustified regulatory actions, in order not to hamper access to quality, safe and efficacious medical products.]

The term "regulatory authority" used in this paper means the national or regional regulatory authority for medical products.

1. Actions, activities and behaviours in violation of laws other than medical product regulations, such as actions or behaviours in conflict with taxation, duties, customs laws.
2. Actions, activities and behaviours relating to manufacturing, storage, distribution, import and export of quality medical products authorized by the national and/or regional regulatory authority.
3. Actions, activities and behaviours of licensee/authorization holders involving minor deviations, as determined by national and/or regional regulatory authorities, which do not compromise the quality or which do not pose a health risk, [such as minor [unintentional] deviations in good manufacturing practice.]
4. Actions, activities and behaviours related to medical products, exclusively meant for own use of a traveller and carried by himself/herself.
5. Actions, activities and behaviours that are related to the protection or infringement and enforcement of intellectual property rights, including data exclusivity.
6. Actions, activities and behaviours related to medical products meant solely for the purpose of research and development and laboratory testing[.] not for human use.
7. [Actions, activities and behaviours] [in case of medical products in transit, which are in compliance with the regulatory requirements of the country of export and the country of final destination.][which may not be in compliance with the regulatory requirements of the country of transit [while preserving the integrity of the medical product in transit.][and except if there are grounds for suspecting the existence of SSFFC medical products.]]

8. Importing, exporting, distributing, including transporting, storing, supplying or selling authorized/licensed medical products from a country to another country where there is no market authorization/licence existing for that product in order to meet a national emergency, extreme urgency or humanitarian crisis with the consent of the country concerned.

= = =