World Health Organization

EXISTING TECHNOLOGIES AND "TRACK AND TRACE" MODELS IN USE AND TO BE DEVELOPED BY MEMBER STATES

Draft document submitted by Argentina

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I.   INTRODUCTION

1.   Over the last years, the implementation of medical products[1] 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[2]) 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 and secondary 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.

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[1] 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".

[2] 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 prejudge 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 illegitimate 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
Batch level	– Possibility of tracking a complete manufactured batch.	– Batches usually involve a large number of units. – Units within each batch are not differentiated or individualized.
Tertiary level (Pallet and/or pack)	– Bulk reading of a cluster of units. – Information more specific than at batch level. – Reduces logistics costs and time at wholesaler level.	– Units within the tertiary packaging are not necessarily identified unequivocally on an individual basis.

Scope	Advantages	Disadvantages
Secondary or outer packaging (unit of sale)	– Unequivocal identification of each unit as sold to the public. – Enables the reconstruction of the distribution chain of each unit.	– Increased implementation complexity.
Primary or immediate packaging (unit of dispensation)	– Greater advantage at hospital level. – Possibility of identifying unequivocally doses administered to patients.	– Increased implementation costs and complexity in serialization process. – Need for availability of more human resources and equipment in healthcare centres. – No comparative advantages as to the rest of the supply chain.

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 strengthen NRRA capacities as progress is made 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 medical products only circulate through the authorized health supply chain;

- It provides safety to patients who use medical products, by reducing the risks associated with illegitimate 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 circulation of stolen and smuggled products;

- It prevents the distribution and/or dispensation of expired, prohibited or recalled products;

- It helps to ensure free medical products samples are properly delivered;

- 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 acquisition of illegitimate 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 enables 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.

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 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 categories per 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 standards.

23. On the other hand, the existence and possibility of using domestic identification and serialization standards are related to the needs inherent to each region or country. Hence, pharmaceutical companies should differentiate the products that they manufacture for exportation to countries and regions that adopt their own standards or, otherwise, importers should repackage medical products to suit the domestic markets.

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
Global or international	– Homogeneity in multinational companies' production. – Possibility of information interchangeability at world level. – Existence of standards already set. – Easier implementation in countries with large volumes of imported products. – Possible cost-cutting at domestic level.	– Need for useful information at national level to be adapted to standard parameters.
Domestic	– Established according to the needs and reality of each country.	– Need to define standards. – Arrangement of codes exclusive for the country. – Possible cost increase at domestic level. – Information interchangeability among countries subject to compatibility.
Mixed	– Leverage of international standards while adapted to the circumstances in and needs of the country.	– Will depend on the definitions adopted.

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 health supply chains for the distribution, storage and dispensation of medical products.

29.   "Point of dispensing check" systems exempt agents at the middle of the health 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 illegitimate 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
Point of dispensing check	– Easier implementation (lesser number of stakeholders involved).	– Illegitimate products are only detected at the point of dispensation, which is subject to an effective validation of the dispensing agent.

System	Advantages	Disadvantages
Full Track and Trace	– Visibility of the whole product supply chain. – Real time detection of irregularities. – More effective recalls. – Enhanced inventory management. – Possibility of conducting epidemiological studies and adopting focused health-related measures in any step of the supply chain.	– More complex implementation (higher number of agents involved). – Possible logistic processes slowdown.
Mixed	– Better response to the circumstances in and needs of the country.	– Will depend on the definitions adopted.

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 health 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 be advisable with a view to seizing 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
Only series	– Inescapable – Additional data associated to the product may be recorded in databases.	– It must be assured that no repetition of series numbers occur among the various stakeholders. – Information cannot be sorted out by product type and/or commercial form; nor can statistical assessments be made.
Product code and series code	– Allows information to be sorted out by product type and/or commercial form and statistical assessments can be made. – Additional data associated to the product can be recorded in the databases.	– Product codes are to be defined or codes used in international standards should be adopted.
Additional data (e.g. batch number, expiration date, etc.)	– May be optional or mandatory. – Allow tracking of products with common specific characteristics. – Possible usefulness for stakeholders' management models.	– Possible need for larger space on packaging as more information is included. – It may lead to the use of a given technology.
Free technology	– Allows the use of technologies already owned by stakeholders. – Cost-neutral implementation for stakeholders. – Facilitates short-term implementation.	– Need for different technologies for automated data reading.

Identification	Advantages	Disadvantages
Linear bar coding	– Widely used. – The chain usually uses reading equipment. – Possibility of printing on the production line.	– Data carrier size increases as more information is added. – Difficulty to place the data carrier on small pharmaceutical containers. – Individual and direct reading by optical means.
Data Matrix	– Allows the storage of a large amount of information in a small space. – Enhanced reading capacity. – Possibility of printing out on the production line.	– The chain may not have available automatic data reading equipment yet. – Individual and direct reading by optical means.
RFID	– Allows massive captures of data in seconds with no need for individual capture from each data carrier. – Reduced reading time. – Comparative advantage for the management of large logistic volumes. – Global logistics cost cuts.	– Use is not widespread. – Individual cost per data carrier, probably higher as compared to the possibility of printing on the line offered by other technologies. – Factors may adversely affect readability. The chain may still not have available automatic data reading equipment. – Printing on the production line is not available (it is a device). – It is recommendable that it be placed within the secondary packaging.
Dual technology (Data Matrix + RFID)	– Leverage of advantages from both technologies according to the steps of the chain. – 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.	– Individual cost per data carrier, probably higher as compared to the possibility of printing on the production line offered by other technologies.

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Figure 1: Linear barcode example

Figure 2: 2D Data Matrix barcode example

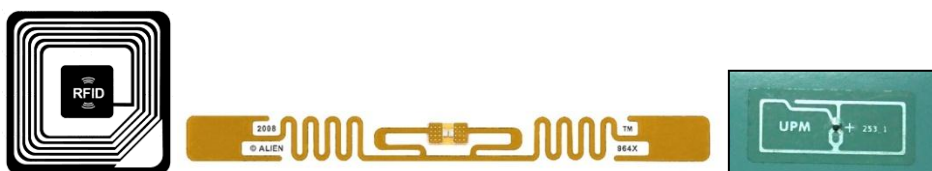Figure 3: Examples of RFID tags

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 product 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, 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.

– 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
Health Authority	– Real time availability of the information relevant for various purposes.	– Requires adequate technical and support capacities at the health authority.
Development outsourcing + management by the health authority	– Leverage of the expertise of dedicated and specialized companies. – Real time availability of the information relevant for various purposes.	– Contracting usually is put out to tender in which technical aspects are to be defined. – Agreements are to be entered into to ensure information continuity and supply. – Need for setting stringent clauses concerning data confidentiality and safety.
Pharmaceutical industry (corporate sector)	– Easier implementation. – Lesser resistance by product registration holders.	– Access by regulatory authority only upon request (even if access is granted by law). – Problems of access to the information of companies that stop operating. – Concerns may be raised about the management of sensitive information by third parties.

Database held by	Advantages	Disadvantages
Pharmaceutical industry (individual firms)	– Easier implementation. – Lesser resistance by product registration holders.	– Access by regulatory authority only upon request. – Problems of access to the information of companies that stop operating. – Possible questioning as to sensitive information management by third parties. – Fragmented information. – Possible system compatibility problems for stakeholders who are to enter information in more than one database.

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 (e.g. falsification or adulteration, fraud, theft of medical products, smuggling, unprescribed sale, etc.)

57.   The products that will be involved are to be defined. For instance, medical products with more falsification 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 reached products with a high incidence of adulteration and fraud on financers, 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
All products	– More information and visibility of the distribution chain of all products.	– More complex implementation. – Need for longer deadlines. – Costs possibly higher. – Increased slowdown of production and logistics processes.
Gradual implementation	– Focus on products considered critical or more significant. – Easier implementation in the short or mid-term. – Lower implementation cost. – Lower negative incidence on production and logistics processes.	– Information limited to the products involved.

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.

V.   EXPERIENCES IN COUNTRIES

65.   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.

66.   (See table).

67.   Mexico and Switzerland had informed they do not have a track and trace system in place yet. The European Union expressed that the regional organization and its Member States are in the process of developing a unique identifier system for medicinal products and once this is finalized, they would be willing to present it to the Member State Mechanism and integrate it into this Section. 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

68.   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.

69.   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.

70.   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.

ANNEX: EXPERIENCES IN COUNTRIES

Country	Argentina	Brazil	China	Colombia	India	Philippines	Turkey	USA
Primary objective of the NTS	Combat against SSFFC, safety of the supply chain, improvement of recall procedures, prevention of reimbursement fraud	Traceability, combat against falsification, safety of the supply chain, improvement of recall procedures	Traceability, tackle SSFFC, safety of the supply chain	Tackle the SSFFC problem	…	–	Tackle the SSFFC problem	Improve supply chain security from illegitimate product
Regulated	Yes (Reg. MS 435/11 and regulations supplementary thereto)	Yes (RDC 54/2013; IN 6/2014 and supplementary regulations to be issued)	Yes	New regulation is currently being developed	Yes	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)
Date of implementation (established or estimated)	First stage: Dec. 15th, 2011	For the three batches traceability data: Dec. 2015 Full implementation: Dec. 2016	Mandatory from Dec., 2015	First stage(new regulation): 2016	Not yet clear (postponement regulation was issued)	30th June, 2015	Jan., 2010	November 2013–2023
Standards	Global and domestic	Global and specific requirements for product identification	Domestic	To be defined	Global	No restrictions	Global	Global and domestic

Country	Argentina	Brazil	China	Colombia	India	Philippines	Turkey	USA
Type of system	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	…	Not identified yet	Full Track and Trace	Resembles full because all members in supply chain involved
Data Carrier	Free (linear barcode, 2D and RFID) on secondary packaging	2D Data Matrix	Linear barcode (Code 128)	Moving to 2D Data Matrix on outer packaging	2D Data Matrix	Barcode, QR code or any equivalent ID system may be used	2D Data Matrix	2D Data Matrix
Information in *Data Carrier*	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	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
Database	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	Government planned to set up a Central Portal for Track and Trace of exported products	Not yet in place	Within the NRA, with centralized information	To be defined

Country	Argentina	Brazil	China	Colombia	India	Philippines	Turkey	USA
Scope	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	It applies only when: a) Medicines are exported from India b) Medicines are sold to the Indian government	–	All prescription medicines (with a few exceptions)	Human prescription drugs in finished dosage form, as defined in section 581(13) which excludes certain products
Observations	In the body of the document	–	Application of data carriers in packaging flaps not allowed Helper codes allowed in flaps	–	–	–	–	–

Country	Argentina	Brazil	China	Colombia	India	Philippines	Turkey	USA
Challenges identified	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 – Complexity of law and requirements – Challenging time periods for implementation