In November 2017, the Table: Experiences in Countries in the document “Existing Technologies, and “Track and Trace” models in use and to be developed by Member States” was updated with the results of the questionnaire on track and trace systems for human medicines by the International Coalition of Medicines Regulatory Authorities (ICMRA) Supply Chain Integrity group. In the table below, the text in the original table is in black and updated text is in red.

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<td>Argentina</td>
<td>Combat against SF Medicines, safety of the supply chain, improvement of recall procedures, prevention of reimbursement fraud.</td>
<td>Yes (Reg. MS 435/11 and regulations supplementary thereto).</td>
<td>First stage: December 15th, 2011</td>
<td>Global and domestic</td>
<td>Full Track and Trace</td>
<td>Free (linear barcode, 2D DataMatrix and RFID) on secondary packaging. The last five years evolution shows that, Datamatrix is preferred and used by most companies.</td>
<td>GTIN and series (Optional data allowed, e.g. batch and expiration date) Mandatory batch and expiration date in 2D Data Matrix and RFID tags</td>
<td>Within the NRA, with centralized information. Development and technological support provided by another government body</td>
<td>Gradual (1) Reg. 3683/11: high cost products (HIV, cancer, AHF) (2) Reg. 1831/12: more massive products, antibiotics, antihypertensive, anti-Parkinsonian, etc.) (3) Reg. 247/13: drugs of abuse (4) Reg. 963/15: high-cost and critical products offered through the internet</td>
<td>In the body of the document</td>
<td>Hospital packaging, inclusion of more products, maintaining daily distribution, optimizing financing models</td>
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<td>Australia</td>
<td>Not in place and not planned</td>
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1 http://www.who.int/medicines/regulation/ssffc/mechanism/en/
2 All the rules are available at the following link: http://www.anmat.gov.ar/trazabilidad/normativa.asp
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<td>Brazil</td>
<td>Analysis of logistic events data and the consequent health control actions within the supply chain of the Brazilian pharmaceutical market.</td>
<td>Yes [SNCM was created by Law 11.903/2009. Law 13.410/2016 modified the previous Law, introducing amendments] – Specific legislation: Resolution RDC 157/2017 and Ordinances IN 17, 18 e 19/2017</td>
<td>The SNCM will begin its implementation in May 2019, being completed in April 2022.</td>
<td>Global and specific requirements for product identification</td>
<td>Full Track and Trace</td>
<td>2D barcode based on ISO/IEC 16022:2006 information technology – 2D Data Matrix</td>
<td>Unique Medicine Identifier – IUM (GTIN – Global Trade Item Number; product registration number, serial number, batch number and expiration date)</td>
<td>Database owned and supported by ANVISA. IT solution to be defined.</td>
<td>All Medicines with some exceptions</td>
<td>Possible adaptations and investments that each stakeholder in the supply chain will have to face with the SNCM</td>
<td></td>
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<tr>
<td>Canada</td>
<td>A DIN (Drug Identification Number) lets the user know that the product has undergone and passed a review of its formulation, labeling and instructions for use. It serves as a tool to help in the follow-up of products on the market, recall of products, inspections, and quality monitoring.²</td>
<td>Yes [Assignment and Cancellation of DINs are regulated under section C.01.014 of the Food and Drug Regulations]</td>
<td>DINs and the DPD (Drug Product Database) have been in existence for decades. Health Canada is still in the early planning phases for IDMP (Identification of Medicinal Products).</td>
<td>Domestic</td>
<td>Early planning stages for IDMP</td>
<td>DIN—a computer-generated eight digit number assigned by Health Canada.</td>
<td>Health Canada does not mandate any particular machine-readable data carrier. Some manufacturers use unique identifiers and barcodes issued by GS1 including a global trade identification number (GTIN).</td>
<td>DINs are assigned by Health Canada and the Drug Product Database, which contains product specific information on drugs approved for use in Canada, is managed by Health Canada.</td>
<td>Human pharmaceutical and biological drugs, veterinary drugs, radiopharmaceutical drugs and disinfectant products.</td>
<td>Data in the DPD is readily available to the public. Generally, Health Canada is moving to become more open and transparent and better custodians of its data holdings, provided there are no legitimate constraints.</td>
<td></td>
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<tr>
<td>China</td>
<td>Realize drug process traceability, tackle SF medical</td>
<td>Yes</td>
<td>Under planning and designing, the date needs to be confirmed</td>
<td>Planned compatibility (with global standards)</td>
<td>Planned Full Track and Trace</td>
<td>Linear barcode and 2D barcode (planned compatibility)</td>
<td>20 digit Electronic Drug Monitoring Codes (EDMC)</td>
<td>Under planning and designing, the government establishes the</td>
<td>All drugs for human use</td>
<td>The T &amp; T system of China will be constructed under the</td>
<td>Key cost drivers to the system have been upgrades to the system. If there are new mandatory requirements for unique identifiers, the cost will be translated to the company. This could translate into limitations in the access to patient medicines.</td>
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<td>products, safety of marketed drugs. Guarantee that patients can purchase legal products from formal channels. Guarantee the right to know of the patients and end users. Useful for data statistics analysis and supervision.</td>
<td>Yes (Decree 207B of 2012 and law 1762 of 2015) The National Traceability and Signaling System, SNTS, of medicines for human use in Colombia is currently being regulated by the Ministry of Health and Social Protection.</td>
<td>First stage(new regulation): 2016</td>
<td>Global</td>
<td>Currently, Point of dispensing check system but moving to Full Track and Trace system</td>
<td>GTIN (International Standard GS1), series, expiration date and batch number</td>
<td>To be defined, SNTS is currently being regulated by the Ministry of Health and Social Protection</td>
<td>Medicines for human use</td>
<td>The draft regulation would establish criteria for prioritizing medicines to be included in the SNTS</td>
<td>Operational obstacles: need for different technologies for automated data reading</td>
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<tr>
<td>Columbia</td>
<td>Guarantee the identification of medicines in any part of the distribution chain, from production to the final consumer, with the aim of avoiding falsification, adulteration, expiration and contraband</td>
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<td>Costa Rica</td>
<td>Not in place and not planned</td>
<td>Regulation exists for medicines’ importers and distributors in which they are required to have a traceability system, and the bills or records related to reception and sell of medicines must have batch</td>
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<tr>
<td>Denmark</td>
<td>To verify the authenticity of the medicinal product and to identify individual packs.</td>
<td>Yes (Regulation No 2016/161)</td>
<td>Expected to be implemented by February 2019 (to be introduced in the EU)</td>
<td>Global</td>
<td>End-to-end system</td>
<td>2D barcode</td>
<td>GTIN</td>
<td>The database is owned and managed by pharmaceutical industry stakeholders with the possibility for national competent authorities to participate in the management board of the entity managing the database.</td>
<td>Prescription only medicinal products for human use, except those specifically white-listed, and OTC for human use, especially black-listed. For white-list and black-list, see Annex I and II of Regulation No. 2016/161</td>
<td>In addition to the database itself, there are the manufacturing costs of placing a unique identifier on the outer packaging, adaption of manufacturers’ production lines and new systems and equipment for wholesale distributors, pharmacies and other persons authorised or entitled to supply medicinal products to the public. Availability of medicines may be impacted due to higher prices to recoup the costs.</td>
<td>Legal obstacles: Access to the database and its information is restricted as set out in Regulation No 2016/161, unless all parties owning data therein agree to share the data.</td>
</tr>
<tr>
<td>EU</td>
<td>Prevent the entry into the legal supply chain of falsified medicinal products</td>
<td>Yes (Directive 2011/62/EU)</td>
<td>The system will be applicable from 9 February 2019 in the majority of the EU Member States. Three Member States (Belgium, Greece and Italy) that already have a</td>
<td>Global</td>
<td>End-to-end verification system with additional verification between the beginning and the end of the supply chain</td>
<td>2D barcode (Data Matrix)</td>
<td>Unique serial number, product code, batch number, and expiry date; possibility to add a national reimbursement number.</td>
<td>Delegated Regulation (EU) 2016/161 provides that the repositories system is set-up and managed by a non-profit legal entity or non-profit legal entities</td>
<td>Human prescription medicinal products (with few exceptions identified according to criteria listed in Falsified Medicines Directive (risk of)</td>
<td>The future EU system provides a new approach to other systems already in place. It is a stakeholders’ model supervised by competent authorities. After</td>
<td>Legal obstacles: Many aspects and characteristics of the planned EU system are regulated by the legislation.</td>
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<td>Fiji</td>
<td>Not in place and not planned. Fiji is in the development stage of strengthening MRA</td>
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<tr>
<td>Ireland</td>
<td>The safety feature is the combination of an anti-tampering device and a 2D barcode. It is not for the purpose of traceability, but rather verification for the purposes of whether a medicine is a falsified medicine or not</td>
<td>Yes</td>
<td>8th February 2019</td>
<td>Domestic (the standard is set out in the EU Commission’s legislation)(^6)</td>
<td>No current system. However, we are part of the EU, which means the Falsified Medicines Directive will apply, including the safety features verification system</td>
<td>2D barcode</td>
<td>Database owned and managed by industry but option for competent authority oversight.</td>
<td>Human medicines subject to prescription (unless specifically exempted) and non-prescription medicines on a specified list. The non-prescription medicines on the list are because of confirmed cases of falsification.</td>
<td>Costs are unknown but will be borne by industry. This includes manufacturers, distributors and pharmacies. There is the cost of the database but also the cost of the equipment.</td>
<td>Common/compatible data standards need to be used. Other obstacles: political willingness to link T&amp;T systems in different countries/regions. The scope and objectives data sharing should be clearly defined.</td>
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<td>Italy</td>
<td>Strengthening measures against possible fraud to the detriment of public health, NHS and treasury; prevention of any illegal activities.</td>
<td>Yes, Unique identifier (Decree of the Ministry of Health on 2 Aug 2001, 1 Feb 2002, and 30 May 2014). Central Data Bank (Law 39 – 1 Marc 2002 (art. 40), Decree of the Ministry of Health – 15 July 2004, 31 July 2007, 4 Feb 2009, 11 Nov 2011, guidelines for the upload of data, and technical specification for the upload of data)</td>
<td>The Central Data Bank (BDC) operated by the Ministry of Health was started on June 2005. The BDC is fully operative.</td>
<td>Domestic</td>
<td>Mixed model: a combination of end-to-end model based over unique identifier, plus traceability of batch/lot level and expiration date, plus traceability of quantity of units for sale: every level is adopted by a specific type of actor in the supply chain.</td>
<td>Before 2016, the unique identifier is carried in two linear barcode on the same sticker. From 2016, the unique identifier is available both in two linear barcode both in 2D barcode over the same sticker.</td>
<td>A medicinal products code that identifies its commercial form and a serial number</td>
<td>The BDC is developed as a Java solution “ad hoc” and uses some products like Oracle for Database, JBoss application server, etc.</td>
<td>All medicines for human use</td>
<td>The Italian model adopted for the T&amp;T system has minimized the cost for the manufactures and supply chain in order to reduce the impact on availability of medicines</td>
<td>Legal obstacles: This possibility should be regulated by law. Other obstacles: the definition of the rules for sharing data with other systems and the costs.</td>
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<tr>
<td>Japan</td>
<td>Strengthen traceability, streamline the supply chain</td>
<td>Yes (Record of sales is mandatory. Putting barcodes on products is requested but not mandatory.)</td>
<td>Standardization of codes was established in 2006. Management and preparation of sales records by manufacturers and wholesalers had been mandatory before the standardization.</td>
<td>Global</td>
<td>Track and Trace system in place. Mandatory sales record keeping for pharmaceutical companies and wholesalers is in place. Barcodes are put on products to facilitate such record keeping.</td>
<td>GS-1 code for identification of products</td>
<td>GS1 DataBar (CC-A), GS1-128</td>
<td>Database owned by pharmaceutical companies and wholesalers</td>
<td>Prescription medicines only</td>
<td>Pharmaceutical companies and wholesalers are impacted by cost related to the system. Negative impacts on access to medicine for patients are not expected.</td>
<td>Legal obstacles: Sales records are owned or managed by companies. The authority does not have data. Operational obstacles: Differences in software used by companies may become an obstacle to share data.</td>
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<tr>
<td>Mexico</td>
<td>Enable the timely identification of products at any stage of the supply chain to</td>
<td>No (Cofepris is initiating the pilot program as it builds the specific</td>
<td>Still in the stage of management of pilot application, the estimate time to</td>
<td>Global</td>
<td>Systems which allow full traceability of the product transactions</td>
<td>GS1 DataMatrix ECC200 code</td>
<td>Serialized identifier for a pharmaceutical product in the client’s physical</td>
<td>Still under discussion with the supplier of pilot program and all the actors</td>
<td>Still under discussion with the supplier of pilot program and all the actors</td>
<td>Still under discussion with the supplier of pilot program and all the actors</td>
<td>No additional information at the moment, due to the progress in the pilot’s</td>
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<tr>
<td>Nigeria</td>
<td>Avoid the revenue of adulterated or falsified product, in addition to maintaining control in the monitoring of the distribution of such products.</td>
<td>Regulatory framework for this system, as well as defining the responsibilities of all participants, both regulatory and regulated.</td>
<td>From beginning to end of its supply chain, including the agents in the middle</td>
<td>Domestic</td>
<td>Full track and trace</td>
<td>Linear barcode, plans include the use of smartphone technology in detecting information within the linear barcode</td>
<td>Plans to develop and implement domestic standards (overt and/or covert features, trace markers) adapted to circumstances and needs. The standards will entail identification of products, facilities and other parties within the supply chain.</td>
<td>NMRA will have 100% ownership of the database. The management of the database will be outsourced.</td>
<td>Involved</td>
<td>Involved</td>
<td>Involved</td>
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<td>Russia</td>
<td>Protection of the population from SF medicines and provision to all customers (citizens) the possibility of checking the legality of the registered</td>
<td>Yes (a project of the federal law was developed, which together with by-laws will regulate the system)</td>
<td>Priority project on the &quot;implementation of automated systems of monitoring of medicines circulation from the manufacturer to the end user&quot;</td>
<td>Global</td>
<td>Full track &amp; trace</td>
<td>ISO standards 16022 (Data Matrix)</td>
<td>GS1 for identification of products</td>
<td>In the experiment, the regulatory bodies have full data access. While pharmaceutical companies participating in the experiment have access only</td>
<td>The experiment includes only the medicines for human use chosen by participating manufacturers. In future all medicines are planned to be</td>
<td>The information will be provided accordingly upon the completion of the experiment</td>
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<tr>
<td>South Africa</td>
<td>medicines of the legal civil circulation. Provision of transparency and development of fair competition in pharmaceutical market.</td>
<td>No</td>
<td>From 1 Feb 2017 to 31 Dec 2017. Implementation is planned by 31 of Dec 2018</td>
<td>Domestic</td>
<td>In the process of implementing systems to monitor medicine availability at facility level. Electronic stock management system are in process of being implemented at hospitals; medicine availability monitoring in place using cellphone technology at primary health care facilities.</td>
<td>The European Article Numbering Code 13 (EAN 13) has been accepted as standard</td>
<td>Information on stock availability</td>
<td>Access to public sector facility information limited to government institutions (Department of Health)</td>
<td>Medicines for human use.</td>
<td>Fragmented systems and limited intra-operability of systems.</td>
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<tr>
<td>Spain</td>
<td>Prevent the introduction of falsified medicinal products in the legal supply chain.</td>
<td>Yes²</td>
<td>9th of February 2019</td>
<td>Global (International Organization for Standardisation/International Electrotechnical Commission standard (‘ISO/IEC’) 16022: 2006)</td>
<td>Planned; End to end verification system</td>
<td>2D barcode</td>
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<td>The repository system is currently being designed and implemented</td>
<td>Most medicines for human use will be included with some exception listed in the regulation. Non-prescription medicines are excluded except some exceptions</td>
<td>The EU system provides a new approach as it is a stakeholders model supervised by competent authorities.</td>
<td>Access to data is only foreseen for EU competent authorities and only for certain purposes.</td>
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<td>Sweden</td>
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<td>Yes, system for verification of safety features appearing on the packaging of medicinal products is entirely ruled by the Commission delegated regulation 2016/161 published 9 Feb 2016</td>
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<td>Purpose of system is not to track products, but to avoid that falsified products enter the legal supply chain</td>
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<td>also listed in the regulation. Risk of falsification determines the inclusion or exclusion of medicinal products.</td>
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<tr>
<td>Switzerland</td>
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<td>However, the Swiss Government is currently discussing some legal bases to implement such a system in Switzerland. For now, it is still impossible to predict whether Switzerland will actually set up such a system or not and how it will be regulated.</td>
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<td>--</td>
<td>Switzerland does not have a T&amp;T system in place yet.</td>
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<td>UK</td>
<td>Reduce the likelihood of falsified medicines entering the system and regulation and 9 February 2019 (as set out in the EU Delegated Regulation 2016/161/EU)</td>
<td>Yes, currently implementing the system and regulation and end-to-end verification system</td>
<td>Global</td>
<td>The Commission Delegated Regulation [2016/161/EU] envisages the use of the product code used within the unique identifier should conform to the unique identifier will be The repository in the UK which will contain the data from the unique identifier will be Majority of prescription only medicines and small number of medicines</td>
<td>The repository in the UK which will contain the data from the unique identifier will be</td>
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<td>In the UK the supply of human medicines is extremely complex. Legal obstacles: MHRA understands that access to the repository and</td>
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<tr>
<td>Uruguay</td>
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<td>Not in place and not planned; getting information about different T&amp;T systems in order to evaluate the future implementation of some of them.</td>
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<tr>
<td>USA</td>
<td>Enable verification of the legitimacy of the drug product identifier down to the package level, enhance detection and notification of illegitimate products in the supply chain; enable anyone in the medicines supply chain to identify and verify the authenticity of an individual pack of medicine for the entire time the product remains on the market</td>
<td>Yes</td>
<td>By November 27, 2023, a secure electronic, interoperable system for product tracing at the package level will be established across the pharmaceutical sector.</td>
<td>Global</td>
<td>Full Track and Trace</td>
<td>While the global standard(s) has not been decided yet, the U.S. law currently specifies that the product identifier be a 2-dimensional data matrix barcode for packages, or requirements of ISO/IEC 15459-3:2014 and ISO/IEC 15459-4:2014.</td>
<td>owned by a not-for-profit organization, SecurMed, and supervised by the MHRA and UK Department of Health. The UK database will be interoperable with the European Hub which is established and managed by industry stakeholders as a not-for-profit organization – the European Medicines Verification Organisation.</td>
<td>available without a prescription if there has been an incident of falsification in the legitimate supply chain. This system only applies to human medicines. Other systems may be in place in due course for medical devices and medicines for veterinary use.</td>
<td>Separately health policy and medicines use differs across the different countries within the UK (Scotland, Wales and Northern Ireland) and these factors need to be addressed in the way in which the system is implemented nationally.</td>
<td>the user requirement specification is covered by legal agreements and non-disclosure agreements.</td>
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<td>Country</td>
<td>Primary objective of the NTS</td>
<td>Regulated</td>
<td>Date of implementation (established or estimated)</td>
<td>Standards</td>
<td>Type of System</td>
<td>Data Carrier</td>
<td>Information in Data Carrier</td>
<td>Database</td>
<td>Scope</td>
<td>Observations</td>
<td>Challenges identified</td>
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<td>drug supply chain, and facilitate more efficient recalls of drug products.</td>
<td>distribution supply chain.</td>
<td>a linear or 2-dimensional data matrix barcode for homogenous cases.</td>
<td>system, include data management issues.</td>
<td>further manufacturing (such as capsules, tablets, lyophilized products before reconstitution). This does not include blood or blood components intended for transfusion, radioactive drugs or radioactive biologics, imaging drugs, certain intravenous products, medical gases, homeopathic drugs, and lawfully compounded drugs.</td>
<td>requirements, including as the requirements relate to product production or manufacturing lines; system attributes to support the secure, interoperable electronic exchange of data (including standards); the use of aggregation and inference during product tracing, including verification.</td>
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