Memorandum of Understanding

Between:

The parties (to be adjusted by National Stakeholders):

- **Innovator industry**
- **Generic medicines industry**
- **Pharmaceutical parallel distributors**
- **Pharmacists**
- **Wholesalers**
- **other**

On the Formation and Governance Model of a Joint Stakeholder-Run Verification System of Pharmaceutical Products in Country

18 May 2015

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Definitions

Definitions

Compatible - Able to exist or occur together without conflict

Constituency(ies) - the stakeholder communities hereafter called The Parties, representing material users of the System that are entitled to full membership of NMVO, comprising (1) the research pharmaceutical companies, (2) generic pharmaceutical companies, (3) self-medication pharmaceutical companies, (4) pharmaceutical wholesalers, (5) community pharmacies, (6) hospital pharmacies, and (7) pharmaceutical parallel distributors.

EMVO - European Medicines Verification Organisation - a non-profit association established by European stakeholders to manage a European central hub that will connect to a series of national or regional data repositories that will serve as the verification platform to allow the authenticity of medicines anywhere in the supply chain in the EEA to be verified. Collectively, the European central hub and the national repositories may be referred to as the "European Medicines Verification System" or the "System".

EMVO Requirements - core documents that are expressly identified as "EMVO: Requirements for the EMVS" and that are part of the foundation documents of the EMVO, elaborating on the EMVO cost allocation and other principles and technical elements of the System.

Exceptional Event - any indication that gives rise to a suspicion that a given product may be counterfeit or that the System may be attacked or another problem that prevents normal or uninterrupted use of the System. An Exceptional Event would include, by way of illustration, a verification / authentication failure (because the serial number is not in the System, or is already logged as having been dispensed or decommissioned due to a batch recall for instance), attempted intrusion by an unauthorised party, or any other activity that suggests an attack on the system. Exceptional events will be assigned escalation levels, and related processes will be set out in the Foundation Documents.

Foundation Documents - the key technical and legal documents to be agreed prior to the establishment of the NMVO that shall be incorporated in this Interim Memorandum of Understanding as and when they are adopted and that memorialise the Parties' agreement on the System architecture and operating rules, including agreed principles on use cases, data validation, response times, the handling of Exceptional Events and System-related processes, and operational and security requirements.

ICT - Information and Communications Technology

Interoperability - Different systems that can interact but have different modi operandi

MAH - Manufacturing Authorisation Holder: which term, for the purposes of this paper, includes both manufacturers and pharmaceutical parallel distributors engaged in repackaging to the exclusion of contractors and subcontractors involved in the manufacturing process but not responsible for putting pharmaceutical products on the market. For the avoidance of doubt, a manufacturer engaging contractors or subcontractors to produce on its behalf shall be considered the MAH.

Marketing Authorisation Holder: for the purpose of this paper this term relates to the entities that hold a marketing authorisation.

Master Data - data related to a sales article that is the same for all packs of this article (e.g. name, article number, dose form, dose count, pack type) that shall be registered in the System.

Medicines - those products required to bear safety features in accordance with the Directive on Falsified Medicines[1] and the related Delegated Acts adopted thereunder.

NMVO - National Medicines Verification Organisation - the national association that will be established by the Parties to manage a national data repository that will connect to the European central hub. It will serve as the verification platform to allow the authenticity of Medicines anywhere in the supply chain in the EEA to be checked. Collectively, the European central hub and the national repositories may be referred to as the "European Medicines Verification System" or the "system".

Parties - on a national level include: (to be adjusted by national stakeholders)

- innovator industry
- generic medicines industry
- pharmaceutical parallel distributors
- wholesalers
- pharmacists

[1] Directive 2011/62 of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products (OJ 2011 L 174/74).

Stakeholder - may be an individual member of the above Parties or any other user of the system, or interested body including government departments and agencies

Verification - Confirmation that a pharmaceutical product exists within the national database with the same details contained within the 2D matrix on the pack

PLEASE NOTE: *This MoU is not intended to be legally binding on the Parties, but is only intended to support the early development of a cost effective product verification and authentication system for national needs.*

1. Introduction

The Directive on Falsified Medicines introduces mandatory, harmonised pan-European safety features in the form of tamper evident packaging and a unique identifier, to be applied to all prescription medicines subject to possible exclusions based on a risk assessment. It aims to prevent falsified medicines infiltrating the legal supply chain and ultimately from reaching patients. The Delegated Acts when adopted will define the characteristics and technical specifications of the "unique identifier" allowing identification of individual packs and the accessibility of national product databases or repositories that allow verification and authentication of each dispensed pack.

The Parties fully support this legislation and will be pleased to work with the EU Commission and National Competent Authorities in establishing an effective system in the interests of patient safety. To this end, the Parties have collaborated in the elaboration of this Memorandum of Understanding with a view to jointly promoting the development of a cost effective and scalable product verification and authentication system that is to be run by stakeholder organisations on a non-profit basis in a way that justifies the related costs to be borne by the relevant Parties.

This Memorandum of Understanding between the national Parties will:

- describe the conditions for the joint implementation of a national system to meet the requirements of the Directive,
- support the internal processes and manage the development/adaptation required,
- form a basis for decision making,
- support and facilitate communication on these issues.

This MoU is not intended to be legally binding on the Parties, its only intention is to support the early development of an NMVO which can implement a cost effective product verification and authentication system for national needs.

The costs of the product verification and authentication system will be borne by the MAH of medicinal products bearing the safety features referred to in Article 54a e) of the European Directive and are shared by national stakeholders according to the principles agreed in the EMVO cost allocation model. The system should not be run for commercial gain.

Participating Parties have agreed that it is necessary to create a comprehensive framework for the implementation of the Directive, which will determine, amongst other issues, data access, control conditions and operating rules of a national database (Framework). This MoU

however, is not in itself the basis of such a Framework. This must be agreed separately amongst the Parties.

The national database will be linked to the European system, which is composed of a European hub, which in turn is linked to a number of other national databases. These databases are the platform for verification by stakeholders to ensure the authenticity of each pack. The European system will be inter-operable between different member countries and work for all prescription medicines that bear the safety features.

The system should be able to handle the varying needs of different countries, based on the common EU platform that enables a harmonised coding system.

With the support of the repository system, verification of the authenticity of the medicinal product from manufacturer to point of dispense, end-to-end verification and authentication can be performed by:

1. Manufacturers inserting master data in the European hub,
2. Actors throughout the supply chain (wholesalers, distributors, pharmacies, pharmaceutical parallel distributors, etc.) using scanning technology to verify the authenticity of the package,
3. pharmaceutical parallel distributors decommissioning individual packs that bear codes and uploading new codes,
4. Actors prior to dispensing to the patient, changing the package status in the database to dispensed.

Subject to agreement between the Parties, potential efficiencies include the possibility of (These are additional functionalities and not necessarily requirements of the Delegated Acts):

- allowing for the automated checking of expiry dates,
- improved pharmacovigilance,
- a reduction in fraud,
- greater effectiveness in preventing recalled products from being supplied to the patient,
- more efficient handling of product returns
- improved stock management.

The Parties fully accept the need for a comprehensive Framework for the implementation of the Directive, which will determine, amongst other issues, data access, control conditions and operational rules of a national database. Access usage will have to be agreed by all Parties taking into account the existing legal position on data access and ownership.

2. A Pan-European Model of Product Verification - 10 Core Principles

The Parties agree that the framework for implementing the Directive should reflect the following key principles:

1. <u>Guaranteeing continuity of protection throughout the entire supply chain:</u>

- Regarding the pharmaceutical parallel distributors obligation to replace mandatory safety features at the level of the European hub, the original pack serial number must be cancelled in the database by the pharmaceutical parallel distributors and a new number provided. The new serial number must be linked to the original product number at the batch level in the database to enable the product to be tracked in case of recalls or other safety issues.

2. <u>Ensuring a single coding and identification system on each pack across the EU:</u>

- Given the movement of medicines across national borders, any effective coding and identification system must be able to exchange information between Member States. There should therefore be a harmonised standard coding system across the EU that allows for the incorporation of relevant national product codes.

- The Parties propose using a two-dimensional code[2] containing a unique serial number to encode all selected products. This code can be verified against a database. This means that pharmacists can rapidly verify the status of each pack before dispensing it to the patient. As well as the serial number, the code would store the expiry date along with the product identification (including a national code) and batch numbers, including suffixes where required by pharmaceutical parallel distributors, providing additional patient safety enhancement.

3. <u>Ensuring product verification database systems can work together across the EU:</u>

- In addition to using a common standard for pack identification in Europe, all national database systems must also be able to work together and exchange information in order to allow any pharmacist, and wholesaler where deemed necessary, in any Member State to check whether the pack has been dispensed before, irrespective of its country of origin.

- There should be sufficient flexibility to implement national solutions within the System.

[2] *Data matrix ECC 200*

- National database systems should meet equivalent quality assurance requirements.
- Without this interoperability, counterfeiters would be able to exploit gaps between national systems to insert falsified medicines into the legitimate supply chain.

4. <u>Verifying every serialised pack at pharmacy level:</u>

- It is the responsibility of all players in the supply chain to ensure that medicines delivered to patients are safe and genuine.
- Pharmacy level verification at the point of dispensing with an interface for wholesalers and pharmaceutical parallel distributors is a robust and cost-effective way to improve patient protection.
- However, unless every individual serialised pack is verified at the point of dispense, patients will not benefit fully from the safety features. The unique serial number can only provide protection against counterfeits if it is routinely checked against a central database and the status changed on the database to 'dispensed' when the product is handed to the patient.
- Systems should be configured so that pharmacists can undertake checks when medicines enter pharmacy stock, as well as at the point of dispense. Since the technical challenges of verification at the point of dispense vary across the EU, pharmacists may initially adopt a system of verification when medicines enter the pharmacy, until such time as any technical issues with regard to point of dispense verification have been resolved.
- The process of verification in the pharmacy should be virtually instantaneous in order to ensure efficient pharmacy workflow and the avoidance of delays. To ensure that products are verified in one scanning action, verification software should be integrated with existing pharmacy software. The process of verification at the wholesale level should allow products to be checked during forward logistics as well as for returning medicines, without changing the status on the database. The process of verification by pharmaceutical parallel distributors should also allow for product checks at the "goods-in" stage of the process without changing the status on the database.
- Stakeholders shall work together to define standard procedures for exceptional events such as verification failure, system failure, etc.

5. <u>Maximising all the potential benefits of mass serialisation:</u>

- Using mass serialisation provides benefits over and above improved counterfeiting prevention. Maximising these should help to encourage widespread use of identification systems and assist all stakeholders.

- The coding system enables the batch number, serial number and expiry date to be machine readable, significantly enhancing patient safety and improving product recall procedures.

- The system may also facilitate the provision of additional services to patients by pharmacists.

6. Focusing on securing patient safety and protecting patient privacy:

- Verification systems are for preventing counterfeits, not for accessing individual stakeholder data.

- Manufacturers do not seek, and will not have access to, individual patient/prescribing profile information.

- Transactional data belongs to the pharmacist or, in relation to wholesaler verification, to the wholesaler or, in relation to pharmaceutical parallel distributors, to the manufacturing authorisation holder who performs this activity. However, relevant stakeholders may need to see certain data to help investigate when there is a verification failure, a product recall or a level of unusual activity related to a specific serial number, in accordance with national circumstances.

- Any additional use of transactional data would need to be agreed between the stakeholders in accordance with national circumstances.

7. Combining tamper-evident packaging with a unique serial number:

- The Parties support the requirement that the safety features should consist of a unique serial number placed on each pack together with packaging that would reveal if a pack has been opened or tampered with.

- Checking a unique, randomised, serial number placed on each pack against a central database at the point of dispense is currently one of the most secure ways to verify product authenticity. However, a product verification system can only secure the content of the pack if it remains sealed at all times. Using tamper evident packaging makes it clear whether the pack has been opened or tampered with and is therefore an essential complement to a product verification system.

- The scope and application of the safety features will be determined in accordance with the provisions of the Directive and related Delegated Acts.

8. Using safety features that are simple, robust and cost-effective:

- The proposed product verification solution should meet the criteria of being practical, affordable and accessible. Unnecessarily complex and costly solutions should be avoided.

- The Directive mandates that the costs of repository systems will be borne by Manufacturing Authorisation Holders. The costs for the fully established System shall be based on a flat fee model to be agreed unanimously by their representative Constituencies. For the avoidance of doubt, in the event that the Manufacturing Authorisation Holder and the Marketing Authorisation Holder are not one and the same legal entity, whichever entity uploads data to the System shall be liable for the user fees payable.

9. Working together in the Interests of patient safety:

- As key stakeholders in the verification process, the Parties are committed to working together to establish an efficient, viable and effective system to protect patients against the threat of counterfeit medicines.

- The establishment and management of product verification systems should be undertaken by relevant stakeholders and governed by jointly managed independent non-profit organisations, building on the current coding environment in the various countries, and meeting the needs of patients and all players in the supply chain.

- Each Constituency will separately be responsible for the System.

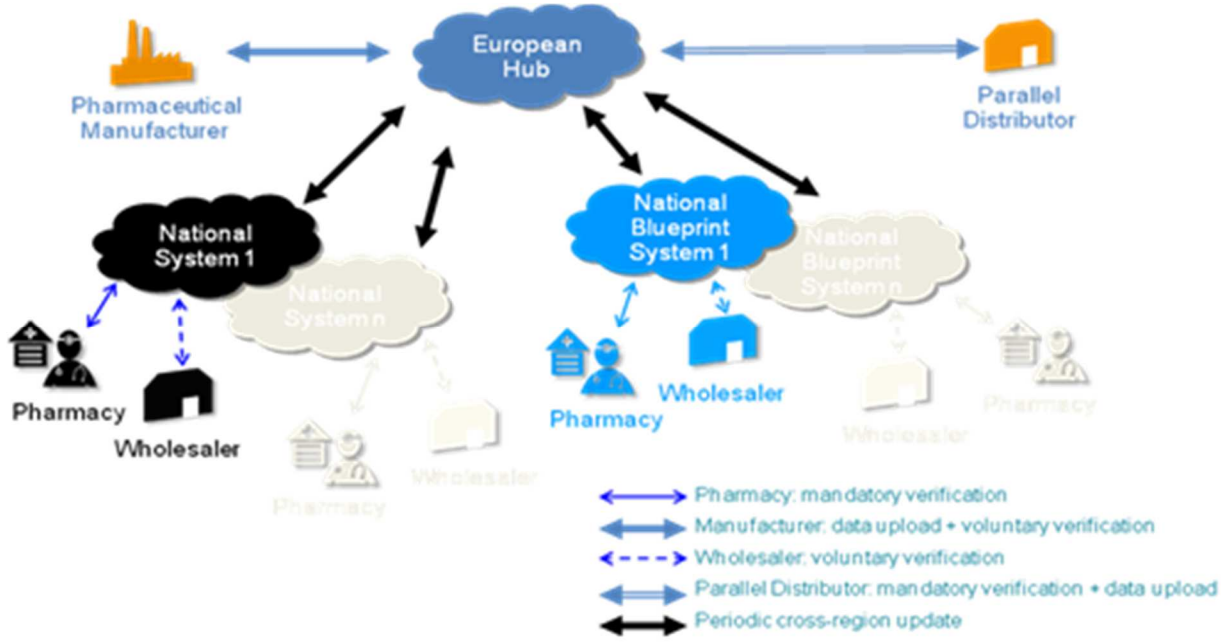
10. Involving other stakeholders

- The Parties will work with the relevant European Union authorities and welcome the involvement of other relevant stakeholder organisations which play an active role in the pharmaceutical supply chain in the further elaboration of the product verification system at the point of dispense. Together we can ensure a strong and comprehensive system to take forward the fight against counterfeiters.

3. System Architecture and Ownership

3.1. Introduction

The Parties support the establishment of a pan-European System as depicted in the figure below.



In order to allow interoperability and implement a cost-effective national verification system, the national repository shall be implemented in line with the EMVO requirements.

This system comprises a single European central hub connected to a series of national information repositories that serve as the verification platforms that pharmacies or other authorised stakeholders can use to check a product's authenticity. No pharmacy or wholesale level data shall be available on the European central hub. National repositories are to be set up and run under the management of the respective national stakeholder organisations (the parties). The "Blueprint" system refers to the national repositories where national stakeholders opt to have their system operated by the EMVO on their behalf and will hereafter be referred to as "centrally operated national systems". All future references to "national systems" shall be deemed to include such centrally operated national systems. Over time, systems may migrate between being national or regional or centrally operated pursuant to the wishes of the relevant stakeholders and the governing rules of their respective organisations.

3.2. EMVO Responsibilities

The European Medicines Verification Organisation (EMVO), a non-profit stakeholder driven international organisation will hold a European hub, set standards in the EMVO requirements, and ensure the quality and availability of the system.

For specific information on the EMVO, which will lead and direct the European hub, see the MoU pertaining to the European stakeholders (see Appendix).

3.3. NMVO's main tasks

The NMVO will lead and direct the national system which is linked to the European hub and will include:

- verification and authentication of national medicines packs,
- a central location for storage of national product data,
- a national point from which alerts will be generated if the system detects an exceptional event.

3.4. National System

For the system to work cost effectively it will comply with the EMVO user requirements and require a legally binding agreement between the Parties (NMVO).

The main purpose of the National System is to serve as the verification platform that pharmacies or other registered parties such as wholesalers, self-dispensing doctors or hospital pharmacies can use to check a product's "authenticity". All data necessary to perform this and other relevant transactions are stored in the respective National Systems.

The National Blueprint System serves as a cost-effective off-the-shelf verification platform that is offered to national stakeholder organisations. The National System uses the interface to the hub and serves the functionality as described in the EMVO user requirements.

<u>The key tasks of the National System are to:</u>

- contain the relevant product serialisation data,
- receive revised/new product serialisation data from the European Hub,
- serve as the verification platform for pharmacies or other registered parties such as wholesalers to check for a product's authenticity,

- serve as the platform for pharmacies to mark a product pack as dispensed prior to handing it over to the patient,
- serve as the platform for registered parties such as pharmacies and wholesalers, to mark a product pack as ‘decommissioned’ or ‘exported out of the EU’.

4. National system product verification

4.1. Safety Feature - Unique Identifier

The system for identifying each individual package must include at least:

1. Product code
2. Batch number and if necessary a suffix/internal code for parallel-distributed products, to have a link to the original batch of the product
3. Expiry date
4. Serial number
5. National reimbursement number where such a number is in use
6. The current status of the unique packaging.
7. Time and date of the change of status

This data is divided into two types:

- Static: e.g. product code, expiration date (i.e. points 1-4 above) that do not change
- Dynamic: e.g. statements that reflect a serial number's changed status (i.e. points 5-7 above).

4.2. Ownership of and access to data

Supply chain security cannot be managed effectively without access to data in certain circumstances. In order to maximise patient safety benefits, having regard to Article 54a of the Directive, it is important to ensure that the effectiveness of the system is not compromised by unreasonable restrictions on access to data.

To this end a distinction needs to be drawn between data generation, ownership and license to use and the provision of access rights. A set of rules to govern these issues is required which grant appropriate user access rights and implement other technical and organisational provisions.

The system will not capture or generate any personal data.

4.2.1 Data generation and ownership

All stakeholders having access to the system will own the product verification data they generate in interacting with the system.

The Parties recognise the sensitive nature of this type of information and propose a System that is highly secured and that permits access to data under strict and defined conditions.

4.2.2 Stakeholder Access Scenarios and Conditions

The Parties have identified the following scenarios where relevant stakeholders would seek access to certain serialisation and product verification information for reasons of patient safety.

4.2.2.1 Negative verification, dispensing and unusual activity

Access to information in the system on impacted serial numbers would allow for quicker investigations into Exceptional Events that indicate a risk of counterfeit products. The parameters of unusual activity are to be defined within the system.

The information involved might include, by way of example, evidence that:

- The serial number is not in the verification system.
- The data elements that are scanned do not match the database information.
- The serial number is already logged as dispensed.
- The serial number has already been decommissioned (e.g. where the product has been repackaged and a new serial number has been established).
- The serial number has already been decommissioned due to recall of a batch.
- Any activity relating to a specific serial number or to a set of serial numbers reflecting practical impossibility relating to time, geography, manufacturer's capacity, or suggesting an attack on the system.

While it is recognised that National competent authorities and other local regulatory authorities will naturally be involved in the case of an Exceptional Event, each affected manufacturer may require some extended data to help track down the source of illicit product insertion. The design of the system will ensure that only the agreed and relevant extended data is made available under these conditions and the European central hub will be responsible for requesting and receiving such data from the national system(s) in order to

provide the requisite level of data abstraction to allow the MAH to fulfil his obligations vis-à-vis the national regulators.

4.2.2.2 Product recalls

Using the status information relating to individual packs, the system would provide near 'real time' identification of information for impacted batches and allow recalls to be more effectively managed.

In a product recall scenario, relevant stakeholders would require access to the status of all impacted serial numbers, including details of which impacted serial numbers have been dispensed or re-packed in accordance with the agreed processes on the handling of Exceptional Events and in line with relevant data protection laws.

For repackaged parallel distributed products, the original manufacturers and the new batch numbers being applied by the pharmaceutical parallel distributors must be linked in the European Hub to permit rapid and efficient recalls where relevant. Again, the European central hub will allow for the appropriate level of data abstraction in terms of what data can be obtained from the national repositories and made available to individual manufacturers.

4.2.2.3 System Maintenance

Occasionally it will be necessary to check whether a transaction(s) has taken place or has been successfully completed or to change data when an error has occurred. The ability to run a report or at least to access data will be required in these circumstances. Access to the data would then be limited to authorised ICT contractors, subject to appropriate safeguards.

5. National system availability and use

5.1. Availability

For security reasons system accessibility may be limited. The system will only be available to stakeholders who need to use it in conjunction with the physical management of the products in the supply chain. Access levels will vary depending on activity.

Manufacturer	Even though manufacturers do not access national systems directly, via the EU-hub they can deposit and decommission data and check the status.
pharmaceutical parallel distributors	Even though pharmaceutical parallel distributors do not access national systems directly, via the EU-hub they can decommission damaged packaging for export, see section 5.3 Ability to check the status as described under paragraph 5.4
Wholesaler	Decommissioning of damaged packaging, exports outside EU, see section 5.3 Ability to check the status as described under paragraph 5.4
Dispensers (including for example in hospitals, in registered pharmacies and dispensing doctors)	Decommissioning of damaged packaging at point of dispense, see section 5.3 The ability to check the status, verify and authenticate at the point of dispense

5.2. Entry Points

A key feature of the System is to offer a single point of entry for manufacturer data in the European Hub (check in). Only a MAH can enter serial numbers into the system. Subject to the agreed data access principles, the information to be provided by a MAH in the code to be affixed to each pack should include the following:

1. Product code (GTIN, NTIN or PPN for Germany)
2. Expiry date
3. Batch number (including suffix or prefix when repackaged)
4. National reimbursement number if used.
5. Serial number

This basic information will allow for subsequent verification and authentication of the product pack by other stakeholders physically handling the product in the supply chain.

The MAH shall specify the country/countries where a pack is to be sold by the wholesale distributor/manufacturer hence a serial number issued for that country. In this way the serial numbers are connected to the national database.

New serial numbers will be listed at repackaging and linked to the country/countries where the package is to be sold. There needs to be a clear relationship between the unique identifier on the original pack and the U.I. by linking the old and new batch numbers in the European Hub. This process should be automated and simple.

5.3. Exit Points

The System will only work if exit points are identified and comply with the System in accordance with the agreed procedures.

In the current scheme envisaged a pack can exist in the following different states:

- Available
- Dispensed, including split packs
- Dispensed in another market
- Decommissioned
- Decommissioned in another system
- Extra EEA trade
- Recalled
- Repacked

In this document, the word “decommission” is a collective term to describe the status of a pack with any of the above, except ‘Available’ status.

Stakeholder	Decommissioning by the stakeholder, relevant check out process.
Manufacturer / Pharmaceutical parallel distributors	Delivery/ return of product, cancellation, accident, damaged packaging, correction of errors at initial registration, unforeseen logistical adjustments, theft of serial numbers or packages.
Pharmaceutical parallel distributors	Decommissioning before repacking the product, with subsequent registration of a new serial number.
Dispensers (including, for example, hospital, community, internet pharmacists and dispensing GPs)	Ability to authenticate and verify. Decommissioning of damaged packaging at point of dispense, see section 5.3.
Wholesaler	Damaged packaging (either because of the wholesalers’ management or through delivery returns from pharmacies). Exporting packages to countries outside the EEA or in countries not participating in the system.

In some circumstances, it may be necessary to reverse a record of authentication. For example, this may occur if a product is authenticated in error, or if a patient does not ultimately collect medicines that have been previously ordered. It should be possible to reverse authentication at any point until the expiry date of the medicine occurs.

5.3.1 Decommissioning

Decommissioning should be mandatory so that the integrity of the system is maintained and that it enhances patient safety by reducing the risk of patients receiving counterfeit medicines. Unless each individual package with a serial number is decommissioned from the system in a proper way, the safety benefits for patients cannot be guaranteed. The unique serial number can only serve as reliable protection against counterfeit medicines if the products are decommissioned systematically. The serial number´s status has to be changed in the system database when a product is released to the patient or repackaged.

5.4. Availability to wholesalers

Wholesalers will have "readable" access for verification purposes. The wholesale distributor must check the delivery units containing medicinal products which carry safety features on the outer packaging. For medicinal products carrying safety features obtained from (i) the MAH or a person who is authorised by the MAH to supply these products, or (ii) the MAH or a person who is authorised by the MAH to supply those products, the wholesale distributor is, however, deemed to have satisfied this condition and thereby Article 80(a)(ca) of the Directive. The receiving wholesale distributor must check medicinal products carrying safety features on the outer packaging obtained from other authorised sources. Similarly, if medicinal products are returned from persons authorised or entitled to supply to the public, the wholesale distributor must verify that they have not been falsified or tampered with by checking the safety features on the outer packaging.

The Parties agree to continue dialogue on developing standard practices in cases requiring the removal of products from the supply chain (such as damaged goods) and for which the serial numbers should be decommissioned from the System.

5.5. Dispensing pharmacies, hospitals and dispensing doctors

Dispensing pharmacies, hospitals and doctors will be able to check the data in the system.

5.6. Other uses of data

In addition to providing all stakeholders with more detailed information on counterfeit products found on the market, the implementation of the proposed System allowing product identification at pack level has the potential to generate other benefits that include, (subject to agreement between the stakeholders at national level): a reduction in the number of fraudulent reimbursement claims; higher effectiveness in preventing recalled products from being supplied to the patient; more efficient handling of product returns, and the facilitation of pharmacists' stock management processes.

Any additional uses of transactional data would be subject to negotiation, and would need to be agreed between the relevant stakeholders on a case-by-case basis in light of national circumstances and in compliance with relevant legislation.

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The various requirements outlined above are necessary to avoid the risk of unscrupulous operators applying for national manufacturing or wholesaling licenses in order to have access to the System at a regional level in a way that would allow them to distort the data to facilitate the entry into the supply chain of counterfeit products. They constitute more reliable systemic safeguards than national ad hoc audits. They provide a framework for an

efficient locked System that facilitates the rapid identification of anyone trying to distort the System that safeguards the interests of patient safety and that can evolve to meet future needs and challenges.

6. Organisational and Governance Structure: Key Parameters

It is envisaged that the NMVO shall be established as a non-profit organisation for an unlimited term. Its statutes will formalise its legal status, financing, organisational structure and decision-making processes. Without prejudice to a final decision on the most cost-effective legal structure and any related mandatory legal requirements, the Parties envisage that the NMVO will be governed by the principles outlined in this chapter.

Minimal assets will be held by the NMVO and the project will be outsourced to one or more ICT suppliers in a project financed type programme governed by a service level agreement.

6.1. Remit

The NMVO will establish and manage the National Repository System that will be interoperable with the European Hub and as such with other national repositories that serve as the verification platforms hosting the data necessary to enable pharmacies or other authorised entities to verify a product's authenticity. It will cooperate with relevant stakeholders in the implementation of the EU Directive on falsified medicines and the relevant Delegated Acts.

The NMVO will facilitate negotiations amongst stakeholders with a view to concluding standard binding agreements governing its relationship with the EMVO. Those agreements shall ensure that good governance principles apply across a System that is fully interoperable to allow participants to most effectively identify, monitor and, wherever possible, reduce specific and common risks to patient safety arising from counterfeit products.

The NMVO will be responsible for:

a. Applying the EMVO requirements and ensuring overall quality (on matters such as data cleanliness, the availability and responsiveness of the System, the appropriate level of security to be respected, etc.),

b. Defining the terms and conditions governing access to the System that shall be objective and transparent and open to any party duly authorised to operate in the legal supply chain anywhere in the European Economic Area,

c. Managing the IT, contractual and human interfaces between the NMVO and EMVO,

d. Providing regular activity reports to members on issues such as System functioning and performance and to generate statistical reports for the purposes of aiding communications on the functioning of the System,

e. Carrying out periodic strategic reviews to ensure that the System evolves over time in the interests of patient safety and in line with the evolution of healthcare infrastructure in Europe,

f. Invoicing and collecting membership fees and any other monies due,

g. Concluding and administering user agreements and related fee and payment arrangements,

h. Liaising with the relevant national regulatory authorities on the use of the System to facilitate product recalls and other patient safety issues,

i. Providing services to stakeholders in the fulfilment of mutually agreed bilateral or multi-party data access as agreed on a case-by-case basis.

The NMVO shall be authorised to carry out all activities that directly or indirectly relate to the realisation of its remit. To this purpose it will be authorised in the governing Statutes to buy, sell or rent all real estate and installations, take a mortgage on such goods, employ relevant personnel and hire contractors as required.

The NMVO can choose to outsource responsibilities (c. to i.) to the EMVO under a service level agreement.

6.2. Membership

The NMVO will be composed of full members and non-voting affiliate members.

Admission. Candidates for membership may be admitted by the General Assembly on a recommendation of the Board of Directors upon satisfying the Board in writing as to their eligibility and their acceptance of and adherence to the Statutes of the NMVO.

Full Members. The procedure governing application or withdrawal of membership will be regulated in the NMVO Statutes. Any disputes as to whether the membership criteria are fulfilled shall be adjudicated on by an independent third party auditor to be appointed by the Board of Directors.

Full members have the following rights and obligations:

- The right to participate in and vote at the General Assemblies,
- The right to participate in and vote at working groups/task forces as may be established from time to time,

- The right to request an independent audit of System security and performance provided such audits are carried out only at reasonable intervals and at the expense of the requesting member,
- The obligation to pay a yearly membership fee,
- The obligation to act in compliance with the Statutes,
- Any other right or obligation that may be decided by the General Assembly or the Board.

Affiliate Members. The following entities are eligible for affiliate membership of the NMVO:

1. Other associations of stakeholders representing users or potential users of the System for authentication purposes.

Affiliate members have the following rights and obligations:

- The right to receive notice of all General Assemblies and the right to attend such meetings in an observer capacity,
- The right to be consulted on the activities of the NMVO as may be decided from time to time by the General Assembly,
- The obligation to pay a yearly affiliate membership fee as may be foreseen pursuant to section 6.4 below,
- The obligation to act in compliance with the Statutes,
- Any other right or obligation that may be decided by the General Assembly or the Board.

6.3. Governance of the NMVO

The work of the NMVO will be carried out by:

6.3.1 The General Assembly

Meetings of the Members. The General Assembly shall hold an ordinary session once a year. Extraordinary General Assemblies can be convened at the request of at least two-thirds of the Constituency votes.

Quorum. There shall be a quorum for the transaction of any General Assembly when a two-thirds majority of Constituencies are represented in person or by written proxy at the date

of the meeting. Each Constituency shall make known the identity of its representative empowered to vote at the General Assembly at least five days prior to each General Assembly.

Management by the Members. The General Assembly shall have full powers to determine the overall policies, objectives, procedures, methods and courses of action required to achieve the remit of the NMVO. The General Assembly shall determine which decisions may be delegated to the Board. It shall review annually, as an agenda item and based on a report of the Board, the adequacy of the NMVO structure, and resources available, in light of its objectives.

Decisions. General Assembly decisions shall include:

1. Approval of the annual budget and the annual accounts,

2. Amendment of the Statutes,

3. Appointment and dismissal of a Chairperson, a Vice Chair and a Treasurer on proposal from the Board,

4. The admission of new members and the revocation of membership rights in accordance with the procedure foreseen at section 6.5 below in the event of (i) liquidation or bankruptcy, or (ii) non-payment of fees due, or (iii) absence of a sufficiently representative membership, or (iv) other conduct not compatible with the aims of the NMVO,

5. The timing and manner of effecting the dissolution and liquidation of the NMVO.

Voting. Each Constituency shall have one vote at any General Assembly but is permitted to send as many representatives as deemed necessary to the General Assembly. In the event that any one Constituency is represented by more than one full member, that Constituency shall come to a fair and reasonable solution as to how the Constituency vote will be exercised and shall provide the Chairperson of the NMVO Board with a full description of the solution agreed.

Decisions at the General Assembly shall be adopted by at least two-thirds of the votes cast by Constituencies present or validly represented unless any Constituent validly exercises a veto right in any of the circumstances listed below. Failure to vote shall be considered as an abstention.

Veto rights. Each Constituency shall have the following veto rights in relation to the General Assembly's decision-making powers after due consultation and debate and provided the exercise of such rights results in an outcome that is compliant with applicable laws:

- Deflecting from the EMVO Requirements (without prejudice to those mandated by the Directive or Delegated Acts) including changes to the agreed principles on data access and management, provided these latter changes concern the respective Member's own data;

- Increases in NMVO membership fees above 15% on a year on year basis;

- Each Constituency representing the Manufacturing Authorisation Holder stakeholders (those being (a) the research based pharmaceutical companies, (b) generic pharmaceutical companies, and (c) pharmaceutical parallel distributors shall have a veto right in relation to increases in the NMVO annual budget above 20% on a year on year basis save where such increase is necessary to comply with the EMVO Requirements.

Attendance Rights. Affiliate Members shall be admitted to the General Assembly in an observer capacity as shall representatives of the European Commission and the competent national authorities. The Board of Directors may agree to admit other external observers.

6.3.2 The Board of Directors

Meetings. The NMVO shall be managed by a Board of Directors that shall meet at least three times a year. An extraordinary session of the Board shall be convened if at least half of the directors request such a meeting.

Composition. The Board shall comprise one delegate from each full member or such other number as may be decided by the General Assembly upon a proposal of the Board. No member can be represented by more than one delegate.

Quorum. The Board shall validly meet and deliberate when at least two Constituencies are represented in person or by written proxy.

Management by the Board. The Board shall ensure that the NMVO operates in compliance with all relevant laws and the governing Statutes. The Board shall have all powers except those reserved to the General Assembly to implement overall policies, objectives, procedures, methods and actions of the NMVO that shall include the following:

1. To propose to the General Assembly a Chairperson, a Vice Chair and a Treasurer from amongst its full members,

2. To ensure minutes are kept of all Board meetings and to communicate decisions to all members,

3. To prepare a budget and the annual accounts,

4. To make recommendations to the General Assembly as to the membership fees payable by full and affiliate members,

5. To delegate the daily management or part of its powers to one or more directors including the ability to appoint a Managing Director or General Manager of the NMVO, or to outsource clearly defined projects to third parties such as the EMVO,

6. To issue, as deemed necessary, internal rules of procedure compatible with the Statutes in order to ensure the proper functioning of the NMVO,

7. To supervise implementation and to monitor on a continuous basis System performance issues, incident management, operational changes, configuration management, and data access security and to report on such issues to the General Assembly,

8. To propose policies to the General Assembly in relation to the implementation and development of the System,

9. To make written and duly reasoned recommendations to the General Assembly as to the admission of new members and the termination of membership as it considers appropriate.

The mandate of the Board members shall be two years. The mandate is subsequently renewable twice and is not remunerated. The directors have a duty of stewardship toward the common interests of the members.

Decisions. Each Constituency shall have one vote at any meeting of the Board and shall make known the identity of its representative empowered to vote at the Board.

Voting: The following acts are subject to unanimous approval for as long as there are three Constituencies, or by votes cast representing at least two-thirds of Constituencies in the event there are more than three:

1. Approving capital expenditure in excess of €100,000 (excluding any payments due to the ICT systems provider(s) that shall be governed by separate contract),

2. Changing the terms of the service agreements with the European Hub,

3. Appointment and removal of the Chair and Vice Chair/Managing Director/Treasurer.

All other decisions shall require a simple majority of the votes of the Constituencies present at a Board meeting or validly represented.

Failure to vote shall be considered as an abstention.

Officers. The NMVO shall have as officers a Chair, Vice Chair and Treasurer.

The Chair and Vice Chair shall ensure that the Board is effective in its tasks of setting and implementing strategy. They will preside over meetings of the Board and the General Assembly and carry out the policies and instructions of both. Their main responsibilities shall include:

1. To convene all meetings of the General Assembly and the Board,
2. To carry out the policies decided by the Board and to propose to the Board appropriate plans and manage their execution once approved,
3. To establish and maintain proper communications with all members,
4. To represent the NMVO and its members to third parties, including governmental and regulatory bodies.

A Managing Director or General Manager may be appointed by the Board who shall be responsible for carrying out those management tasks delegated by the Board.

6.4. Revenue/Subscriptions

Each Constituency will be liable to pay a fixed equal annual fee (until its third year of being fully operational) as determined by the General Assembly on a recommendation of the Board, to cover the organisational and running costs of the NMVO. In the event that any one Constituency is represented by more than one full member, that Constituency shall come to a fair and reasonable solution as to how its annual fee will be attributed between its members.

Affiliate members may be asked to pay an annual fee to cover the costs of their participation in the General Assembly.

Payment shall be made not later than 60 days of a request for payment.

The Board may approve new or additional subscriptions or contributions from full members to fund special projects, members' attendance at the General Assembly or other *ad hoc* sums for items not covered by the annual budget, as well as increases in the annual membership and the usage fees, for as long as these are proportionate and in line with achieving the objectives of the NMVO.

6.5. Dispute Resolution, Applicable Law and Jurisdiction

The Board may but will not be obliged to, propose to attempt to resolve in an amicable manner any dispute concerning the validity, interpretation, enforcement, performance or termination of the Statutes, membership, and usage rights through mediation or through any other form of alternative dispute resolution.

All issues, questions and disputes concerning the validity, interpretation, enforcement, performance or termination of the NMVO's Statutes which cannot be resolved by the Board shall be governed by and construed in accordance with National law. No effect shall be given to any other choice of law or to any conflict-of-laws rules or provisions that would result in the application of the laws of any other country.

The NMVO may take any and all action before any competent court to reclaim monies due by users or members. Otherwise, any dispute which cannot be resolved by the Board concerning the validity, interpretation, enforcement, performance or termination of the Statutes, membership, and usage rights shall be exclusively and definitively settled by binding arbitration pursuant to the Rules of Arbitration, by three arbitrators appointed according to those rules. The language of the arbitration shall be XXX. The place of arbitration shall be XXX. Nothing contained in this clause shall limit the right of any member or user to seek from any court of competent jurisdiction, pending appointment of an arbitral tribunal, interim relief in aid of arbitration or to protect or enforce its rights.

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7. Appendix 1: EMVO Requirements