

Memorandum of Understanding

between

EFPIA

EGA

PGEU

GIRP

EAEPIC

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

17 October 2014

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Table of Contents

Definitions

1.	Introduction.....	4
2.	A Pan-European Model of Product Verification – 10 Core Principles	6
3.	System Architecture and Ownership	10
3.1.	Introduction	10
3.2.	System Ownership	10
3.3.	Key Tasks of the EMVO	11
3.4.	Data Storage at the European Hub	11
3.5.	System Interoperability Expectations.....	12
4.	Product Verification Data Access and Visibility – Requirements to be Incorporated in the Delegated Acts.....	14
4.1.	Product Safety Features.....	14
4.2.	Data Serialisation	14
4.3.	Ownership of and Access to Data	15
5.	Access Management and System Architecture.....	17
5.1.	Controlling Entry and Exit.....	17
5.2.	The “Check Out” Process.....	17
5.3.	The Subsequent “Check In” Process.....	18
5.4.	Access by Wholesalers	19
5.5.	Dispensing Pharmacies, Hospitals and Doctors	19
5.6.	Use of Data for Other Purposes	19
6.	Organisational and Governance Structure: Key Parameters.....	21
6.1.	Remit	21
6.2.	Membership	23
6.3.	Governance of the EMVO	24
6.4.	Revenue/Subscriptions	28
6.5.	Dispute Resolution, Applicable Law and Jurisdiction.....	28

Definitions

AESGP – Association of the European Self Medication Industry.

Constituency(ies) – the stakeholder communities representing material users of the System that are entitled to full membership of EMVO, 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.

EAEPC - European Association of Euro-Pharmaceutical Companies representing Europe's licensed parallel distribution industry comprising licensed wholesalers who supply ("export") and/or purchase ("import") and repackaged legitimate European medicines in free circulation.

EFPIA – European Federation of Pharmaceutical Industries and Associations.

EGA – European Generic Medicines Association.

EMVO – European Medicines Verification Organisation – an international not-for-profit association established by stakeholders to manage a European Hub that will connect to a series of national or regional data repositories that will serve as the verification platforms to allow the authenticity of Medicines anywhere in the supply chain in the EEA to be checked. Collectively, the European Hub and the national/regional 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 and that bear the date and initials of each Full Member, or the initials of a person duly authorized to represent a Constituency in the event that one Constituency comprises more than one Full Member, elaborating on the basic cost allocation and other principles and technical elements of the System.

EMVS – European Medicines Verification System – the technical components of the overall European Stakeholder Model (ESM), i.e. the actual operational system.

ESM – European Stakeholder Model – the overall vision of the stakeholders. This term covers the underlying principles contained in this Memorandum of Understanding (MoU), in the EMVO Requirements as well as the cost allocation model to be agreed amongst the Constituencies representing Manufacturing Authorisation Holders.

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 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.

GIRP – European Association of Pharmaceutical Full-Line Wholesalers

HOPE – European Hospital and Healthcare Federation

Manufacturing Authorisation Holder(s) - for the purposes of this paper, this term includes both manufacturers and 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 Manufacturing Authorisation Holder.

Marketing Authorisation Holder(s) - the company identified on the Marketing Authorisation for any given product in any given country in which the System applies.

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 Medicines¹ and the related Delegated Acts adopted thereunder.

PGEU - Pharmaceutical Group of the European Union representing community 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).

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 risk assessment. It aims to prevent falsified medicines reaching patients without prior detection by competent authorities and/or the relevant stakeholders in the supply chain.

The European Commission will define the mechanics of how this system will work in Delegated Acts that are to be adopted by mid 2014. The Delegated Acts 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 of each dispensed pack.

EFPIA, EGA, PGEU, GIRP and EAEPIC (the “Parties”) fully support this legislation and will be pleased to work with the Commission 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 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 stakeholders.

This document is not legally binding but is an expression of the fundamental policy principles agreed between the Parties who continue to work together in defining the EMVO Requirements that will govern the operations of the System as well as the cost allocation model to be agreed between Manufacturing Authorisation Holders Constituencies. Those documents will form an integral part of this Memorandum of Understanding as and when they are adopted. Formal adoption of this Memorandum of Understanding by each of the Parties is conditional on their having agreed them.

The System is composed of a European Hub connected to a series of national or regional data repositories that serve as the verification platforms that pharmacies and other authorised parties can use to check a product’s authenticity. The System will be interoperable between the various countries and will allow for the reconciliation of parallel distributed products through the European Hub. The European Hub will also allow the performance of key tasks such as the proper handling of multi-country packs. Specifically, the System will constitute an end-to-end real time verification tool enabling: (i) Manufacturing and/or Marketing Authorisation Holder to upload serial data; (ii) healthcare professionals throughout the supply chain (i.e. wholesalers, pharmacists or hospital pharmacists, dispensing doctors and parallel distributors) to verify that a product is genuine; (iii) parallel distributors to decommission individual codes and upload new codes (linking the new code to the old code at batch level); and (iv) dispensing pharmacists, doctors and hospital pharmacists to decommission individual codes.

The proposed System should accommodate different needs in different regions but be based on common principles to ensure mandatory coding and verification of products in line with a harmonized coding system.

Properly structured, the proposed System ensures verification of product authenticity by professionals at the point of dispense and provides a modern technology solution that will enhance patient safety as well as having the potential to generate additional spillover benefits in the future. Subject to agreement between the stakeholders at the national level, potential efficiencies include the possibility of allowing for the automated checking of expiry dates, better pharmacovigilance, 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 improved stock management processes for pharmacies.

The European Hub will be established and managed by a not-for-profit stakeholder organisation referred to as the “EMVO” (European Medicines Verification Organisation). This Memorandum focuses primarily on the structure and governance of the EMVO. It also includes a number of key principles and features that will govern the national and regional repositories in order to ensure interoperability of the System at a pan-European level. Specifically, it sets out the requirements that the Parties consider ought to be included in the Delegated Acts in order to close security loopholes and to achieve these efficiencies in a proportionate and cost-effective manner.

It explains, in some detail, why fully secure product verification in the interests of patient safety requires a system that ensures:

- Limited and differentiated access to the system by categories of registered stakeholders depending on the nature of their handling of products,
- The necessary transparency in the supply chain as to exit and entry points to allow the detection of falsified medicines and enable a clear allocation of responsibility/liability in the supply chain in accordance with applicable laws,
- The timely reconciliation of parallel distributed products allowing verification that the number of doses checked out from a national or regional system is greater or equal to the number of doses subsequently checked in to another national or regional system, subject to agreed data access principles.

The Parties fully accept the need for a strict framework for data access, control conditions and database operational rules. Access usage will have to be agreed between manufacturers, wholesalers, pharmacists and parallel distributors and, where appropriate, other stakeholders, including EGA, HOPE and AESGP, 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. **Guaranteeing continuity of protection throughout the entire supply chain:**

- As regards the obligations on the parallel distributor 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 parallel distributor 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. **Ensuring a single coding and identification system on each pack across the EU:**

- 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 code² 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 product identification (including national code) and batch numbers, including suffixes where required by parallel distribution, providing additional patient safety enhancements.

3. **Ensuring product verification database systems can work together across the EU:**

- 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 or regional 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. Verifying every serialised pack at pharmacy level:

- 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 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 dispensing, 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 dispensing. Since the technical challenges of point of dispensing verification 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 dispensing 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 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. Maximising all the potential benefits of mass serialisation:

- 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 belong to the pharmacist or, in relation to wholesaler verification, to the wholesaler or, in relation to 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 dispensing 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 product verification solution proposed 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 be severally responsible for the System.

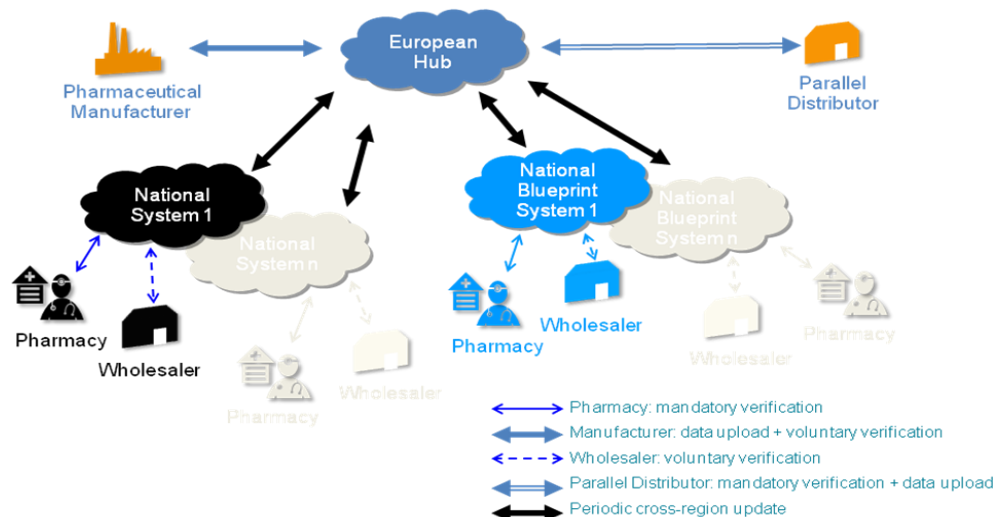
10. Involving other stakeholders

- 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 point of dispensing. 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.



This System comprises a single European Hub connected to a series of national/regional information repositories that serve as the verification platforms that pharmacies or other authorised parties can use to check a product's authenticity. No pharmacy or wholesale level data shall be available on the European Hub. The national/regional repositories are to be set up and run under the control of the respective national stakeholder organisations. The "National Blueprint" system refers to those national/regional repositories where the relevant 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/regional 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. System Ownership

The stakeholder organisations representing Manufacturing Authorisation Holders shall agree an equitable and proportionate means of sharing the upfront costs of establishing the European Hub.

To the extent that the establishment of the System at the level of the European Hub requires any capital investment in equipment or other assets, including any intellectual property rights, such assets will be the property of the EMVO. Ownership of assets shall not in itself confer any rights to the data processed by the system whether at the level of the European Hub or at the level of any national/regional repository. (Data ownership is discussed separately at section 4.3 below.) Capital investments subsequently made by other stakeholders in relation to the System (such as the acquisition of

scanners and related software) shall be owned by the respective stakeholders making those investments.

3.3. Key Tasks of the EMVO

The EMVO will manage the European Hub that will constitute:

- A centralised location for the storage of product Master Data,
- A single entity from which regional/national systems can obtain revised/new product serialisation data,
- A means by which multi-country packs can be systematically marked as 'unavailable' in all affected markets once a pack has been dispensed in one market,
- A mechanism by which parallel distributed product can be reconciled at a batch level,
- A central point from which product recall actions can be initiated (without prejudice to the ability of the responsible manufacturing authorisation holder_ to initiate a recall in accordance with established recall procedures at national level),
- A central point from which those alerts that cannot be handled solely at the national level can be managed; the System design will generate alerts in case the automatic checking procedures detect an Exceptional Event.

3.4. Data Storage at the European Hub

The operations of the European Hub will entail the following data storage functions:

- A repository for manufacturing Master Data needed to run the verification system whilst minimising the data upload requirements from both the manufacturer to the hub and from the hub to the regional systems,³
- A means of cross-referencing the Master Data with that employed by the various national/regional repository systems,
- A repository to allow parallel distributed products to be reconciled, retaining knowledge of which batches, or parts thereof,_went to what location, to assist with recall activities and with multi-country pack distribution,

³ Although some overlaps are likely, this data set will not be in competition with any data sets kept at national level for other purposes, such as reimbursement or pharmacovigilance.

- A store of transient stock data to allow cross border transactions to be fully reconciled,
- A volatile store to allow uploaded serial data from the manufacturing entity to be held ready for distribution to the relevant national systems; once transferred, these data will be removed from the European Hub,
- A repository containing access credentials and configuration information such as the electronic locations of the various national systems, etc.

3.5. System Interoperability Expectations

In order for the System to operate efficiently at the lowest cost point possible, there are a number of requirements that both the EMVO and each of the national/regional repositories will have to agree as fundamental and binding in bilateral service level agreements. These are likely to include the following (non-exhaustive) requirements:

- The application interface used to access the European Hub. It will be the responsibility of the EMVO to ensure that this interface is well documented, evolves (as required), and is provided with relevant support and test environments. The interface will include:
 - the definition and format of any files and data exchanged,
 - strict conditions governing verification requests by MAH, especially those involving a large volume of serial numbers,⁴
 - the method and format for unsolicited data exchanges (e.g. recall notification, intra-EU parallel distributed product notifications, multi-regional pack sale),
- System availability, performance and security standards, time to fix, maintenance schedules, etc.,
- Each user will be held responsible for the ‘cleanliness’ of its own data and the European Hub will be configured to deny acceptance of any data that do not meet strict, yet to be defined, criteria in order to avoid the effectiveness and ultimately the ‘reputation’ of the hub being damaged by rogue data,
- Each participating MAH will be contractually required to use the European Hub for all transactions that result in Medicines being placed into any country/region in the European Economic Area (EEA) for sale,

⁴ Since MAH may only have indirect access to a national repository through the European Hub, there is a need for pre-agreed conditions under which such requests, and in particular “bulk verification” requests, will be transferred from the hub as well as response times for the national repositories to respond to such requests.

- The EMVO will provide a focal point of contact for regulatory authorities to facilitate examination of pack/batch status. Where the European Hub no longer holds the physical pack data for a given product, it will be possible to identify both the origin and destination of the product batch thus providing a valuable tool to allow for improved effectiveness of post alert investigations.

4. Product Verification Data Access and Visibility – Requirements to be Incorporated in the Delegated Acts

The Directive mandates the introduction of a unique identifier, combined with tamper evident packaging applied to prescription medicines (with limited exceptions), and potentially some non-prescription medicines, as the basic mechanism to exclude the introduction of falsified medicines into the legal supply chain. The proposed stakeholder-governed model incorporates these features into a comprehensive system capable of controlling or monitoring all entry and exit points of the pharmaceutical supply chain.

4.1. Product Safety Features

The Parties will endeavour to agree on appropriate standards for effective tamper evidence, including the identification of what categories of safety features are equivalent, in the interests of ensuring patient safety.

4.2. Data Serialisation

The proposed serialisation System shall hold at least the following essential data components, subject to agreed access principles.

1. Product code,
2. Batch number and, in the case of parallel distributed products, suffixes where appropriate, in addition to a link to the original manufacturer's batch number,
3. Expiry date,
4. Serial number,
5. Product Master Data,
6. The current status of the unique serialisation number (i.e., commissioned, de-commissioned, dispensed),
7. By whom/where a change of status has happened,
8. Time and date of the change of status.

These data are split into two types:

- Static: e.g. product code, expiry date (items 1-5) which do not change, and
- Dynamic: e.g. information reflecting the serialisation number's changing status (items 6-8): as the serial number is loaded, verified, dispensed etc., these events will be recorded.

4.3. Ownership of and Access to Data

Supply chain security cannot be effectively managed without access to data in certain circumstances. In order to maximise patient safety benefits, it is important to ensure that the effectiveness of the System is not compromised by undue restrictions on access to data.

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

The System will not generate any personal data.

4.3.1 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.

4.3.2 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:

4.3.2.1 Negative verification and 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 product. 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 local regulatory authorities will naturally be involved at a national level, each affected manufacturer will 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 are made available under these conditions and the European Hub will be responsible for requesting and receiving such data from the relevant national system(s) in order to provide the requisite level of data abstraction to allow MAH to fulfil their obligations vis-à-vis the regulators.

4.3.2.2 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 repacked parallel distributed products, the original manufacturer's and the new batch numbers being applied by the parallel distributor must be linked in the System to permit rapid and efficient recalls. Again, the European Hub will allow for the appropriate level of data abstraction in terms of what data can be obtained from national/regional repositories and made available to individual manufacturers.

4.3.2.3 System maintenance

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

5. Access Management and System Architecture

5.1. Controlling Entry and Exit

For security reasons, access to the System should be strictly limited on a needs only basis to those stakeholders who physically handle products in the supply chain. Levels of access will vary depending on the nature of the activity as outlined below.

Entry Points: A key feature of the System is to offer a single point of entry for manufacturer data (check in), as mandated by the Directive. Only the MAH can enter serial numbers into the system. That basic information will allow for subsequent verification of the product pack by other stakeholders physically handling product in the supply chain.

Exit Points: The System will only work if exit points are identified and comply with the System in accordance with the agreed procedures. The exit points and rights of access to the System are identified below:

- MAH (check in, check out, verification rights),
- Authorised wholesalers⁵ (verification of authenticity as laid down at section 5.4 below),
- Registered pharmacies, including registered online pharmacies,⁶ hospital pharmacies (check out, verification rights),
- Registered dispensing doctors (check out, verification rights).

In some specific instances there will be a requirement for an “undo” capability within the System where a serial number has accidentally or prematurely been “checked out”, for example, where a product has been prepared for dispense but is not collected by the patient.

5.2. The “Check Out” Process

Once introduced into the System, products must subsequently be “checked out” (meaning that their serialization numbers are to be decommissioned) by the relevant stakeholders in the following scenarios:

- By the MAH in the event of product returns, recalls, accidents, damaged products, the correction of uploading errors in the initial check in phase, unforeseen logistics adjustments, theft of serialisation numbers/packs,
- By the parallel distributor (check out prior to repackaging and subsequent application of new serialisation numbers),

⁵ As foreseen by Article 77(a)(1) and Article 77(b)(4) of the Falsified Medicines Directive.

⁶ As foreseen by Article 85(c) of the Directive.

- By the pharmacists, dispensing doctors/hospitals on dispensation (using scanning technology),
- By wholesalers in the event of (1) destruction by the wholesale distributor or (2) when returned by pharmacists, or (3) individual product sale to another EEA Member State, or (4) their export outside of the EEA/other participating countries.

Unless every individual serialized pack is correctly “checked out” at each of the points listed above, patients will not benefit fully from the safety features. The unique serial number can only provide protection against counterfeits if it is systematically checked out and the status changed on the database to “dispensed” when the product is handed to the patient or repackaged by a parallel distributor.

5.3. The Subsequent “Check In” Process

All participating MAH must commission a new serial number in the systems in the countries of intended sale (“check in”). This will be a highly automated and straightforward process.

Subject to the agreed data access principles, the information to be provided by MAH in the code to be affixed to each pack should include the product identification code (including national code), the expiry date, the originator's batch number,⁷ a suffix or prefix (where the MAH is repackaging), and the new serial number that ensures the product can be matched with the issuing MAH, as well as satisfying the relevant labelling/identification requirements at national level.

A link between the set of newly commissioned serial numbers and the originator's set of serial numbers is necessary to enable the System in a timely manner to reconcile parallel distributed products by verifying that the number of doses 'decommissioned' does not exceed the number of doses subsequently checked in or 'commissioned' into the system.

For practical reasons and reasons of proportionality, the link must be established between a number of decommissioned (checked out) serial numbers from any one production batch of the original MAH, and the number of new serial numbers checked in. This simple rule makes the System as robust as possible in terms of safeguarding patient safety by:

1. Facilitating product verification,
2. Enabling the swift recall of original and repackaged products should that prove necessary for whatever reason,
3. Ensuring that leftover products from individual packs that are assembled into a new pack have the same expiry date.

⁷ This is not a uniform requirement in all Member States currently.

5.4. Access by Wholesalers

Wholesalers will have “read” access for verification purposes. The delivery units containing medicinal products which carry safety features on the outer packaging must be checked by the wholesale distributor. For medicinal products carrying safety features obtained from the Manufacturing Authorisation Holder or the Marketing Authorisation Holder, or a person who is authorized by them to supply these products, the wholesale distributor is, however, deemed to have satisfied the condition above and thereby Article 80(a)(ca) of the Directive. Medicinal products carrying safety features on the outer packaging obtained from other authorised sources must be checked by the receiving wholesale distributor. Similarly, if medicinal products are returned from persons authorized or entitled to supply to the public, the wholesale distributor must verify that they are not falsified or tampered with by checking the safety features on the outer packaging.

The scope and application of the verification process of the safety features at the level of the wholesale distributor will be determined by the Delegated Acts.

The Parties agree to continue the dialogue to develop ways of working in the case of events which require 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 Doctors

Pharmacies will have “read” access for verification purposes. The decommissioning of packs that are dispensed by registered pharmacies (including registered on-line pharmacies), self-dispensing doctors or hospital pharmacies through the use of scanners must be mandatory so that the system is closed and effective in terms of ensuring patient safety.

5.6. Use of Data for Other Purposes

In addition to providing all stakeholders with more detailed information on counterfeit products found on the market, the implementation of the proposed System that allows 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.

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 EMVO shall be established as an international not-for-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 EMVO will be governed by the principles outlined in this chapter. These principles may form the basis for the governance of national/regional repositories to be agreed on a case-by-case basis between the relevant stakeholders.

Minimal assets will be held by the EMVO and the project will be outsourced to one or more ICT suppliers in a project financed type programme governed by a contract conferring control rights tantamount to ownership rights to the EMVO.

The EMVO will do more than simply oversee an ICT system collecting and processing data. It will also be responsible for setting standards, ensuring quality, system availability, and full accountability to all affected stakeholders.

An initial group of Manufacturing Authorisation Holders may choose to make the necessary capital investment in a European Hub trial phase to be able to offer an interface to national systems even before the EMVO is established. Any trial phase will operate in line with the principles agreed in this Memorandum of Understanding. Ownership and management of such interface, including any ICT service contract, shall be transferred to the EMVO upon its establishment. The Parties desire the EMVO to be self-financing as of the fourth year of operation without prejudice to its not-for-profit mandate.

6.1. Remit

The EMVO will establish and manage the European Hub that will be interoperable with national/regional repositories that serve as the verification platforms hosting the data necessary to enable pharmacies or other authorized 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 EMVO will ensure effective protection of patient safety by allowing proper handling of multi-country products via an automated system that also allows for the reconciliation of parallel distributed products over the lifespan of a batch. It will facilitate negotiations amongst stakeholders with a view to concluding standard binding agreements governing the relationships between the EMVO and the respective organisations responsible for the national/regional repositories. 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 EMVO will be responsible for:

- Developing the criteria to be used in the design of the relevant ICT systems and outsourcing the design and operation of such systems to one or more reputable ICT service providers,
- Setting technical standards and ensuring overall quality (on matters such as the interfaces to and from the European Hub, data cleanliness, the availability and responsiveness of the System, the appropriate level of security to be respected, etc.),
- Defining specifications and standard operating procedures for:
 - the regular operation of the System,
 - the identification and handling of Exceptional Events as well as the requisite automated filtering algorithms, the elaboration of severity classes and appropriate follow-up procedures in specific scenarios that shall form part of the Foundation Documents,
- 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,
- Managing the IT, contractual and human interfaces between the European Hub and each national/regional system,
- Centrally operating any national/regional repository at the request and on the behalf of the relevant national stakeholders,
- Providing regular activity reports to members on issues such as System functioning and performance, and generating statistical reports for the purposes of aiding communications on the functioning of the System,
- 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,
- Facilitating the determination of appropriate national cost-sharing models including for the provision of centrally operated systems,
- Invoicing and collecting membership fees and any other monies due,
- Concluding and administering user agreements and related fee and payment arrangements,
- Liaising with the relevant European and national regulatory authorities on the use of the System to facilitate product recalls and other patient safety issues,

- 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 EMVO 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.

6.2. Membership

The EMVO 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 EMVO.

Full Members. EFPIA, EGA, EAEPC, PGEU and GIRP and all other pan-European associations representing any Constituency in the supply chain that is a material user of the System are eligible for full membership for as long as their members are operating in at least 16 EEA countries and represent at least 25% of their respective Constituency's EEA-wide market share by transactional volume as measured by a recognised, reputable source of market data. Should any full member, once admitted, fail to satisfy these membership criteria, they shall be entitled to maintain full membership rights for one additional year after which, if the criteria remain unfulfilled, they shall no longer qualify as a full member but may elect to become an affiliate member subject to the discretion of the General Assembly to maintain full membership rights where otherwise any Constituency would no longer be represented. The procedure governing withdrawal of membership will be regulated in the EMVO 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 Assembly meetings,
- 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 EMVO:

1. A representative of each national or regional repository, including a representative and duly appointed delegate from any centrally operated national system,
2. Other associations of stakeholders at a national or a pan-European level 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 Assembly meetings and the right to attend such meetings in an observer capacity,
- The right to be consulted on the activities of the EMVO 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 EMVO

The work of the EMVO will be carried out by:

6.3.1 The General Assembly

Meetings of the Members. The General Assembly shall meet in 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 EMVO. 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 EMVO structure, and resources available, in light of its objectives.

Decisions. Decisions at General Assembly meetings 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 a proposal of 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 EMVO,
5. The timing and manner of effecting the dissolution and liquidation of the EMVO.

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 EMVO Board with a full description of the solution agreed.

Decisions at General Assembly meetings 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:

- Changes to 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;
- Changes to the agreed principles on the cost allocation model that serve as a guidance for charging Manufacturing and/or Marketing Authorisation Holders on an annual basis for the use of the System as set out in the EMVO Requirements;
- Increases in EMVO 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 EMVO 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 EMVO 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 EMVO 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 EMVO 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 (1) the membership fees payable by full and affiliate members, and (2) the service fees to be charged to MAH in accordance with and proportionate to each national repository system's effective use of the European Hub in the preceding year,
5. To delegate the daily management or part of its powers to one or more directors including the ability to appoint a Managing Director of General Manager of the EMVO, or to outsource clearly defined projects to third parties,

6. To issue, as deemed necessary, internal rules of procedure compatible with the Statutes in order to ensure the proper functioning of the EMVO,
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 each 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 national/regional/centrally organised repositories,
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 EMVO 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 organize on an annual basis a meeting with representatives from the national/regional repositories with a view to ensuring an efficient governance of the system,
5. To represent the EMVO 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 EMVO. The Parties envisage that the initial running costs of the EMVO will not exceed €1 million in the first year and that costs thereafter will be kept under regular review. 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 General Assembly meetings 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 EMVO.

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 EMVO's Statutes which cannot be resolved by the Board shall be governed by and construed in accordance with Belgian law. No effect shall be given to any other choice of law or to any conflict-of-

laws rules or provisions (Belgian, foreign or international), that would result in the application of the laws of any country other than Belgium.

The EMVO 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 of CEPANI, by three arbitrators appointed according to those rules. The language of the arbitration shall be English. The place of arbitration shall be Brussels. 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.
