Memorandum of Understanding

between

- **Association of Innovative Pharmaceutical Industry (AIFP)**
- **Czech Association of Pharmaceutical Companies (ČAFF)**
- **Association of European Medicines Distributors (AEDL)**
- **Association of Medicines Wholesalers (AVEL)**

(hereinafter the "Stakeholders")

on the creation and management of the medicines verification system in the Czech Republic

from December 2015

Purpose of the Memorandum

The purpose of this Memorandum is to contribute to a mutual understanding between the Stakeholders regarding the necessary steps that must be taken in connection with the adopted European, so-called anti-falsification, legislation, in particular

- Directive 2011/62 of 8 June 2011 amending Directive 2011/83/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, and
- The delegated act adopted based on this Directive, specifically the Commission Delegated Regulation of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (document No. C (2015) 6601 final).

The goal of this Memorandum is to provide for the maximum involvement of all stakeholders in this legislation and, by reaching an understanding, to contribute to the fulfillment of the requirements laid down in the aforesaid European legislation.

This Memorandum is not legally binding. It is the Stakeholders' mutual understanding of the principal matters.

Definitions

Stakeholders – entities representing the System users entitled to a full-fledged membership in the National Medicines Verification Organization (NMVO), which includes (1) the manufacturers of original medicinal products, (2) the manufacturers of generics, (3) the manufacturers of OTC medicinal products, (4) the distributors of medicinal products, (5) pharmacies, (6) hospital pharmacies and (7) the parallel distributors of medicinal products.

Stakeholders – on a national level include:

- Association of Innovative Pharmaceutical Industry (AIFP)
- Czech Association of Pharmaceutical Companies (ČAFF)
- Association of European Medicines Distributors (AEDL)
- Association of Medicines Wholesalers (AVEL)

EMVO – **the European Medicines Verification Organization** – a non-profit organization founded by European interest groups and associations in order to protect the legal supply

chain against the infiltration of falsified medicinal products. The organization's goal is also to manage the European hub that shall be linked to national and regional data repositories and shall serve as a verification platform allowing to verify the authenticity of medicinal products anywhere in the supply chain in the European Economic Area. The European hub and national data repositories are collectively also referred to as the "European Medicines Verification Organization (EMVO)" or the "System."

ESM (European stakeholder model) – the model designed as a way to meet the safety feature requirements pursuant to Directive 2011/62/EU.

ICT – information and communication technology.

Interoperability – the ability of different systems to cooperate with each other, to provide services to each other and to achieve a mutual effective collaboration.

Unique identifier – a sequence of numeric or alphanumeric characters unique to a given pack of a medicinal product.

The unique identifier consists of the following data elements:

- **The product code** – a code allowing an identification of at least the name, the common name, the pharmaceutical form, the strength, the pack size and the pack type of the medicinal product bearing the unique identifier;
- **The serial number** – a numeric or alphanumeric sequence of maximum 20 characters generated by a deterministic or non-deterministic randomization algorithm;
- **The national reimbursement number or other national number** identifying the medicinal product, if required by the Member State where the medicinal product is intended to be placed on the market;
- **The batch number**;
- **The expiry date**.

Medicinal product – medicinal products bearing safety features in compliance with the Directive on falsified medicinal products[1] and related delegated acts adopted in compliance with the Directive.

MAH – a marketing authorization holder of a medicinal product.

Incident – any indication raising a suspicion that a given medicinal product may be falsified or the System attacked or that some other problem disallowing a regular or continuous use of the System occurred. An incident includes e.g. a failed verification/checking (because the unified identifier is not in the System or is displayed as already issued or decommissioned e.g. because the production batch has been recalled), an infiltration attempt by an unauthorized person or any other activity indicating that the system has been attacked. Incidents shall be escalated and

[1] Directive 2011/62 of 8 June 2011 amending Directive 2011/83/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 (Official Bulletin 2011 L 174/74).

assigned relevant procedures in the Founding Documents.

NMVO – **National Medicines Verification Organization** – a national non-profit legal entity founded by the Stakeholders with the goal to create and manage the Czech data repository that shall be linked to the European hub. It shall serve as a verification platform allowing to verify the authenticity of medicinal products anywhere in the supply chain in the European Economic Area. The European hub and national data repositories may be collectively also referred to as the "European Medicines Verification Organization (EMVO)" or the "System."

Packaging – for the purposes of this Memorandum, where reference is made to packaging, it shall apply, in compliance with the aforesaid delegated act, to outer packaging or to immediate packaging if the medicinal product has no outer packaging.

Verification – checking that a given medicinal product has the same data in the national database and in the two-dimensional barcode on the packaging.

EMVO requirements – the fundamental documents that are explicitly marked as "EMVO: EMVS Requirements," are a part of the founding documents of the European Medicines Verification Organization (EMVO) and specify the allocation of costs of the EMVO's activity as well as other principles and technical elements of the System.

Implementing Regulation – the delegated act adopted based on this Directive, specifically the Commission Delegated Regulation of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (document No. C (2015) 6601 final), which is not in effect as of the signing day of this Memorandum since, in compliance with Article 290 (2) of the Treaty on the Functioning of the European Union, the European Parliament or the Council may raise objections. In compliance with Article 121c of Directive No. 2001/83/EC, the European Parliament or the Council may object to a delegated act within a period of 2 months from the date of notification (the European Parliament or the Council may extend that period by 2 months).

Serialization – the process of furnishing a medicinal product with the unique identifier.

Sequenced medicinal products – medicinal products bearing the unique identifier

Participant – a member of the Stakeholders or any other user of the System, or an involved party, including state authorities and institutions.

Outer packaging – in compliance with the definition in Directive 2011/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use, outer packaging means packaging into which the immediate packaging is placed.

Immediate packaging – in compliance with the definition in Directive 2011/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use, means the container or other form of packaging immediately in contact with the medicinal product.

Manufacturer – for the purposes of this document, means the manufacturers as well as the parallel distributors of medicinal products that repackage medicinal products, but does not include suppliers and sub-suppliers that are involved in the production process but are not responsible for placing medicinal products on the market. In order to eliminate any doubts, a manufacturer that hired a supplier or sub-supplier to manufacture in its stead shall be considered a manufacturing authorization holder.

Decommissioned medicinal product / "decommissioned" – packaging status, except for the status "Available."

Founding documents – the fundamental technical and legal documents that shall be approved prior to the foundation of the NMVO and shall repeat the Stakeholders' agreement about the architecture and operation rules of the System, including agreed use principles, data validation, response time, the handling of Incidents and System-related processes, as well as operation and safety requirements.

1. Introduction

The Directive on the falsification of medicinal products implements mandatory and harmonized safety features of packaging, which shall clearly indicate whether or not it was tampered with, as well as unique identifiers, which shall be used in all medicinal products subject to prescription, except for those specified in the Directive. The goal of the Directive is to make sure that falsified medicinal products do not enter into the legal supply chain and are not dispensed to patients. The Implementing Regulation defines the characteristics and technical specifications of the unique identifier that enables to identify every packaging and the availability of national databases of medicinal products or repositories that shall allow to verify the authenticity of every dispensed packaging.

The Stakeholders follow this legislation and shall actively cooperate with the EU Commission and the competent national authorities in creating an effective system in the interest of safety of Czech patients. This is why the Stakeholders of the Memorandum cooperate with each other in order to jointly develop and implement an effective system of verification of the authenticity of medicinal products that they shall operate on a non-profit basis in a way to justify the financing of related costs by the relevant Stakeholders.

The cost of the system of verification of the authenticity of medicinal products shall be borne by the manufacturing authorization holder of medicinal products bearing the safety features specified in Article 54a (e) of the Directive, and other participants shall pay such costs based on the principles agreed in the EMVO cost allocation model. The System may not be operated to generate commercial profits.

The Stakeholders have agreed to create a comprehensive framework for the implementation of the Directive that shall lay down, among other things, access to data, verification conditions and operation rules of the national database or data repository.

The Czech database shall be linked to the Europeans system consisting of the European hub that is linked to many other national repositories. These repositories form a platform for the participants to verify the authenticity of every packaging of a medicinal product. The European system shall be interoperable between individual Member States and shall work for all medicinal products that are required to bear safety features.

The System must be able to handle the changing needs of different Member States and shall be based on the common EU platform that shall provide for a harmonized coding system.

The integrity of the anti-tampering device and the authenticity of the unique identifier may be immediately verified within the repository system from the production place all the way to the dispensing place by:

1. The manufacturers that shall enter at least the following information into the repository system:
    a) The data elements of the unique identifier;
    b) The coding system of the medicinal product code;
    c) The name and the common name, the pharmaceutical form, the strength, the pack size and the pack type of the medicinal product;
    d) The Member State(s) where the medicinal product is intended to be placed on the

market;

e) The record-identifying code, if applicable;
f) The name and address of the manufacturer placing the safety features;
g) The name and address of the marketing authorization holder;
h) The list of distributors that the marketing authorization holder authorized based on a written agreement to store and distribute, on its behalf, the medicinal products that are subject to its marketing authorization.

2. The supply chain entities (distributors, pharmacies, parallel distributors of medicinal products, etc.) that use scanners to verify the authenticity of packaging;

3. The parallel distributors of medicinal products that decommission coded packaging and entering new codes;

4. The entities that change the packaging status in the database to “dispensed” when dispensing medicinal products to patients.

The Stakeholders fully understand the need for a comprehensive framework for the implementation of the Directive that shall specify, among other things, access to data, verification conditions and operation rules of the Czech database. All Stakeholders shall have to agree on such access and use.

2. All-European Model of Verification of Medicinal Products – 10 Fundamental rules

The Stakeholders have agreed that the framework for the implementation of the Directive in the CR must be in compliance with the following rules:

1. Guaranteed continual protection in the entire supply chain:

- As to the obligation of the parallel distributors of medicinal products to replace mandatory safety features in the European system, the parallel distributors of medicinal products must decommission the original unique identifier of packaging in the database and enter a new one. The new unique identifier must be linked in the database to the original unique identifier on a batch level so that the medicinal product could be traced back in case of a recall or other safety problems.

2. Unified system of coding and identification of every packaging in the entire EU:

- Since medicinal products move across state borders, every effective coding and identification system must ensure the exchange of information between the EU Member States. This is why, the entire EU must have a harmonized standard coding system that shall enable to include relevant national codes of medicinal products.

- The Stakeholders shall code all select medicinal products with the two-dimensional barcode[2] carrying the unique identifier. It shall be possible to verify this barcode in the database. The dispensing persons (in particular pharmacists) shall be thus able to verify the status of every packaging prior to its dispensing to the patient. The unique identifier of the barcode shall include the expiry date as well as the identification of the medicinal product (including the national code) and the batch number.

3. Compatibility of the Czech medicines verification system with the other EU medicines verification systems:

- In addition to using the joint standard for the identification of medicinal products, all national database systems, including the Czech system, must provide for mutual cooperation and the exchange of information so that every pharmacist and distributor in each Member State could check whether the given packaging has already been dispensed, regardless of the country of its origin.

- The national database systems must meet the equivalent quality requirements.

4. Verification of every packaging of a sequenced medicinal product by a pharmacy:

- All supply chain participants must ensure the safety and authenticity of medicinal products supplied to patients.
- The verification of every packaging of a medicinal product by a pharmacy at the dispensing place, with the link to the distributors and parallel distributors of medicinal products, is a robust and cost-effective way of increasing patient protection.

[2] Data matrix code ECC 200

- The safety features shall not benefit the patient unless every sequenced packaging of a medicinal product is verified at the dispensing place. The unique identifier can protect against falsification only if it is routinely checked in the repository system and as soon as the medicinal product is dispensed to the patient, its status in the database shall be changed to "decommissioned."

- The systems must be set up in a way so that pharmacists could verify medicinal products upon the moment they are dispensed to patients or, in compliance with Article 25 (2) of the Implementing Regulation, at any time they are in a pharmacist's physical possession.

- The process of verification in a pharmacy must be practically immediate in order to ensure an effective work procedure in the pharmacy and to avoid delays. In order to verify medicinal products with single scan, verification software must be integrated into the existing pharmacy software. The process of verification by distributors must enable to verify medicinal products during their dispatching and to verify returned medicinal products without changing the status in the database. The process of verification by the parallel distributors of medicinal products must also enable to verify medicinal products upon their receipt without changing the status in the database.

- The participants must jointly define the standard procedures for Incidents, such as failed verification, System breakdown, etc. It is necessary to set up a system that shall make it possible to dispense a medicinal product in case of an Incident.

5. Maximalization of all potential benefits of serialization:

- Mass serialization not only makes the prevention of falsification more effective but also provides other benefits. Their maximalization shall promote the use of identification systems and shall become beneficial for all participants.

- Thanks to the coding system, the unique identifier, including the batch number and the expiry date, is machine-readable, which significantly increases patient safety and improves the procedures of medicinal product recalls.

6. Patient safety and the protection of patients' privacy:

- The verification systems are to prevent the falsification of medicinal products and not to obtain access to patient data.

- The manufacturers do not try to obtain access to the personal data of individual patients or to information about their prescribed medicinal products and shall not have access to such data.

- Transaction data belong to a pharmacist or to a relevant distributor, provided that verification is performed by distributors, or to the manufacturing authorization holder that performs this activity in connection with parallel distributors. However, in case of failed verification, recalled medicinal products or an unusual activity concerning a specific

safety feature, it may be necessary to provide other participants (MAH, national authority, etc.) with access to some data as well in order to investigate the Incident in compliance with applicable legal regulations.

- Any further use of transaction data would have to be agreed upon between the participants in compliance with Czech legal regulations.

7. Combination of a safety feature proving the integrity of packaging with the unique identifier:

- The Stakeholders follow the EU Directive's requirement stipulating that the safety features must include the unique identifier that every packaging must bear as well as the anti-tampering device. The verification of the randomized unique identifier appearing on every packaging based on the data in the European or national system at the dispensing place is currently one of the most secured ways of verification of the authenticity of a medicinal product. However, the medicines verification system can guarantee the content of packaging only if the packaging remains intact. The use of the anti-tampering device is an essential part of the medicines verification system.

- The extent and application of the safety features are laid down in the Implementing Regulation that has not come into effect as of the signing day of this Memorandum.

- Use of simple, robust and cost-effective safety features: The proposed solution of the verification of medicinal products must be practical, affordable and technically accessible. It is necessary to avoid unnecessarily complicated and costly solutions.

- The Directive stipulates that the cost of the repository systems shall be borne by the manufacturing authorization holders of medicinal products. The cost of a fully implemented system shall be based on the model that the Stakeholders shall unanimously approve. In order to eliminate any doubts, it is necessary to point out that if the manufacturer and the marketing authorization holder are two different legal entities, the entity entering the data in the system shall be responsible for payment of due user fees.

8. Cooperation in the interest of patient safety:

- The Stakeholders as the key participants in the process of verification are obliged to cooperate with each other in order to create an effective, functioning and efficient system of the protection of patients against falsified medicinal products.

- The medicines verification system must be created and managed by competent participants. These systems must be jointly managed by an independent non-profit organization, and it is necessary to use the current coding environment in different Member States, to satisfy the needs of all supply chain entities and mainly to protect patients.
- Each Stakeholder shall be held liable for the system separately.

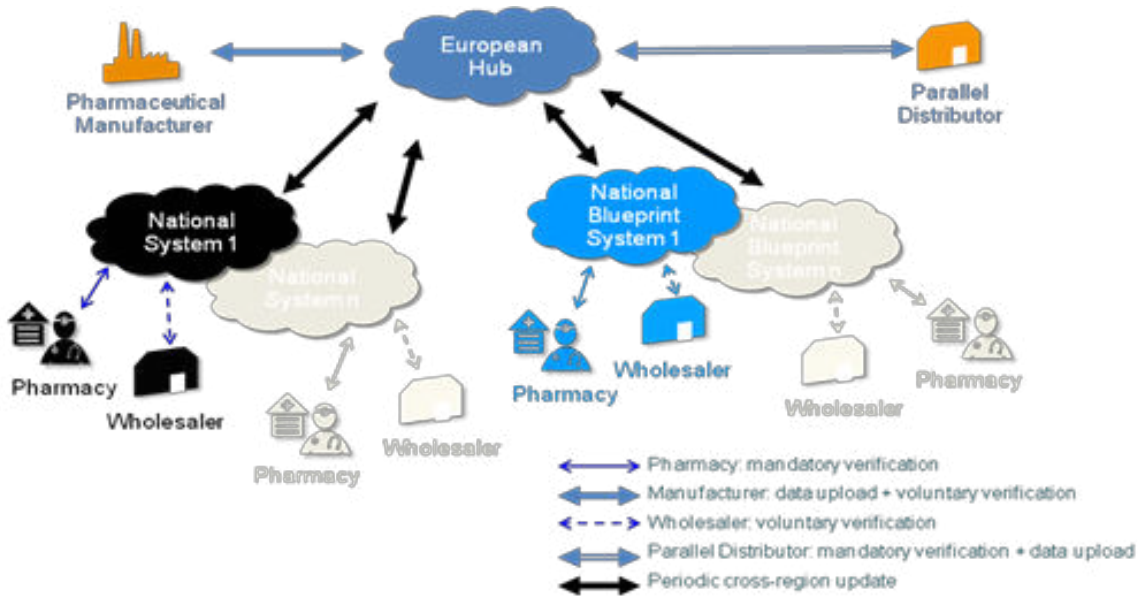
9. Involvement of other parties

- The Stakeholders shall cooperate with competent authorities of the European Union and national authorities and shall welcome other relevant participating organizations or entities playing an active role in the pharmaceutical supply chain once the medicines verification system is further developed.

3. System Architecture and Ownership

3.1 Introduction

The Stakeholders support the creation of the European system that is depicted in the following figure.



In order to provide for interoperability and to create a cost-effective national system of verification, the national repository must be created in compliance with the EMVO's requirements.

This system includes a unified European hub linked to many national information repositories that serve as verification platforms and can be used by all authorized participants to verify the authenticity of medicinal products. The European hub shall not contain any accumulated data from individual pharmacies or distributors. The national repository shall be created and operated by the relevant Stakeholders. A "model" system means a national repository that, based on the national participants' decision, shall be operated by the EMVO and therefore such systems shall be referred to as "centrally operated national systems." Any further reference to "national systems" includes these centrally operated national systems as well. Over time, the systems may migrate between nationally, regionally or centrally operated forms, depending on the decision of relevant participants and the management rules of their organizations.

3.2 Obligations of the EMVO

The European Medicines Verification Organization (EMVO) shall manage the European hub, specify the EMVO standards and ensure the quality and availability of the system.

The specific information about the EMVO that shall control and manage the European hub is available in the Memorandum of Understanding signed by the participants on a European level

on 15 February 2012.

3.3 Main tasks of the National Medicines Verification Organization

The National Medicines Verification Organization (NMVO) shall control and manage the Czech system linked to the European hub and shall ensure for the Czech Republic:

- The system of verification of the authenticity of medicinal product packaging;
- The central repository for entering data about medicinal products;
- The site that shall generate alerts in the case that the System detects an Incident.

The main purpose of the Czech system is to serve as a verification platform that pharmacies or other entities concerned, such as distributors or hospital pharmacies, can use to verify the "authenticity" of a medicinal product.

The Czech system must mainly:

- Receive and manage relevant data about the serialization of medicinal products;
- Receive revised/new data about the serialization of medicinal products from the European hub;
- Serve as a verification platform for checking the authenticity of a medicinal product for pharmacies, distributors and other entities concerned;
- Serve as a platform for pharmacies that shall indicate the packaging of a medicinal product as decommissioned upon its dispensing to the patient;
- Serve as a platform for the entities concerned that shall indicate the packaging of a medicinal product as "decommissioned" or shall change the status back to "active."

4. The Czech Medicines Verification System

4.1 Safety feature – unique identifier

The system for the identification of every packaging must include at least the following:

1. The code of a medicinal product;
2. The batch number and, if necessary, also the suffix / internal code, in the case of a parallel distribution of medicinal products to ensure the link to the original batch of medicinal products.
3. The expiry date;

4. The national reimbursement number or other national number;

5. The serial number;

6. The current status of every packaging;

7. The time and date of the status change.

These data are divided into:

- Static: e.g. the code and expiry date of a medicinal product (i.e. Items 1 – 4 above) that remain the same;

- Dynamic: e.g. data showing the status change in the production number (i.e. Items 5 – 6 above).

4.2 Data ownership and access

Sometimes, under certain circumstances, it is necessary to provide access to data to ensure the safety of the supply chain. In order to ensure maximum patient safety and in view of Article 54a of the Directive, it is important to make sure that the effectiveness of the System is not jeopardized by unreasonably restricted access to data.

Therefore, it is necessary to distinguish between data generation, data ownership, data use authorization and access rights. It is necessary to set up rules for granting user access rights and adopting other technical and organizational measures.

The System shall not record or generate any personal data.

4.2.1 Data generation and ownership

The Stakeholders having access to the System shall own the data about the verification of medicinal products that they shall generate when interacting with the System.

The Stakeholders understand that such data are sensitive and therefore shall accept a system that is highly secured and allows to access data under strictly specified conditions only.

4.2.2 Access scenarios and conditions

The Stakeholders specified the following scenarios, based on which relevant participants could request access to certain data about serialization and verification of medicinal products in order to secure patient safety.

4.2.2.1 Negative verification, dispensing and unusually activities

Access to information about the unique identifiers concerned in the system would speed up the investigation of the Incidents indicating potentially falsified medicinal products. The parameters of an unusual activity must be defined in the System.

Such information may include e.g. evidence that:

- The unique identifier is not in the verification system.
- The scanned data features do not correspond to the data in the database.
- The unique identifier is shown as decommissioned.
- The unique identifier has already been decommissioned (e.g. in the case that the medicinal product was repackaged and a new unique identifier was generated).
- The unique identifier has already been decommissioned due to a recalled batch.
- There is any activity concerning the specific unique identifier or the unique identifier group that is suspicious in terms of time, geographical position or the manufacturer's capacity or that indicates that the system has been attacked.

In case of an Incident that shall be handled by competent regulatory authorities, every manufacturer and MAH concerned may request additional data that would help them find the source of illegal tampering with medicinal product data. Under such circumstances, the System shall make it possible to access approved and relevant data only, and the European hub shall be responsible for requesting and obtaining such data from the national system to ensure a necessary level of data abstraction and to make it possible for MAHs to meet their obligations toward regulatory authorities.

4.2.2.2 Recall of a medicinal product

Thanks to information about the status of every packaging, the System shall identify recalled batches almost in "real time," which shall allow to manage the recall of medicinal products more effectively.

In the case that medicinal products are recalled, the relevant participants shall need access to the status of all unique identifiers concerned, including information about which unique identifiers were decommissioned or replaced in compliance with the approved processes of Incident solving and in compliance with the applicable regulations on the protection of personal data.

In the case that it concerns repackaged parallelly distributed medicinal products, the information about the original batch number in the European system shall be linked to the new batch number used by the parallel distributor of medicinal products so that the medicinal products could be recalled quickly and effectively. The European hub shall ensure a necessary level of data abstraction and shall make the data accessible to individual manufacturers and MAHs.

4.2.2.3 System maintenance

In justified cases, it shall be necessary to check whether or not a certain transaction was done or successfully completed or to change data in case of an error. Under such circumstances, the System shall be required to generate reports or at least provide access to data. Access to data shall be limited to authorized ICT providers, based on applicable security rules.

5. Access to and Use of the National System

5.1 Access

Access to the national system shall be limited for security reasons. The System shall be accessible only to the participants that need to use it in connection with the physical handling of medicinal products in the supply chain. The level of access shall differ, depending on the activity performed.

Manufacturers	Although the manufacturers of medicinal products do not have direct access to the national systems, they can enter and delete data and check the status through the European hub.
Parallel distributors	Although the parallel distributors of medicinal products do not have direct access to the national systems, they can decommission unique identifiers through the European hub prior to repackaging. They can check the status as described in Paragraph 5.4.
Distributors	They can decommission unique identifiers e.g. when medicinal products are to be liquidated, packaging is damaged, medicinal products are distributed outside the EU, see Paragraph 5.3 They can check the status as described in Paragraph 5.4.
Pharmacists (including e.g. persons dispensing medicinal products in hospitals, registered pharmacies)	They can decommission unique identifiers e.g. when damaged packaging is decommissioned at the dispensing place, see Paragraph 5.3 They can check the status and verify authenticity at the dispensing place.

5.2 Entry sites

The basic function of the System is to provide an integrated place for entering the data into the European hub. Unique identifiers can be entered into the System by the manufacturer only. Based on approved data access principles, the information that the manufacturer provides in the unique identifier on every packaging includes:

1. The code of the medicinal product;

2. The expiry date;

3. The batch number (including the suffix or prefix in case of repackaged medicinal products);

4. The serial number;

5. The national reimbursement number or other national number.

This basic information shall help other participants that physically handle the medicinal product in the supply chain to verify the authenticity of the relevant packaging of the medicinal product.

The manufacturer must state the country/countries where the distributor shall place the medicinal product on the market and thus also the unique identifier issued for such a country. This is how production numbers are links to the national database.

In the case that medicinal products are repackaged, new unique identifiers shall be entered and linked to the country/countries where the relevant packaging shall be placed on the market. There must be a clear link between the unique identifier on the original packaging and the unique identifier on the new packing, which shall be ensured by linking the old and new batch number in the European hub. This process must be simple and fully automated.

5.3 Output sites

The system shall work only if output sites are designated and compatible with the System in compliance with the approved procedures.

Based on the so-far intended plan, the packaging of a medicinal product may have the following status:

- Available
- Dispensed, including separate packaging
- Dispensed on a different market
- Decommissioned
- Decommissioned in another system
- Sold outside the EEA
- Recalled
- Repackaged.

The term “decommissioned” used in this document means any status except for “available.”

Participant	Decommissioned by the participant
Manufacturers / parallel distributors	Delivered/returned medicinal products, cancellation, accident, damaged packaging, correction of errors made during data entering, unforeseen logistic changes, stolen production number or packaging.
Parallel distributors	Decommissioning before the repackaging of a medicinal product with follow-up registration of a new unique identifier.
Pharmacists (including e.g. hospital, regular and Internet pharmacies)	Authenticity checking and verification. Decommissioning of damaged packaging at the dispensing place, see Paragraph 5.3.
Distributors	Damaged packaging (due to the management of distributors or through returned medical products from pharmacies), packaging exported to the countries outside the EEA or to the countries not participating in the System.

Under certain circumstances, it may be necessary to change the status of the unique identifier. For instance, when a medicinal product is verified as authentic by mistake or when a patient does not pick up the medicinal products he has already ordered. It must be possible to change the status of the unique identifier at any time until the medicinal product expires.

5.3.1 Decommissioning

Decommissioning is mandatory in order to maintain the integrity of the System and to reinforce patient safety. This shall reduce the risk that a patient shall get a falsified medicinal product. Unless every packaging bearing the unique identifier is decommissioned from the System, it shall not be possible to guarantee patient safety. The unique identifier can serve as a reliable protection against falsified medicinal products only if such medicinal products are systematically decommissioned. The status of the unique identifier must be changed in the System database anytime a medicinal product is dispensed or repackaged.

5.4 Accessibility for distributors

The distributors shall have access to “reading” for the purposes of verification. The distributor must check medicinal products bearing safety features. However, this requirement, i.e. the requirement pursuant to Article 80(a) (ca) of the Directive, shall be considered met by the distributor if the medicinal products bearing safety features were obtained (i) from the manufacturing authorization holder or the person authorized by manufacturing authorization

holder to supply such medicinal products or (ii) from the marketing authorization holder or the person authorized by the marketing authorization holder to supply such medicinal products. The receiving distributor must check the medicinal products bearing safety features if the distributor received such medicinal products from other authorized sources. The distributor must also verify medicinal products returned from the persons authorized or competent to supply to the public as to whether they are authentic and were not tampered with by checking the safety features on the packaging.

The Stakeholders have agreed to continue with the drafting of standard procedures for recalling medicinal products from the supply chain (e.g. damaged goods) and decommissioning their unique identifiers from the System.

5.5 Dispensing pharmacies

The dispensing pharmacies shall be able to check the data in the System.

5.6 Other use of data

In addition to providing detailed information about falsified medicinal products identified on the market to all participants, the implementation of the proposed system allowing to identify medicinal products via packaging may provide other benefits as well, e.g. (based on an agreement between the individual participants on a national level): the reduction of fraudulent reimbursement claims; more effective prevention of dispensing recalled medicinal products to patients; more effective handling of returned medicinal products and easier stock management in pharmacies.

Any additional use of transaction data would have to be agreed upon between the relevant participants on a case-to-case basis, based on the situation in the given country and in compliance with the applicable legal regulations.

****

The different requirements specified in this Memorandum are necessary in order to eliminate the risk that fraudulent entities shall apply for a manufacturing or distribution authorization to gain access to the System on a regional level, to distort data and to facilitate the entry of falsified medicinal products into the supply chain. These requirements provide a more reliable and systematic protection than national audits performed ad hoc. They create a framework for an effective closed system that shall help to quickly identify anybody trying to compromise the System that protects patient safety and that can be further developed to accommodate future needs and challenges.

6. Organizational and management structure: Key Parameters

The National Medicines Verification Organization in the Czech Republic shall be founded as a non-profit organization for an indefinite time period. Its legal form, financing, organizational structure and decision-making processes shall be regulated in its by-laws. Without prejudice to the final decision about the best legal structure and related mandatory requirements arising from legal regulations, the Stakeholders assume that the National Medicines Verification Organization shall follow the principles described in this document.

The National Medicines Verification Organization shall have minimal funds, and the project shall be carried out externally by one or several ICT providers as part of the project-financed program based on an SLA.

6.1 Competences

The National Medicines Verification Organization (NMVO) shall create and manage the Czech repository system that shall be interoperable with the European hub and, as such, also with other national repositories that serve as platforms for the verification of the authenticity of medicinal products by pharmacies or other competent entities. It shall cooperate with the relevant participants in implementing the EU Directive on falsified medicinal products and related delegated acts.

The NMVO shall facilitate different participants' negotiations concerning standard binding agreements regulating their relationship with the EMVO. These agreements shall guarantee that the principles of proper management shall be applied in the entire system and that the System shall be fully interoperable and shall allow the participants to effectively identify, monitor and reduce as much as possible specific and common risks for patient safety caused by falsified medicinal products.

The NMVO shall be responsible for:

a) Applying the EMVO requirements and ensuring overall quality (data accuracy, system accessibility and reactivity, observation of the relevant level of security, etc.);

b) Defining the conditions regulating access to the System that must be objective and transparent so that the System would be open to every entity authorized to operate in the legal supply chain anywhere in the EEA;

c) Managing ICT, the contractual and personnel interface between the NMVO and the EMVO;

d) Submitting regular reports on the activity of its members and the functioning and performance of the System and for generating statistical reports in order to facilitate communication bout the functioning of the System;

e) Performing periodical and strategic reviews to ensure that the System keeps developing in the interest of patient safety and in compliance with the development of the healthcare infrastructure in Europe;
f) Invoicing and collecting membership fees and other due payments;

g) Executing and administrating user contracts and agreements about related fees and payments;

h) Negotiating with the relevant national regulatory authorities about the use of the System in order to facilitate the recall of medicinal products and about other issues concerning patient safety;

i) Providing the participants with services in fulfilling mutually agreed bilateral or multilateral data access agreements executed as needed.

The NMVO shall be authorized to perform all activities directly or indirectly related to the exercise of its competence. Therefore, based on its by-laws, the NMVO shall be authorized to purchase, sell or lease real estate and movables, to execute mortgage loan contracts with respect to such real estate and movables, to employ necessary personnel and to hire external providers as needed.

The NMVO may decide to fulfill its obligations (pursuant to Items c through i) externally through the EMVO based on a service agreement.

*****

In _____, on

_____
For AIFP, MUDr. Martin Minarovič,
Chairman of the Board of Directors

In _____, on

_____
For ČAFF, Mgr. Martin Mátl,
Executive Director

In _____, on

_____
For AEDL, MUDr. David Rosecký,
Chairman of the Board of Directors

In _____, on

_____
For AVEL, RNDr. Tomáš Votruba, CSc., MBA
Executive Director