Delegated Act on the Detailed Rules for a Unique Identifier for Medicinal Products for Human use, and its Verification

Concept Paper submitted for Public Consultation

Response from PHAGRO|German Association of Full line Wholesalers

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Introduction

PHAGRO as a member of the European Association of Pharmaceutical Full-line Wholesalers (GIRP) fully supports GIRPs submission to the public consultation. Therefore, PHAGRO will not contribute data regarding national costs related with the implementation of the different options described in the public consultation. GIRP has made precise cost calculations for 25 EU member countries including Germany.

However, PHAGRO has additional input to several issues that reflects the specific needs and demands of an important national pharmaceutical market like Germany.

PHAGRO is member of the initiative “securPharm” by the German stakeholders in the pharmaceutical market representing the associations of the pharmaceutical industry (BAH, BPI, vfa), the full line wholesalers (PHAGRO) and the pharmacists (ABDA). The securPharm stakeholders propose a German medicines verification system as part of a pan-European system that will be tested in a pilot in 2013 which is supposed to constructively accompany the implementation of the Directive on Falsified Medicines.

PHAGRO represents all 13 full line wholesalers in Germany. PHAGRO members distribute more than 80% of all medicines dispensed by public pharmacies, while the rest is largely distributed through direct sales by manufactures. The PHAGRO members serve as the backbone of the distribution of pharmaceuticals in Germany by delivering more than 3.8 million packs to 21.400 pharmacies daily. This requires a great deal of efficiency and speed of internal wholesale work processes. This efficiency and speed has to be maintained in order to guarantee the timely delivery of medicines ordered by pharmacies wherever and whenever required by patients.

A. CONSULTATION TOPIC N°1: CHARACTERISTICS AND TECHNICAL SPECIFICATIONS OF THE UNIQUE IDENTIFIER

Policy option n°1/1:
Leaving the choice of the technical specification to the individual manufacturer
Policy option n°1/2:
Harmonisation through regulation

Consultation item n°1: Please comment on points 1 and 2 (policy options n°1/1 and n°1/2). Where do you see the benefits and disadvantages of each policy option?

PHAGRO recommends policy option n°1/ 2, **harmonization through regulation**. The benefits are already enumerated in the concept paper.

Speaking about harmonisation, it is necessary to review the different functional levels with their differing requirements.

- Harmonisation Level: Data for Verification

The verifiable data content, to be used in the databases, should be harmonised throughout Europe.

- Harmonisation Level: Syntax

The syntax to be used should be based on the international standard ISO / IEC 15 434 "Information technology - Automatic Identification and data capture techniques - Syntax for High-capacity ADC media".

- Harmonisation Level: Structure

Allow the use of standardised Application Identifier (AI) and Data Identifier (DI) with the associated system identifiers according to ISO / IEC 15418/ANSI MH10.8.2 "Information technology - Automatic identification and data capture techniques / Data Identifier and Application Identifier Standard" within the data carrier.

- Harmonisation Level: Data Carrier

The regulations should be based on the international ISO standards.

- Harmonisation overall

Committing to the specification of just one commercial operator or user group leads to a distortion of competition. Critical are the use of:

  - Single proprietary specifications.
  - Specifications which promote the commercial interests of a service or a product.

2.1. Regulation of the composition of the serialisation number

2.1.1. Manufacturer product code and pack number

Consultation item n°2: Where do you see the advantages and disadvantages of the approach set out in point 2.1.1.?

As a general remark, PHAGRO would like to draw the attention of the European Commission to a lack of clarity in the terminology “serialisation number” and “unique identifier” which is misleading. In several cases, the term “serialisation number” is used when referring to the complete data content of the code, in other cases, serialisation number” is used where actually the term “unique identifier”, in the sense of a combination of „Product code“ and „Individual pack number“ is meant. In this context, we suggest, in order to differentiate it from other product groups e.g. medical devices referred to as “Unique device identifier (UDI)”, that the term be expanded to “unique medicinal product identifier (UMI)”. We propose that this explanation should be incorporated in the Delegated Act. Furthermore, the corresponding terminology of the standards ISO/IEC 19762 Part 1 + 2 should be applied.

PHAGRO supports the use of harmonized and internationally recognized standards for the identification of products but disagrees with the approach as set out in point 2.1.1.

A country prefix is not necessary for verification. The reference is also potentially ambiguous. The definition of the country prefix is inexplicit. What is meant - the country of manufacture or the country of sales? The international uniqueness of the product code is of paramount importance. The "Manufacturer product code" proposed is unnecessarily restrictive. Until now a "Manufacturer code” has not been established in Germany (or other countries like Austria, Belgium, France, Italy, Portugal and Spain). Such a code is therefore not easily applicable. The introduction of a new "Manufacturer product code" would add a high burden on Europe's healthcare system. Instead, there should be an internationally unique product code ideally generated by a national registry (or the manufacturer as second best).

Please note that the guidance document referred to in footnote 16 quotes the optional use of the GTIN as the product code from GS1. Commitment to the use of a fee-based use of a single (monopoly) organization is for competitive reasons critical.

2.1.2. Additional product information

Consultation item n°3: Where do you see the advantages and disadvantages of the approach set out in points (a) and (b) of point 2.1.2? Please comment.

PHAGRO pledges for the compulsory inclusion of batch number and expiry date in the pack code as set out in points (a) and (b), in addition to the product code and serial number. Each product should be encoded with four data elements, i.e. product code, serial number, batch number and expiry date.

Their inclusion would enable wholesale distributors and pharmacists to automatically read the batch number, serial number and expiry date, significantly enhancing patient safety and improving product recall procedures. Not requiring the inclusion of batch number and expiry date in the pack code, as well as product code and serial number, would represent a wasted opportunity to tackle the significant dangers for patients posed by currently sub-optimal recall processes, requiring manual checking of every pack of medicines.

(a) Batch number

The Falsified Medicines Directive by virtue of Article 80 (e) requires wholesale distributors to record the batch number at least for those products carrying the safety features. In practice, this means that wholesale distributors must capture and record the batch numbers of the medicines dispatched to their customers (retail pharmacies and other persons authorized to supply medicinal products to the public).

It is obvious that batch number recording represents additional costs for pharmaceutical wholesalers and if fewer batch numbers need to be recorded, these costs would decrease. Costs do not only arise for the recording of the batch numbers, but also for the related specific handling, storing and replenishing of different batches. Wholesale distributor's commission the orders of their customer at a very high speed, ensuring a rapid delivery of medicinal products to pharmacies so that patients can receive their medicines when expected (the average delivery time of full-line wholesalers is 2.66 hours).

Therefore, machine-readable batch numbers contained on the outer package of medicines is an absolute pre-requisite for batch number recording.

Furthermore, the availability of the batch number in a machine-readable format on the outer package of medicines also facilitates recalls on the batch level in the distribution chain (both at wholesale distributor and pharmacy levels). Currently, storage shelves need to be searched manually for all products with the concerned batch number. Should the batch number not be available in a machine-readable format as part of the code, the process of commissioning orders will be severely disrupted. For wholesale distributors, it

is therefore of vital importance that the batch number is included into the code and is available on the package in a machine-readable format.

If the batch number is not printed on the pack in a machine-readable format, the batch number information would have to be captured manually. The time required to capture batch numbers manually however would run beyond acceptable levels, drastically slowing down the work-flow in the warehouse. Furthermore, significant error rates in addition to the high costs for the manual capturing of batch numbers can be expected.

For cost calculations examining the different options of batch number capturing PHAGRO likes to refer to GIRPs response.

(b) Expiry date

The argumentation for the inclusion of the expiry date into the code in a machine readable format is largely the same as for the batch number. The inclusion of the expiry date in the machine-readable code is also necessary for the stock management process in the wholesale distributors' facilities.

Furthermore, it is essential in case the new GDP guidelines make a FEFO (first expired first out) stock management system mandatory. The FEFO system has been included in the current draft GDP guidelines.

(c) National reimbursement number

Option 1: the national reimbursement number is replaced by the abovementioned serialization number

Option 2: The abovementioned serialization number includes the national reimbursement number. In this case, the serialisation number could be composed as follows:

Manufacturer Product code (which includes the prefix of the country)	Unique identification number of the pack	National reimbursement number (see point c)	Expiry date (see point b)	Batch number (see point a)
XXXXXXXXXXXXX	XXXXXXXXX	XXXXXXXX	XXXXXX	XXXXX

Consultation item n°4: Which of the two options set out under point (c) of point 2.1.2 is in your view preferable? Where do you see advantages and disadvantages? Please comment.

In Germany, the product number for pharmaceuticals is the Central Pharma Number (PZN) which is allocated based on central registration by IFA (Informationsstelle für Arzneispezialitäten). The PZN serves for all logistic practices and is embedded into all IT

systems and business processes. The allocation rules follow the specific characteristics of pharmaceuticals. Centrally issued and registered by IFA the PZN is the only unique product number for pharmaceuticals in Germany. Replacing the PZN by new numbers would be highly complex, error prone and expensive as many business processes and IT systems are based on this number. In addition, the German reimbursement system requires the use of the PZN as anchored in article 300 of German Social Security Code. Therefore, PHAGRO would like to draw the attention of the Commission to Article 168 paragraph 7 of the Treaty on the Functioning of the European Union where it is stated that Union action shall respect the responsibility of the Member States for the definition of their health policy such as reimbursement issues.

In summary, replacing the PZN as pointed out in option no. 1 would not be possible.

On the other hand, a parallel existence of two product identifications as pointed out in option no. 2 would mean increased complexity and risks associated with the ambiguous declaration of pharmaceuticals. The existence of two parallel product identities (new manufacturer product code and existing national product and reimbursement numbers) in the market would mean:

- Potential source of error through use of the wrong primary key.
- Two product identifier that follow different allocation rules.
- Additional costs of maintaining two product identifiers.
- Additional costs due to double license fees for the product codes.
- Potentially additional costs due to higher volume of data (increased code size).
- Potential error through inaccurate timing of synchronisation during the update of the product code.

Regarding the consultation paper, both, options 1 and 2 have advantages and disadvantages, therefore both are not fully accommodating present needs.

PHAGRO supports the use of harmonised and internationally recognized ISO Standards for the identification of products. But instead of being replaced by a new manufacturer product number, existing national product numbers should be made globally unique and become applicable across Europe

There exist several ways by which national product numbers can be made globally unique and can be used across Europe. IFA that serves as an ISO-certified issuing agency as well has already transformed the PZN into the globally unique PPN (Pharmacy Product Number). The PPN in combination with a unique identification number of the pack will be perfectly able to meet the verification requirements set out by the Commission.

Therefore, PHAGRO recommends a third option where harmonisation would mean:

- Use of ISO Standards for the symbology of the pack code.
- Use of ISO Standards for syntax and structure of the content of the pack code
- The Pack Code consists out the following items:
    1. Globally unique Manufacturer Product code, that includes national product and reimbursement numbers
    2. Unique identification number with the pack (serial number)
    3. Expiry date
    4. Batch number

2.2. Regulation of the technical characteristics of the carrier

Consultation item n°5: Please comment on the three concepts described under point 2.2. Where do you see the benefits and disadvantages of each of the three concepts. What are the costs for each concept? Please quantify your reply, wherever possible, by listing for example:
- costs for reading devices for the different carriers;
- costs for adapting packaging lines of medicines packaged for the EU market.

2D-Barcode

PHAGRO supports a 2D-Bar Code holding the information related to each single pack (product code, batch number, expiry date, a unique randomized serial number and, where necessary, the national product number) as:

- It has the ability to store the information multiple times in the same code which allows a reading even if 25% of the code is damaged;
- It is applicable to small packs;
- It is widely used and thus tried-and-tested (the 2D Data Matrix has been an ISO standard for 12 years and is widely used globally);
- Manufacturers have wide experience of its use due to requirements in France, South Korea, Turkey and other countries;
- It is future proof.

Based on current analysis, PHAGRO recommends a 2D barcode (Data Matrix Code) as the data carrier as the only reasonable technical solution. The Data Matrix Code has technical and economic advantages in comparison to the two other concepts and in our view should be used for serialisation of pharmaceutical products in Europe.

B. CONSULTATION TOPIC N° 2 - MODALITIES FOR VERIFYING THE SAFETY FEATURES

Consultation item n°7: Please comment on the three policy options set out in points 1 to 3. Where do you see the benefits and disadvantages? Please comment on the costs of each of these policy options. Quantify your response, wherever possible.
This applies in particular to the:
- number of wholesale distribution plants;
- costs for adapting such plants;
- duration of scanning of the serialisation number;
- number of pharmacies, including hospital pharmacies;
- number of medicinal products dispensed by pharmacies and a hospital pharmacy.

The European Association of Pharmaceutical Full-line Wholesalers (GIRP) has submitted a detailed response to three options regarding the modalities for verifying safety features. GIRPs submission also includes a detailed cost analysis of the running costs as well as capital costs and depreciation of policy options no. 2/2 and no. 2/3.

PHAGRO as a GIRP member is fully in line with GIRPs submission. Because of the importance of the coming modalities for verifying safety features PHAGRO wishes to stress the key points regarding the wholesalers view on the modalities described in the following three policy options.

1. Policy option n°2/1: Systematic check-out of the serialisation number at the dispensing point

Systematic check-out of the serialisation number at the point of dispense is the only safe and secure way to protect patients from receiving falsified, expired or recalled medicines. It also fulfils the terms of the Directive to protect patients from receiving falsified medicines.

PHAGRO therefore fully supports this policy option.

2. Policy option n°2/2: As in policy option n°2/1, but with additional random verifications at the level of wholesale distributors

While we believe that policy option n°2/1 already sufficiently protects patients from receiving falsified medicines, PHAGRO together with the associations of its supply chain partners is in the process of elaborating a German Medicines Verification System called securPharm that foresees wholesalers to take part in the verification of medicines carrying safety features on a risk assessment basis and to have "read" access to the repository for verification purposes. "Write" access for decommissioning damaged products or those designated for export outside the EU could be an option as well.

PHAGRO believes that a systematic check-out of the serialisation number at the dispensing point with additional risk-based verification at the level of wholesale distributors protects the legal supply chain against the entry of falsified medicines.

PHAGRO and GIRP present the risk-based verification of medicines as follows:

For medicinal products carrying safety features obtained from (i) the MAH[1] or a person who is authorised by the MAH to supply these products, or (ii) the marketing authorisation holder or a person who is authorised by the marketing authorisation holder to supply those products, the wholesale distributor is deemed to have satisfied 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 authorised 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.

3. Policy option n°2/3: As in policy option n°2/1, but with additional systematic verification by the wholesale distributors

Systematic check-out of the serialisation numbers at the dispensing point with systematic verification by the wholesale distributors is not feasible for wholesale distributors in terms of costs and time effort associated with this policy option:

The enormous and very complex throughput of medicinal products in wholesale distributors' warehouses (commissioning of up to 22 packs per second in peak times with an average order commissioning time of less than 1 hour) requires a high speed of action in respect to the delivery of products. Wholesale distributors fear a dramatic decrease in the speed of commissioning and delivery from the warehouse as well as a dramatic and unsustainable cost increase, which would be related to the reading of every

[1]MAH – Manufacturing Authorisation Holder(s) which term, for the purposes of this paper, 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 MAH.

single pack of medicine. Speed however is the most crucial aspect of wholesale distributors operations, as medicines have to be delivered as ordered by pharmacies and required by patients.

Under the assumption that all RX-packs carry safety features and that each pack is only scanned once during the time it is in the possession of the wholesale distributor, GIRP calculated that the financial impact of this policy option in terms of running costs would be 613.3 million Euros for the EU 25 (no data available for Malta and Cyprus). This calculation is based on the number of additional employees that would have to be hired to cope with the additional workload of scanning all packs and the additional warehouse space they require as well as its maintenance costs. Significantly increased workload would result in the need to significantly increase the warehouse space, which in many cases would mean to either move to a bigger warehouse, as many warehouses cannot simply be extended (e.g. hindrance through surrounding buildings).

Further investments costs in warehouses in terms of additional equipment and upgrades to the existing warehouse management systems and software licenses (capital costs including depreciation and interest) are estimated at 13.4 million Euros for EU 25 (excluding Malta and Cyprus).

Adding the annual running costs and annual capital costs, the total estimated annual cost of policy option n°2/3 for wholesale distributors would be 626.8 million Euros for the EU 25 (excluding Malta and Cyprus). In sum, the arising overly burdensome costs would go against the principle of proportionality as mentioned in Article 54a n°2d, which expressly refers to the fact that the European Commission must take account of the particular characteristics of the supply chains in Member States when determining the verification process.

The financial burden arising from policy option n°2/3 would consume the annual profit of wholesale distributors in Europe and endanger the supply of medicines to European patients.

For the reasons argued above, PHAGRO completely rejects policy option n°2/3.

C. CONSULTATION TOPIC N°3 - PROVISIONS ON THE ESTABLISHMENT, MANAGEMENT AND ACCESSIBILITY OF THE REPOSITORIES SYSTEM

Consultation item n°8: Please comment on the three policy options set out in points 1 to 3. Where do you see the benefits and disadvantages? Please comment on the costs of each of these policy options. Please quantify your reply, wherever possible.

This applies in particular to the estimated one-off costs and running costs for a repositories system. Where possible, please provide information on past experiences with a repositories system at individual company level and at national level (taking into account the experiences of Member States and companies).

1. Policy Option 3/1 'stakeholder governance'.

PHAGRO supports policy option **3/1 'stakeholder governance'.**

securPharm as a model for stakeholder governance

PHAGRO, the associations of the pharmaceutical industry (BAH, BPI, vfa) and the pharmacist association (ABDA) are jointly developing a model for a cost-effective and scalable product verification system in Germany named securPharm to be run by a stakeholder organisation on a non-profit basis.

securPharm could serve as a model for implementing the Falsified Medicines Directive on national level. The system is developed in coordination with the European umbrella organisations of the German stakeholders, which ensures that the national and the European approaches follow the same rules. It would be interoperable with a European Hub currently developed as the European Stakeholder Model (ESM) by EAEPC, EFPIA, GIRP and PGEU.

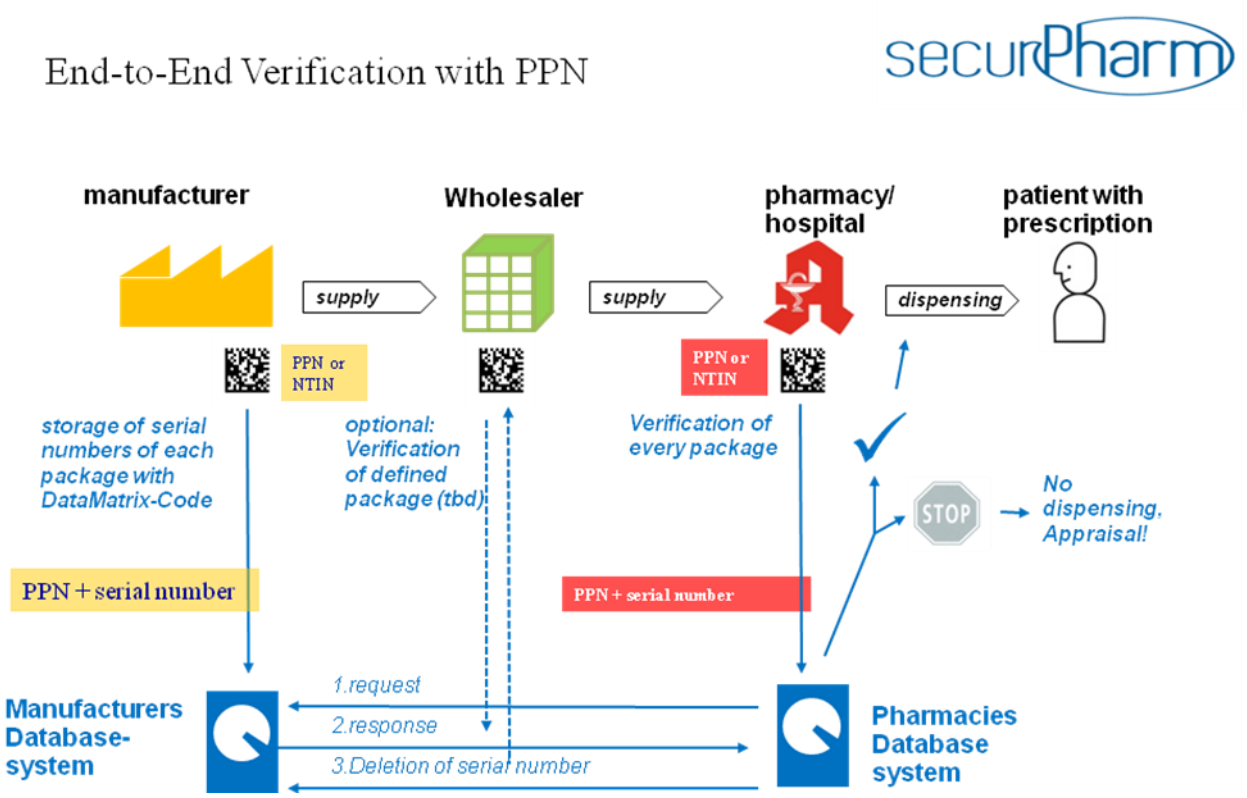
Given that stakeholders will use and pay for the needed verification system, a stakeholder-governed system is the optimal approach to ensure patient safety in a cost-effective manner. It drives for cost-effectiveness which is necessary in the current economic climate, it ensures that it is the people who know the system best that deal with it and it is a consensus driven model as it includes all relevant partners in the pharmaceutical sector.

Design of securPharm

The aim of the project is to establish a system to optimize the protection of patients against falsified medicines by means of the identification of a randomized serial number with regard to the individual packaging of medicinal products and its verification against

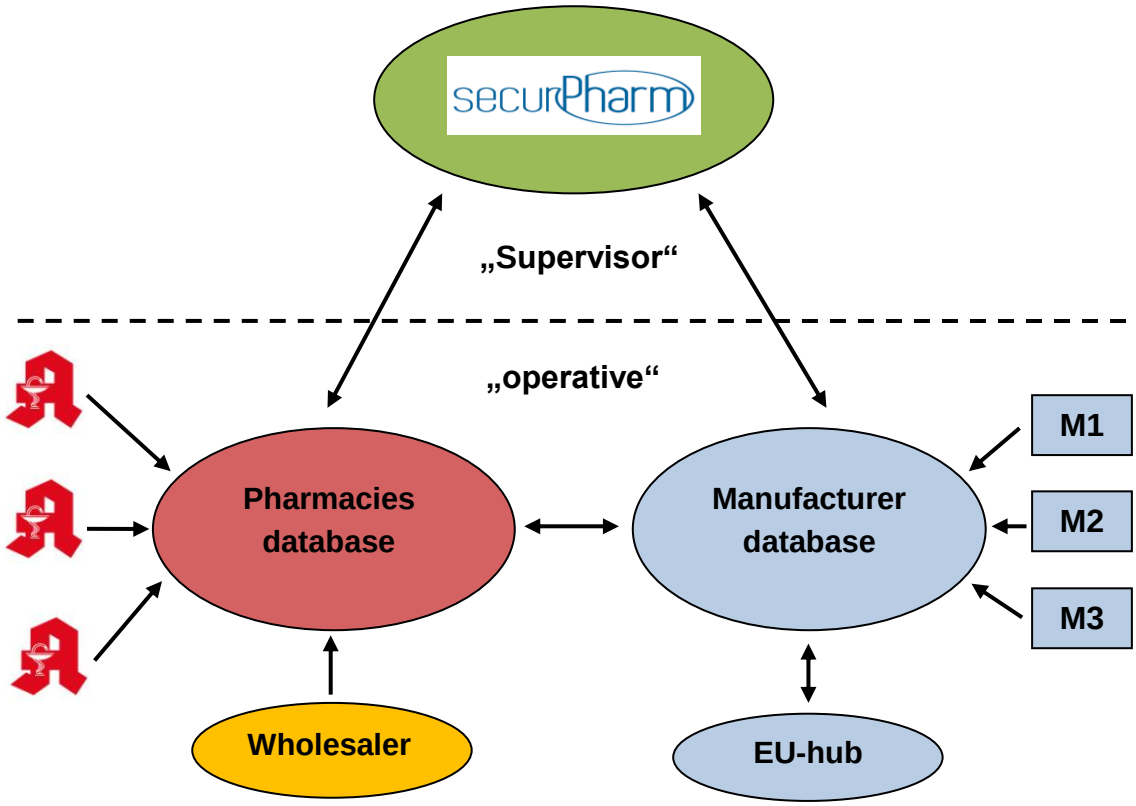
original data held available by the pharmaceutical entrepreneur. The serial number shall be coded in a Data-Matrix-Code together with the product number, the batch number and the expiry date on the level of the individual package.

The verification should in principle follow the “end to end” approach, meaning that the pharmaceutical entrepreneur labels the packs accordingly while the verification and the registration of the dispensing to the patient takes place online in the pharmacy. Independently, wholesalers can verify products as well.



securPharm is based on the principle of separate databases owned and run by the respective stakeholder. The contents and rules for the exchange of data between market partners as well as data storage and procedures for making public cases of falsifications, attempts of falsifications or other abnormalities are set by an “umbrella organization” which is jointly borne by all stakeholders.

Decision for a three-part Database System



Importantly, and in line with the Falsified Medicine Directive, the development of securPharm will be linked with the government, public agencies and the European Commission. As a fundamental principle, a stakeholder governance model will always run in partnership with public authorities as well as all other relevant actors along the supply chain such as parallel traders.

A pilot of securPharm is currently under development and will be run in the beginning of 2013.

4. Other issues related to the repository system

Consultation item n°9: Please comment on point 4.1. Are there other items of information which should be taken into consideration when addressing the issue of commercially sensitive information in the delegated act?

4.1. Information of a commercially sensitive nature

Protection and security of the data have the highest priority for the technical and organizational realization of the verification of medicinal products and are to be ensured by the stakeholders in their fields of responsibility. Data have to be protected against attacks by counterfeiters and hackers according to the state of technology.

Regarding information of a commercially sensitive nature, the concept of separate databases guarantees that the stakeholders keep the access and sovereignty over their own data. They process and operate their respective areas themselves and keep all rights and duties of their own data pools. Manufacturers will receive no pharmacy-specific information on the inquiring pharmacy. The anonymity will be accordingly agreed by contract and guaranteed through technical measures.