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 securPharm e.V.

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Introduction

On 16 February 2011 the European Parliament adopted the falsified medicines directive (2011/62/EU). The directive was approved by the Council on 27 May and published in the Official Journal of the EU on 1 July. Parts of those measures consist in the obligation of the Member States to introduce the verification for certain medicinal products in order to ensure, in addition to other measures, the authenticity of the packaging of medicinal products. In light of this project of the European Union the main German stakeholders agreed to develop and implement a concept in Germany aiming at the verification of the packaging of medicinal products using a Data-Matrix Code. The German associations of the pharmaceutical industry BAH, BPI and vfa, the pharmaceutical full-line wholesalers PHAGRO and ABDA (Federal Union of German Associations of Pharmacists) have joined forces and are implementing a pilot project in Germany together with their members under the name of securPharm for this purpose. This initiative is developed in coordination with the European umbrella organisations (EAEPC, EFPIA, GIRP, PGEU), which ensures that the national and the European approaches are not in conflict.

We therefore endorse the joint comments of the European umbrella organisations EAEPC, EFPIA, GIRP and PGEU to this consultation. Our own response shall be regarded as supplementary, highlighting some specific aspects from the German point of view.

The core of the pilot project securPharm, which is a unique project in Europe as it covers the area of a complete Member State and numerous products and pharmacies, is an “end-to-end”-verification, by which the authenticity of a medicinal product is verified in the pharmacy by checking an individual randomised package number before the medicinal product is dispensed to the patient. Thus, an unequivocal differentiation between genuine products and falsifications will be possible.

The German stakeholders are committed to test an end-to-end verification at the dispensing point in the pharmacy during the beginning of the year 2013. The serial

number shall be coded in a Data-Matrix-Code together with the national central pharma number (PZN) of the individual package. Independently, wholesalers may but are not required to verify the products. Emphasis is put on the compatibility of the verification process with the different software systems in the pharmacies. The pilot provides guidance for a subsequent fast and comprehensive implementation of the verification of medicinal products in Germany. The pilot test also describes the real market situation to the extent that it takes into account the coexistence of medicinal products with and without safety features.

The concept which was favoured by the stakeholders follows the principle that the transaction data of the medicinal product remains in sole property and possession of the respective stakeholder. The stakeholders keep the sovereignty over their data. They process and operate their respective areas themselves and keep all rights and duties of their own data pools. Manufacturers receive no pharmacy-specific information on the inquiring pharmacy. The anonymity will be accordingly guaranteed through technical measures.

The territorial scope of the project is limited to the Federal Republic of Germany.

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?

securPharm 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. Therefore, any use of single proprietary specifications and specifications which promote the commercial interests of a service or a product should be avoided.

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, the securPharm stakeholders 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.

securPharm supports the use of harmonized and internationally recognized standards for the identification of products and comments to the approach as set out in point 2.1.1. as follows:

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 (potentially monopoly) organization should for competitive reasons not be made.

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.

a) + b) Batch number and expiry date

securPharm pledges for the inclusion of batch number and expiry date in the pack code as set out in points (a) and (b) at least on a voluntary basis, in addition to the product code and serial number.

Their inclusion would enable wholesale distributors and pharmacists to automatically read the batch number and expiry date, which will be important to fulfil certain legal requirements set by the directive 2011/62/EU such as batch recording by wholesalers. This could also improve product recall procedures which would enhance patient safety. Furthermore, such a feature would bring added value for storage organisation by wholesale distributors and pharmacists.

(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. In addition, the German reimbursement system requires the use of the PZN as anchored in legal statutes. Therefore, replacing the PZN as pointed out in option no. 1 would not be possible.

securPharm would also like to draw the attention of the Commission to the fact that the PZN is the only unique product number for pharmaceuticals in Germany due to the fact that it is centrally issued and registered by IFA[1].

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 possible 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.

The securPharm stakeholders support 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) [2]. 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, securPharm recommends a third option where the following data elements are included in the pack code:

1. Globally unique product code, that includes existing national product numbers, or – where the latter does not exist – another product identifier.
2. Unique identification number for the pack (serial number).

[1] http://www.ifaffm.de/
[2] http://www.ifaffm.de/leistungen/_index.html

securPharm recommends to include batch number and expiry date on a voluntary basis.

This information should be encoded using a coding scheme that fulfils the following principles:

- Only one ISO compliant symbology should be used for the data carrier (DataMatrix code).
- Standardised syntax and structure should be used for the pack code's content.

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

The securPharm stakeholder support a 2D-Bar Code holding the information related to each single pack (product code, a unique randomized serial number and, where necessary, the national product number and the batch number and expiry date on a voluntary basis as well) 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, securPharm 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.

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.

Therefore, the securPharm stakeholders endorse **policy option n° 2/1, Point-of-Dispensing Verification by the pharmacist.** Pharmacy level verification at the point of dispensing with an interface for wholesalers is a robust and cost-effective way to improve patient protection.

Systems should be configured so that pharmacists can undertake checks at any point after receipt of goods, as well as performing the check-out operation at point of dispensing. The process of verification in the pharmacy should be virtually instantaneous in order to ensure efficient pharmacy workflow and avoid delays. In order to ensure that products are verified in one scanning action, verification software should be integrated with existing pharmacy software.

Other points of dispensation to consider - Check Out Rights

Once introduced into the System, products must subsequently be “checked out” (meaning that their serial numbers are to be decommissioned) by the relevant stakeholders. Check out rights should be provided for the following actors and scenarios:

- By the pharmacists at the point of dispense, including legitimate internet pharmacies, hospital pharmacies;

- By the parallel distributor engaged in repackaging. The pack should be checked out prior to repackaging and new serialised product codes applied and checked into the system. The old and new serialised numbers must be linked at the batch level in the database to enable the product to be tracked in case of recalls or other safety issues;

- 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 wholesalers in the event of (1) disposal due to damage or expiry, whether caused at the wholesaler's premises or returned as damaged by pharmacists, or (2) their export outside of the EEA/other participating countries.

Unless every individual serialised pack is correctly "checked out" at one of the points listed above, patients will not benefit fully from the safety features. The unique serial number can only provide protection against falsified medicines if it is systematically checked out and the status changed on the database to "dispensed" when the product is handed to the patient or processed in repackaging.

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, wholesalers should have unlimited "read" access to the repository for verification purposes.

securPharm stakeholders believe that a systematic check-out of the serialisation number at the dispensing point could be accompanied by an additional risk-based verification at the level of wholesale distributors.

securPharm presents the risk-based verification of medicines as follows:

For medicinal products carrying safety features obtained from (i) the MAH[3] 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

[3]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.

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.

We therefore strongly oppose systematic verification by wholesale distributors as suggested in policy option n° 2/3, as this is costly, disproportionate to the objectives of the Directive, and would provide no greater level of safety to patients than point of dispensing verification. In this respect, we welcome the fact that track-and-trace is at no point mentioned as a policy option in the Concept Paper.

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.

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'.

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

securPharm as a model for stakeholder governance

The ABDA, BAH, BPI, PHAGRO and the vfa 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 are not in conflict. It should be interoperable with a European Hub currently developed as the European Stakeholder Model (ESM) by EAEPC, EFPIA, GIRP and PGEU.

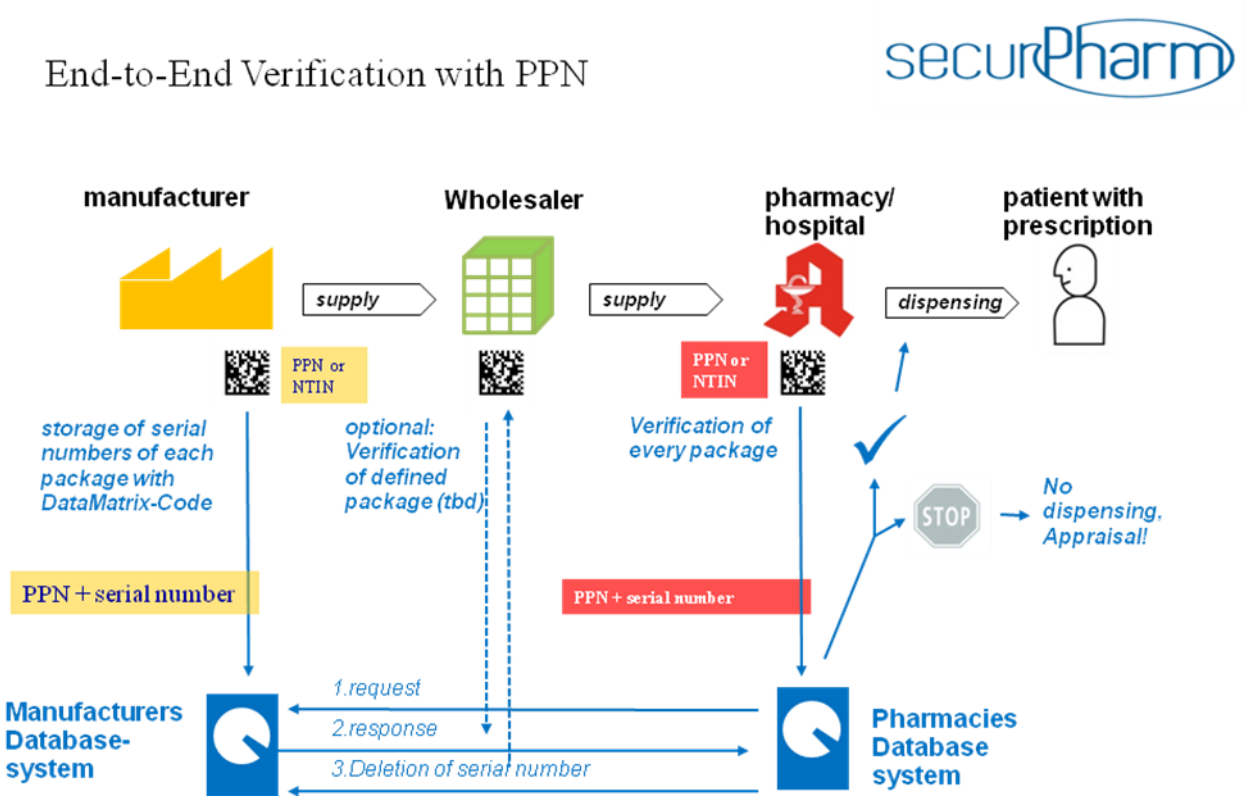
Given that stakeholders will use and pay for the needed verification system, a stakeholder-governed system is the optimal approach to ensure patient safety in a cost-effective manner. It drives for cost-effectiveness which is necessary in the current economic climate, it ensures that it is the people 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

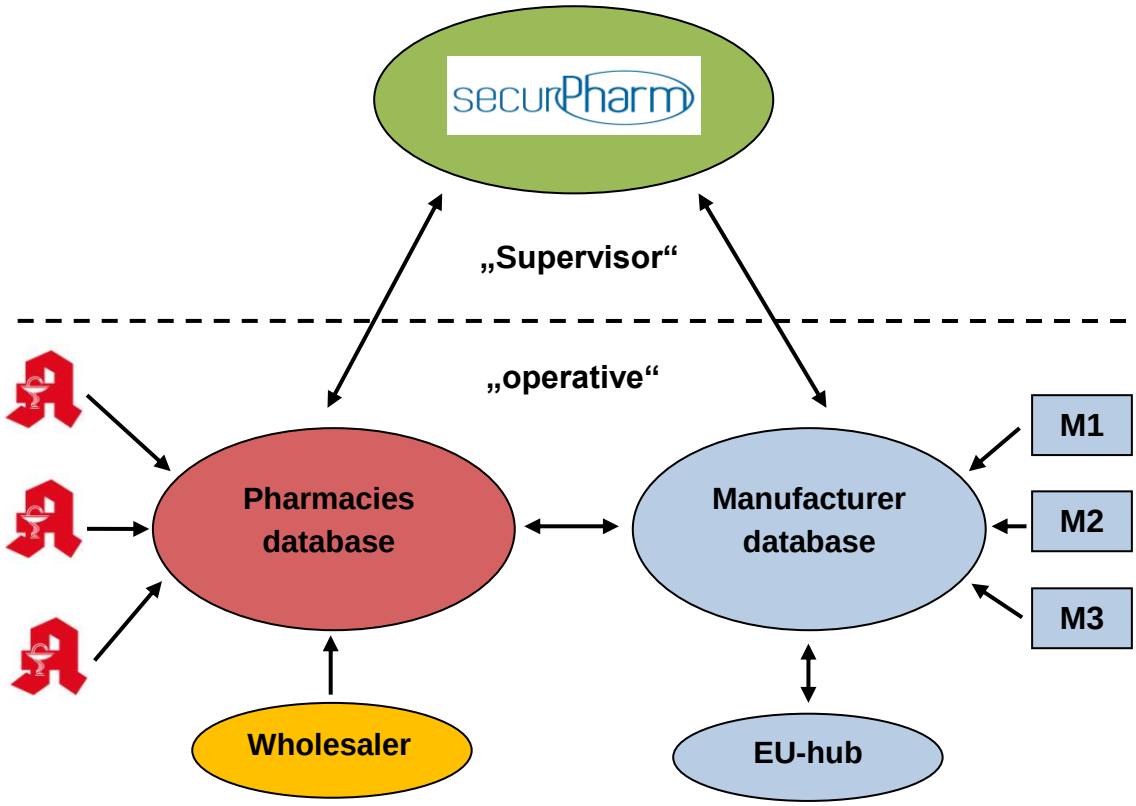
be coded in a Data-Matrix-Code together with the product number, the batch number and the expiry date on the level of the individual package.

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.

Additional remark

In item no. 60 of the concept paper it is stated that the costs of the repositories system shall be borne by the manufacturing authorisations holders of medicinal products bearing the safety features. But the manufacturing authorisation holder, especially when he only is acting as contract manufacturer, will not be the addressee in the verification process. This is in any case the marketing authorisation holder, who is responsible for the product in the market. Therefore only the marketing authorisation holder will be obliged to install a repositories system and should therefore bear the costs.