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Subject: Opinion on the concept paper of the European Union concerning the introduction of a safeguard system for medicinal products

Dear Sir/Madam,

On 18 November 2011, the European Commission published a concept paper for public consultation entitled "**Delegated Act on the detailed Rules for a Unique Identifier for Medicinal Products for Human Use, and its Verification"**.

We use a system of safeguards for medicinal products which provides primarily for **verification of authenticity by the end client**, in keeping with Directive 2011/62/EU. The system was developed in coordination with an IT company and has been widely accepted by our clients.

Based on our experience so far, we are pleased to express our opinion (see attachment), within the time prescribed, on the issues raised in the concept paper.

Yours faithfully,

GALENpharma GmbH IT´S TRUE - The Authenticating Company GmbH

(signature)

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Opinion on the concept paper of the European Union on the introduction of a safeguard system for medicinal products

The concept paper on the introduction of a Europe-wide safeguard system for medicinal products outlines current ideas for such a system and poses questions concerning technical practicalities and foreseeable costs.

Our company is already working together with an external IT service provider to run a pilot project which has met with a high level of customer acceptance. We therefore wish to take this opportunity to present a technical scenario in which all the fundamental problems of a Europe-wide safeguard system for medicinal products could be solved.

Based on this scenario, we then provide concise answers to the questions raised in the concept paper, as far as is possible at this stage.

1. Requirements for a Europe-wide safeguard system for medicinal products

A Europe-wide safeguard system for medicinal products must meet various requirements. A number of these requirements were already mentioned in the concept paper and in EU Directive 2011/62/EU[1] of 1 July 2011. In particular, the latter states:

"These safety features should allow verification of authenticity and identification of individual packs (....)"

"The illegal sale of medicinal products to the public via the Internet is an important threat to public health as falsified medicinal products may reach the public in this way. It is necessary to address this threat."

"Past experience shows that such falsified medicinal products do not reach patients only through illegal means, but via the legal supply chain as well. This poses a particular threat to human health [...]."

The central idea is to give each packaged unit a unique identifier (UID), thereby making it possible to identify any packaged unit. A databank or repository is also created in which all UIDs issued are saved. It is then possible to check whether a given UID exists in this repository.

It must be possible to mark a UID as allocated at a given point (referred to as check-out) before the corresponding medicinal product is used. An allocated UID may not be re-used or issued a second time.

It is striking that the concept paper states that, only pharmacies have so far been considered as being responsible for checking out UIDs. Thus, the only sales channel taken into account is the public pharmacy, thereby disregarding the widespread practice of purchasing medicinal products via the Internet. In our opinion, it is imperative for consumers to be able to check the authenticity of a medicinal product themselves, when it has been purchased from a source other than the public pharmacy.

A safeguard system limited only to the standard trade chain would to a large extent fail to cover the imperatives of consumer protection. Two figures by way of example: at present, the talk is of nine proven cases in which falsified medicinal products entered the German national trade chain. On the other hand, German customs alone secured approximately 10 million falsified tablets in 2010. We therefore need a system which both improves safety in the trade chain and covers Internet trade. The product developed by our IT service provider takes account of both aspects in an appropriate, sustainable manner.

2. Specific requirements

[1] The German original incorrectly refers to Directive 2011/26/EC.

(a) A fundamental examination of the situation gives rise to at least the following requirements for a Europe-wide safeguard system for medicinal products:

• The databank must be permanently accessible via safe Internet channels. There should be no real downtime.

• It must be possible for end clients to consult the databank using simple devices and technologies already available on the market.

• To prevent counterfeiters from producing valid UIDs, UIDs must be issued on a non-deterministic basis.

• UIDs must indeed be unique in their specific contexts.

• A UID must be sufficiently non-deterministic, and issued and transferred (to the packaging machines) under secure conditions.

• The installation and operational costs of such a system should be minimal for all market stakeholders (manufacturers, logisticians, wholesalers, pharmacists, medical practices and hospitals). Among other things, this means keeping expenditure for the software manufacturers involved to a minimum.

• The installation and operational costs of such a system should be minimal for all market stakeholders. In particular, such a system should not be time-consuming or cause delays in pharmacies.

• For pharmaceutical laboratories which supply a number of European countries, such a system must function on a cross-border basis.

• For pharmaceutical laboratories which already use UIDs or other product protection system, the cost of conversion or integration of the new system must be acceptable.

• UIDs must be machine-readable so that the repository can be consulted on an automated basis.

• The data carrier used for the UID must be cost-effective.

(b) Other possibilities should be taken into account when introducing this system:

• The data carrier for the machine-readable UID can also be used to provide other product-specific information in machine-readable format. The type of information would presumably depend on the target market for the packaged units. In Germany, it would make sense for the "PZN" (pharmaceutical central code), lot number and expiry date to be provided.

• The repository can be used to make other product-specific information available (e.g. name of product or active substance, indication of the pharmacy-sale requirement or prescription requirement, "Dear Doctor letters", etc.). The UIDs can be used as a key for retrieving data stored in the repository.

(c) Further requirements may arise once a Europe-wide safeguard system for medicinal products has been successfully introduced, with a view to increasing use of the system:

• assuming that it is possible to identify every package of medicinal products in Europe, it is then possible for packages to be *tracked* from the point of manufacturer through all stages in transport to the point of sale *(tracking).* If packages with copied UIDs are on the market, their movements can then be *traced.*

• If a comprehensive *track&trace* is made obligatory, all market stakeholders can be required to first

register and then authenticate their identity when tracking medicinal products. This possibility is already suggested in the EU Directive.

3 Creating UIDs as unique markers

As stated in the requirements, a UID must be a unique marker for a package, with no duplicates. There are various ways to create UIDs:

• A randomly produced string is generated which is guaranteed to be unique in the entire repository. Only this string will then be used as a UID.

• A randomly produced string is generated and it is ensured that this string has not yet been used for the same product. The combination of a unique product marker and the generated string is then used as the UID.

• If a unique marker already exists (e.g. serial numbers allocated during production), a randomly produced string is nevertheless generated. The unique marker and the generated string is then used as the UID.

All three variations are equally suitable provided that the random element is sufficient.

4 Data carriers for UIDs

The concept paper proposes various data carriers:

• one-dimensional barcode: such a barcode requires either a lot of space on the packaging or can only include a small amount of information.

• two-dimensional barcode: such a barcode requires comparatively less space on the packaging and can include a sufficient amount of information in one symbol. Furthermore, it allows not only for error recognition (as do one-dimensional barcodes) but also for error correction. This makes the reading of even damaged symbols possible.

• RFID transponder: a transponder can cover any amount of information for fixed dimensions. However, it is comparatively expensive. *One RFID transponder alone is more expensive than the printing of the UID and the repository operation combined.*

A two-dimensional barcode therefore appears to be the appropriate choice. Extensive use is made of special "Datamatrix ECC 200" symbols in line with ISO/IEC 16022. ISO/IEC 15415 sets out print quality requirements for two-dimensional barcodes with a view to ensuring that reading problems do not occur.

Based on ISO/IEC 16022, ISO/IEC 15434 describes a data format which allows various user data to be stored in one data matrix symbol. On this basis, ANSI MH10.8.2 describes a number of set data identifiers (DI) in order to distinguish between these data.

The user data to be deposited are supplemented by the corresponding data identifier in accordance with ANSI MH10.8.2, combined in accordance with ISO/IEC 15434 and converted into one data matrix symbol in accordance with ISO/IEC 16022.

Example of a UID in the data matrix symbol

A UID is to be created from a product identification and a random string as a serial number, and then be combined with the lot number and expiry date in a data matrix symbol.

First of all, the DIs must be determined. There are *1P* for the product identification, *S* for the random string , *IT* for the lot number and *14D* for the expiry date.

Datum	DI	Value	Result
Product identification	*1P*	productabc	IPproductabc

Serial number	S	1234567890	S1234567890
Lot number	*IT*	batch132	lTbatchl23
Expiry date	*14D*	31 July 2015	14020150731

These prepared data are combined with a special separation symbol T and a special start symbol S. This creates the following string:
S1PproductabcT S1234567890T 1Tbatch123T 14D20150731.

This string is converted into a data matrix symbol:

5 Dealing with other information

Depending on the target market, there are various additional product features which are normally indicated (e.g. the PZN in Germany) or must be indicated.

These can be integrated without difficulty in the described system. If the corresponding data needs to be made available *offline*, they can be integrated under a corresponding DI in the data matrix symbol itself. Otherwise, they can be recorded in the repository and consulted by using the UID *online*.

6 Distribution and integration of the repository

The concept paper proposes various models for the repository:

- a central European repository managed by the EU
- central State-managed repositories for each Member State
- independent repositories managed by the manufacturers.

A central repository, which then includes the UIDs of all packages of medicinal products in Europe and processes all related enquiries (UID check-outs, tracking of UIDs, information searches), must have sufficiently large dimensions. State management and the extensive technical measures required lead us to expect that such a system would incur disproportionate costs.

Repositories which are linked to State borders create major problems for manufacturers which operate in a number of Member States, since they must then be in several systems. For identical products, separate UID master data must then be managed and coordinated.

If there were many independent repositories, it would almost inevitably lead to severe fragmentation. All market stakeholders would need to be able to work with all repositories. *The costs of operating an independent repository are too high for small-scale manufacturers.*

As mentioned at the start, as a cost-aware, medium-sized pharmaceutical laboratory, we have developed an alternative, cost-efficient scenario with our IT service provider which has none of these problems.

- There is a known, centrally registered number of repositories. The UID includes a code indicating to which repository it belongs.
- Several manufacturers can store their UIDs in shared repositories. A manufacturer can use different repositories for different products or target markets.

• Access to repositories is standardised. Technical implementation of the repository may take any form.

• Creation of the UID can vary, depending on the repository.

Such a decentralised solution with the possibility of common access makes sense for all types of use:

• A large pharmaceutical laboratory can easily operate their own repository. Technical implementation of the project is then entirely up to them.

• For small manufacturers, the costs of safely running an in-house repository are clearly too high. Such companies can then work together with a repository operator, which provides its clients with a repository and guarantees availability.

• Manufacturers which already use serial numbers can choose a repository with a suitable UID structure.

• Any existing (State) systems can easily be integrated.

The technical details concerning the administration of the repositories can then be settled between the pharmaceutical laboratory and the repository operator as necessary. For example, it would be possible to produce the random parts of the UIDs in the repository and affix them to the packaging of medicinal products, or, the other way round, to generate the UIDs at the packaging stage and store them in the repository. *Such technical details do not require State regulation.*

Example for repository enquiries

The central point in this scenario is an index available to the public via Internet in which all repositories are recorded. A URL must be entered for each repository in addition to its identifier, allowing the repository to be accessed via Internet, and from whose data fields a UID is composed in this repository.

Such an index could have the following entries:

Identifier	Name	URL	UID structure
0001 0002	Repository A	https://www.url.com/repo	*S* serial number
	Repository B	https://repo.pharma.org/	*S* Serial number
			1P product identification

In the first repository, the serial number alone is used as the UID. In the second repository, the combination of serial number and product identification is the UID.

• A data matrix symbol for a product entered in the first repository must contain only the serial number in addition to the identifier.

• A data matrix symbol for a product entered in the second repository must contain the serial number and the product identification in addition to the identifier.

If the UID on a package of medicinal products needs to be consulted, the identifier must first of all be ascertained. The identifier in the central index must then be retrieved. The UID is composed using the list of DIs entered there, and a request is sent to the corresponding URL repository.

7 The role of the EU in this scenario

Instead of operating its own repository, the EU (or EU Member States) play only a supervisory role in

this scenario.

The tasks of State organisations are straightforward in this scenario:

• the central index must be prepared and maintained.

• Possible access to the repository must be standardised. Possible access refers to the use of a UID, the retrieval of further information or the storage of tracking information.

• New repositories must be checked for feasibility and certified. This check should cover at least the following points:

- it must be possible to guarantee the availability of the repository. The data inventory must be appropriately safeguarded from damage;

- it must be guaranteed that the UIDs in the repository system are unique;

- the UIDs in the repository system must be sufficiently random;

- the exchange of UIDs between packaging production and repository must be systematically secure.

• Where appropriate, other DIs (for the repository identifier, product identification used in Europe such as PZN, etc.) must be entered in ANSI MH10.8.2. Alternatively, an independent set of DIs can be established which meets the requirements of the European pharmaceutical market.

Corresponding certification guarantees the necessary quality standard for the IT infrastructure of the repositories and thereby availability. It also ensures that all repositories are entered in the central index.

Answers to the questions in the concept paper

Question 1

As described in the scenario above, the EU must simply establish repository specifications.

Questions 2 to 4

As described in the scenario above, these elements may take any form.

In the system we use, the UID is simply composed of a random string. Where appropriate, we would integrate the values for lot number and expiry date in machine-readable format into the data matrix symbol as additional details. We would integrate the PZN into the data matrix symbol in machine-readable format as a further detail.

These details are normal and sufficient in the German market.

We cannot give an indication of which details are common or necessary in other countries. It should also be borne in mind that other details may be required in the future. A corresponding system must therefore be expected to show sufficient flexibility.

Furthermore, it cannot be assumed that the various European pharmaceutical markets will be unified in the near future. Therefore, it is unnecessary and would not make sense to establish general regulations concerning additional details. Since the country in which a medicinal product is to be sold is clear at the packaging stage (language on packaging and package insert), a data matrix symbol with the corresponding details can be affixed at this point.

Questions 5 and *8*

The advantages of using data matrix symbols vis-à-vis other possibilities have already been explained in detail in the scenario above.

In the system developed by our IT service provider, which will later act as repository operator, the costs for the packaging and running of the repository can be reduced to less than EUR 0.10 per package of medicinal products.

In our current system, we use the UIDs only for the final authenticity test and not for tracking the packages as in option 2/3. Furthermore, we do not operate a warehouse ourselves but have sub-contracted storage and dispatch to another company. We therefore cannot provide any details on equipment costs for our warehouses.

Question 6 and 7

For reasons of feasibility, we assume that the UIDs are first used in order to run an end consumer check and, where appropriate, a check-out in accordance with Option 2/1.

In a later development, there can then be complete tracking of all packages of medicinal products in accordance with option 2/3. Only this has real added value for identifying the origin of falsified medicinal products.

It should be noted that the data volume in case 2/3 is enormous.

In such a case, our system allows a check-out in accordance with 2/1 to be used for the particular purpose of activating an end customer check. An end customer enquiry would then only be successful if the related packaging was sold and correctly checked out by a pharmacist beforehand. This could further improve the safety of the pharmaceutical market.

Question *8*

The central point of the scenario described above is a system in line with option 3/1, with corresponding supervision/certification by the authorities.

Our IT service provider can operate a repository which would in the long term cost us less than EUR 0.10 per package of medicinal product in total and would free us from one-off investments in IT infrastructure and, in the developed system, also from equipment costs for our packaging lines, since we could use existing technology. *The cost factor is extremely relevant for us, and we assume that no State system would be anywhere near as cost-effective.*

Questions 9 and 10

The system developed by our IT service provider stores only the data needed for operations. It can be adjusted to the respective national provisions and legislative requirements concerning data protection (in particular health records).

In our considerations to date, we assume that tracking data may be consulted only subject to a relevant judicial decision in the event of misuse. In particular, as a pharmaceutical manufacturer, the transport and marketing channels for our products cannot be followed using our system.

Questions 11 and 12

We propose that, apart from a few justified exceptions, only medicinal products which require prescriptions should be protected. We do not think it makes sense to include products in this group which, due to low costs, would be completely unappealing to counterfeiters. In our opinion, extensive protection for all medicinal products requiring prescriptions would be neither meaningful nor purposeful.

Furthermore, we suggest that, a positive list be used to ensure compulsory protection first and foremost for medicinal products which have already been falsified due to their appeal for the counterfeit trade or based on past experiences. Such a positive list can then be updated by statutory order and brought into line with the current situation.