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PHARMIG response to the European Commission Concept Paper: Delegated Act on the Detailed Rules for a Unique Identifier for Medicinal Products for Human Use, and its Verification

PHARMIG, the association of the Austrian pharmaceutical industry, would like to thank the European Commission for the opportunity to comment on the Concept paper for the Delegated Act on the Detailed Rules for a Unique Identifier for Medicinal Products for Human Use, and its Verification.

Please find following our comments.

A. Consultation Topic N°1: Characteristics and Technical Specifications of the Unique Identifier

1. Policy option n°1/1: Leaving the choice of the technical specification to the individual manufacturer
2. 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?

PHARMIG comment:

Due to the need of clear technical specifications a harmonised standard is highly preferred. Because of the complexity of the planned serialisation project individual systems for each manufacturer would bear the risk of incompatibilities.

Moreover defining harmonised standards for all member states is one of the key functions of the European Union.

2.1. Regulation of the composition of the serialisation number

2.1.1. Manufacturer product code and pack number

Manufacturer Product code (which includes the prefix of the country)	Unique identification number of the pack
XXXXXXXXXXXXX	XXXXXXXXX

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

PHARMIG comment:

To create a unique identifier a number will have to be composed which has to be unique for each single pack in the whole European Union. This unique identifier will be composed of a manufacturer product code and a random serialisation number at least (for further details please read our comments below). The manufacturer product code has to be linked to one specific product. Therefore we propose to use the following spelling since it meets the requirements in a better way:

U N I Q U E I D E N T I F I E R	
Manufacturer Product code (which includes the prefix of the country)	*Random serialisation number of the pack*
XXXXXXXXXXXXX	*XXXXXXXXX*

A further definition of the 'manufacturer product code' is requested, also depending on the outcome of consultation item n°3 and n°4 (additional product information).
In general we propose a hierarchical composition of the unique identifier to allow definite identification and to avoid double data output in the following way:

First part of the unique identifier:

Level 1: Country Code or prefix of the country

Level 2: Manufacturer Product Code: this code should enable a definite identification of the product and its country of destination, strength and package size. In Austria it should be possible to use the 'Pharmazentralnummer' ('Pharma Central Number') within the Manufacturer Product Code (see consultation item n°4)

Level 1 and 2 can in the following be summarised as the 'manufacturer product code' how it is addressed in this concept paper.

Level 3 and 4: see consultation item n°3 and n°4

Second Part of the unique identifier:

Random serialisation number of the pack

2.1.2. Additional product information

(a) Batch number

(b) Expiry date

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.

PHARMIG comment:

We support the inclusion of both – batch number and expiry date – into the serialisation number. Inclusion of both data would facilitate identification and increase product safety.

(c) National reimbursement number

Option 1: the national reimbursement number is replaced by the abovementioned serialisation number.

Option 2: The abovementioned serialisation 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.

PHARMIG comment:

In Austria there is no 'national reimbursement number'. Alternatively there is the so called 'Pharmazentralnummer' ('Pharma Central Number') in place. This 7-digit number is assigned to every medicinal product (prescriptive and non-prescriptive) as well as to other products distributed by pharmacies.

We recommend not to implement a national reimbursement number as additional information into the unique identifier but to allow using it directly within the Manufacturer Product Code (see consultation item n°2).

Apart from a standardised composition of the unique identifier it will also be essential to standardise the application identifiers which also have to be part of the unique identifier. The following application identifiers might be appropriate:

(01)…Manufacturer Product Code

(10)…Batch number

(17)…Expiry Date

(21)…Random serialisation number of the pack

Summarising our comments to consultation items n°2, n°3 and n°4, we suggest to compose the serialisation number as follows, the indicated numbers of digits seem suitable according to our point of view:

U N I Q U E I D E N T I F I E R			
Manufacturer Product code (consisting of country code and manufacturer product code, in Austria integration of the 'Pharmazentralnummer')	*Batch number*	*Expiry date*	*Random serialisation number of the pack*
(01)14digits	*(10)12digits*	*(17)6digits*	*(21)12digits*

The random serialisation number of the pack should be placed in hierarchy after batch number and expiry date because in our opinion the unique identifier should bear all product specific informations. This allows to limit the random serialisation number.

For the random serialisation number a pool of numbers should be available (depending on effective number of digits) from which the manufacturer can randomize by himself the required serialisation numbers.

Again we want to point out that by the combination of all four parts of the unique identifier one unique number for each single pack should be created. The random serialisation number of course can be used again in combination with different manufacturer product codes, batch numbers or expiry dates. Otherwise the requirements regarding serialisation number especially regarding number of digits would increase dramatically.

2.2. Regulation of the technical characteristics of the carrier

2.2.1. Linear barcode

2.2.2. 2D-Barcode

2.2.3. Radio-frequency identification (RFID)

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?

PHARMIG comment:

2D-Barcode is highly preferred because of its capacity to store all the suggested data. A linear bar code bearing the same amount of data needs too much space what would create problems for small packages. RFID is seen as too costly and technically not fully developed yet. It also might cause interferences due to its signal.

The 2D-barcode should have a maximum size of 12x12mm which would enable to place it also on small sized packages.

However when laying down the details for the serialisation number as well as for the carrier it should be made possible for the manufacturers to choose the supplier for the carrier by themselves. We refuse a system which would create a monopole for a single supplier.

B. Consultation Topic N°2: Modalities for Verifying the Safety Features

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

Consultation item n°6: Regarding point 1 (policy option n°2/1), are there other points of dispensation to be considered? How can these be addressed in this policy option?

PHARMIG comment:

Apart from handing over the medicinal product at the dispensing point other processes within production and distribution where the product is removed out of the supply chain have to be considered, for example:

Reference samples

Elimination of e.g. damaged products

Recalls

Professional samples for doctors

Clinical trials with registered products

Furthermore a procedure has to be established which enables to cancel the accidental check-out within a defined time-frame. An accidental check out for instance would be a wrong or mistaken disposal at the point of dispensation. For such cases specific rules have to be issued.

Additionally specific rules regarding check-out also have to be issued for those who do not hand over the medicinal products directly to the final consumer, e.g. hospital pharmacies or reblistering establishments.

In Austria there is quite a high number of dispensing doctors. It has to be assured that a check-out has to be possible at these points of dispensation as well.

We recommend an obligatory linkage of the check-out at the dispensing point with the inventory management system of the pharmacies. By this means it is guaranteed that the medicinal products cannot be dispensed without checking the serialisation number. We also recommend an automatic check-out when the expiry date of a medicinal product is exceeded.

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

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

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?

PHARMIG comment:

We recommend a systematic check-out of the serialisation number at the dispensing point (when the medicinal product is physically handed over to the patient) together with the possibility of verifications at the level of wholesale distributors. We do not support systematic verifications by the wholesale distributors because it would not provide a greater level of safety to patients than point of sale verifications.

The case-by-case verifications at the level of wholesale distributors shall be performed on a suspect case basis and no provisions regarding frequency or extent of the verifications shall be given. Especially for products obtained directly from the manufacturing authorization holders or a person authorized by them there is no reasonable suspicion for falsification given. On the other hand products obtained from other authorised sources (for example from other wholesale distributors) must be verified in the system by the receiving wholesale distributor. Similarly, if products are returned from persons authorised to supply to the public, the wholesale distributor must verify the products in the system.

Verifications of course have to be possible as well at any other point of the supply chain (e.g. distribution warehouse, taking delivery at pharmacy).

Precise provisions have to be released regarding the repositories system, especially on which level the permissions for operating within this system will be assigned. These permissions can be given to a company (manufacturer, wholesale distributer, pharmacy,…) and then administered within the organisation of this company or the

permissions are addressed directly to the operating people. It has to be assured that manipulations within the repository system are traceable.

In Austria there are 1292 pharmacies, 46 hospital pharmacies and 930 dispensing doctors (by 2011). 9 wholesale distributers cover more than 90% of the Austrian market.

C. Consultation Topic N°3: Provisions on the Establishment, Management and Accessibility of the Repositories System

1. Policy option n°3/1 – 'stakeholder governance'
2. Policy option n°3/2 – EU governance
3. Policy option n°3/3 – national governance

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?

PHARMIG comment:

We clearly prefer a stakeholder based governance (policy option n°3/1) because this enables the development of a cost effective and scalable product verification system that is to be run by stakeholder organizations on a non-profit basis in a way that justifies the related costs to be borne by the relevant stakeholders. There has to be flexibility to adapt the system to local (national / regional) conditions. The system must enable cooperation between several countries so that the EU-wide flow of goods is not disordered or interrupted. In order to achieve these requirements we support the model of a centralised check-in of the unique identifiers together with a local query and check-out of the data.

4. Other issues related to the repositories system

4.1. Information of a commercially sensitive nature

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?

PHARMIG comment:

All additional data (except unique identifier and check-out) generated in the course of the serialisation process have to be absolutely secure and there must be no possibility for access or evaluation as well as circulation of the date to third parties.

Data may only be used in case of falsification or in case of strong suspicion. Also authorities may use the data only in accordance with the manufacturer.
I shall be possible for the manufacturer to have access to his own data (status, verifications, date and place of check-out).

4.2. Protection of personal data
4.3. Re-packaging of medicinal products

Consultation item n°10: Please comment on points 4.2 and 4.3. What aspects should be taken into consideration in the delegated act?

PHARMIG comment:

regarding 4.3.: *Quality standards, especially technical standards, regarding all safety features have to be equal for manufacturers and re-packers.*
The unique identifier of the re-packed product has to be linked to the unique identifier of the original pack and its manufacturer due to product safety reasons.

D. Consultation Topic N°4: Lists Containing the Medicinal Products or Product Categories which, in Case of Prescription Medicines Shall not Bear the Safety Features, and in Case of Non-prescription Medicines Shall Bear the Safety Features

1. Identification criteria

Consultation item n°11: Which approach seems the most plausible from your view? Can you think of arguments other than those set out above? Can you think of other identification criteria to be considered?

PHARMIG comment:

regarding point 78 of the concept paper: *We assume that this only applies for the unique identifier but – in regards to product and patient safety – not for the tamper-evidence and not for the carrier (code without unique identifier).*

regarding point 83 of the concept paper: classification criteria for drawing up the 'black list' and the 'white list'

- ***price of the medicinal product:*** *In the concept paper it is mentioned that products at a very low price are less at risk of being falsified. Therefore a manufacturer's gross price of more than 2 EUR is considered as high price. We do not rate a manufacturer's gross price of 2 EUR to be attractive for falsifying the corresponding medicinal product.*

  As a consequence we suggest a manufacturer's gross price of at least 10 EUR as the acceptable limit for a high price medicinal product regarding falsifying risk. This limit of course has to be harmonised with the consumer price index on a regular basis. Medicinal products with a price below this limit should be definitely listed in the 'white list'.

  Via a risk based approach (see consultation item n°12) it has to be possible for medicinal products with a price higher than this limit to be listed in the 'white list' if the other risks are low for these products.

- ***sales volume of the medicinal product:*** *In the same way as it has been addressed for the price data have to be defined regarding sales volumes. It*

also has to be considered if a product is marketed EU-wide or only on a local basis.

- ***specific characteristics of the product:*** *In the concept paper only one 'specific characteristic' is quoted: products that are delivered directly from the manufacturer to hospital pharmacies. For the drafting of the initial delegated act we expect a complete list of 'specific characteristics' as regarded by the European Commission.*

regarding point 85 of the concept paper: EU-scope non-optional: *We agree that a medicinal product which falls within the scope must bear the unique identifier. In terms of patient and product safety it is not justifiable to interdict a manufacturer to apply the unique identifier on an optional basis. The manufacturer shall have the right to opt a product into the 'black list' as well as out from the 'white list'.*

regarding point 86 of the concept paper: identification criteria: *A flexible approach on a case-by-case basis is clearly preferred. The problem is too complex for considering only one identification criterion (e.g. different pharmaceutical dosage forms for one brand name or one active pharmaceutical ingredient).*

2. Applying the classification criteria

Consultation item n°12: Please comment on the quantified approach set out above.

PHARMIG comment:

In principle we support a quantified approach for applying the classification criteria. However the example listed in the concept paper seems to be too strict (1 point or 5 points for each criterion). We therefore propose a graduated system with well-defined limits (a range of 1 – 5 points for each criterion).

The procedure for the assessment of the criteria for 'white list' and 'black list' has to be addressed to the manufactures and the competent authorities at the earliest time point. Even on a small market like Austria there are more than 3500 non-prescriptive medicinal products. Therefore it has to be clearly addressed how the classification of several 10000 non-prescriptive medicinal products within the whole EU will be

conducted. The manufacturers shall have the possibility to play a part in the procedure of creating the lists.

E. Consultation Topic N°5: Other Issues

1. Procedures for the notification of medicinal products from the national competent authorities to the Commission
2. Date of application of the delegated act

Consultation item n°13: Please raise any other issue or comment you would wish to make which has not been addressed in the consultation items above.

PHARMIG comment:

regarding point 90 of the concept paper:

We assume clarification in the final delegated act that 'the date of application of the delegated act is three years after the date of publication of the delegated act' refers to the production date (= date of release by the Qualified Person) of the pharmaceutical products bearing safety features.

Products which have been produced prior to the date three years after publication of the delegated act will not have to bear the safety features, so these products will be available to the market until their expiry date is reached.