E-MAIL

Österreichische Apothekerkammer

ÖAK · Spitalgasse 31 · A-1091 Vienna · P.O. Box 57 · DVR: 24635

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Di/Sch
Executed by:
Mag. Ditfurth
DW 198

E-Mail –Address:
Sanco-pharmaceuticals@ec.europa.eu

Spitalgasse 31
A-1091 Vienna
P.O. Box 57
DVR: 24635

Telephone:
+43-1-40 414-100
Fax:
+43-1-408 84 40

E-Mail:
info@apotheker.or.at
Homepage:
www.apotheker.or.at

Subject:
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

Dear Sir and Madam,

The Austrian Chamber of Pharmacists has welcomed the introduction of the EU Falsified Medicines Directive.

The Austrian Chamber of Pharmacists fully supports the PGEU/EFPIA/GIRP/EAEPC Joint Response.

First of all we would like to provide you with the following information about the Austrian Chamber of Pharmacists:

The Austrian Chamber of Pharmacists is the legal professional representation of all pharmacists, self-employed as well as employed, who work in community or hospital pharmacies in Austria. Membership to the Chamber is mandatory, which means that every pharmacist who is working in a pharmacy in Austria or who has worked in a pharmacy and is looking for a job in a pharmacy again automatically becomes a member of the Austrian Chamber of Pharmacists.

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

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?

We would prefer policy option n° 1/2 i.e. harmonization through regulation. Because of the movement of medicines across national borders a harmonization will guarantee interoperability across European Member States to exchange information. Therefore a harmonized standard coding system across the EU would be the best solution. We also share the view that this option would be the more cost effective one.

Policy option n°1/1entails the risk that the proposed flexibilisation of the coding and identification system could lead to a high fragmentation of product coding in the European Union. Therefore policy option n° 1/1 is not a good solution.

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

A viable safety feature should contain following data elements i.e. product code, serial number, batch number, expire date and like in Austria common the in cooperation of a national identification number.

We want to point out that for pharmacists it's of utmost importance to be able to enter certain data manually in the event that the machine-readable code cannot be read electronically. Therefore the benefit of human-readable data is obvious.

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

We support the inclusion of batch number and expire date in the serialisation number in machine readable form. Their inclusion would enable pharmacists to automatically read batch number, serial number and expire date, which would enhance patients safety and improve product recall procedures.

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.

Please be aware of the fact that Austria like other countries has a national number for the pharmaceutical product identification in place. It is required to mention it on the product packaging in a machine readable format of a barcode. Therefore it is of utmost importance for us that our national identification number for medicines ("Pharmazentralnummer") remains in force.

Both options have advantages and disadvantages therefore both options do not accommodate the present needs.

In order to ensure that the coding system facilitates other functionalities such as reimbursement, the EU harmonised standards should allow the incorporation of relevant national codes.

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.**

The linear barcode represents an outdated technology which is not designed to hold more than 1 or 2 data elements on consumer packaging.

We support a 2D barcode, i.e. a. DataMatrix code as the data carrier. The 2D-Barcode should contain the following information to each single pack: Product code, batch number, expiry date, a unique randomized serial number and the national reimbursement (product) number.

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

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?

We endorse policy option n° 2/1, Point-of-Dispense Verification by the pharmacy. But we also place great emphasis on the requirement that the system should be designed in a way that pharmacists can also undertake checks at any point after receipt of goods and are able to undertake the check-out procedure at point of dispensing.

Since the technical challenges of point of dispensing the verification process varies across the EU, pharmacists may initially adopt a system of verification when medicines enter the pharmacy, until such time as any technical issues with regard to point of dispensing verification have been resolved.

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 serialization number;**
- **number of pharmacies, including hospital pharmacies;**
- **number of medicinal products dispensed by pharmacies and a hospital pharmacy.**

Policy option n ° 2/2 is the best solution, i.e. systematic check out of the serialization number at the dispensing point with additional random verifications at the level of wholesale distributors.

Verification at the point of dispensing is currently one of the most secure ways to verify product authenticity.

In that context, we want to emphasize the importance that the process of verification must be designed in a way that the dispensing procedure in the pharmacy is not disturbed respectively will not be prolonged (i.e. no additional scanning process, response times).

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 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).

We strongly support policy option n°3/1 the stakeholder governance model. We believe that the implementation led by stakeholders will help to secure the supply chain against counterfeit medicines. Likewise in the same way such a verification system meets also the needs of all users at reasonable costs.

We support the stakeholder governance model and the repository structure proposed under the ESM, for the reasons given in the PGEU/EFPIA/GIRP/EAEPC Joint Response.

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?

There must be a very high degree of data security. Each stakeholder in the authentication system should own the data generated with the system. Transactional data should belong to the party who performs this activity.

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

We believe that the repositories system should not contain personal data related to patients, as this is not necessary in order to fulfill the purpose of the unique identifier.

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

In principle all prescription-only medicines should be subject of the same level of security. If there are exceptions, these should be extremely limited.

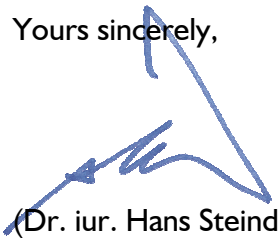
From our point of view the best identification criteria for identifying medicinal products should be by the name of the active pharmaceutical ingredient (INN). The identification by INN is also in the line with our current system.

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

We support the inclusion of the widest possible range of prescription-only medicines. Exceptions should be very exceptional. We also support the quantified approach set out in the Concept Paper.

If you have any further questions, please do not hesitate to ask.

Yours sincerely,



(Dr. iur. Hans Steindl)
Director