Bundesamt für Sicherheit
im Gesundheitswesen

sanco-pharmaceuticals@ec.europa.eu

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Kontakt: MMMag. Bernd Unterkofler, MBA
Telefon: +43 (0) 505 55-36650
E-Mail: bernd.unterkofler@ages.at

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

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

2.1. Regulation of the composition of the serialisation number

The Austrian Federal Office for Safety in Health Care is the opinion, that the delegated act should harmonize the TECHNICAL SPECIFICATIONS and not create a broad framework.

Austria supports the inclusion of the batch number and expiry date into the serialization number. In Austria there is no „national reimbursement number". A so called „Pharmazentralnummer" is in place. This number is assigned to every medicinal product as well as to other products distributed by pharmacies.

Austria prefers the following composition of the unique identifier (Option 2 set out in point c):

- *Manufacturer Product Code (consisting of county code and manufacturer product code, in Austria integration of the „Pharmazentralnummer")*

- *Batch number*
- *Expiry date*
- *Random serialisation number of the pack*

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?

The Austrian Federal Office for Safety in Health Care is the opinion that there are also other points of dispensation to think of like the Marketing Authorizations Holder regarding free medical samples, or medicinal products used in clinical trials.
Furthermore a procedure has to be established for recalls or for other medicinal products which are given back to the manufacturer.

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

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

*The Austrian Federal Office for Safety in Health Care prefers Policy option 3/2 (*EU governance *)or 3/3 (*national governance*) for the establishment, management and accessibility of the Repositories System.*

For the Federal Office
Yours sincerely
Bernd Unterkofler

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