Delegated act on the detailed rules for a unique identifier for medicinal products for human use and its verification

HOPE position

HOPE is the acronym of the European Hospital and Healthcare Federation, an international non-profit organisation, created in 1966. HOPE includes national associations of public and private hospitals and of owners of hospitals. Today HOPE is made up of organisations coming from 27 Member States of the European Union, as well as from Switzerland and Serbia as observer members.

The lack of evidence that falsified medicines entered hospitals in Europe prevents us from having matter for root-cause analysis. There is similarly no evidence that a counterfeit medicine entered the supply chain in between the point of entry into the hospital pharmacy system and it being checked out again. The discussion in the paper seems then mostly based on community pharmacies and not the specifics of hospitals.

The main concern of HOPE is around the points of dispensation and verification of safety features. There are indeed major differences in supply chain end point and in practice between community pharmacies and hospital pharmacies, the most important being that the usual end point of the medicines supply chain is the direct administration of the medicine to the patient at the bedside is not the handover of a packet to the patient.

CONSULTATION TOPIC N°1:
CHARACTERISTICS AND TECHNICAL SPECIFICATIONS FO THE UNIQUE IDENTIFIER

Consultation item n°1: Please comment on points 1 and 2 (policy options n° 1/1 and 1/2). Where do you see the benefits and disadvantages of each policy option?

Yes, leaving the choice of technical solution for the serialisation number and its carrier to the individual manufacturer would clearly lead to a high degree of fragmentation going against the goal of the directive.

Yes, harmonisation is preferable but using regulation might not be the right approach. The first step would be to analyse the design and procurement of equipment required.

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

The inclusion of Manufacturer Product code and Unique identification number of the pack is an advantage for traceability.

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?

The Batch number (a) and the expiry date (b) should be included within the core required information with the unique identifier serialisation number. This would help a more efficient management of pharmaceuticals in hospitals as well as increase safety.

Consultation item n°4: Which of the two options set out under point (c) of 2.1.2 is in your view preferable? Where do you see advantages and disadvantages? Please comment

Considering the diversity of nation reimbursement systems option 1 cannot be envisaged.

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.***

Linear barcode readers might be present in all community pharmacies in Europe but they are not present in all hospitals.

2D data matrix reading is not in use in most hospital pharmacies in Europe.

RFID is not an option for the present issue.

Concerning the evaluation of costs changes would require, it is difficult to estimate without having a clear picture of the existing systems in place. But the costs would definitely not be only the purchase of reading equipment but also changes in (or installation of) software, recruitment and training of staff.

In the context of severe cuts that a lot of hospitals are facing, it goes without saying that this additional burden will create difficulties.

CONSULTATION TOPIC N°2: MODALITIES FOR VERYIFYING 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?

Consultation item n°7: Please comment on the three 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.***

As mentioned in the introduction there are major differences between community pharmacies and hospital pharmacies.

The receipt of medicines in the hospital pharmacy is clearly the only point in the process where the check out of the safety feature for ensuring the detection of falsified medicines in the supply chain could takes place. And since packet scanning is usually not a practice in hospital pharmacies, the verification takes place when receiving bulk purchase of medicines. Requiring verification and check of every box of medicines would require major changes in hospital pharmacy process. It would add substantial burden disproportionate to present risk.

The delays in the preparation of delivery orders that policy option n°2/2 would create is of great concerns for hospitals.

As already mentioned policy option n°2/3 of systematic individual pack level verification would add significant costs not only for wholesalers but also for hospitals. It would not be proportionate for hospital pharmacy. The differences between what marks the end of the supply chain in hospital and in community pharmacy need to be better analysed.

CONSULTATION TOPIC N°3: PROVISIONS ON THE ESTABLISHMENT, MANAGEMENT AND ACCESSIBILITY OF THE REPOSITORIES SYSTEM

Consultation item n°8: Please comment on the three 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 response, 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).

HOPE has been involved in the discussion with stakeholders but has not yet reached a conclusion.

In any case, the system should be realistic, proportionate to the risk and privilege fast reaction time.

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?

No answer

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

Provisions relating to personal data and on repackaging should not be included in the delegated act.

CONSULTATION TOPIC N°4: LISTS CONTAINING THE MEDICINAL PRODUCTS OR PRODUCT CATEGORIES WHICH, IN THE CASE OF PRESCRIPTION MEDICINES SHALL NOT BEAR THE SAFETY FEATURES, AND IN THE CASE OF NON-PRESCRIPTION MEDICINES SHALL BEAR THE SAFETY FEATURES

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?

Having multiple parameters creating two lists is creating confusion.

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

Having multiple parameters creating two lists is creating confusion and might encourage counterfeit activities.