

Consultation item No. 1

Since the labeling of drugs is tested by the Agency, and also because of the possible need to support the general depository of data to identify unique serialization, stakeholders and regulatory authority should consider a centralized procedure and harmonized standard in the case of centrally authorized medicinal products and national procedure in other cases. Harmonized regulation could simplify administrative process that consequently will simplify process and reduce costs for stakeholders.

Consultation item No. 2

In case of unique identification number of the pack (UINP) there is no need to assign any other identification number. UINP could contain manufacturer's product code as well as other data.

Consultation item No. 3

Batch number and expiry date could be included in UINP but also should be mentioned on the package legible for human.

Consultation item No. 4

Reimbursement status in Latvia can change faster than registration status. It is not available to attach reimbursement identifier to UINP, but reimbursement system could use a part of UINP for their needs.

Consultation item No. 5

Any technical obstacles can produce additional costs for pharmacies and hospitals. In case of medicinal product price limit margins actual in Latvia it could cause the loss of cost-effectiveness of such solutions, and can escalate the prices for the users of medicinal products. Linear barcode has additional disadvantage – it can be mismatched with EAN13 and other barcodes already used by manufacturers and stakeholders. However we cannot predict the actual cost of technical solution for code reading abilities, because of changing costs of human resources, inflation etc. RFID is not user-friendly method of identification and costs more than barcode.

Consultation item No. 6

It would be advisable that every stakeholder ensure the check-out of serialization number to ensure the safety features are born.

Consultation item No. 10

The usage of additional UINP in repackaging of medicinal products could produce additional costs for whole chain of product life cycle.