Coding & Serialisation

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

European Commission - Health and Consumers Directorate-General - Unit D/3

Response European Association of Euro-Pharmaceuticals Companies (EAEPC)
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The main objective of the Delegated Act should be to lay the foundation for the development of a **harmonised system across the EEA based on international standards** that provides a **high level of security for patients** while being **cost-effective** and **integrating into existing structures** in the distribution chain.

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About the European Association of Euro-Pharmaceutical Companies ('EAEPC')

The EAEPC is the representative voice of companies engaged in legitimate intra-community trade of medicines, and currently has some 70 members from 21 countries in the EEA area.

The following remarks are complementary to the input delivered by the stakeholder group consisting of EFPIA, EAEPC, GIRP and PGEU, and represent the views of the EAEPC with regard to selected issues under consultation, which are considered particularly important from the perspective of parallel distributors.

The design of an end-to-end verification system must be supportive of existing processes in the supply chain, not only in pharmacy and wholesale, but also in manufacturing, including the specifics of parallel distributors who repackage. The direct involvement from the outset of experts from these sectors with their professional experience has ensured that both the concept and the detailed design of the stakeholder model are technically robust and cost-effective.

At this stage, the EMVO concept appears to be well advanced and technically mature and now enters a tender process with the aim of verifying already robust cost estimates.

Consultation topic No. 2; consultation item No. 7

MODALITIES FOR VERIFYING THE SAFETY FEATURES

It is self-evident that the FMD will have major and far-reaching effects for parallel distributors and re-packagers, not least on operational costs. The new regulations will require investment in capital equipment (scanners, conveyors, etc.) and software development, as well as modifications in manpower requirements.

Such, however, is the disparity in EAEPC company member size (larger companies will be able to mechanise the new processes, whereas many smaller operators will continue with manual procedures), that we have not at this time been able to make a full assessment of the financial impact of the new regulations.

We continue with our investigations and will be pleased to share these with the Commission at a later date.

Consultation topic No. 3; consultation item No. 8

PROVISIONS ON THE ESTABLISHMENT, MANAGEMENT AND ACCESSIBILITY OF THE REPOSITORIES SYSTEM

A European Hub as a core data repository is effective, but the Commission should see to it that as few as possible national satellites (= national databases serving connected pharmacies and wholesalers) are attached to the Hub in order to limit overall system costs.

A European Hub is cost effective because it serves as the only interface for each manufacturing authorisation holder to the system. It enables speedy and secure uploading of data (i.e. serial numbers), reduces complexity for interaction with the system and minimises connection costs. This applies to all manufacturers, including parallel distributors.

The cost estimates presented in the Joint Stakeholder response demonstrate that the overall system costs depend largely on the number of satellite databases attached to the Hub and to a much lesser extent on the volume of packages captured by the system. While operating a system on a national (stakeholder-based) model of local repositories would intuitively seem to be the most user friendly fit, or close to the thinking in national terms of classic health policy (e.g. reimbursement), this approach collides with the prerogative of cost-effectiveness; such a 27-member-state system would inflate overall system costs without adding value to patient safety. We therefore invite the Commission, Member States and the European Parliament, in the development of the Delegated Act, to endeavour to achieve a system with a few, possibly regionalised databases attached to the Hub

Consultation topic No. 3; consultation item No. 9:

INFORMATION OF A COMMERCIALLY SENSITIVE NATURE

It is not only the EAEPC's view that data protection merits the Commission's full attention, independent of the future operation through EU-central and/or national databases. The commercial data which will be deposited there is sensitive and confidential, for the respective stakeholders, particularly for manufacturers, including parallel distributors. We support the principle that 'he who creates the data owns the data'. The Commission should ensure that the principle of exclusive data ownership is protected in full.

Consultation topic No. 3; consultation item No. 10:

REPACKAGING OF MEDICINAL PRODUCTS

A) Re-boxing

Repackaging for parallel distribution currently has two forms: re-labelling (as the default option) and re-boxing when re-labelling does not provide for effective market access. Re-boxing consists of producing new outer packaging, sourced under GMP from certified cardboard manufacturers, and controlled destruction of original package material. Trademark law normally determines repackaging form, unless overruled by health authorities' regulation and/or practice.

The EAEPC has consistently argued that, under patient safety, including compliance considerations, re-boxing provides greater package integrity, and higher patient confidence and acceptance. This view is consistently shared by pharmacists, doctors, patients and wholesalers alike.

Requirements introduced by the FMD for the replacement of existing safety features, and the addition by parallel distributors of two new safety features - in addition to the already necessary labelling characteristics under national or EU law - inevitably should lead to re-boxing as the default form of repackaging in order to ensure patient safety and compliance. The Delegated Act should incorporate this solution as mandatory in order to live up to the patient safety objective of the directive as amended, as this clearly outweighs the intellectual property rights of private enterprises.

Replacement of a unique serial number with a new one appears straightforward. Current production processes suggest this being done inline in the assembly line. For security reasons a new code number should be printed as a rule directly on the outer carton and not on a label to be affixed to the package; exceptionally a label printed code could be envisaged if and when the characteristics of the package e.g. small size or flexible tube, or syringes with a concave rather than a flat surface, do not allow direct printing on the outer packaging.

Replacement of tamper-evident safety features with features of equivalent effect means in practice that any existing tamper-evident safety feature must be breached in order to exchange the patient information leaflet (and if extra labelling must be provided on any immediate packaging). Replacement tamper-evident safety features can effectively be applied only on new outer packaging. The covering up of broken seals would inevitably, and visibly, lead to damaging the original package, and thereby also very negatively to affect patients' confidence and acceptance of the product, with the attendant compliance effects. It is therefore necessary for the Delegated Act to require new outer packaging in order to ensure compliance with Articles 47(a) and 54(o).

EAEPC and EFPIA are working on an agreement on re-boxing and tamper-evident safety features. However, it is conditional for such an agreement that the Delegated Act makes re-boxing mandatory.

B) Tamper-evident safety features

Directive 2011/62/EU, at Article 54(a), paragraph 2, holds that the Commission "shall adopt, by means of Delegated Acts, …measures supplementing point (o) of Article 54 with the objective of establishing the detailed rules….".

Article 54 (o) requires two types of safety features to appear on the outer packaging, namely a feature to verify authenticity and identify individual packs, as well as a device for tamper evidence. This provision is addressed to any operator who must comply with the rules regarding outer packaging, i.e. including parallel distributors. We conclude therefore that parallel distributors have equal rights in choosing the type of tamper-evident safety feature as any other manufacturer.

The corresponding recital no. 11 further suggests that safety features should be harmonised at EU level. This will require some kind of Community legal instrument, and as the Commission is already mandated to adopt supplementary measures for point (o) of Article 54, which by definition includes both types of features, we hold the view that the Commission should regulate on this matter.

To that effect we recommend that the Commission establishes an equivalence list "by effect" of tamper-proof/tamper-evident safety features, applicable EU-wide, from which any manufacturer can freely choose. Such a list would lead to EU-harmonisation and further serve to avoid otherwise foreseeable disputes with national regulators and between manufacturers and parallel distributors.