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

Doc.-Ref. Sanco ddg1.d.3(2011) 1342823 (18/11/2011)

COMMENTS FROM:

Name of Organisation or individual
Bundesministerium für Gesundheit (Germany) -Federal Ministry of Health-

The Federal Ministry for Health is pleased to comment on the consultation paper mentioned above:

Consultation item n° 1:

To avoid fragmentation of the technical specifications of the safety feature and the related risks to the verification of authenticity, the second option (**policy option n° 1/2)** should be preferred.

Consultation items n° 2, 3, 4:

The second option (point c) of 2.1.2) allows the safety feature to carry additional data relevant for the medicinal product without major additional resources. This option should be endorsed. Moreover, the batch number is necessary for the documentation requirements stipulated in the Directive. In addition, it would make batch recalls from the supply chain much easier to carry out. Beyond that, the national reimbursement number should be part of the code of medicinal products that must bear safety features to prevent the packaging from being cluttered by two sets of coding. To prevent errors because of the use of different numbers it would be useful, if the reimbursement number would be part of the manufacturer product code.

Consultation item n° 5:

The linear bar code is not optimally suited for carrying a major quantity of information. This can lead to problems with small outer packagings. However, one-dimensional bar codes provide the advantage that pharmacies already have the necessary readers in place.
By contrast, the 2D bar code also allows major amounts of data to be packed on a relatively small area. In light of the above-mentioned preferred option (use of the code for product name, serialisation number, batch number and expiry date), therefore, it is to be endorsed on grounds of data quantity. In this case, the costs to the pharmacies will just amount to the costs of purchasing reading devices that, in the context of the securPharma project, are estimated at approx. €1000 to €1500 per pharmacy.

Identification by means of RFID chips is more cost-intensive than printed bar codes and there is the concern over a possible interference with product quality.

On account of the foregoing, we favour the identification of individual packs of medicinal products by means of 2D bar codes.

Here, it must be borne in mind that the carrier is expected to allow data to be recorded in various currently used and recognised coding formats, and that the compatibility and readability of these formats must be ensured. This prevents a monopoly of individual suppliers and considers security systems already in place in several Member States.

Consultation item n° 6:

Under particular circumstances medicinal products can be dispensed in a doctor's surgery. In these cases it must be ensured that here, too, authenticity is verified and the product is checked out of the system.

Consultation item n° 7:

The first option describes pure end-to-end checks. The advantage is that wholesale distributors will not be saddled with additional costs. The disadvantage is that no further checks will be done on the way from the manufacturer to the dispensing point and therefore, falsified medicines might, in some cases, remain on the market for long periods of time (without, however, being dispensed). Moreover, the option contradicts the Directive that, in Article 80 ca), stipulates that the wholesale distributor must check the safety features to verify that the medicinal products received are not falsified.

However, comprehensive verification by the wholesale distributors would cause them unreasonable costs and also involve considerable problems with large packaging units, since they would have to be unpacked to allow the codes to be scanned. Therefore, an appropriate way to check for the presence of falsified products in the supply chain would be to have wholesale distributors carry out random checks. Here, the source of the medicinal products should be taken into account (pharmaceutical entrepreneur or subsidiary company with a wholesale authorisation under section 52a of the German Medicinal Products Act (AMG), fellow wholesalers, products returned by pharmacies).

Moreover, parallel importers who, after relabeling them, are going to market the products under their own name, should be able/required to verify the serialisation numbers and check them out of the repository before being able to check them into the repository prior to placing them on the German market.

Therefore, we prefer option 2 **(policy option n° 2/2)**.

Consultation item n° 8: Comments/advantages and disadvantages of the three options

Regarding the repositories system, the options raised have their pros and cons. The crucial point is to ensure data protection and to avoid any possible misuse of the data.

Moreover, the endeavour may not add any financial or staff burden to the Member States.

This item has to be further discussed based on the results of the study pursuant Article 4 of Directive 2011/62/EU.

D. Consultation topic N° 4:

Moreover, the paper argues that the scope of the unique identifier is non-optional, i.e. certain medicinal products must bear the safety features while other may not bear it. This is not in line with the wording of the Directive. The latter only stipulates which medicinal products shall bear the safety feature and which ones are not required to bear it. It is silent on which medicinal products may bear the safety feature.
This item has been the subject of intensive discussion at several RAG meetings. Also when translating that document, care was taken to choose a formulation that allows the optional affixing of safety features.

On this crucial consultation topic in this paper, there is no consultation item. However, it is precisely the scope of the safety feature (unique identifier) that has the greatest impact on the stakeholders involved.

If exemptions from this obligation are only to be granted under stringent conditions, this would be tantamount to an obligation to label next to all prescription medicines with unique identifiers. This is not necessary under safety aspects and would imply major costs for the manufacturers. Here the need for safety on the one hand must be properly reconciled with reasonable burdens on the stakeholders on the other, especially given that the number of falsified medicinal products detected in the EU's legal supply chain has been negligible so far.
Therefore, the lists should be drafted strictly in line with the criteria for assessing the risks of falsification given in the Directive and the requirement for safety features be limited to the cases where an actual risk is known to exist.

By the same token, a sense of perspective should be maintained when sketching future trends. It cannot necessarily be foreseen at an early stage which specific medicinal product is at risk of being falsified. Here too, therefore, assessments should be strictly facts-based. Consequently, the instrument should be sufficiently flexible to be swiftly adjusted to current developments as needed.

Consultation item n° 11:

One ATC code might cover a vast range of different medicinal products with highly disparate risks of being falsified.
While identification by brand name is precise, relevant lists are very resource-intensive to draw up and maintain.
Therefore, the most reasonable solution would be consistent classification by name of the active substance; if necessary, supported through a flexible case-by-case approach.
An added criterium might be, for instance, the quantity of active substance per single dose or per pack.

Consultation item n° 12: Comment on the proposal

Assessment:
The aim behind this proposal seems to cover the largest possible amount of prescription medicines by safety features. Under the proposed points-based classification, a product will necessarily score six points if at least one point per criterium applies.

By setting the "high price" criterium at two euros per pack, all of these medicines will score at least ten points under the foregoing approach and will be covered, as a result.
In Germany, approx. 85% of all prescription medicines sell for a manufacturer's gross price above two euros per pack.
Application of these criteria would be totally different if the possible score would be set between zero and five and expensive medicines start at €100.

Consultation item n° 13:

After determining the identification criteria, the Commission should first of all submit a list. Further notifications of falsified medicines identified in the EU and third countries are already registered by the Member States and the EMA.