DELEGATED ACT ON THE DETAILED RULES FOR A UNIQUE IDENTIFIER FOR MEDICINAL PRODUCTS FOR HUMAN USE, AND ITS VERIFICATION
COMMENTS FROM THE SPANISH AGENCY FOR MEDICINES AND MEDICAL DEVICES.

As an overall remark, we consider that a cost benefit approach when deciding about these elements is of capital importance, in particular in the current context.

A. Consultation Topic nº 1: Characteristics and technical specifications of the unique identifier.

When considering the characteristics and technical specifications of the identifier, it must be taken into account that a flexible approach is needed in order to allow the identifier to be adapted to the continuous progress of this kind of technologies.

Consultation item nº 1:

We are in favour of policy option 1/2, harmonization through regulation because at this moment the different technical solutions are not interchangeable. The harmonization is needed to ensure interoperability of the system between different manufacturers, making verifications easier for wholesalers, pharmacies and other agents (e.g. competent authorities) in different Member States. The use of different products coding would make very difficult to manage the system. Disadvantages of the second policy option are negligible when compared to the advantages; the anticipated cost for companies which already have a system of serialization in place is minimal.

Consultation item nº 2:

Serialization number as per point 2.1.1. limits the amount of information that can be carried by the technology without any justification. Such requirement would be voluntarily and needlessly restricting the amount of information machine-readable. We consider there is no justification for the implementation of such a limited system that would not permit the fulfillment of some of the other purposes for which the safety feature may be used.

With regard to the manufacturer's product code we consider that this concept should be clarified. We have already a European code for manufacturer and importers in EudraGMP (MIA: Manufacturers Importers Authorization number). Would this refer to this code? Or it is a new code that refers to the manufacturer plus a code of the country where it is established? In the case of imported medicinal products, would it be the code of the EU importer? When a medicinal product has several manufacturers or partial manufacturers, will different manufacturers codes for different batches of the same medicinal product be included?

Consultation item nº 3:

Technologies such as 2D barcodes (in its different standards) may carry a lot of information as alphanumeric characters without added costs, once the supporting hardware (printers, readers) is available. So it seems reasonable to include more information such as batch code and expiry date, which are relevant, for instance, for pharmacovigilance, product recalls and facilitates management of stocks and record keeping (i.e. by wholesalers). 2D barcodes could be read and information used with the sole purpose of managing stock, with or without checking the number in the repository.

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Batch numbers are linked to expiry dates so if it is necessary to choose between both, the batch will be more important to be included.

Consultation item nº 4:

2D barcodes can integrate national reimbursement number apart from the serialization number, without replacing it (Option 1). This could allow the individual package to keep the original serialization number in different Member States: e.g. in intracommunitary or parallel trade the number would change if the repackager (manufacturer) code changes and each Member State could add its own reimbursement number.

Including the national reimbursement number in the 2D barcode is much more cost-effective than having two parallel systems in place. It offers the advantage as well to allow for a one-scan only at the dispensing point fulfilling both purposes.

Consultation item nº 5:

Best available option is matrix or 2D-barcode (particular standard to be determined): it can carry a lot of information in alphanumeric characters (more data per unit area than linear barcodes), it is easily scalable and very robust, and technologies are readily available (readers, printers, barcode generation software...) at affordable prices. This technology has become widespread in industry (e.g. electronic gadgets, medical devices and some medicinal products, for internal tracking of materials). An example of the widespread use of this technology is its use in handheld devices (mobile phones, tablets...), e-tickets...

2D barcode readers can be based in different technologies (laser, camera...), they are compatible with all software platforms and flexible (many can read both 1D and 2D barcodes). Current prices start from 120 euro approximately.

Due to the limited carrier capacity of linear barcodes, they cannot be considered as fit for this purpose.

Concerning RFID[1], the main advantage of this technology is that it allows to "read" the tag when it is out of the line of sight, but within the range used by the antenna. This limitation (range) diminishes the impact of this advantage (the longest the range, the more energy the interrogator must use to activate the tag, the more heat could be generated and the greater the risk of label tracking). Although research in RFID-tags manufacturing has reduced costs, they are still much more expensive than barcode technologies. There are also privacy concerns, including illicit tracking of products and profiling of patients after the sale.

B. Consultation Topic nº 2: Modalities for verifying the safety features.

Consultation item nº 6:

Systematic check-out of the serialization number at the dispensing point is the cornerstone of the authentication by using the safety features. Thus this verification and check-out should be performed at all points where the medicinal products are supplied to patients (pharmacies, hospital pharmacies, retailers, drugstores...).

[1] Only passive tags are considered.

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If a repackager replaces the safety feature (after verifying the authenticity), it should be checked out as well (thus avoiding the re-use of this serialization number), although traceability to the original medicinal product codes should be ensured, in order to allow for prompt action (e.g. recalls) if needed.

Consultation item nº 7:

Policy option nº 1/2 is an unavoidable verification, at the point prior to delivering the medicine to the patient.

Additional random verifications based on risk criteria at the level of wholesale distributors (Policy option nº 2/2) can be used. In this case, serialization number cannot be checked out by the wholesaler. A risk based programme of verification by wholesalers could take into account product-related risks (e.g. products with history of falsification, products that are new to the wholesaler, products with problems of supply), supplier-related risks (a new supplier has been approved)...or it could be performed on request of competent authorities for certain products.

Concerning policy option 3, it would be an excessive burden for wholesalers, with the current technological means, without a real justification on public health risks in the EU current scenario of falsification of medicinal products. The wholesaler could not check out the serialization number, so this verification is less effective that the verification performed at the point of dispensing. If technologies in the future allow for these controls without a high burden for wholesalers, this policy could be then considered as the balance between benefits and costs would substantially change.

If all the information (reimbursement number, individual identifier) is integrated in one machine-readable barcode, the time consumed in scanning when medicines are dispensed will be shortened.

Concerning the quantitative information requested, numbers of wholesalers, community pharmacies and hospital pharmacies in Spain are 328, 21,000 and 800 (these two last figures are approximate).

C. Consultation Topic nº 3: Provisions on the establishment, management and accessibility of the repositories system.

Consultation item nº 8:

Policy option nº 3/1, stakeholder governance, raises some concerns:

- About the protection of information, extremely valuable from a commercial perspective, when the database is managed by or on behalf of stakeholders.
- Greater differences in the systems across EU could be developed, which may hinder verifications in intra-EU trade.
- There could be a conflict of interests, difficult to handle, between stakeholders when taking decisions related to the (access, selection, property of) information included in the repository

Policy option nº 3/2 could turn the repositories system unmanageable. The EU-wide traffic volume in both directions (in-manufacturers, out-pharmacies, wholesalers) could be very intense. Retail supply of medicinal products is not harmonized at EU-level, and national features of distribution and dispensing systems could be ignored/ disregarded.

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Policy option nº 3/3 would permit a better adjustment of the repository to the national systems. Contribution of stakeholders in the set up of the system would ensure better acceptability. A mixed system (developed by stakeholders, managed by a public body) could be a compromise solution.

Consultation item nº 9:

In any case, the access of stakeholders to the information included in the repository should be limited to the information related to their own products (in the case of MAH/manufacturers) or their activity (in the case of wholesalers or pharmacies).

A direct online access to the information from this/these database(s), including information relevant to pharmacovigilance/reimbursement purposes, should be granted to National Competent Authorities. Provisions ensuring this access should included clearly on the delegated act.

Consultation item nº 10:

Personal data should not be generated or stored in the repository system, as these data do not contribute to the purpose of the system and health-related personal information is highly sensitive.

Repackagers should check out the serialization number from the repository. Concerning paragraph 76, an alternative to the replacement of the serialization number could be considered. Unique identification number from the original manufacturer could be kept, while changing the manufacturer product code (thus generating a new serialization number, see chart in paragraph 29 of the concept paper). Whichever of the options is chosen, traceability between old and new codes should be ensured, as it is crucial in recalls.

B. Consultation Topic nº 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 nº 11:

We are in favour of a case-by-case approach. In certain cases decisions could be taken for a whole ATC group, while in other cases only some subtypes or even brands could be listed.

It should be considered that prescription status of a given product is not harmonized in all Member States.

In addition to that, we think that the capacity of the Commission to adopt decisions about safety features for products authorized under national procedure and marketed in one Member State only is questionable.

It should be also taken into account that Members States that will use the information for prevention of reimbursement fraud, all reimbursed medicinal products (with or without prescription) will bear safety features.

For products (with or without prescription) not included in the lists, there should be procedure to include it promptly in the lists when a real risk of falsification is detected.

Consultation item nº 12:

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A semi-quantitative approach offers many points for discussion. A good way to test how good the risk quantification tool is working is to challenge it with simulated cases and evaluate how good/bad the outcome is. We generally agree with the results obtained.

Concerning criteria 2 (incidents in the EU) we would like to change the wording (change "Several incidents" by "One or more incidents"). We consider that one incident of falsification should be enough to get the highest score.

E. Consultation Topic nº 5: Other issues.

Consultation item nº 13:

Concerning the notification to the Commission of medicinal products at risk/not at risk by Member States, we consider that this system should exclude nationally registered products present in the market of one Member State only. In this case, this issue concerns exclusively to that Member State and the decision should be adopted at a national level; the legal basis for intervention of the Commission is unclear.

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