April, 26th 2012

Response of the Ministry of Health, Welfare and Sport, the Netherlands, to the concept paper submitted for public consultation Sanco.ddg1.d.3 (2011)1342823

DELEGATED ACT ON THE DETAILED RULES FOR A UNIQUE IDENTIFIER FOR MEDICINALPRODUCTS FOR HUMAN USE, AND ITS VERIFICATION

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

The Netherlands recommends policy option **n°1/2, i.e. harmonization through regulation.**

Given the movement of medicines across national borders, any effective coding and identification system must be able to exchange information between Member States. Option **n°1/ 2** will ensure interoperability across EU Member States and thereby protect patients against receiving falsified medicines via the legal supply chain. European wide harmonization through regulation (to a certain extent) will also reduce overall costs by avoiding fragmentation which would be costly to integrate into verification systems. The Delegated Act should require the use of existing and internationally recognized standards which are already used for serialisation numbers and their carriers in existing verification systems (e.g. in France, South Korea, Turkey and other countries).

Option **n°1/1** would give the manufacturer the greatest flexibility to use the appropriate technical solution; however, this flexibility could result in a high fragmentation due to different specifications and data carriers on the market, potentially using different standards for equipment and processes. These differing standards and processes would be costly and difficult to integrate and would call into question the effectiveness of the system in preventing patients from receiving falsified medicines via the legal supply chain. Policy option N° 1/1 should therefore be ruled out. But the Netherlands finds it important that manufacturers are involved on the elaboration of the characteristics and technical specifications of the unique identifier. Cost effectiveness and proportionality are important factors. An impact assessment should be undertaken to guarantee that the most appropriate cost-effective system will be put in place.

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

The Netherlands supports the use of harmonized and internationally recognized standards for the identification of products and stresses the inherent cost-effectiveness of basing the approach on established international standards. This will ensure smooth transition from current state-of-play across the EU and flexible implementation.

Basing the approach on established international standards – in line with systems in place in other countries (e.g. France, South Korea, Turkey…) - will also help ensure alignment with national healthcare cost reduction initiatives.

In contrast, if Member States select coding systems outside the internationally recognized standards, this is likely to generate a highly fragmented system. This would increase costs significantly for Manufacturing Authorisation Holders (MAHs). It would also hinder interoperability thus making it more difficult to ensure prompt verification, patient

safety and alignment with other national programmes. Clearly, this situation should be avoided.

A balance has to be struck among interoperability between countries and national requirements. Different standards of product coding are used at national level. Adding a unique identification number to the package will only be required in case of a high risk product.

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? Please comment.

A cost-effective system mandates the inclusion of batch number and expiry date in the pack code, in addition to the product code and serial number. Their inclusion would enable wholesale distributors and pharmacists to automatically read the batch number, serial number and expiry date, significantly enhancing patient safety and improving product recall procedures. It would also facilitate the provision of additional services to patients by pharmacists.

Moreover, a system incorporating batch number and expiry dates into a code would allow pharmacists and wholesalers to:

- Optimise their inventory management (according to expiry dates);
- Track materials such as narcotics, record batch numbers as required by the FMD "at least for products carrying safety features" and in some countries (e.g. France) as required by law;
- Help prevent the dispensing of expired or recalled products, and confirm the identification of products subject to recall;
- Optimise reporting on adverse events in biological and biosimilar products, which present distinctive safety challenges, through batch number recording as encouraged for under EU pharmacovigilance rules[1];
- Other healthcare providers, such as hospitals, would also derive value from this optimum pack code during administration of products to help prevent medical errors and administer short dated products, etc.

Not requiring the inclusion of batch number and expiry date in the pack code, as well as product code and serial number, would represent a wasted opportunity to tackle the significant dangers for patients posed by currently sub-optimal recall processes, requiring manual checking of every pack of medicines.

In order to function as a viable safety feature, the serial number on the pack has to be serialised randomly and should be used in conjunction with the product code to form the "serialised product code", referred to as the "unique identifier" in the FMD.

In summary, to ensure the system cost-effectively delivers on its goals, all prescription-only packs should be encoded with four data elements, i.e. product code, serial number, batch number and expiry date. The additional costs of including these data elements in the pack code are likely to be negligible, but this requires further investigation.
The batch number and expiry date are currently on the pack of medicinal products. It is important that the necessary data on the packaging remains readable and available for the patient (for example the expire data should not only appear in a barcode due to the fact that for the patient it will not be possible to detect the relevant information).

[1] Volume 9A of the Rules Governing Medicinal Products in the European Union: Pharmacovigilance for medicinal products for human use Chapter I.4.

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

To include a National reimbursement number is not preferable for the Netherlands. Moreover the future system should be flexible in order to reflect the different national systems.

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.

The **linear barcode** is not designed or suited holding more than 1 or 2 data elements on consumer packaging. It would be unable to carry the necessary amount of data and still fit on the majority of packs. It is not the most effective solution (large barcodes may mean larger packs or may require the linear barcode to be split into two to three separate linear barcodes), it would be more difficult to print and more prone to damage and could have lower read rates than the Data Matrix code. On the other hand the linear barcode is widely used and in most cases able to read by existing scanning systems. Additional requirements will lead to higher costs.

Radio-frequency identification (Rfid) is not yet fully reliable and mature enough, as well as too expensive and therefore not the most cost-efficient.

2D-Barcode (2D Data Matrix), this carrier can carry a large number of data on a small label, however many pharmacies in Europe are not equipped with a suitable reader, this will bring extra start-up costs for reading devices. While the requirement to purchase scanners will generate an additional cost, the price difference between a linear code scanner and a 2D scanner is negligible. And new scanners could be purchased as part of the normal replacement cycle for equipment, therefore at no extra costs. Scanning equipment that can read both linear and 2D codes is also available.
For readability, the 2D barcode on a package should be limited to no more than two codes. The basic requirement is that the patient does not suffer from the additional information (for example 2Dbarcode) on the package and has the necessary information including information in Braille.

Taking into account the future requirements the 2D Data Matrix code is the most effective carrier to hold the information relating to each single pack (product code, batch number, expiry date, a unique randomized serial number and, where necessary, the national product number) as:

- It has the ability to store the information multiple times in the same code which allows a reading even if 25% of the code is damaged;
- It is applicable to small packs;
- It is widely used and thus tried-and-tested (the DataMatrix has been an ISO standard for 12 years and is widely used globally);
- Manufacturers have wide experience of its use due to requirements in France, South Korea, Turkey and other countries;
- It is flexible, i.e. it can adapt and respond to technical advancements/changes of the future.

To conclude, the use of a 2D Data Matrix code is recommended for efficiency and effectiveness. It should also take into account initial costs and structural costs.

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?

The Netherlands endorses **policy option n° 2/1, Point-of-Dispensing Verification by the pharmacist.** Systematic verification by wholesale distributors as suggested in policy option n° 2/3, is not warranted as this is more costly, disproportionate to the objectives of the Directive, and would provide no greater level of safety to patients than point of dispense verification. In this respect, we welcome the fact that track-and-trace is at no point mentioned as a policy option in the Concept Paper.
We oppose policy option n° 2/3 (systematic verification of all packs by wholesalers) as this is costly, disproportionate to the objectives of the Directive, and would provide no greater level of safety to patients than point of dispensing verification.

Pharmacy level verification at the point of dispensing with an interface for wholesalers is a robust and cost-effective way to improve patient protection. Systems should be configured so that pharmacists and parallel distributors can undertake checks at any point after receipt of goods, as well as performing the check-out operation at point of dispensing/repackaging. Irrespective of the model chosen, since the technical challenges of point of dispensing verification may initially vary across the EU, pharmacists should be permitted initially to verify (checking out) medicines as they enter the pharmacy, until such time as any technical issues with regard to point of dispensing verification have been resolved.

Consultation item n°7: Please comment on the three policy options set out in points 1 to 3. Where do you see the benefits and disadvantages? Please comment on the costs 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.

The Netherlands is in favor of a system that gives wholesalers access to the database to authenticate for the drug through random verification. Systematic verification by wholesalers increases the costs, and does not necessarily lead to an improvement of patient safety. The Directive already offers a constellation of measures.

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

The Netherlands is of the opinion that more information on estimated costs is needed and needs to provide by the European Commission before a balanced advice can be provided, to make an informed choice how a stakeholder governance policy option does precisely compare with a national governance policy option?

Given the many transactions that take place on a daily basis a national system of repositories seems to be the most appropriate.

With the design of the system the European Stakeholder Model (ESM) can be taken into account. The (ESM), proposed by EAEPC, EFPIA, GIRP and PGEU, is composed of a series of national data repositories (linked via a European Hub), that serve as the verification platforms which pharmacies and other registered parties can use to check a pack's authenticity. The system will be interoperable between EU Member States (with the possibility of further expansion to EEA countries and beyond), with flexibility to account for national needs. Importantly, and in line with the FMD, the European Stakeholder Model will be developed in partnership with governments and public agencies – as well as all other relevant actors along the supply chain.

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?

Commercially sensitive information should be protected. Even when a database is introduced the manufacturer should have the right to access only his own data, whereas inspectorates/National Competent Authorities will have access to all data. There is need for further elaboration in terms of who has access to what information at what level.
In very specific circumstances which have to be defined in advance by the involved stakeholders, it might be necessary to be able to access certain information (e.g. in cases where counterfeits are discovered, in case of recalls, testing the system).

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

4.2 The Netherlands subscribes to the fact that the repositories system would not contain personal data. Protecting personal data is important.

4.3 With the repackaging of medicines the source (quantity) should be taken into account in relation to the number of new packages.

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?

The Netherlands would be more in favor of a blacklist which is easier to check (instead of verifying an extensive white list). Generic drugs should only be blacklisted as it emerges from the risk analysis. Proportionality is the key focus. Regarding risk analysis a more detailed approach on the basic criteria is needed.

The preference of the system will also be depending on the number of products that will assess as high risk. Whatever system is adopted it should be proportionate and relative according to the price of the products. Lower priced products should contribute in a relative way to more expensive products.

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

We need a further substantiation of the criteria as described in the quantified approach. For example, how is the price of> 2 euro established? This should be further developed.

Consultation item n°13: Please raise any other issue or comment you would wish to make which has not been addressed in the consultation items above.

An updated impact assessment (in follow-on 2008) should be performed to identify the current potential health risks. Measures that should be taken must be cost effective and in proportion.