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COSTEFF response to the European Commission Concept Paper on the delegated act on the detailed rules for a unique identifier for medicinal products for human use, and its verification

April 2012

email:

sanco-pharmaceuticals@ec.europa.eu

Dear Sir or Madam,

Public consultation on the delegated act on the detailed rules for a unique identifier for medicinal products for human use, and its verification

COSTEFF is a European association promoting the interests of its members – healthcare companies and organisations – determined to bring cost-efficiency and innovation to the heart of health policies in Europe. Created in July 2009 by a group of private healthcare companies, COSTEFF is a pan-European advocacy group that seeks to create a new alliance around the issue of cost-efficiency and innovation in healthcare, including both public and private actors. COSTEFF wants to promote free movement of goods, fair competition in the healthcare sector and the development of an EU legal framework conductive to greater dialogue across the various branches of healthcare.

You can find out more about how our members benefit patients and delivers growth for the European health care market on the COSTEFF website http://www.costeff.eu/.

We welcome the opportunity to comment on this European Commission Concept Paper on the delegated act on the detailed rules for a unique identifier, and its verification. We look forward to continuing to work together with the Commission to devise processes which will guarantee the safety of patients whilst continuing to ensure free movement of goods on the European market.

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A. Consultation Topic n°1: Characteristics and technical specifications of the unique identifier

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?

Consistency across the EU is the most important consideration. Consequently, interoperability within the European Union will be guaranteed. The coding should build upon the data matrix code according to ISO/IEC 16022; the data structure as well as the syntax on ISO/IEC 15418 and ISO/IEC 15434.

Leaving the choice of the technical specification to the individual manufacturer should be approached with caution as it could open the door to variability. Therefore, COSTEFF is convinced that all manufacturers should be mandated by a Regulation to apply the same technical specification. No additional National Requirements are necessary.

A harmonised approach will not only smoother implementation, it will also guarantee cost efficiency and less bureaucratic effort. COSTEFF supports the harmonisation of requirements, laid out in policy option n°1/2. However, any serialisation number, product code, and additional product information should be implemented with attention to avoid adding a layer of complexity and escalate administrative costs.

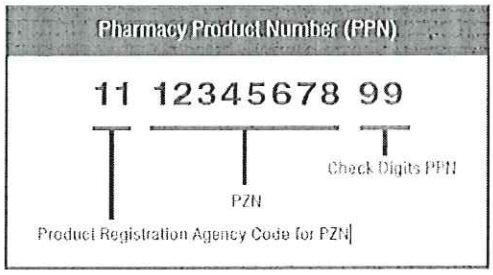
Consultation item n°2: Where do you see the advantages and disadvantages of the approach set out in point 2.1.1.?

PPN

Source: IFA-Coding-System Spezifikation PPN-Code, November 2011, p. 13

The above illustrated data matrix code is called Pharmacy Product Number (PPN) and was originally developed by securPharm, a German based stakeholder project. For more information, please visit the website: www.securpharm.de. The PPN protects against counterfeiting of medicinal products by: The coding of packages is the basis for verification; automatic identification of medicinal products in the supply chain; and machine readability of batch number and expiry date.

In Germany, the PPN would be generated by the Pharm Centralisation Number [*Pharmazentralnummer*] (PZN). The PPN incuding the PZN looks like follows:



Source: IFA-Coding-System Spezifikation PPN-Code, November 2011, p. 6

An Issuing Agency, the IFA, provides the Product Registration Agency Code (PRA-Code) for any national numbering system (NTIN) used in pharmaceutical applications. PZN will determine the pharm centralisation number. Using this prefix, any national product number is translated into an unambiguous product number PPN. A two digit checksum safeguards the PPN against errors in data entry or data transmission. For further information, please visit the website: www.ifa-issuing-agency.org .

In a nutshell, the package could look as follows:

Source: IFA-Coding-System Spezifikation PPN-Code, November 2011, p. 1

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?

COSTEFF agrees with the proposal of including additional product information, namely the batch number and the expiry date. However, we emphasise the importance of data protection. All product related information included in the serialisation number will be checked against the information stored in the respositories system. Therefore, we are confronted with high commercially sensitive data. Therefore, we urge the European Commission to pay special attention to data protection issues. Please also see our response to consultation item n°9.

This process ensures that each medicinal product package which leaves the supply chain via a distribution path or is removed from circulation in another manner (e.g. damage or recall), can be marked as "used" in the system.

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?

COSTEFF would opt for 'Option 2' – the serialisation number includes the national reimbursement number. This will ensure – in the most cost efficient manner – that national systems can adapt to the cross-border serialisation number. Including the national reimbursement number would provide for extracting the national identification out of the serialisation number and using them for further processing. Therefore, national processes would not have to be changed nor adapted.

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.

COSTEFF is of the opinion that concept n°2, the 2D-Barcode, should be applied: Each original product which is affected by the guideline is provided with a unique identity by the manufacturer, in the form of its own 2D-Barcode, as well as a seal on each side of the package opening. The importer verifies and confirms the authenticity of each individual package by determining the identity by means of a comparison with the repositories system.

The serialisation number of the original package is marked as "used" when the product is re-packaged. Each new package resulting from re-packaging is again provided with a unique identity, i.e. with a new serialisation number. The 2D-barcode should contain additional information such as the identification of the medicinal product, the batch number and the expiry date.

On each re-pack, a seal is to be placed on each side of the opening of the package from the pharmaceutical company. After re-packaging, the seal of the original manufacturer is replaced with the seal of the importer.

At the same time, we oppose a linear barcode as well as the radio-frequency identification (RFID). A linear barcode increases in size with the number of characters. Some pharmaceutical packages would simply not provide for the necessary package space. At the same time, RFID is just too expensive and would ask for disproportional adaptions at a company's production line. COSTEFF would also like to point out the environmental effect: RFID would lead to a massive gain in Electronic Equipment Waste.

A 2D-Barcode provides for a cost-efficient and reliable option.

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B. Consultation Topic n°2 – Modalities for verifying the safety features

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?

A systematic check-out of the serialisation number at the dispensing point will guarantee that the medicinal products are genuine when dispensed to the patient. At the same time, implementing costs will be manageable. Therefore, this option will achieve the objectives of preventing falsified medicines reaching patients.

COSTEFF would like to point out that there are also other dispensing points that are not mentioned in the Commission's paper. Just to mention a few examples: doctors' samples, at veterinarians, or at dentists. Basically, all these dispensing points would be obligated to deal with the systematic check-outs.

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 each 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.

While the importer verifies and confirms the authenticity of each individual package by determining the identity by means of a comparison with the repositories system, the detailed procedures for other actors – such as wholesalers – have not yet been defined.

As with cost effectiveness of health care systems, authenticity of medicinal products for the safety of consumers is a focal point for COSTEFF. Therefore all the authorised market participants must have the opportunity to verify the authenticity of each medicinal product package. Naturally this also applies to wholesale dealers. In the view of COSTEFF, wholesale dealers should have access to the future system as do all the other market participants, in order to be able to verify the authenticity of medicinal products. The authorisation of the individual market participants in the system should be restricted to the necessary functions.

COSTEFF wants to point out that Directive 2011/62/EC does not mandate to guarantee 'traceability' as pointed out as an advantage of policy option n°2/3. The Directive states clearly that safety features should allow verification of the authenticity and identification of individual packs, and provide evidence of tampering. However, traceability of each individual

pack is not necessary as the verification of the authenticity of each individual package will safeguard patients from falsified medicinal products.

Still, COSTEFF tends to support option n°2/3. This option guarantees that also the wholesale dealers can verify the authenticity of the package. In contrast, option n°3/3 would require for the not mandated track & trace and be extremely expensive. Hereby, we will create a huge collection of data without any additional value for the consumer.

C. Consultation Topic n°3 – Provisions on the establishment, management and accessibility of the repositories system

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).

In order to ensure verification throughout Europe, a transnational central system is to be preferred – in concrete: policy option n°3/2 – EU governance. Only through such a system can verification be ensured. The more systems that have to be synchronised, such as policy option nr°3/3 and also nr°3/1 suggest, the more complex are the synchronisation procedures. In decentralised systems, considerable costs and expenditure would accrue for the implementation of data transfer mechanisms and data synchronisation. In addition, enormous cost-intensive configuration effort for the interaction between the different systems would have to be expended. Therefore a pan-European repositories system to which all actors are connected, taking into consideration the cost-benefit factor, is to be preferred.

All the authorised agents who import medicinal products must, independent of the country of origin, be able to verify whether packages have already been distributed in another country. Only in this manner can the package in question actually be verified, with the serialisation numbers, within the EU area.

On the other hand, the challenge of a central data system lies in the fact that when establishing such a system, different legal framework conditions have to be observed in the different countries. In detail, the pan-European repositories system contains the following:

- Each pharmaceutical company loads the serialisation numbers it has assigned into the data system;
- The data system includes a mechanism where medicinal product packages which have left the supply chain or which have been removed from circulation in another manner, are reported as "used" in the system;
- Pharmacists' data systems are linked to the central data system, without the pharmacists having the same access to the central data system as that of manufacturers and importers.

However, COSTEFF is also open for further discussions on option nr°3/3 – national governance. Therefore, it must be guaranteed that importers have the option of a systematic check-out of the serialisation number equal to the dispensing point. Hereby, we assume that each national system is a closed system which will guarantee easy check-outs of serialisation numbers to enable free movement of goods within the European internal market. These check-outs can be done via "expiration". COSTEFF wants to point out that this option still has to safeguard data protection. Information of commercially confidential nature needs special attention and must only be accessible for authorised public agencies [please also see answer on Consultation item n°9].

COSTEFF would like to point out that in Germany there will be a project starting in 2013, led by IFA and SecurPharm, which will introduce a national coding system. This system will incorporate all actors along the distribution line and could serve as a welcoming best practice example in putting together a concrete example of a repositories system.

Policy option n°3/1 – Stakeholder governance will not guarantee a European level playing field.

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?

A consequence of the establishment of a data base and/or the merging of the national data bases may be that information regarding the extent of deliveries, the source and target of deliveries or the identity of wholesale dealers is collected. In theory, such details can be utilised to re-trace such details out of economic interests and not for pure reasons of security technology. This data is economically sensitive for an entire branch of industry and is therefore to be provided with the best possible protection. COSTEFF demands that such a data base be accessible for authorised public agencies only.

The corresponding data includes:

- Product master data: Must contain data for identification and verification only. Product master data does not constitute competition for the national medicinal product data base;
- Serialisation data of the manufacturer (for the national systems);
- Access authorisation and configuration.

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

The linking of a new serialisation number to an old one by the importer is not possible, but it also is not necessary. Frequently, the importer must adjust the original package to the pack sizes which are common in a member country, in order for them to be distributed. Once parts of several original packages are utilised for a new package, linkage is excluded because the individual parts (e.g. several blisters) of a package are not serialised separately. This applies independently of whether the blisters are re-packaged into new packages produced by the

importer or whether further blisters are added to an original package. However, linkage is not necessary because, as mentioned above, the importer verifies the authenticity of each individual package when receiving the goods.

For example, the importer must adjust the pack size when he/she buys packages with eight tablets (with two blisters with four tablets), but only packages with twelve tablets are being sold on the national market. In this case, three packages with eight tablets each become two packages with twelve tablets and three blisters each for the national market. Thus it is evident that linkage of the old serialisation number with a new serialisation number is not possible.

In this connection, COSTEFF would like to draw attention to special cases which legislative authorities should take into account. Otherwise, gaps might appear which facilitate counterfeit medicinal products entering the market. For example, it must be taken into consideration that medicinal products leave the supply chain not only via distribution through pharmacies. In accordance with German pharmaceutical law for example, medicinal products which as a rule are distributed by pharmacies only, may in legally regulated exceptional cases also be supplied to other agents by the pharmaceutical company. The administration of medicinal products meant for humans to animals (and also supplying such products to the animals' owner) is permitted – and practised - under German law (§ 47 clause 1 no. 6 of the Pharmaceuticals Law [*AMG = Arzneimittelgesetz*]).

And another example: According to the current state of affairs, the consumer may return purchased medicinal products to the pharmacy. However, from the viewpoint of COSTEFF, the question of what is to be done about the serialisation number of the returned package in this case has not yet been clarified. Should the package be for sale again, and the serialisation number thus reactivated, the door is wide open for falsification, because it can hardly be checked whether the returned package really is in its original state or whether it was replaced with a falsified product.

D. Consultation Topic n°4 – Lists containing the medicinal products or categories which, in the case of prescription medicines shall not bear the safety features, and in the case of non-prescription shall bear the safety features

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?

COSTEFF supports a flexible approach on a case-by-case basis. A flexible approach would facilitate the requirements set in the Commission's paper.

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

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The quantified approach sounds reasonable, but it should be reviewed very soon.

E. Consultation Topic n°5 – Other issues

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.

COSTEFF is a European association promoting cost-efficiency and innovation of health policies in Europe. Being committed to European policy solutions and heavily involved at European level since years makes COSTEFF an integral part of the EU stakeholder environment. Therefore, we would very much appreciate to be invited to the European Commission's stakeholder list. We are greatly motivated to participate at all stages of the European policy process with our knowledge and experience.

COSTEFF would like to thank the European Commission for the opportunity to input into the establishing of safety features and hopes that this process will guarantee a functioning playing field for all health care market participants, while safeguarding the highest protection of patients.

If you have any further questions regarding our response, please do not hesitate to get in contact with us.

Kind regards

Thilo Bauroth
Member of the Board