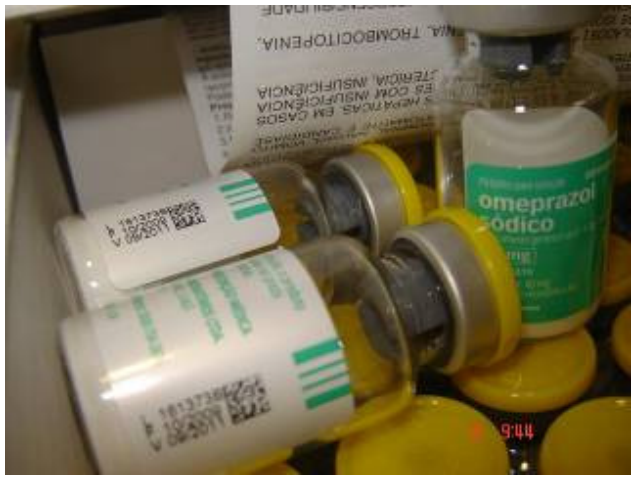
European Association of Hospital Pharmacists (EAHP)

Consultation Response

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



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A PROPORTIONATE SYSTEM FOR HOSPITALS AND A SYSTEM THAT FACILITATES SINGLE DOSE BARCODING

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1) A PROPORTIONATE SYSTEM FOR HOSPITALS

- **In designing the Delegated Act on the Unique Identifier the Commission must understand the differences that exist between the different end points in the medicines supply chain, especially the differences between community pharmacy and hospital pharmacy.**
- In community pharmacy the end point is typically a packet of medicines being dispensed to a patient following production of a prescription or an over the counter sale. The community pharmacy does not typically buy-in very large stocks of particular medicines at one time.
- However in hospital pharmacy, much larger amounts of medicines are bought in to the pharmacy than in a community setting due to the typically large number of hospitalised patients being served, often in specialised hospital units.
- Also, in contrast to community pharmacy, the end point of the medicines supply chain is not the handover by a pharmacist of a packet to the patient, but most often the direct administration of the medicine by a nurse to the patient at the bedside. In hospital, in relation to verification, the packet is not always the initial item of entrance to the hospital, nor the final component of use.

To be proportionate and effective, careful consideration therefore needs to be given to where in the process the "check out" of the safety feature for ensuring the detection of falsified medicines in the supply chain takes place within the hospital. In some cases this might be proportionate at the bulk level, akin to proposed wholesaler requirements. We welcome further discussion with the Commission on this.

The EAHP calls for the Commission to give separate consideration to hospital pharmacy in relation to the development of the Unique Identifier system. This includes what the requirements of verification in hospitals might be, at what stage and in what circumstances (e.g. bulk versus packet level verification).

Further to this, bedside scanning of single dose medicines in hospitals has become a recognised, proven and important final safety feature in the process of medicines administration.

A European medicines verification system should therefore seek to be interoperable with, and facilitate, the practice of barcoding to the single dose administered in hospitals (see next page).

2) A SYSTEM THAT FACILITATES SINGLE DOSE BARCODING

- Medication errors are the single most common cause of preventable adverse events in the healthcare system. A complete identification of a medicine, up to the moment of administration, is therefore a key element of a safe medicines dispensing procedure. Indeed, preliminary studies have suggested the use of bar coded single dose reduces medication errors by 41.4%[1].
- In recognition of the patient safety case, and the effect on reducing errors, in the USA, all pharmaceuticals products sold to hospitals must now bear a barcode on the smallest unit of measure — the size dispensed to the patient (since April 2006)[2]
- Following the US Institute of Medicine report "to err is human" in 2003, the Council of Europe established a Group of Experts on Safe Medication Practices to advise Ministers on the management of patient safety and prevention of adverse drug events in healthcare. Its report in 2006 made a clear recommendation that the national and European legislative framework should *"require complete and unambiguous labelling of every single unit of use of all licensed medicines products (e.g. tablet, vial and nebules), including the international nonproprietary name (INN), trade name, strength, expiry date, batch number and a data matrix bar code. The data matrix barcode should contain a GS1 Global Trade Item Number (GTIN) identifier in addition to the expiry date and batch number."*[3]
- Furthermore, the barcoding of single dose medicines also assists in:
    - **the comprehensive management of medicines alerts and recalls;**

  The nature of medicines use in hospitals means that drugs which are dispensed in multiple dose blisters often have to be cut, separated and spilled out from blister during drug dispensing. As a consequence, without an identifying barcode, information may be absent from the individual dose. Barcoding of the single dose of medicine administered in hospital improves this situation by making the track and trace of the unique dose within the hospital, for various purposes including alerts and recalls, always possible.

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[1] Poon EG et al. Effect of Bar-Code Technology on the Safety of Medication Administration. N Eng J Med 2010;362:1698-707 http://www.nejm.org/doi/full/10.1056/NEJMsa0907115

[2] http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074377.htm

[3] http://www.coe.int/t/e/social_cohesion/soc-sp/medication%20safety%20culture%20report%20e.pdf

- **the management of patient safety in an ageing society**

The demographic future of Europe will see a steady rise in the number of elderly patients in the years to come. This patient group is particularly associated with multimorbidity and polypharmacy, which, combined with the effects of age-related frailty, heightens risk factors when medication administration errors occur. Barcoding of the single dose, and its role in reducing error, can provide essential assistance for health systems in meeting the challenge of an ageing society. The technology's patient safety benefits can potentially apply not only in the hospital setting, but also feasibly in nursing and residential homes for the elderly infirm.

- **managing information in the interests of systems and outcomes improvement**

As costs of medications for all health systems continue to increase, accurate information about how medicines are used by patients, in what dose forms and for what conditions becomes ever more valuable in terms of making evidence-based improvements. Comprehensive barcoding of the single dose of medicine by industry will open new possibilities of understanding and knowledge about overall medication use.

- **providing further assurances against potential counterfeit intrusion and fraud**

There are numerous points in the chain between medicines manufacture and medicines administration where unscrupulous individuals have opportunities to replace legitimate medication with counterfeit medication. For example, in many reimbursement systems hospitals are able to attain medicines at a discounted rate to community. Barcoding by manufacturers and wholesalers of the single dose for use in hospitals can therefore provide a further visual assurance of the legitimate nature of a medicine at the point of administration in the hospital, or its potentially suspect origin if discovered within the community supply chain.

The European Association of Hospital Pharmacists (EAHP) therefore calls on the Commission to actively ensure the specifications for a system of unique identification for medicines do not have unintentional consequences for barcoding of the single dose medicine in hospitals (e.g. through an inappropriate barcode specification and other requirements).To avoid unintentional negative patient safety implications, the forthcoming impact assessment should give a particular consideration to what impacts the specifications of the verification system will have on manufacturer and wholesaler barcoding of the single dose.

ANSWERS TO CONSULTATION QUESTIONS

CONSULTATION TOPIC ONE: CHARACTERISTICS AND TECHNICAL SPECIFICATIONS FO THE UNIQUE IDENTIFIER

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

The EAHP consider option 2 to be preferable, agreeing with the Commission that harmonisation of technical specification (serialisation number and carrier) of the unique identifier should enable a smoother implementation of the policy goal in comparison to leaving the choice of technical specification to the individual manufacturer (option 1). We agree with the Commission that option 1 could lead to a high degree of fragmentation of product coding in the EU, and undesirable outcome in relation to an efficient pan-European medicines supply chain.

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

The proposal at 2.1.1 appears to the EAHP as reasonable at this stage.

Consultation item Number 3: Where do you see the advantages and disadvantages of the approach set out in points (a) and (b) of point 2.1.2?

EAHP support the requirement in a Delegated Act for the Batch Number (a) and the expiry date (b) to be included within the core required information with the unique identifier serialisation number. This will facilitate:

- storage management;
- verification processes;
- medicines recall; and,
- the commencement of medicines alerts.

Furthermore, we urge the Commission in its considerations in this area, to be aware of the report on medication safety produced for the Council of Europe in 2006 by a Committee of Experts. This called in clear terms for the updating of *"national and European legislative framework to require complete and unambiguous labelling of every single unit of use of all licensed medicines products (e.g. tablet, vial and nebules), including the international nonproprietary name (INN), trade name, strength, expiry date, batch number and a data matrix bar code[4]."*

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

EAHP consider option 2 to be preferable – that the serialisation number includes the national reimbursement number (rather than be replaced by the serialisation number). This would appear to provide greater flexibility in relation to the various reimbursement systems that apply across Europe and the fact this is very much a national issue.

Consultation item Number 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 generally preferred system of the EAHP is the 2D Barcode as it offers the best possibilities for the barcoding of single dose medicines administered in hospitals. As mentioned in the Commission's consultation document, the 2D code enables a large amount of data to be stored on a small label, a critical need in relation to small units of medicine.

As an example in practice, the 2D barcode allows small vials to be accurately coded and scanned which would otherwise be difficult with a linear barcode on a curved surface.

[4] http://www.coe.int/t/e/social_cohesion/soc-sp/medication%20safety%20culture%20report%20e.pdf

A 2D barcode would therefore help to make the Unique Identifier system compatible with the expressed desire of the EAHP to have medicines barcoding to the single dose administered in hospitals.

RFID remains a possibility for single dose barcoding but it is still a relatively new barcode technology and we await further evidence of its comparative usefulness and feasibility for single dose barcoding in comparison to the more tested 2D.

See EAHP statement on barcoding for more information:

http://www.eahp.eu/Advocacy/Statements

CONSULTATION TOPIC TWO: MODALITIES FOR VERYIFYING THE SAFETY FEATURES

Consultation item Number 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?

Yes – the Commission should give consideration to the differences in supply chain end point that exists between community pharmacy and hospital pharmacy.

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To be proportionate and effective, careful consideration therefore needs to be given to where in the process the “check out” of the safety feature for ensuring the detection of falsified medicines in the supply chain takes place within the hospital.

In some cases this might be proportionate at the bulk level, akin to proposed wholesaler requirements. We welcome further discussion with the Commission on this.

The EAHP calls for the Commission to give separate consideration to hospital pharmacy in relation to the development of the Unique Identifier system. This includes what the requirements of verification in hospitals might be, at what stage and in what circumstances (e.g. bulk versus packet level verification).

Consultation item Number 7: Please comment on the three 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***

Clearly the Commission's forthcoming Impact Assessment will be central to better understanding the benefit cost ratios of the various options described.

From a hospital pharmacy perspective, in order to effectively prevent against counterfeit medicines, it is essential to have the datamatrix with the serial number **on the package**.

This is a prerequisite requirement for any preferred option chosen by the Commission.

CONSULTATION TOPIC THREE: PROVISIONS ON THE ESTABLISHMENT, MANAGEMENT AND ACCESSIBILITY OF THE REPOSITORIES SYSTEM

Consultation item Number 8: Please comment on the three 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 response, 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 EAHP is aware of these different suggested repository systems, is conscious that all offer both advantages and disadvantages and has not yet formed a settled view as to which would be the most beneficial and proportionate in relation to hospital practice. We will continue discussions with the manufacturing industry, patient groups and other professionals on the issue and will await the publication of the Commission's impact assessment on the topic with much interest.

We do however suggest that patient safety requirements be a key part of the Commission's consideration and determination in this area and should be evidenced within the impact assessment.

Another important aspect is ensuring the verification system has a fast reaction time. Pharmacies are busy environments and any reaction time more than a half a second could cause significant slowing of processes.

Consultation item Number 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?

EAHP does not have a considered view on this issue at the current time.

However, in view of the hospital pharmacist profession's interest as members of the supply chain, in managing medicine shortage problems and advising on best medicines use, we request to be included within any future discussions between the Commission and

stakeholders on the regulation of information of a commercially sensitive nature within the repositories system.

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

Beyond supporting the protection of personal data, and supporting Article 47a of Directive 2001/83/EC regarding repackaging of medicines, EAHP does not have further considered views on these issues at the current time.

CONSULTATION TOPIC FOUR: 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 Number 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?

Identification criteria

EAHP is generally cautious of a system based on identification by brand name, for the reasons identified by the Commission in the consultation paper: the differing brand names of identical medicinal products in the EU and the fact that brand names can change.

EAHP suggests a flexible approach to identification criteria between Anatomical Therapeutical Chemical Code and active pharmaceutical ingredient.

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

EAHP consider that any medicine that has had numbers of incidents of falsification should automatically be subject to the requirements of the Falsified Medicines Directive's verification requirements.

CONSULTATION TOPIC FIVE: OTHER ISSUES

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

EAHP would like to meet with Commission officials to provide further evidence and information on the points raised in this response, and to potentially expand on areas the Commission seeks further clarity of understanding on e.g. the hospital aspect of the medicines supply chain.

EAHP would also like to emphasise the strength of views of hospital pharmacists in practice on the need for barcoding of single dose medicines administered in hospitals. For many years it has been a priority policy objective of the EAHP as mandated by our General Assembly of National country delegates and was mostly recently updated and re-ratified in 2011[5].

[5] http://www.eahp.eu/Advocacy/STATEMENTS