

EAHP STATEMENT ON THE NEED FOR BARCODING OF THE SINGLE DOSE ADMINISTERED IN HOSPITALS

JUNE 2012 (UPDATED FROM 2007 & 2010 STATEMENTS)

What is meant by barcoding of the single dose?

By “single dose” EAHP refers to the single item of medicine in an individual packaged component. This could for example include the single medicine within a perforated multi-dose blister pack, a syringe, a vial or an ampoule*.

For the primary purpose of reducing medication errors and protecting patient safety, EAHP’s statement calls for each single dose of medicine used within hospitals and supplied to the hospital by manufacturers or wholesalers to include an individual barcode in GS1 datamatrix format.

* See also glossary section at end of statement

Why is it important to bar-code the single dose administered in hospitals?

Bar-coding the single dose of medicine administered in hospitals:

- **Enables significant improvements for patient safety to be achieved (reducing medication administration errors by over 40% according to some studies¹);**

This is because it provides real time assistance to the healthcare professional at the patient bedside enabling verification that what is being administered is the right drug, in the right dose, via the right route of administration, to the right patient, and at the right time².

- **Assists in the comprehensive management of medicines recalls and alerts**

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 and an accurate control at the bedside is not feasible. Barcoding of the single dose of medicine administered in hospitals would improve this situation making the tracking and tracing of the dose within the hospital always possible.

- **Provides further assurances against potential counterfeit medicine intrusion**

There are numerous points in the chain between medicines manufacture and medicines administration where unscrupulous individuals have opportunities to replace legitimate medication

¹ Poon EG et al. Effect of Bar-Code Technology on the Safety of Medication Administration. N Eng J Med 2010;362:1698-707

² Estimates in America have suggested 500,000 medication errors can be prevented within 20 years from such technology

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2004/ucm108250.htm>

with counterfeit medication. Barcoding by manufacturers of the single dose provides a further assurance of the legitimate nature of a medicine at the point of administration.

- **Supports comprehensive management of medicines information in the interests of systems and outcomes improvement**

As costs of medications for all health systems continues to increase, accurate information 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.

- **Helps to prepare health systems for an ageing society**

The demographic future of Europe will see a large increase in the number of elderly patients over the coming year. 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 apply not only in the hospital setting, but also in nursing and residential homes for the elderly infirm.

What is the evidence for barcoding the single dose from elsewhere?

The United States of America

Driven by a desire to reduce medication administration errors, in the USA for the past 5 years it has been a regulation mandated by the FDA that medicines supplied to hospitals are bar-coded to the smallest unit of administration³. The FDA estimates that the bar-code rule, when fully implemented, will help prevent nearly 500,000 adverse events and transfusion errors over 20 years. The economic benefit of reducing health care costs, reducing patient pain and suffering, and reducing lost work time due to adverse events is estimated to be \$93 billion over the same period⁴.

The Council of Europe

Barcoding of the single dose of medicine is a principal (and unfulfilled) recommendation of the Group of Experts commissioned by the Council of Europe to advise Ministers on the management of patient safety and prevention of adverse events in healthcare.

Its report in 2007 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 nebulas), including the international nonproprietary name (INN), trade name, strength, expiry date, batch number and a data matrix*

³ FDA-Barcode label requirement for human drug product and blood (<http://www.fda.gov/oc/initiatives/barcode-sadr/default.htm>); FDA Guidance for Industry. Bar Code Label Requirements. Questions and Answers. Revision 1. October 2006 (<http://www.fda.gov/cber/gdlns/barcode.htm>)

⁴ <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2004/ucm108250.htm>

bar code. The data matrix barcode should contain a GS1 Global Trading Index Number (GTIN) identifier in addition to the expiry date and batch number.⁵

EAHP's Call for Action

First passed as policy in 2007, and updated in 2010, the General Assembly of the European Association of Hospital Pharmacy renews its request that:

- the pharmaceutical industry produce medicines in single dose packs; and
- as a part of manufacture, institutes mandatory inclusion of a barcode on each single dose of medicine intended for administration in hospital. This barcode should be in datamatrix GS1 format.

Furthermore, to ensure uniform, consistent and pan-European implementation of such a patient safety improvement, the EAHP calls for bar-coding of the single dose of medicine for use in hospitals to be part of regulatory requirements at both national and European levels.

The European Commission is currently constructing a Delegated Act which will set out specifications for a medicines traceability system across Europe, as required by the 2011 Falsified Medicines Directive. EAHP consider that the future European medicines identification system should be introduced in the context of joined-up thinking on European-wide medicines related issues, and not address counterfeit issues solely without reference to other solutions it might provide. **EAHP therefore requests that this Delegated Act include provisions which enable and assist manufacturer and wholesaler barcoding of the single dose of medicine administered in hospitals.**

The European Commission will also conduct an impact assessment on the characteristics of a European unique medicines identification system. **EAHP consider that this impact assessment should include cost-benefit analysis and therefore calls for the assessment to include an investigation of the benefits that could be delivered by systematic barcoding the single dose of medicine administered in hospitals - including the quantification of patient safety improvements.**

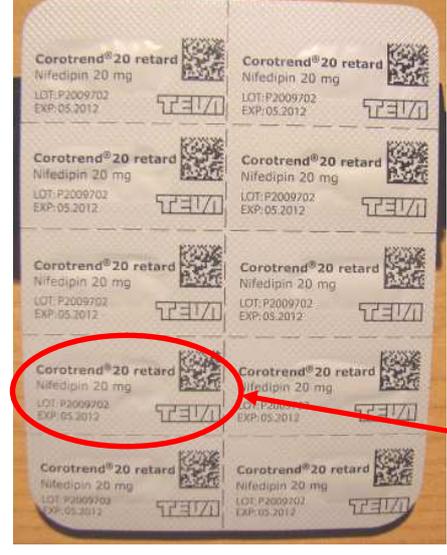
EAHP advises the use of 2D barcode technology based on GS1 standard

More information and evidence supporting this statement and its recommendation is available at the barcode campaign section of the EAHP website:

<http://eahp.eu/Advocacy/Bar-coded-unit-doses>

⁵http://www.coe.int/t/e/social_cohesion/soc-sp/medication%20safety%20culture%20report%20e.pdf

Annex One: A Glossary of Terms

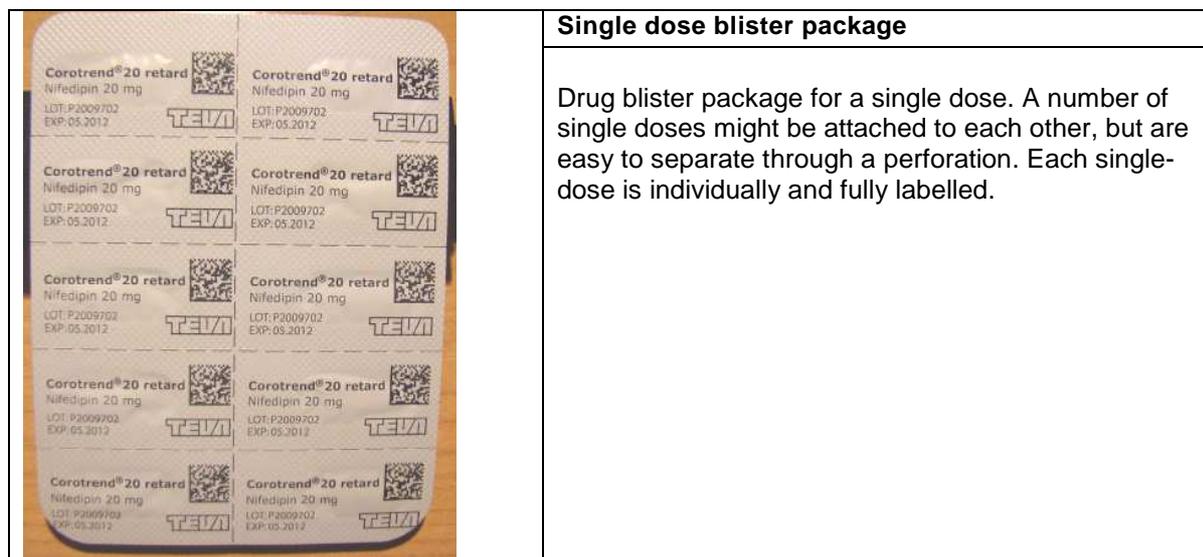
	<p>Single Dose</p> <p>The single item of medicine in an individual packaged component.</p> <p>This could for example include:</p> <ul style="list-style-type: none"> • the single medicine within a multi-dose blister pack, • a syringe, • a vial or • an ampoule. <p>A single item of medicine in an individual packaged component, in this case a medicine within a multi-dose blister pack.</p>
---	--

	<p>Unit Dose</p> <p>A unit dose package contains the particular dose of the drug <u>for a specific patient according to the patient-specific prescription.</u></p> <p>Unit-dose packages are dispensed for one or several days by a centralized supply service unit and are labelled specifically for a patient.</p> <p>A “unit dose” must therefore be understood to be different in meaning from the term “single dose”.</p> <p>A patient specific unit dose, within a bespoke unit dose package.</p>
---	--

	Primary Packaging
	<p>The primary packaging of any product is the first level of packaging that packs and protects the product.</p> <p>For example, for a soft drink, the can or bottle is the primary packaging.</p> <p>In the case of medicines used in hospitals, this might be the blister pack in which a medicine is contained (in contrast to the medicines packet which is secondary packaging – see below), or the physical syringe, vial or ampoule (illustrated left).</p>

	Secondary Packaging
	<p>Secondary packaging is the packaging outside the primary packaging, perhaps used to group primary packages together.</p> <p>In the case of medicines this could be the box packet containing a number of blister packs, and for syringes, vials and ampoules potentially an outer blister, wrap or pouch.</p>

	Multiple dose blister
	<p>Package which fully encloses the drug. Each dosage form is individually packaged. The individually blistered identical dosage forms are attached to each other to one strip. The labelling is imprinted on the complete strip but not on the individual blistered dosage forms.</p>



Annex Two: EAHP's recommended requirements for the technical specifications of a barcode for the single dose of medicine

A) The primary packaging⁶ of a medical product must fulfil 3 basic functions:

1. precisely describe the content of the drug up to final control at bedside
2. enable easy and safe use of the drug
3. provide protection against environmental influences such as light, moisture, pressure and microbial contamination during transport, handling and storage.

To enhance the comfort of use, the packaging should be light in weight and additional labelling needs to be easily possible. The package material has to be compatible with the drug and should be environment-friendly in regards to production and disposal.

B) Requirements for the single dose packaging

1. Size and form

1. single dose packing for a single application, preferably in a standardized size (e.g. 3.5 x 3.5 cm),
2. alternatively, perforated multiple dose blister packs that can be easily divided into single doses packing (each of them must contain the whole information),
3. ready to use, no further manipulation necessary,
4. easy to pack into automatic dispensing systems.

⁶ See glossary of terms

2. Information on the single doses

The printing must be easy to read, durable and clear. Each single dose must contain the:

- trade name
- application form
- active substance(s)
- quantity of active substance(s) ,
- manufacturer's name
- expiry date
- batch number
- barcode including the identification of the drug (GTIN), the expiry date and the batch number. When the production facility is incompatible with an on-line printing of variable data, the barcode can temporarily be limited to the identification of the drug.

Hospital pharmacists strongly recommend the use of the recognized international GS1 (ex- EAN) identification system for bar codes. The GS1-128 (ex- EAN-128) standard appears to be the best standard for the traceability of single dose units. Taking into account the problem of the available space, we recommend printing it as a datamatrix.

For ampoules, syringes, and vials, the same information should be provided on a label (not engraved on the glass), with additional information regarding the total amount and volume (x mg = y ml) and the concentration of the solution (z mg/ml).

END

References

- FDA-Barcode label requirement for human drug product and blood (<http://www.fda.gov/oc/initiatives/barcode-sadr/default.htm>)
- FDA Guidance for Industry. Bar Code Label Requirements. Questions and Answers. Revision 1. October 2006 (<http://www.fda.gov/cber/gdlns/barcode.htm>)
- Rainu Kaushal MD et coll, Pediatric Medication Errors : what do we know ? What gaps remain ?, Ambulatory pediatrics, 2004, 4(1), 73-81
- Schneider M.P. and coll., Evaluation of nurses' errors associated in the preparation and administration of medication in a pediatric intensive care unit, Pharm World Sci, 1998, 20(4), 178-182
- Fontan J.E et coll, Medication errors in hospitals: computerized unit dose drug dispensing system versus ward stock distribution system, Pharm World Science , 2003, 25(3), 112-117
- Asha Lustig, Medication error prevention by pharmacists-An Israeli solution, Pharm World Science, 2000, 22(1), 21-25

- Thornton P. D. et coll., Towards safer drug during prescribing, dispensing and administration in hospitals, J Qual. Practice, 1999, 19, 41-45
- Unit Dose labelling for Solid and Liquid Oral Dosage Forms, FDA, sec. 430.100, 2/1/84 (http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg430-100.html)
- Expiration Dating of Unit Dose Repackaged Drugs, sec. 480.200, FDA, 2/1/84, revised 3/95 (http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg480-200.html)
- Greater New York Hospital Association (GNNYHA), 10 juin 2003 (<http://www.fda.gov/ohrms/dockets/dailys/03/Jun03/061203/02n-0204-c000055-01-vol14.pdf>)
- Healthcare Information and Management Systems Society (HISMS) , aout 2005, (www.fda.gov/ohrms/dockets/dockets/05d0202/05D-0202-EC3-Attach-1.pdf)
- Anti-counterfeit drug Initiative-public Meeting, October 2003, p5, (<http://www.fda.gov/oc/initiatives/counterfeit/oct2003meeting/panel3.html>)
- FDA Rule Requires Bar Codes on drugs and bloods to help Reduce Errors, (<http://www.fda.gov/oc/initiatives:barcode-sadr>)
- Pedersen G. A. and coll., ASHP notional survey of pharmacy practice in hospitals settings: Dispensing and Administration, Am J Health- syst Pharm 2006, 23, 327-345
- Johnson CL, Carlson RA, Tucker CL, Willette C. Using BCMA Software to Improve Patient Safety in Veterans Administration Medical Centers. J Healthcare Inf Manag 2002;16:1
- Helmons PJ, Wargel LN, Daniels CE. [Effect of bar-code-assisted medication administration on medication administration errors and accuracy in multiple patient care areas.](#) Am J Health-Syst Pharm 2009;66:1202-10
- Franklin BD, O'Grady K, Donyai P, Jacklin A, Barber N. The impact of a closed-loop electronic prescribing and administration system on prescribing errors, administration errors and staff time: a before-and-after study. Qual Saf Health Care 2007;16:279-84
- Poon EG et al. Effect of Bar-Code Technology on the Safety of Medication Administration. N Eng J Med 2010;362:1698-707

European Association of Hospital Pharmacists (EAHP)

Rue de Abbé Cuypers,3
B- 1040 Brussels, Belgium
Tel: +32 2 741 6822
Fax: +32 2 734 7910
www.eahp.eu

The European Association of Hospital Pharmacists is a Federation of national associations of hospital pharmacists. Its European membership includes more than 21,000 professionals. EAHP's aim is to establish a common pharmaceutical policy in Europe. It represents the interest of the profession at the European level, contributes to the scientific development of hospital pharmacy and to the advancement of the position and role of the pharmacists in hospitals.