



European Association of Hospital Pharmacists

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Why bar coded unit doses?

10 reasons to implement unit doses and bar codes in Europe:

- ☞ to guarantee the permanent identification of a pharmaceutical product and secure its traceability within the hospital medicinal product network/circuit essentially in order to prevent medication-related errors; in the US, all pharmaceuticals products sold to hospitals must bear a barcode on the smallest unit of measure – the size dispensed to the patient (since April 2006);
- ☞ to avoid mis-reading and understanding of labels: there is no common technology to read the product information by means of technical equipment and therefore no homogeneity (neither from manufacturer to manufacturer, nor from country to country). In order to track & trace products it is essential to have:
 - National product identification
 - Expiry date AND
 - Batch number
 - ... in a machine readable format;
- ☞ to combat counterfeit;
- ☞ to enhance the intra-Europe distribution and trade of medicines;
- ☞ to alert faster and better on potential interactions;
- ☞ to avoid risk of degradation of medical products from bulk containers (without packaging) because they could be sensitive to moisture, light or temperature;
- ☞ to reduce the rate of medication error up to 85%(*). In the USA, unit dose systems dispense most medications from the pharmacy in a ready-to-administer form and are widely used in hospitals. Studies that have evaluated the impact of unit-dose dispensing on medication errors report reduction in medication error rates ranging from 53% to 85%;
- ☞ to protect children and help the elderly patients;
- ☞ to eradicate the second most common cause of medical errors (around 25%): a recent article from the UK mentions that the second common cause of errors is in dispensing the right medicine but in the wrong strength and in particular for medicine with narrow therapeutic index, the third most common error (5%) being mislabelling;
- ☞ to reduce staff costs (time spending on re-packaging and manually labelling), waste costs and raw material costs for repackaging.

Our plea is intended to the pharmaceutical Industry in order to encourage it to produce unit-dose packaging presentations particularly for pharmaceutical products approved for hospitals.

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Who supports it?

☞ Council of Europe

Report: “Creation of a better medication safety culture in Europe: Building up safe medication practices”, 19 March 2007, drafted by expert group on safe medication practices.

This report emphasises a certain number of priority actions and recommends, in particular, the updating of European and national legislation in order to obtain the full and non-ambiguous labelling of each unit dose for all products.

This label should comprise the non-proprietary name, brand name, dosage, batch number and Data Matrix code. In Chapter III of this document relating to “Improving the safety of naming, labelling and packaging of the medicines marketed in Europe”, one of the key point is the availability of ready-to-use, unit-dose presentations in order to minimise errors;

http://www.coe.int/t/e/social_cohesion/soc%2Dsp/Medication%20safety%20culture%20report%20E.pdf

☞ European Commission

The last version of the European “guideline on the readability of the label and package leaflet of medicinal products for human use (revision September 2006)” available for consultation on the UE website mentions for the first time on section C.1, Blister pack packaging: Where a unit-dose blister presentation is proposed, all the information required for blister packs must appear on each unit presentation.

http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/docs/doc2006/09_2006/readability_consultation_2006_09_25.pdf

☞ The pharmaceutical industry

Through the voice of its pan-European association EFPIA, in favour of 2 dimensional bar-codes but not necessarily on unit doses and in a view to fight counterfeit:

<http://www.efpia.org/content/default.asp?PageID=263&DocID=2455> and

<http://212.3.246.100/Objects/2/Files/codingRIFD0906.pdf>

(*)The exact number of error rates associated with the implementation of unit dose and bar code systems in hospitals is uncertain. This is due to the limited number of studies, a variation in definitions and methodologies that have been used in the existing studies and the small number of institutions involved in these studies, making any one study subject to local and regional variations in providers, patient populations, etc. Furthermore, healthcare organisations differ in their definition of medication error and reporting of these errors is a voluntary process. As a

For definitions and references, please read the EAHP Document: “Unit doses and bar coded needed for patient safety.doc”, EAHP, June 2007