

REQUEST FOR THE PRODUCTION OF SINGLE DOSE-PACKED DRUGS

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Request summary

To improve patient safety in drug therapy and to ensure the highest quality in medical treatment in European hospitals, the General Assembly of the European Association of Hospital Pharmacists, EAHP, demands:

- the production of single dose-packed drugs from the pharmaceutical industry,
- the mandatory inclusion of a barcode on each single dose.

Hospital pharmacists are also calling on decision makers, politicians and national administrations to implement the introduction of bar-coded single dose-packed drugs in national and European regulations.

Introduction

In hospitals, personalised treatments are prepared in the pharmacy or in the ward, and are administered by nurses to the patients. A complete and unambiguous identification of the drug up until the moment of the administration is a key element of a safe dispensing procedure. Unfortunately, when drugs are dispensed in multiple dose blisters, they have to be cut during drug dispensing, and, as a consequence, some information may be absent of the resulting dose and an accurate control at the bedside is no more feasible.

A growing number of hospitals have implemented a unit dose dispensing system, with an individualised preparation of drugs, manually in the pharmacy, or with automated dispensing machines in the pharmacy or in the ward.

To improve the efficiency of these safer procedures hospital pharmacists urge the pharmaceutical industry to supply drugs packed in single-dose units.

Hospitals have or are implementing a computerised prescription system, which allows a final control just before the administration of drugs to patients, via a bar-code system contained in the singledose pack. This final check performed electronically by comparing the prescription with the actual prepared drugs significantly increases the patient's safety, as the human controls are not without failure (performance $\approx 85\%$). These systems also improve the traceability up to the patient level, which is more and more requested by national regulations.

In the USA, the inclusion of a barcode on each individual dose is now mandatory, and the FDA expects to avoid 500'000 adverse drug events each year.

Preliminary studies have suggested a 50 to 80% reduction of administration errors when drugs are scanned at the bedside.

Requirements

A. *The primary packaging of a medical product must fulfil 3 basic functions:*

- precisely describe the content of the drug up to final control at bedside
- enable easy and safe use of the drug
- 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**

- single dose packing for a single application, preferably in a standardized size (e.g. 3,5x3,5 cm),
- alternatively, perforated multiple dose blister packs that can be easily divided into single doses packing (each of them must contain the whole information),
- ready to use, no further manipulation necessary,
- easy to pack into automatic dispensing systems.

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 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

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Glossary / Definition of terms

- **Multiple dose blister:** 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.

- **Single dose blister package:** Drug blister package for a single dose. A number of single doses might be attached to each other, but are easy to separate through a perforation. Each single-dose is individually and fully labelled.
- **Unit dose package:** A unit dose package contains the particular dose of the drug for a specific patient according to the patient-specific prescription. Unit-dose packages are dispensed for one or several days by a centralized supply service unit and are labelled specifically for a patient.
- **Secondary packaging:** Is the outer packaging and contains several primary packages. It is the standard packaging in which medicinal products get delivered by the pharmaceutical industry. It is appropriately labelled and provides all relevant information to the product.

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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.