Joint recommendations on the labelling of parenteral preparations [1]

dated 2 November 2009

I. Background

Mistakes in the assembling and dispensing of medicines in hospitals put patient safety at risk. Mistaking one medicine pack for another similar in appearance is one of the most common errors in medication. The consequences of this can be especially serious when parenteral preparations are involved. The danger of confusion is also particularly great with these preparations because their labels are usually small and provide only a little space for text.

Although there is no substitute for the user reading the pack label with care, standards in the labelling of medicines can make it easier to avoid mistakes.

The named associations of the pharmaceutical industry, in consultation with the Swiss Society of Public Health Administration and Hospital Pharmacists (Gesellschaft schweizerischer Amts- and Spitalapotheker (GSASA)), have made a contribution to traceability and drug safety throughout the supply chain in the form of these recommendations.

II. Recommendations

A. Label content

Principle:

Medicines legislation stipulates what particulars must appear on packs of medicines (cf. Medicines Authorisation Regulation (Arzneimittel-Zulassungsverordnung, AMZV[2]), and its associated annexes).

The present recommendations present these regulations in more specific terms for application in practice.

1. Minimum particulars
(Annex 1 Point 1 Para. 1 AMZV)

As a minimum the following particulars of relevance to drug safety must appear on every label:

- *Proprietary name/drug name*
- *INN*
- *Total quantity* [3] *of the active substance*
  (consistently with reference to the values expressed as the salt or base per substance)
- *Total volume* [4]
- *Concentration* [5]
- *Possible routes of administration* (in brief: i.v., s.c., etc.)
- *Expiry date (EXP)*
- *Batch/lot number (LOT)*

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[1] ASSGP: http://www.assgp.ch/, Intergenerika: http://www.intergenerika.ch/, Interpharma: http://www.interpharma.ch, SGCI Chemie Pharma Schweiz: http://www.sgci.ch, VIPS: http://www.vips.ch, GSASA: http://www.gsasa.ch

[2] http://www.admin.ch/ch/d/sr/812_212_22/index.html

[3] The total quantity should be expressed in the units of measure conventional in international usage (e.g. mg).

[4] The total volume should be expressed in the units of measure conventional in international usage (e.g. mL).

[5] The concentration should be expressed in the units of measure conventional in international usage (e.g. mg/mL). The expression of concentrations as percentages should be avoided.

If there is space on the label, the following particulars should be appended:

2. Identification codes

The use of standardised machine-readable identification codes on primary and secondary packaging is recommended. It is common practice to use the *Global Trade Item Number* (GTIN, as data structure) in the form of a *Datamatrix Barcode* (2D, as data medium). The primary and secondary packaging are distinguished by a different GTIN. The standards organisation GS1 has published GTIN allocation rules to create global uniformity [6].

A second phase is planned in which the batch/lot number and the expiry date will be shown on the data matrix data medium in addition to the GTIN.

3. Particulars of authorisation holder and of storage
(Annex I Point 1 Para. 1 Letters c and f AMZV)

The following particulars should appear on the label only if they do not detract from the legibility of the minimum particulars and the machine-readable identification code (see above):

- particulars of the authorisation holder in accordance with Annex I Point 1 Para. 1 Letter c AMZV and
- any storage instructions in accordance with Annex I Point 1 Para. 1 Letter f AMZV, if they differ from standard (15°C to 25°C).

4. Superfluous information in the hospital context:
(particulars according to Annex 1 Point 1 Para. 1 Letter h AMZV)

The warning to keep medicines out of the reach of children and the instruction to observe the information given in the patient information leaflet are essentially superfluous for parenteral preparations used in hospitals. As a general rule, these particulars may be omitted in favour of information relevant to safety following the preceding Priorities 1 to 3 provided that the corresponding comments appear on the secondary packaging [7].

B. Design appearance of the label:

- ***Imprint:*** The particulars should not be printed onto the container itself. The contrast between the label background and the print colour should make it easy to read.
- ***Font size:*** The text should be printed in a font size of at least 1.4 mm and in a “sans serif” font (e.g. “Arial”). “Times New Roman” and similar fonts in particular should not be used.
- ***Text direction:*** It should not be necessary to turn the container to be able to read all the particulars on one line of the label at a glance. Basically, we recommend that the text is printed parallel to the longitudinal axis of the container. Printing at right angles to this axis should be chosen only if the container is large enough.
- ***“Tall Man Letters”:*** To make a clearer distinction between different active substances whose names are similar in appearance and sound, we recommend printing the distinguishing elements of the words in “Tall Man Letters”. – *Example:* DOPamine / DOBUTamine.
- ***Colours:*** If colours are used on the label, they should serve primarily to distinguish between active substances and dosages. Their use to differentiate between therapeutic groups within the product range of one company should be avoided due to the risk of confusion.

  Colour codes (e.g. for individual groups of high-risk drugs) should follow the principles of any ISO standards in existence (e.g. in the case of anaesthetics).

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[6] See http://www.gs1.org/1/gtinrules/index.php/p=static/t=healthcare

[7] According to the AMZV, Swissmedic may authorise drugs manufacturers in specific cases to omit the particulars required by Annex 1 Point 1 Para. 1 AMZV (Annex 1 Point 1 Para. 2 AMZV). Swissmedic has explained its position in a letter dated 29.05.09 to the SGCI Chemie Pharma Schweiz, as follows: “The particulars mentioned (the warning to keep medicines out of the reach of children and the instruction to observe the information given in the package leaflet) may be omitted from the label. We base this on the assumption that these particulars will appear on the outer wrapping.”