Joint recommendations[1]

for the avoidance of confusion affecting the primary package and labelling of *liquid* pharmaceutical dosage forms

Companies in the pharmaceutical industry will endeavour, in so far as this is technically feasible and compatible with the internationally standardized regulatory framework, to improve the primary packaging and labelling of liquid forms of pharmaceuticals on the basis of the following recommendations:

A. Label content

Principle: Medicines legislation stipulates which particulars must appear on packs of medicines (cf. Medicines Authorisation Regulation (Arzneimittel-Zulassungsverordnung, AMZV[2]) and its associated annexes. The present recommendations set out these regulations in more specific terms for application in practice.

1. Minimum particulars
(Annex 1 AMZV: Point 1 Para. 1[3])

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

- *Proprietary name/drug name*
- *INN / DCI*
- *Total quantity[4] of the active substance* (consistently with reference to the values expressed as the salt or base per substance)
- *Total volume[5]*
- *Concentration[6]*
- *Possible routes of administration* (in brief: i.v., s.c., etc.)
- *Expiry date (EXP)*
- *Batch/lot number (LOT)*

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

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 *Data Matrix Bar Codes* (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.[7]

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[1] These recommendations are supported by:
ASSGP (Swiss Self-Medication Federation, http://www.assgp.ch), **Intergenerika** (Federation of Generics Manufacturers in Switzerland, http://www.intergenerika.ch), **Interpharma** (Federation of Researching Pharmaceutical Companies in Switzerland, http://www.interpharma.ch), **scienceindustries** (Economic Federation Chemical Pharma Biotech Industry, http://www.sgci.ch), **VIPS** (Association of Pharmaceutical Companies in Switzerland, http://www.vips.ch), **Foundation for Patient Safety** (http://www.patientensicherheit.ch), **GSASA** (Swiss Association of Public Health Administration and Hospital Pharmacists, http://www.gsasa.ch)

[2] http://www.admin.ch/ch/d/sr/c812_212_22.html; http://www.admin.ch/ch/f/rs/c812_212_22.html

[3] http://www.admin.ch/ch/d/sr/812_212_22/app1.html; http://www.admin.ch/ch/f/rs/812_212_22/app1.html

[4] The total quantity is to be expressed in standardized international units of measurement (e.g. mg).

[5] The total volume is to be expressed in standardized international units of measurement (e.g. ml).

[6] The concentration is to be expressed in standardized international units of measurement (e.g. mg/ml). Concentrations should not be expressed as percentages.

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

As a second step the batch/lot number and the expiry date shall be shown on the data matrix data medium in addition to the GTIN.

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

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

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

4. Non-essential information in the hospital context:
(AMZV Annex 1: Point 1 Para. 1 Letter h)

The warning statement to keep medicines out of 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 above Priorities 1 to 3, provided that the corresponding comments appear on the secondary packaging[8].

B. Design appearance of the label

- ***Imprint:*** The particulars should not be printed on 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 alignement:*** 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 be 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 pharmaceutical ingredients whose names are similar in appearance and sound, we recommend printing the distinguishing elements of the words in "Tall Man Letters"[9]. – *Example:* DOPamine / DOBUTamine.
- ***Colours:*** Where colours are used on the label, they should serve primarily to distinguish between active pharmaceutical ingredients and dosages. Their use to differentiate between therapeutic groups within the product range of one company should be avoided to prevent the risk of confusion.

  Colour codes (e.g. for individual groups of high-alert drugs) should be guided by the principles of any ISO standards in existence (e.g. for anaesthetics[10]).

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[8] According to AMZV Swissmedic may authorise drug 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 explained its position in a letter dated 29.05.09 to SGCI Chemie Pharma Schweiz (now: scienceindustries) as follows: "The particulars mentioned (the warning to keep medicines out of 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".

[9] http://www.ismp.org/Tools/tallmanletters.pdf; see Annex 1, Section A.e

[10] http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=43811