

## Joint recommendations<sup>1</sup> for the avoidance of confusion caused by pharmaceutical packaging and labelling which look similar (“look alike”)

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 packaging and labelling of their pharmaceutical products so as to avoid confusion caused by pharmaceutical packages and labels which look similar (“look alike”), on the basis of the following recommendations.

### Secondary packaging:

#### Presentation of the information relevant to safe differentiation upon administration<sup>2</sup>

Information element	on 3 sides	on 1 side	Solid forms (Orals) <sup>3</sup>	Liquid forms (Parenterals)*
Brand name	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
INN	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Dosage form	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Total quantity of active substance <sup>4</sup>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Total volume of active substance <sup>5</sup>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>
Concentration <sup>6</sup>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>
Possible administration routes	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>

Quantity of content (number of units)		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Medically essential information		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Storage instructions		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Period for allowed use after opening		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Children’s Warning statement		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Reference to package insert		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Manufacturer / Marketing Authorisation Holder		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Exp. / Lot		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Marketing authorization number		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Machine-readable code		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

<sup>1</sup> 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.sgc.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>)

<sup>2</sup> Basis: Annex 1 to the Pharmaceuticals Licensing Regulation (AMZV):

[http://www.admin.ch/ch/d/sr/812\\_212\\_22/app1.html](http://www.admin.ch/ch/d/sr/812_212_22/app1.html); [http://www.admin.ch/ch/f/rs/812\\_212\\_22/app1.html](http://www.admin.ch/ch/f/rs/812_212_22/app1.html); [http://www.admin.ch/ch/d/sr/c812\\_212\\_22.html](http://www.admin.ch/ch/d/sr/c812_212_22.html); [http://www.admin.ch/ch/f/rs/c812\\_212\\_22.html](http://www.admin.ch/ch/f/rs/c812_212_22.html)

<sup>3</sup> These recommended indications apply as appropriate to other pharmaceutical presentations.

<sup>4</sup> The total quantity is to be indicated in standardised international units of measurement (e.g. mg).

<sup>5</sup> The total volume is to be indicated in standardised international units of measurement (e.g. ml).

<sup>6</sup> The concentration is to be indicated in standardised measurement unit (e.g. mg/ml). Concentrations should not be expressed as percentages.

## Further aids

### for the avoidance of confusion on the primary packaging and marking:

- **“Tall Man Letters”**

To differentiate more effectively between the designations of different active pharmaceutical ingredients which look and sound alike it is advisable to indicate the differentiating word elements in “Tall Man Letters”. –

*Example:* DOPamine/ DOBUTamine.

- **Colours**

Where colours are employed on the label, they should be used in the first instance to differentiate 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 medicines) should be guided by the principles of any ISO standards in existence (e.g. for anaesthetics<sup>7</sup>).

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<sup>7</sup> [http://www.iso.org/iso\\_catalogue/catalogue\\_tc/catalogue\\_detail.htm?csnumber=43811](http://www.iso.org/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=43811)