Joint recommendations[1]

for the avoidance of confusion caused by *similar sounding* designations of pharmaceuticals ("sound 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 similar sounding pharmaceutical packages and labels ("sound alike"), on the basis of the following recommendations.

The "*Guideline on package design to prevent labelling errors*" (Editor: UK National Patient Safety Agency, NPSA)[2] has proved expedient and practical as a basis.

A Recommendations for the designation of pharmaceuticals (choice of brand names)

a. for the designation of new pharmaceuticals (originator product)

When new pharmaceuticals are licensed, Swissmedic ensures that brand names which sound similar to existing brand names or active pharmaceutical ingredient designations (potential future generics) are avoided as far as possible. It uses *electronic systems and algorithms* to verify the designation for which an application is made. These are standard practice and have proved expedient for the US authorities (Food & Drug Administration, FDA) and the European Union (European Medicines Agency, EMA) and also for companies which operate internationally. Pharmaceuticals used at the strictly national level are therefore also covered.

Swissmedic should, in particular, use and publish the algorithm which has been successfully adopted by the EMA. It must be technically designed in such a way as to be usable as a system with public access for industrial companies and other stakeholders, i.e. also as an instrument for self-testing. Where the EMA has already conducted an algorithm review, Swissmedic should make use of that review.

b. for the designation of pharmaceuticals already authorised with a registered trademark

In this case, experience shows that changes are harder to make (including the trademark point of view), except in the presence of acute risk to life and limb (here the health authorities such as Swissmedic have legal instruments at their disposal). The causes of risks of confusion in this area must be remedied as far as possible and in a proportionate manner for practical application either by suitable measures taken by the manufacturer or, if possible and appropriate, in distribution.

c. for the designation of generics

Nowadays generics are marketed primarily with the designation of the active pharmaceutical ingredient (INN/DCI) issued by the WHO in direct association with the name of their manufacturer (or marketing authorisation holder) as a suffix (and not, as used to be the case, under own creative brand names or designations). In this area, the specific avoidance of the "sound alike" problem is more difficult (examples include cephalosporins) so that complementary solutions must be sought together with the "look alike" problem.

[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.nrls.npsa.nhs.uk/resources/?EntryId45=59829; http://www.npsa.nhs.uk/

d. Pharmaceutical designations between which a clear optical and acoustic difference can be made

When choosing the brand name (creative marks or designations) of new pharmaceuticals, the companies (marketing authorisation holders) make sure to avoid designations which may lead to optical and acoustic confusion with existing brand names or names of active substances of pharmaceuticals.

e. Designations of active substances which look or sound similar must be differentiated by suitable print presentations

To the extent that the designations of active pharmaceutical ingredients (INN/DCI) stipulated by the World Health Organisation WHO for a pharmaceutical product may give rise to optical confusion, a clear distinction must be made between them by a suitable presentation of the printed wording. The concept of Tall Man Letters[3] has proved an expedient solution in the first place for INN/DCI which may give rise to confusion and also for the brand names of legacy pharmaceutical products. This concept is to be used subsidiarily, i.e. in all cases where no other solution is instrumental for the desired result. This likewise applies to the designation of generics in so far as they are identified with the INN/DCI and name of their manufacturer (marketing authorisation holder) as the suffix.

It is important for the concept of Tall Man Letters to be *used uniformly* to make a clear differentiation, i.e. in specific cases the same number of letters must be written in capitals in the designation of all the particular pharmaceuticals concerned. When licensing such pharmaceutical products, Swissmedic must pay particular attention to this point. A *Swissmedic specification* based on publications and examples already mentioned in this connection would be helpful[4].

B Individual objectives and possible detailed solutions

a. Clearly distinguishable designation of the dosages of a particular pharmaceutical

Confusion between different dosages of a pharmaceutical product is to be avoided by one or more suitable measures. The company should provide a clearly recognisable concept for differentiation between dosages, even if the product respects the corporate design. Methods for this purpose include the presentation of the wording, the font size, the colour coding and the layout of this information on the outer package. Exclusive approaches, such as the optically progressive or symbolic graduation of dosages, are to be avoided because they are not as a rule intuitively understandable. *The font size of the dosage indication* must be *at least equivalent* to that of the *brand designation* on the package.

b. Rules for the provision on the outer package of information which is important for safe pharmaceutical administration and use

Information which is important for an assured differentiation in the use and administration of pharmaceuticals must stand out clearly from any other information that is less important in this regard. The presentation of the wording, font, colour coding and layout of this information on the outer package (secondary package) must be designed to ensure reliable perception of this information.

The information which is relevant for reliable differentiation concerning dispensing must be clearly distinguishable from other information. In particular, the indication of the *dosage* must differ clearly from the indication of the *quantity* contained in a package (number of tablets, capsules, etc.) on the package itself (i.e. the latter information is as a rule to be given in substantially smaller characters than for the dosage).

The information which is relevant for reliable differentiation with dispensing and perceptible by the human eye must be shown, in so far as the package size so allows, in each case fully on three sides which are not facing each other on the outer package (Reason: to facilitate detectability when the package is in a different position in the warehouse or on the shelf).

Variable information, such as the batch number and expiry date, must be provided together with the product identification on *one side* or on *a tab* of the outer package which contains no important information.

[3] http://www.ismp.org/Tools/tallmanletters.pdf
[4] http://www.ismp.org/Tools/tallmanletters.pdf

To rule out problems with electronic processing, the *GS1-Datamatrix*, which comprises variable information such as the batch number and expiry date as well as the GTIN[5] and *barcode* (EAN-13)[6], *must not* be applied on the same side of the outer package.

c. Keep free space for individual dosing indications on the outer package

On the outer package (secondary package), a suitably large space separate from the information relevant to reliable differentiation of the administration requirements, must be provided to enable individual dosing indications of the physician or pharmacist to be noted or affixed on stickers.

C Recommendations concerning the procedure for practical implementation

Improvement steps, differentiated according to the degree of possible confusion of brand names and the information on the secondary package:

Avoiding confusions of brand names or active pharmaceutical ingredient designation forming part of brands	***Avoidance of confusion based on the information given on the outer package (secondary package)***
Primary: New pharmaceutical product Use of the algorithm (by companies and Swissmedic) to exclude confusion of brand names with other brand and active pharmaceutical ingredient names.	**Differentiate dosage indications** Font size, colour code and other suitable differentiation measures as part of the corporate design concept to distinguish between dosages.
Subsidiary: Pharmaceuticals already licensed Use of Tall Man Letters, especially for INN / DCI (including generic brand names). Example: DOPamine / DOBUTamine.	**Font size of dosage indication** At least equivalent to that of the brand designation.
	Arrangement for assured differentiation of information relevant to administration (pursuant to AMZV Annex 1 and the table in the Joint recommendations for the avoidance of confusion caused by pharmaceutical packaging and labelling which look similar, "look alike" of August 2012) On each of three sides of the package not facing one another as part of the corporate design concept to differentiate between dosages.
	GS1 Datamatrix and barcode Must not appear on the same side of the package.
	Individual dosing information Allow sufficient space on the package.
	Font size for indication of quantity of tablets, ampoules etc. in the package Clear differentiation from the dosage indication (as a rule use smaller type).

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[5] http://www.gs1.org/1/gtinrules/index.php/p=static/t=healthcare
[6] http://www.gs1.ch/de/leistungsbereiche/identification-communication/standardisation/GS1-System/barcode-identification/datentraeger/010-ean13.php