

## Joint recommendations of ASSGP, Intergenerika, Interpharma, scienceindustries and vips<sup>1</sup>

of 13 August 2012

# Communication upon the cessation or interruption of the supply of a particular pharmaceutical

### ***Background and legal situation***

Where a company ceases or interrupts the supply of a particular pharmaceutical – for whatever reason – this may present a disadvantage to the patients concerned. That is the case in particular if no adequate therapeutic alternative is available at reasonably short notice either in Switzerland or abroad.

An adequate therapeutic alternative is lacking if no licensed pharmaceutical containing the same or a comparable active substance is available to treat a particular condition.

Where a licence holder ceases the distribution of a pharmaceutical or interrupts distribution for more than one year, it must notify that fact to Swissmedic pursuant to Art. 8a para. 2 of the Pharmaceuticals Regulation (Arzneimittelverordnung, VAM; Ordonnance sur les médicaments, OMéd<sup>2</sup>). Swissmedic will then in principle revoke the licence (Art. 9a VAM/OMéd<sup>3</sup>).

The licence holder must also ensure notification (pursuant to Art. 35 para. 1 letter e VAM/OMéd<sup>4</sup>) in the event of “unusual restrictions of distribution” as part of the obligation stipulated in VAM/OMéd to notify because of “presumed pharmaceutical risks established in Switzerland”. VAM/OMéd does not stipulate a time limit within which this compulsory notification must be made.

### ***Own responsibility of pharmaceutical industry companies***

With a view to avoiding supply gaps as far as possible, the Swiss organisations of the pharmaceutical industry named above have reached agreement on the following recommendations to their members.

The pharmaceutical companies endeavour, as a matter of principle, to retain the pharmaceuticals manufactured and distributed by them in their product range as long as a sufficient need for them exists on the part of practitioners and patients.

For technical manufacturing or other reasons, temporary limitations of delivery may occur. Likewise, a company is at liberty to cease the commercial sale of a pharmaceutical for whatever reason. The following recommendations do not restrict that freedom.

In particular, the decision of a company to waive the market licence of a pharmaceutical must not be made dependent on whether alternative sources of supply or treatment opportunities are found to exist (see the second recommendation below).

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<sup>1</sup> Replaces the similar recommendations of 14 April 2005: [http://membernet.sgci.ch/plugin/template/sgci/\\*/17424](http://membernet.sgci.ch/plugin/template/sgci/*/17424)

<sup>2</sup> [http://www.admin.ch/ch/d/sr/812\\_212\\_21/a8a.html](http://www.admin.ch/ch/d/sr/812_212_21/a8a.html); [http://www.admin.ch/ch/f/rs/812\\_212\\_21/a8a.html](http://www.admin.ch/ch/f/rs/812_212_21/a8a.html)

<sup>3</sup> [http://www.admin.ch/ch/d/sr/812\\_212\\_21/a9a.html](http://www.admin.ch/ch/d/sr/812_212_21/a9a.html); [http://www.admin.ch/ch/f/rs/812\\_212\\_21/a9a.html](http://www.admin.ch/ch/f/rs/812_212_21/a9a.html)

<sup>4</sup> [http://www.admin.ch/ch/d/sr/812\\_212\\_21/a35.html](http://www.admin.ch/ch/d/sr/812_212_21/a35.html); [http://www.admin.ch/ch/f/rs/812\\_212\\_21/a35a.html](http://www.admin.ch/ch/f/rs/812_212_21/a35a.html)

**Recommendation 1:**

**Cessation of distribution: Communication after complying with the obligation to notify Swissmedic**

Upon the cessation of distribution of a particular pharmaceutical, the licence holder must comply with his obligation to notify pursuant to Art. 8a VAM/OMéd in a timely manner.

After making the notification, the licence holder will inform the professional circles concerned, in particular the distribution partners, of the cessation of distribution. This will make it easier for physicians, distribution partners and patients to adjust in good time to the new situation.

The licence holder will immediately inform Swissmedic and the professional circles concerned, in particular the distribution partners, of any subsequent changes to the timetable for the cessation of distribution.

The licence holder shall in every case mark such information for the professional circles as an “Important Notice” (Section 148.1 of the Pharma Code<sup>5</sup>).

**Recommendation 2:**

**Interruption of distribution: Communication to Swissmedic and the professional circles concerned**

Where the licence holder cannot guarantee the supply of a particular pharmaceutical for whatever reason even temporarily, he must inform Swissmedic and the professional circles concerned as quickly as possible in a manner which is appropriate to the particular situation.

The licence holder shall in every case mark such information to the professional circles as an “Important Notice” (Section 148.1 of the Pharma Code).

Wherever possible and reasonable, the licence holder shall also help to facilitate the search for suitable sources of supply or therapeutic alternatives.

**Recommendation 3:**

**Cessation or interruption of distribution: search for suitable therapeutic alternatives**

The licence holder will contact Swissmedic and, where appropriate, the professional circles concerned as soon as possible to facilitate the search for alternative sources of supply or therapeutic alternatives. The purpose of these contacts is to avoid or at least alleviate adverse consequences for the patients concerned.

The following measures, in particular, are to be considered in this context:

- Application for simplified licensing, e.g. for foreign packages which are not yet authorised in Switzerland, provided that the necessary conditions are satisfied.
- Where the pharmaceutical concerned is still protected by patent: grant of a licence for the relevant pharmaceutical to be produced in a hospital or community pharmacy.
- Transfer of the brand or distribution rights to another manufacturer or distributor.

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<sup>5</sup> [http://www.sgci.ch/plugin/template/sgci/\\*/11388](http://www.sgci.ch/plugin/template/sgci/*/11388)