Purpose

The form "Confirmation regarding substances from GMO" is intended to assist with harmonising the mandatory labelling of medicinal products, which contain or may contain substances entirely or partly manufactured from genetically modified organisms. It ensures the correct application of Article 15, paragraph 3 of the Ordinance on Medicinal Products (VAM; SR 812.212.21) in connection with Art. 7 of the Federal Department of Home Affairs Ordinance on Genetically Modified Food (VGVL; SR 817.022.51). For the said substances, the applicant must state:

- The type of GMO (bacteria, algae, fungi, viruses, cells, plants, animal)
- The precise description of the GMO (e.g. E. coli, CHO cells, corn, etc.)
- Whether the substance (active substance or excipient) is obtained from genetically modified micro-organisms, has been separated from the organisms, has been purified, can be chemically defined and has been manufactured in a contained system in accordance with the Ordinance on the Contained Use of Organisms ESV; SR 814.912 (Art. 7, paragraph 7bis, VGVL)
- Whether the content of this substance obtained from GMO, in terms of the individual excipient or active substance (not the total mass of the medicinal product) is ≤ or > 0.9%. If the content is ≤ 0.9%, it is also mandatory to state whether appropriate measures have been taken to prevent the presence of such a material (Art. 7, paragraph 7, VGVL).

This shows whether a labelling regarding the GMO source of the individual substances is required in the product information sheet and on the packaging materials and, if appropriate, what information must be stated. See also the decision flow chart under point 5.

Scope

The form (ZL000_00_013e_FO Confirmation regarding substances from GMO) must be submitted as of 1 April 2010 for applications relating to human medicines, for first authorisations, extensions of authorisations and variations of the quality of an active substance or of an excipient, together with the form ZL000_00_005e_FO Full declaration if the medicinal product consist of active substances or excipients that contain, or could contain, a fraction manufactured from GMO. The form does not have to be submitted for co-marketing products.
3 Legal basis for these provisions

Article 15, paragraph 3 of the Medicinal Products Ordinance (VAM) stipulates the following regarding the declaration of substances manufactured using GMOs:

“For the labelling of substances and mixtures thereof that could be components of medicinal products and food, the provisions of the Ordinance on Food of 1 March 1995 apply” (today, Article 7 of the Federal Department of Home Affairs Ordinance on Genetically Modified Food (VGVL) of 23 November 2005).“

Article 7, paragraph 1 of the VGVL states the wording to be used, i.e.: “manufactured using genetically modified X” (X = name of the GMO).

Article 7, paragraph 4 of the VGVL states where this wording must be placed: (“the wording must be placed in the list of ingredients, in parentheses, directly after the ingredient, the substance or the micro-organism concerned…”). Alternatively, the wording may be noted with an asterisk (*) and included as a footnote, in the same sized font, directly after the declaration of contents. Paragraph 9 states that no further wording is permitted. The conditions to be fulfilled concerning the content of the substance from GMOs in order to be exempt from using the said wording are stated in Article, 7, paragraph 7 of the VGVL. Article 7, paragraph 7bis specifies other criteria that also permit exemption from the said wording (see also section 1 of this information sheet).

4 Mandatory labelling for substances obtained from GMO in Switzerland

The legal prescriptions regarding the labelling of substances obtained from GMO in medicinal products vary within the European Union. The Swiss legislators have decided to make the labelling of substances from GMO mandatory, and stipulated the requirements in the legislation on food and therapeutic products (see Art. 3, paras. 2 and Art. 17 of the Gene Technology Act [SR 814.91]).
5 Decision flow chart for GMO labelling

Basis: Art. 15, CAM, paragraph 3 in connection with Art. 7, VGVL

Start

Active substance or excipients contain or could contain fraction of active subst. or excip. from GMO?

Art. 15 para. 3 VAN

Active substances or excipients without a fraction of active subst./excip. from GMO?

The question is negated in the form Application for Authorisation / Variation. The form Confirmation of substances from GMO does not have to be submitted.

Active substances or excipients with fraction of active subst./excip. from GMO?

Active substances or excipients with >0.9 % (m/m) GMO?

Art. 7, para. 7, letter a. VGVL

Typically excipients, e.g. lecithin, corn starch, etc.

Criteria from Art. 7, para 7, VGVL fulfilled?

NO

Active substances or excipients with >0.9 % (m/m) GMO?

Art. 7, para. 7, letter a. VGVL

Active substances or excipients with fraction of active subst./excip. from GMO?

Typical example: recombinant protein from CHO cell cultures

Mandatory labelling in accordance with Art. 7 para. 1; submit completed form and text of product information

Active substance or excipient from genetically modified microorganisms, separated, purified and chemically definable, manufactured in contained system (Art. 7 para. 7bis VGVL)

Active substance or excipient content >0.9 % (m/m GMO, per component) and appropriate prevention precautions taken (Art. 7 para. 7 letters a und b VGVL)

Appropriate prevention precautions taken?

NO

Art. 7 para. 7, letter b. VGVL

YES

No substances with mandatory labelling, submit signed form

Active substance or excipient content >0.9 %, or possibly >0.9 % (m/m; per component) (Art. 7 letter a. VGVL)