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Traditional herbal medicinal products and simplified registrations for homeopathic medicinal products: pharmacovigilance requirements and EudraVigilance access

Note for clarification

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1. Purpose of this document

The purpose of this document is to clarify pharmacovigilance requirements for **traditional herbal medicinal products registered further to a simplified registration procedure (traditional use-registration)** on the basis of Article 16a of Directive 2001/83/EC[1] and **homeopathic medicinal products registered further to the special, simplified registration procedure** under Article 14(1) of Directive 2001/83/EC and the process for obtaining access to adverse reaction reports in EudraVigilance for traditional use herbal medicinal products.

2. Pharmacovigilance requirements

The **pharmacovigilance requirements** are defined in Directive 2001/83/EC as follows:

- In accordance with Article 16(3) of Directive 2001/83/EC, the pharmacovigilance requirements provided in Title IX (Pharmacovigilance) of Directive 2001/83/EC shall apply to ***homeopathic medicinal products***, with the **exception of *homeopathic medicinal products registered further to the special, simplified registration procedure*** under Article 14(1) of Directive 2001/83/EC).
  - Therefore in accordance with the legislation, there are no reporting obligations for suspected adverse reactions for holders of simplified registrations for homeopathic medicinal products.
  - In addition, holders of registrations for homeopathic medicinal products referred to in Article 14(1) of Directive 2001/83/EC shall not be required to submit Periodic Safety Update Reports (PSURs), except when one of the cases provided for in Article 107b(3)(a) or (b) of Directive 2001/83/EC is applicable i.e. unless laid down as a condition in the marketing authorisation or requested by a Competent Authority.

For ***herbal medicinal products*** the pharmacovigilance requirements provided in Title IX of Directive 2001/83/EC shall apply. In addition, as per Article 16g(1) of Directive 2001/83/EC, the pharmacovigilance obligations provided in Articles 101 to 108b of Directive 2001/83/EC shall apply, by analogy, ***to traditional herbal medicinal products registered further to a simplified registration procedure (traditional use-registration)*** on the basis of Article 16a of Directive 2001/83/EC. However, holders of registrations for traditional herbal medicinal products referred to in Article 16a of Directive 2001/83/EC shall not be required to submit PSURs, except when one of the cases provided for in Article 107b(3)(a) or (b) of Directive 2001/83/EC is applicable i.e. unless laid down as a condition in the marketing authorisation or requested by a Competent Authority.

3. Obtaining Access to EudraVigilance

Six months following the announcement of the successful audit of EudraVigilance, the “simplified reporting” of suspected adverse reactions to EudraVigilance as set out in Article 107 and Article 107a of Directive 2001/83/EC will apply. To this extent, pharmaceutical companies will no longer receive reports of suspected adverse reactions that were reported by patients or healthcare professionals to national Competent Authorities through the EU Member States, but will gain access to these reports via EudraVigilance.

[1] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (Consolidated version: 16/11/2012).

The provision of granting access to EudraVigilance to pharmaceutical companies to the extent necessary for them to comply with their pharmacovigilance obligations is set out in Article 24(2), 5th paragraph of Regulation (EC) No 726/2004[2]. The level of access to EudraVigilance data for all stakeholders is set out in the EudraVigilance Access Policy (revision 3).

More specifically, access provided to pharmaceutical companies is medicinal product specific and is determined on the basis of the data submissions on medicines (Article 57). In practice this implies that only where the medicinal product data are available in the XEVMPD (the database designed to support the collection of data on medicines based on Article 57), it can be determined which pharmaceutical companies can access suspected adverse reactions in EudraVigilance based on the medicine(s) reported as suspect or interacting.

In order to obtain access to reports of suspected adverse reactions in EudraVigilance and thus, to comply with their pharmacovigilance obligations, ***holders of traditional use registrations for herbal medicines should submit the information for these medicines using the electronic format referred to as Article 57 format or eXtended EudraVigilance Product Report Message (XEVPRM) format***. ***Registration holders should*** also ***ensure that the information is kept up to date***.
The Article 57 database already allows for data submission for traditional use registrations for herbal medicines in line with the requirements and business processes described in Chapter 3.II: Extended EudraVigilance product report message (XEVPRM) user guidance.
Please refer specifically to question 1.2 of the document "Electronic submission of Article 57(2) data Questions & Answers (Q&As)" (EMA/159776/2013).

For ***homeopathic medicinal products registered further to the special, simplified registration procedure under Article 14(1) of Directive 2001/83/EC***, pharmacovigilance requirements do not apply and therefore there is no need for the medicines data submission using the electronic format referred to as Article 57 format or eXtended EudraVigilance Product Report Message (XEVPRM) format; however registration holders of these homeopathic medicinal products can submit such data on a voluntary basis as the system allows for this.

In accordance with Article 1(2) of Regulation (EU) No 658/2014[3], "*Homeopathic and herbal medicinal products registered in accordance with, respectively, Article 14 and Article 16a of Directive 2001/83/EC, and medicinal products which are authorised to be placed on the market in accordance with Article 126a of Directive 2001/83/EC, shall be excluded from the scope of this Regulation*". ***Therefore no fees will be charged for submission of data in the Article 57 database*** as Regulation (EU) No 658/2014 does not apply to ***traditional herbal medicinal products, nor to homeopathic medicinal products registered through the simplified procedure***.

[2] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Consolidated version: 05/06/2013).
[3] Regulation (EU) No 658/2014 of the European Parliament and of the Council of 15 May 2014 on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use.