PSUR SUBMISSION

1. Which medicinal products are exempted from routine submission of PSURs?

For medicinal products included in the EURD list (https://www.ema.europa.eu/en/glossary-terms/eurd-list) possible exemptions from the regular PSUR presentation is reported in the column "*Are PSURs required for products referred to in Articles 10(1), 10a, 16a of Directive 2001/83/EC as amended*?" limited for the reported legal bases.

For medicinal products not included in the EURD list, the following categories are exempted from routine submission of PSURs in Italy:

- generic medicinal products authorised under Article 10(1) of Directive 2001/83/EC,
- medicinal products authorised under Article 10a of Directive 2001/83/EC,
- traditional herbal medicinal products autorised by simplified registration procedure under Article 16a of Directive 2001/83/EC,
- homeopathic medicinal products autorised by simplified registration procedure under Article 14 of Directive 2001/83/EC,
- medicinal products authorised under Article 4.8 (ii) or Article 4.8a (iii) of Directive 2001/83/EC;

2. As Marketing Authorisation Holder (MAH) for medicinal products authorised under Ministerial Decree (D.M.) 8 November 1993, which received the marketing authorisation number according to D.M. 2 October 1995 e s.m.i. (ex galenici da Formulario Nazionale), how shall I present my PSUR?

For medicines authorized under the D.M. 8 November 1993, which received the marketing authorisation number according to D.M. 2 October 1995 e s.m.i. (ex galenici da Formulario Nazionale), there can be 3 scenarios:

1. for active ingredients and associations of active ingredients not included in the EURD list, the submission of the PSUR is required, and the standard cyclicity established by the national legislation applies (art.26 of the Decree of the Ministry of Health 30 April 2015). The PSUR should be uploaded to the PSUR Repository as national.

2. for the active ingredients and associations of active ingredients included in the EURD and where specific legal basis are exempted from routine submission (see EURD list column "*Are PSURs required for products referred to in Articles 10(1), 10a, 16a of Directive 2001/83/EC as amended? Yes/No*"), the MAHs are exempted from PSUR submission. Nonetheless, the MAHs are obliged to comply with the conclusions of the respective PSUSA procedures.

3. for the active ingredients and associations of active ingredients included in the EURD list and for which the presentation of the PSUR is required for all the legal bases (see EURD list column "*Are*

PSURs required for products referred to in Articles 10(1), 10a, 16a of Directive 2001/83/EC as amended? Yes/No"), the MAH should submit the PSUR according to the cyclicity reported in the EURD list for the respective active ingredient or association of active ingredients. The PSUR should be uploaded to the PSUR Repository and will be assessed within the PSUSA procedure.

3. As MAH for medicinal products authorised under the Article 2 of d.P.R. 6 October 1998, n. 392 (ex Presidi Medico Chirurgici), how shall I submit my PSUR?

See answer to Question 2.

The exemptions mentioned in questions 1, 2 and 3 apply unless there is a specific condition in the authorisation or if PSUR submission is required by a National Competent Authority, EMA, EC, or in response to a specific request. National competent authorities can also request PSUR for generic medicinal products at any time on the grounds detailed in Article 107c (2) of the Directive.

All the MAHs should refer to the latest approved version of the EURD list, published at the EMA website.

4. If the active substance (or composition) contained in a medicinal product for which I hold a MA has been removed from the EURD list, how and when shall I sumbit the PSUR?

Changes of EURD list become binding 6 months after publication. For the PSUR submission cycle at national level, the MAH shall follow the requirements of art. 26 of the Decree of the Ministery of Health of 30 April 2015.

E.g., if the entry of the active substance was removed in January 2023, this change will be effective after 6 months, therefore the PSUR submission date should be calculated as follows: January 2023 + 6 months + cyclicity required at national level (specified by art.26 Ministerial Decree 30 April 2015). The PSUR reference period will have to cover from the DLP (Data Lock Point) of the last submitted PSUR to the new DLP.

January 31, 2025