

Transitional measures for submission of PSURs for nationally authorised medicinal products for human and veterinary use

In accordance with Article 104(6) of Directive 2001/83/EC as amended by 2004/27/EC (human code) and to Article 75 (5) of Directive 2001/82/EC as amended by Directive 2004/28/EC (veterinary code). Periodic Safety Update Reports (PSURs), “unless other requirements have been laid down as a condition for the granting of the marketing authorisation” shall be submitted immediately upon request or at least every six months after authorisation until the placing on the market. PSURs shall also be submitted immediately upon request or at least every six months during the first two years following the initial placing on the community market and once a year for the following two years. Thereafter, the reports shall be submitted at three-yearly intervals, or immediately upon request.”

The new requirements for PSUR submissions for nationally authorised medicinal products apply as of 30 October 2005.

The practical implementation of the new PSUR provisions for medicinal products nationally authorised before 30 October 2005 will be as follows:

Marketing authorisations for medicinal products not yet renewed

PSURs will currently be submitted at either six-monthly or yearly intervals depending on the date of authorisation of the product, unless otherwise agreed at the grant of the marketing authorisation. It is considered in the best interest of public health protection for these products to maintain their current PSUR submission periodicity up to their first renewal. Thereafter, PSURs should be submitted every three years, unless other requirements have been laid down as a condition of the marketing authorisation.

Marketing authorisation for medicinal products already renewed at least once

There is an agreement among the European Commission and the national competent authorities that for all medicinal products authorised through national or MR procedures PSURs have to be submitted no later than 30 October 2008 i.e. no later than three years after the date of application of the revised legislation. In terms of data lock points for PSURs it means that these should be no later than 30 August 2008, taking into account that marketing authorisation holders need 60 days to make a PSUR. Applying these principles it means that:

- For products having a marketing authorisation with an expiry date no later than 30 April 2009 the next PSUR should be submitted with the renewal application no later than 30 October 2008 (taking into account the requirement in the revised legislation that a renewal application should be submitted six months before expiry of the current MA). Thereafter PSURs should be submitted every three years, unless other requirements have been laid down as a condition of the marketing authorisation.
- For products having a MA with an expiry date after 30 April 2009 the next PSUR should be submitted no later than 30 October 2008. The precise date of submission should be agreed with the national competent authorities. Thereafter PSURs should be submitted every three years, unless other requirements have been laid down as a condition of the marketing authorisation.

Endorsed by the Commission on 17 November 2005.