

GUIDELINE

for the date of submitting the Periodic Safety Update Reports (PSURs)

This document provides instructions about considering the new PSUR arrangements after the Decree No. 128/2009. (X.6.) MARD (hereunder MARD Decree) has come into force.

The deadline for submitting the reports is the Data Lock Point of the "Time period covered by the PSUR" + 2 months.

In case of variations the National Food Chain Safety Office, Directorate of Veterinary Medicinal Products (NFCSO DVMP) decides on the date of the further PSUR presentations and/or modifications.

In case of the renewal of the marketing authorization the PSUR should be submitted.

In case of products authorized by a Mutual Recognition Procedure the dates of submitting the Periodic Safety Update Reports adjust to the date determined by the Reference Member State – unless other requirements have been laid down as a condition for the granting of the Marketing Authorization.

In case of PSUR submitted under Work-sharing, the dates of submitting the PSUR adjust to the date of harmonized Data Lock Point of the concerned active substance which is found on the website of Heads of Medicines Agencies (www.hma.eu).

I. In case of products given a marketing authorization after the Decree No. 128/2009. (X.6.) MARD has come into force:

1. The Periodic Safety Update Reports – unless it is otherwise decided as a condition of issuing the marketing authorization – should be sent to the Institute immediately upon request of the CAO DVMP, and at least every six month until the placing on the market.
2. Following the initial placing on the market the Periodic Safety Update Reports should be sent to the Institute immediately upon request of the NFCSO DVMP, every six month during the first two years, then once a year for the following two years. Thereafter the PSURs should be sent every three years, or immediately upon request of the NFCSO DVMP.

(For example1: The date of issue of the marketing authorization is: 15.08.2010., the product will enter into the market on 28.11.2011. The time periods covered by the PSURs to be submitted:

2010.08.15. - 2011.02.14.; 2011.02.15. – 2011.08.14.; 2011.08.15. – 2012.02.14.;
2012.02.15. – 2012.08.14.; 2012.08.15. – 2013.02.14.; 2013.02.15. – 2013.08.14.; 2013.08.15. – 2014.02.14.;
2014.02.15. – 2015.02.14.; 2015.02.15. – 2016.02.14.;
2016.02.15. – 2019.02.14.; 2019.02.15. – 2022.02.14.....)

For example2: The date of issue of the marketing authorization is: 15.08.2010., the product will enter into the market on 02.09.2010. The time periods covered by the PSURs to be submitted:

2010.08.15. - 2011.02.14.;

2011.02.15. – 2011.08.14.; 2011.08.15. – 2012.02.14.; 2012.02.15. – 2012.08.14.; 2012.08.15. – 2013.02.14.;

2013.02.15. – 2014.02.14.; 2014.02.15. – 2015.02.14.;

2015.02.15. – 2018.02.14.; 2018.02.15. – 2021.02.14.....)

II. The marketing authorization of the product wasn't renewed before the date 13. July.2006.

1. From the date of Marketing Authorisation the Periodic Safety Update Reports should be sent to the Institute immediately upon request of the NFCSO DVMP, every six month during the first two years, then once a year for the following two years. Thereafter the PSURs should be sent every three years, or immediately upon request of the NFCSO DVMP.
2. In each case the MA Holder is required to send additionally the missing PSUR data.

(For example: The date of issue of the marketing authorization is: 15.08.2003.; the application for the renewal is submitted on 15.02.2008, the date of the decision regarding the renewal of the marketing authorization is 01.12.2008. The time periods covered by the PSURs to be submitted:

15.08.2003 - 14.02.2004.; 15.02.2004 – 14.08.2004.;15.08.2004 - 14.02.2005.; 15.02.2005 – 14.08.2005.;

15.08.2005 – 14.08.2006.; 15.08.2006 – 14.08.2007.;

15.08.2007 – 14.08.2010.; 15.08.2010 – 14.08.2013.....)

III. The marketing authorization of the product was at least once renewed before the date 13. July 2006.

1. From the date of the renewal of a marketing authorization the PSURs are to be sent every three years, unless other requirements have been laid down as a condition for the granting of the Marketing Authorization.
2. In each case the MA Holder is required to send additionally the missing PSUR data..

(For example: The date of the marketing authorization is: 25.03.1999. The date of the renewal of the marketing authorization is: 10.07.2004. The time periods covered by the PSURs to be submitted:

10.07.2004 – 09.07.2007.; 10.07.2007 – 09.07.2010.; 10.07.2010 – 09.07.2013.....)