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# SÚKL Information for Marketing Authorisation Holders on the EU Synchronisation of PSUR submission schemes of medicinal products authorised through national, mutual recognition and decentralised procedures

Under the auspices of the Heads of Medicines Agencies an EU project on synchronisation of PSUR submission schemes has been launched to ensure that medicinal products containing the same active substance follow the same PSUR (Periodic Safety Update Report) submission scheme in all EU Member States. The Project is supported by EFPIA (European Federation of Pharmaceutical Industries and Associations), AESGP (Association of the European Self-Medication Industry) and EGA (European Generic medicines Association).

**HBD – EU Harmonised Birth Date for submission of PSUR**

The PSUR submission scheme is based on the product's "birth date". This date is usually linked to the marketing authorisation date. The International birth date (IBD) is the date of the first marketing authorisation, the EU birth date is the date of the first authorisation in Europe. Submission of PSURs is normally determined by the date of national authorisation; these dates may differ in the various Member States. Thus, the same product of one marketing authorisation holder can follow different PSUR schemes in the various EU Member States. This results in duplicate work of both MAHs and competent authorities, which may even have negative impact on quality of the reports. Besides that, original medicinal products and generics usually have different birth dates and therefore it is difficult to ensure the same safety information in SPCs of similar products. The above mentioned problems may be substantially reduced if **all medicinal products with the same active substance have the same birth date within the EU, i.e. EU HBD (Harmonised birth date).**

## EU synchronisation of PSUR submission schemes

At the beginning of January 2006, marketing authorisation holders of original medicinal products were requested to propose EU HBDs and corresponding DLPs (Data lock points) of their products. Their proposals were then adopted by the Heads of Medicines Agencies. The regularly updated list of adopted EU HBDs and DLPs together with accompanying documents and information on this project can be found on the HMA website (http://www.hma.eu/).
The project is based on the principle of common PSUR submission scheme according to HBD and assessment work shared by Member States. The Member State in charge of making the PSUR assessment report for a particular active substance is called the PSUR Reference Member State (P-RMS) and is indicated on the list of EU HBDs. The objective of PSUR synchronisation project is to make only one PSUR version acceptable for all EU Member States.

The common submission scheme and shared assessment should bring the following benefits:

- Marketing authorisation holders of original products make only 1 PSUR for the concerned product with active substance once every 3 years and this PSUR can be simultaneously submitted in all EU Member States.

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- marketing authorisation holders of generic products enjoy the same advantages and, where appropriate, may collaborate on the preparation of PSURs. The marketing authorisation holders of generic product are also expected to submit PSURs in accordance with EU HBDs and DLPs.
- Competent authorities will be able to mutually share the assessment work of PSURs and harmonisation of SPC texts will become easier.

**Information for marketing authorisation holders on the procedure for synchronisation of PSUR submission schemes based on EU HBD**

For majority of products the introduction of EU HBD means that the PSUR submission schemes need to be changed.

Both the marketing authorisation holders and competent authorities will benefit from the synchronisation of PSUR submission schemes of medicinal products authorised through national, mutual recognition and decentralised procedures. Owing to the fact that under national legislation the synchronisation will cause a change in marketing authorisation of the given medicinal product and that this change cannot be made ex officio, only upon request of the marketing authorisation holder, the synchronisation can be successfully completed only if the concerned marketing authorisation holder applies for a variation to marketing authorisation under Section 26a (3) of the Act on Pharmaceuticals, i.e. a **change in the date and submission periodicity of PSUR**. The only exception to the above procedure applies to marketing authorisations granted through mutual recognition procedure or decentralised procedure where the Czech Republic is a Concerned Member State (CMS). In such cases legislation requires that the decision of the Reference Member State (RMS) is recognised. If the RMS does not require the implementation of change in the date and periodicity of PSUR submission by means of a variation to marketing authorisation, submission of such application in CR is also not required.

The Institute recommends that marketing authorisation holders of medicinal products with HDB apply for a Type II variation as soon as possible using the following guidance:

- Marketing authorisation holders of medicinal products **authorised through national or mutual recognition procedures with CR acting as RMS** are recommended to apply for Type II variation at least 6 months prior to the established DLP. In accordance with the EC recommendation to change the date and periodicity of PSUR submission on the Community level without application for variation (Notice to Applicants, Volume 9A, Part I., 6), and in view of Czech national regulations, the mutual recognition procedure on variation to marketing authorisation concerning medicinal products authorised through MRP with the Czech Republic as RMS will not be initiated; submission of a national application for variation in the Czech Republic will be considered sufficient.
- Marketing authorisation holders of **medicinal products authorised through mutual recognition procedures with CR as CMS** do not have to apply for Type II variation. They should submit PSUR in accordance with the RMS requirements.

Since it is in the public interest to make changes in PSUR submission schemes on the basis of HBD, as required by the synchronisation project, we recommend that applicants submit simultaneously with the application form also a request for waiver of costs reimbursement under Section 112 (3) (b) of the Act on Pharmaceuticals giving the reasons as quoted bellow:

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This application for Type II variation refers to the PSUR synchronisation based on HBD which is being conducted on the EU level. This excercise is intended to ensure coordinated monitoring of product safety in the EU and, where necessary, to ensure flexible incorporation of information following from submitted PSURs into the SPCs of concerned medicinal products. Implementation of the above variation to marketing authorisation is conducted in the public interest. Simultaneously, this variation will mean a change with implications for a wide scope of persons. Pursuant to Section 112(3)(b) of the Act on Pharmaceuticals, the above mentioned facts provide grounds for waiver of reimbursement of costs incurred on the assessment of this application. On the grounds of the above mentioned facts we apply for a waiver of cost reimbursement fees for activities performed in respect of the assessment of this application for a variation to marketing authorisation for medicinal product ……*MA No*..... consisting in synchronisation of PSUR submission schemes based on EU HBD.

*Note*: Pursuant to the Act on Administrative Fees the administrative fee of 2000,- Kč must be paid by the applicant not later than upon submission of the application.

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