

Procedure of maintenance in force the Marketing Authorisation - exemption from the sunset clause

Submitted by marpie on Fri, 22/04/2016 - 12:27

Procedure of maintenance in force the Marketing Authorisation – exemption from the sunset clause in Poland

In accordance with DIRECTIVE 2001/82/EC Article 28 (...)

“4. Any authorisation that is not followed within three years of its granting by the actual placing on the market of the authorised veterinary medicinal product in the authorising Member State shall cease to be valid.

5. When an authorised veterinary medicinal product previously placed on the market in the authorising Member State is no longer actually present on the market in this Member State for a period of three consecutive years, the authorisation granted for that veterinary medicinal product shall cease to be valid.

6. The competent authority may, in exceptional circumstances, and on human or animal health grounds, grant exemptions from paragraphs 4 and 5. Such exemptions shall be duly justified.”

Accordingly to above, to avoid the sunset clause for MA in Poland, before the MA become invalid, MAH should submit to the **Office for Registration of Medicinal Products, Medical Devices and Biocidal Products** (02-222 Warszawa, Al. Jerozolimskie 181C, Poland) proper application.

1. Cover letter for exemption of the sunset clause with basic information about product and MAH, and some reasons to keep this MA in force. (There is no special application form.)
2. Original or notarised copy of the Extract from Chamber of Commerce for MAH (that includes i.a. information about the company as well as authorized person to act and sign on behalf of the company), and translation of this document into Polish by sworn translator. These documents should be original or copies legalized by notary. The Extract from Chamber of Commerce cannot be older than 6 months (the date of issue is crucial). In case when the applicant has submitted these documents recently, please provide us with the photo-copy of these documents and with the originally signed declaration by authorised person that these documents have been submitted. Please note that this declaration should contain the name of VMP, procedure number as well as the date of submission.

3. Proof of payment for application **4 200 PLN (valid from 30 July of 2015)**. The payment must be net of bank charges and performed before the application (payment details should be given to enable identification).

- **Bank account for international payments:**
- **Payee: Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych**
- **Bank: Narodowy Bank Polski, Plac Powstańców Warszawy 4, 00-950 Warszawa, POLAND**
Account No.: PL30 1010 1010 0094 1022 3100 0000
NBP BIC Code: NBPLPLPW

4. Letter of authorization for person for communication and to act on behalf of MAH originally signed by the authorized person to signing on behalf of the company (according to the Extract from Chamber of Commerce). This letter can be bilingual for example English/Polish or the Polish sworn translation can be made. This document should be original or copy legalized by notary.
5. Proof of payment for the letter of authorisation. Please note that the fee of **17 PLN** should be paid for each authorised person and for each application form and it has to be paid at the account of Urząd Miasta Stołecznego Warszawy, Centrum Obsługi Podatnika. The account number is:

PL 21 1030 1508 0000 0005 5000 0070, code SWIFT – CITIPLPX.

All documents should be sent in paper version.

ADDRESS: 02-222 Warszawa, Al. Jerozolimskie 181C, Poland

IF YOU HAVE ANY QUESTIONS, PLEASE DO NOT HESITATE TO CONTACT US!

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