STATE INSTITUTE FOR DRUG CONTROL
Kvetna 11, 825 08 Bratislava 26, Slovak Republic

Additional requirements for submission of the MRP and DCP dossier in the Slovak republic

1. **The State fee** has to be paid prior the submission of the application (*Act No. 140/98 §21a) par. 3), about the medicinal product and medical devices*. The applicant should submit the application form for the registration (renewal or variation) at the State Institute for Drug Control (SIDC) in order to get a reference number for the application. The reference number will be the Variable symbol for the bank transfer. After bank transfer, the applicant should submit the confirmation form of the payment which is published on the **http://www.sukl.sk/payment_reg.doc** . In the case, that the bank transfer has not been realized, the applicant should submit the confirmation of the transfer and within the 5 working days it is necessary to submit the confirmation of the successful bank transfer to the SIDC.
   A NEW SYSTEM FOR PAYING OFF THE STATE FEE IS BEING PREPARED AND WILL BE UPDATED.

2. **The application form** filled in the **Slovak language** (application forms are published at: **http://www.sukl.sk/regziad.doc, http://www.sukl.sk/zmeziad.doc, http://www.sukl.sk/preziad.doc.** and a european application form **filled in the English**. These are published at: **http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-2/b/applicformversion_10_05.doc, http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-2/b/applicformhomeo_2005_12.doc, http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-2/c/mr-renewal-form_2004_06.doc, http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-2/c/renewal_%202006-17- 07.doc**

3. The **proposed SPC, PIL, Labeling** should be submitted in Slovak language (according to the *Act. No 140/98 §21 par.4 k) l) and m), about the medicinal product and medical devices)*, **within five days after the national implementation phase has started and colored Mock – ups** should be submitted **within five days after national approval of Labeling.**
   The SPC, PIL, Labeling should be in line with current version of QRD published on: **http://www.emea.eu.int/htms/human/qrd/qrdtemplate.htm**
   The SPC, PIL, Labeling and the colored Mock -ups should be submitted in a paper copy and electronically as well.

4. The certification of incorporation of the applicant – company (copy) and the future Marketing Authorization Holder (MAH) in **business register** (original or verified copy). Original or verified copy of business register is necessary to submit only in the case, that the applicant and the future MAH (if different) submit the application form for registration process via MRP/DCP for the first time in the Slovak Republic. To the contrary, it is sufficient to submit the copy of the business register of the applicant and the future MAH.

5. **Copy of GMP certificates and Manufacturing authorizations**:

   • **if the manufacturing site is in the EU, EEA (Norway, Iceland, Lichtenstein),**
   or in countries, to which an appropriate MRA refer to (Canada, Australia, New Zealand, Japan, Switzerland):
   - copy of manufacturing authorization from EU, EEA or MRA countries – not older than 2 years and
   - copy of GMP certificate from EU, EEA or MRA countries – not older than 2 years, if the GMP is not already a part of manufacturing authorization.

   • **if the manufacturing site is outside the EU (third countries):**
   - original or verified copy of manufacturing authorization from the competent authority from the relevant country - not older than 2 years and
   - original or verified copy of GMP certificate issued by country from EU, EEA or MRA – not older than 2 years

6. **Statement for the MA transfer to local subsidiary** (if relevant).

7. **TSE certificate or a declaration**, that the product does not contain potential TSE agents.

8. **Annex 23.** Within this document applicant has to declare, whether medicinal product or active substance within the medicinal product is or is not protected by a patent or a supplementary protective certificate and a way, by which applicant will on the request from patient organisations made available the **package information leaflet in formats appropriate for the blind and partially sighted**.

9. **In case of submitting registration dossier for several strengths,** were a part of the documentation for all these strengths is identical (Module 1-5), applicant should submit these "identical" Moduls only once as a paper copy and the rest of the identical documentation has to be submitted electronically (on a CD).