GUIDELINE
for completing the Periodic Safety Update Report (PSUR)

1.The report should be completed in Hungarian or in English.

2.The deadline for presenting the reports is the Data Lock Point of the „Time period covered by the PSUR" + 2 months (e.g. if the date of issue of the marketing authorization is 15.05.2003 and the product entered into the market within half year of the authorization, the time period covered by the third PSUR is: 15.05.2004.-14.11.2004.; the deadline for submitting the PSUR is: 14.01.2005.).

3.The reports completed in accordance with the Guideline should be sent to the Directorate in each case specified by the MARD Decree being in force at the time of issuing the marketing authorization of the product, even if no ADR Report was submitted.

4.For the date of submitting the PSURs according to the date of issue of the marketing authorization or the date of the renewal see the "Guideline for the date of submitting the Periodic Safety Update Reports (PSURs)" in our website.

5.It there is any change in the data of the 1. page (e.g. MA Holder, product name, manufacturer), or in the Summary of Product Characteristics (e.g. change in the composition, addition of a new target species, amendment of the route of administration) since submitting the previous Periodic Safety Update Report, this should be recorded in the Appendix I. If there is no change in the data, "none" should be stated.

6.The 1 – 6 points of the Periodic Safety Update Report are to be filled as appropriate.

7.If no report arrived from Hungary, the European Union or a 3rd country during the time period covered by the PSUR, the data included in 2 – 5 points do not have to be indicated; only the 1. page of the report, the data for the sales volumes and the estimated number of treated animals under the 1. point and the Annex II/A: Declaration should be sent to the Directorate.

8.If the product was not in trade anywhere during the time period covered by the PSUR, and no adverse reactions were observed during the additional examinations (e.g. clinical studies after the authorization), the data included in 1 – 5 points do not have to be indicated, only the 1. page of the report and the Annex II/B: Declaration should be sent to the Directorate.

9.The Annex II/A and Annex II/B Declarations (if necessary) should be signed and sealed by the MA Holder (or the authorized person responsible for pharmacovigilance). (Without signature and stamp the Declaration cannot be accepted.)

10.The suspected adverse reactions are required to be summarized according to the 2. point, the other pharmacovigilance data are required to be summarized according to the 3. point.

11.If the product is authorized in more strength and/or for more target species, the data should be evaluated - under the 4. and 5. points - separately, in respect of all the strengths and/or target species.

12.As the Annex III, the valid authorized Summary of Product Characteristics should be submitted. In case of a national authorization the SPC in Hungarian language should be submitted; if the product was authorized according to a Mutual Recognition Procedure or a Centralized Procedure, the SPC in English approved in that given procedure should be submitted.

13.In Annex V the information about each report should be indicated. It is asked to be completed in a most detailed form.

14.The data of the report always apply to the time covered by the PSUR. In case of a renewal of a marketing authorization the summarized data of reports submitted during the period between the issue of the marketing authorization (or the previous renewal, respectively) and the renewal should be specified.

15.In case of an application for the renewal of a marketing authorization, on the basis of the guideline on Pharmacovigilance, EUDRALEX volume 9, a complete PSUR – with all the points and annexes filled – should be submitted. (At the renewal procedure it is not enough to submit the simplified form given in the 7. and 8. points of the guideline.)

16.In case of products authorized by a Mutual Recognition Procedure it is not enough to submit the simplified document under the 7. point; on the basis of the guideline on Pharmacovigilance, EUDRALEX volume 9, a complete PSUR – with all the points and annexes filled – should be submitted.