European Medicines Agency
Evaluation of Medicines for Human Use

London, 13 September 2005
Doc. Ref. EMEA/52890/2005

GUIDANCE FOR THE PROVISION OF DATA (excluding paediatric data) NOT YET SUBMITTED TO THE EMEA

This guidance only addresses data not previously submitted to the EMEA and for which no regulatory actions are deemed necessary by the MAH according to the regulatory requirements referred to in Article 23 of Directive 2001/83/EC, as amended[1] and Article 15(2) of Regulation (EEC) No 2309/93, as amended (as of 20 November 2005 according to Article 16(2) of Regulation (EC) No 726/2004)[2]. Details on the content, format and timelines of the data to be submitted are provided in the guidance hereafter.

It is assumed that all data requiring regulatory action have been already submitted to the EMEA.

1) Which information is to be provided?

➢ The MAH has to identify all studies not previously submitted to the EMEA (excluding paediatric data, please refer to the *Guidance to marketing authorisation holders for the provision of additional paediatric data not yet submitted to the EMEA (Doc. Ref. EMEA/157537/2005*)) for which no regulatory actions are or has been deemed necessary as referred to below.

In that case, the information/data concern clinical efficacy/safety and also non-clinical trials.

- Clinical studies/trials
  - Phase I to IV commercially-sponsored[3] clinical trials;
  - Completed or discontinued or on-going[4] studies;
  - Published or not;

  Trials should be identified regardless of the region where they were performed, the aim, outcome, population studied (excluding paediatric data) and indication.

  For discontinued trials, the reasons for discontinuation should be stated.

- Non-clinical studies
  - Commercially sponsored[3] studies;
  - Completed or discontinued or on-going[4] studies;
  - Published or not.

[1] By Directive 2004/27/EC (31 March 2004)

[2] In the following sentence '*…any new information which might entail the amendment[variation] of the particulars and documents…*'as laid down in the above mentioned articles, '*…any new information…*' and '*… which might entail the amendment of the particulars and documents…*' mean when interpreting in conjunction that any change to the data provided in the initial dossier has to be submitted to the Agency as soon as they might meet the requirements as laid down in the Commission Regulation (EC) No 1085/2003 or the Volume 9 - Pharmacovigilance - of the Rules Governing Medicinal Products in the EU i.e. that they might entail amendment to particulars or documents such as the dossier and the marketing authorization and/or might have an impact on the risk-benefit balance of the medicinal product. In case of any doubt, the MAH should have submitted the information to the Agency.

[3] Does NOT include investigator-sponsored trials

[4] Without prejudice to any regulatory actions deemed necessary by the MAH after completion of the study

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2) Format and content of information submission?

The data as detailed above should be presented as follows:

1) a cover letter :

   - giving the number of non-clinical and clinical studies identified,
   - including the MAH's confirmation that after having assessed the data not submitted to the EMEA there is no need for regulatory actions in accordance to Article 23 of Directive 2001/83/EC, as amended and Article 15(2) of Regulation (EEC) No 2309/93, as amended (as of 20 November 2005 according to Article 16(2) of Regulation (EC) No 726/2004) [2].

2) a line listing of all the studies identified and presented by type of non-clinical (pharmacology / pharmacokinetics / toxicology) and clinical (pharmacology / pharmacokinetic / efficacy / safety / others) studies to be reported. The appropriate attached templates should be used to provide the mentioned line listing. A separate table for non-clinical and clinical studies should be completed and within each table, studies shall be classified by type of studies as detailed above. The MAH might need to adapt some items of the proposed templates where appropriate depending on the type of studies.
   If a synopsis is available, the MAH can just fulfil information about study code and study title and cross-refer to the synopsis for the other items of the tabular format.

3) If available, enclosed synopses of the individual studies.

Please note that for multiple applications, a cover letter per product is to be provided however, the attached tabulated information are likely to be identical and cross-referred, if relevant.

3) Timelines?

MAH are requested to provide the above information to the EMEA (via the respective PTL) and the Rapporteur by the end of 1Q2006.

If the MAH has no information to submit, this should also be confirmed in writing to the EMEA (via the respective PTL) and the Rapporteur.

4) Number of copies?

Please submit simultaneously:
- 2 paper copies and 1 electronic version of your submission to the EMEA.
- 1 paper copy and 1 electronic copy of the submission to Rapporteur only.

Templates* for the line-listing

- **For non-clinical study**

Study code	Study title	Testing facility	Duration of the study	Study objective(s)	Species / strain	Number of animals	Test product, dose, mode of administration	Report availability (Yes, please specify language / No)	Reason for discontinuation (where appropriate)

- **For clinical study**

Study code	Study Title (incl. Phase of develop-ment)	Investigator(s) or nominated principal investigator	Country (ies) where the centres were/are located	Duration of the study (date of first enrolment, date of last completed)	Study objective(s) / type of study**	Study design (if this information is not contained in the full study title)	Primary endpoint (secondary endpoint if available)	Number of patients (planned and recruited)	Medical condition (therapeutic indication) (if not in study title)	Test product, dose, mode of administration	Duration of treatment	Report availability (Yes, please specify language / No)	Reason for discontinuation (where appropriate)

** The MAH might need to adapt some items where appropriate depending on the type of studies*
*** (e.g. pharmacology / pharmacokinetic / efficacy / safety / others)*