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**Question & Answer N. 18/2007**  
**Data requirements – experts report**

<b>Status</b>	<b>Public</b>
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## QUESTION

A Company wishes to make an application for a mutual recognition procedure under Article 13 (1) of Directive 2001/82/EC as amended for a generic product. What are the requirements regarding the inclusion of expert reports in the dossier, as no data will be provided for Part III or Part IV, only bioequivalence studies.

## ANSWER

It is necessary to include all expert reports (Safety, Residue & Clinical Part) in Part I of an application for a generic product.

An expert report is required for Part III and IV of the dossier as described in volume 6B of the Notice to Applicants. As specified, the expert report should focus on:

### Part III Expert Report

- the grounds for claiming bioequivalence and justification for omitting toxicity & residues studies;
- an evaluation of the proposed user warnings;
- for injectable products (im & sc), an evaluation of injection site residues;
- an evaluation of the proposed withdrawal periods.

### Part IV Expert Report

- the grounds for claiming bioequivalence;
- an evaluation of the bioequivalence studies or a justification why studies were not performed with reference to the Guidelines for the conduct of bioequivalence studies for veterinary medicinal products (EMA/CVMP/016/00).

Every claim and warning on the SPC not known from or inferred from the Summary of Product Characteristics of the reference veterinary medicinal product should be justified.

The expert should also comment on the information provided regarding the excipients and formulation.