SCIENTIFIC DISCUSSION

1. Introduction

This application has been submitted as an informed consent application in accordance with Article 10c of Directive 2001/83/EC, as amended.
Therefore, consent from the MAH of the Insuman application has been given allowing access to Module 2 to Module 5 of the initial dossier of this authorised product and any subsequent post-marketing procedures submitted, assessed and approved.

As a consequence, quality, safety and efficacy of the Insulin Human Winthrop medicinal product are identical to the up-to-date quality, safety and efficacy profile of Insuman. Information on the scientific discussions can be found in the European Public Assessment Report (EPAR).

The approved indication is: "Diabetes mellitus where treatment with insulin is required. Insulin Human Winthrop Rapid is also suitable for the treatment of hyperglycaemic coma and ketoacidosis, as well as for achieving pre-, intra- and post-operative stabilisation in patients with diabetes mellitus".

2. Quality, non-clinical and clinical aspects

Since this application is an informed consent of the Insuman application, the quality, non-clinical and clinical data in support of the Insulin Human Winthrop application are identical to the up-to-date quality, non-clinical and clinical data of the Insuman dossier that have been assessed and approved (including all post-marketing procedures).

3. Pharmacovigilance

PSUR

As requested by the applicant and agreed by the CHMP, the PSUR cycle of Insulin Human Winthrop will correspond to the one attributed to the cross-referred product, Insuman, unless otherwise specified.

Detailed description of the Pharmacovigilance system

The CHMP considered that the Pharmacovigilance system as described by the applicant fulfils the legislative requirements.

Risk Management Plan

The applicant submitted a risk management plan.
The CHMP, having considered the data submitted in the application, is of the opinion that the applicant should provide an updated Risk Management Plan which is in line with the CHMP Guideline on Risk Management Systems for medicinal products for human use, within three months following the European Commission Decision on the granting of the marketing authorisation.

4. Overall conclusions, risk/benefit assessment and recommendation

Since this application is an informed consent of the Insuman application, the CHMP considered that the risk-benefit balance of Insulin Human Winthrop was favourable and therefore recommended the granting of the marketing authorisation for the following indication:

"Diabetes mellitus where treatment with insulin is required. Insulin Human Winthrop Rapid is also suitable for the treatment of hyperglycaemic coma and ketoacidosis, as well as for achieving pre-, intra- and post-operative stabilisation in patients with diabetes mellitus."