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 KARVEZIDE application, which had been submitted as a full application under Article 8(3) of Directive 2001/83/EC as amended, 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 IRBESARTAN HYDROCHLOROTHIAZIDE BMS medicinal product is identical to the up-to-date quality, safety and efficacy profile of KARVEZIDE. Information on the scientific discussions can be found in the KARVEZIDE CHMP assessment report and in the European Public Assessment Report (EPAR).

The approved indication is: “Treatment of essential hypertension. This fixed dose combination is indicated in patiens whose blood pressure is not adequately controlled on Irbesartan or Hydrochlorothiazide alone”.

2. Quality aspects

Since this application is an informed consent of the KARVEZIDE application, the quality data in support of the IRBESARTAN HYDROCHLOROTHIAZIDE BMS application are identical to the up-to-date quality data of the KARVEZIDE dossier which have been assessed and approved (including all post-marketing procedures).

3. Non-clinical aspects

Since this application is an informed consent of the KARVEZIDE application, the non-clinical data in support of the IRBESARTAN HYDROCHLOROTHIAZIDE BMS application are identical to the up-to-date non-clinical data of the KARVEZIDE dossier, which have been assessed and approved (including all post-marketing procedures).

The applicant will submit an updated Environmental Risk Assessment as a post authorisation follow up measure.

4. Clinical aspects

Since this application is an informed consent of the KARVEZIDE application, the clinical data in support of the IRBESARTAN HYDROCHLOROTHIAZIDE BMS application are identical to the up-to-date clinical data of the KARVEZIDE dossier, which have been assessed and approved (including all post-marketing procedures).

- User consultation

The product information of the informed consent application remains identical to that of the cross-referred product KARVEZIDE. The applicant submitted a justification for not performing the user consultation based on the fact that the cross-referred product was first approved in August 1997 and the Package Leaflet has been available to patients in the EU for more than 8 years; therefore consultations with target patient groups on the draft package leaflet were not included in this submission. This was considered acceptable by the CHMP.

5. Pharmacovigilance

PSUR

As requested by the MAH and agreed by the CHMP, the PSUR cycle of IRBESARTAN HYDROCHLOROTHIAZIDE BMS will correspond to the one attributed to the cross-referred product, KARVEZIDE, until 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 CHMP did not require the MAA to submit a risk management plan beyond the provision of adequate information in the SPC and suitable packaging as well as ongoing pharmacovigilance activities to continuously monitor the safety profile of the product due to the following points:

- safety profile of the cross-referred product KARVEZIDE has been established in both clinical trials and in post-marketing experiences
- identified and/or potential safety events of interest related to the cross-referred product KARVEZIDE has been continuously assessed, documented and closely monitored through global pharmacovigilance activities.

The CHMP, having considered the data submitted in the application, is of the opinion that no additional risk minimisation activities are required beyond those included in the product information.

6. Overall conclusions, risk/benefit assessment and recommendation

Since this application is an informed consent of the KARVEZIDE application, the CHMP considered that the risk-benefit balance of IRBESARTAN HYDROCHLOROTHIAZIDE BMS was favourable and therefore recommended the granting of the marketing authorisation for the following indication "Treatment of essential hypertension. This fixed dose combination is indicated in patiens whose blood pressure is not adequately controlled on Irbesartan or Hydrochlorothiazide alone".