



European Medicines Agency

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## **PUBLIC STATEMENT ON**

### **Irbesartan Hydrochlorothiazide BMS (irbesartan/hydrochlorothiazide)**

#### **WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION**

On 19 January 2007 the European Commission issued a Marketing Authorisation valid throughout the European Union for the medicinal product Irbesartan Hydrochlorothiazide BMS (irbesartan/hydrochlorothiazide). Irbesartan Hydrochlorothiazide BMS is approved for the treatment of essential hypertension in adult patients whose blood pressure is not adequately controlled on irbesartan or hydrochlorothiazide alone.

The marketing authorisation holder (MAH) responsible for Irbesartan Hydrochlorothiazide BMS was Bristol-Myers Squibb Pharma EEIG. The European Commission was notified by letter dated 20 October 2009 of the MAH's decision to voluntarily withdraw the Marketing Authorisation for Irbesartan Hydrochlorothiazide BMS for commercial reasons.

Irbesartan Hydrochlorothiazide BMS has not been marketed anywhere in the European Union and there is no intention to market Irbesartan Hydrochlorothiazide BMS in the future. Irbesartan Hydrochlorothiazide BMS was an informed consent application to Karvezide.

The MAH will maintain the Marketing Authorisation for another medicinal product containing irbesartan/hydrochlorothiazide, i.e. Karvezide.

On 11 November 2009 the European Commission issued a decision to withdraw the Marketing Authorisation for Irbesartan Hydrochlorothiazide BMS. Pursuant to this decision the European Public Assessment Report for Irbesartan Hydrochlorothiazide BMS will be updated to reflect that the Marketing Authorisation is no longer valid.

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