Irbesartan BMS

Procedural steps taken and scientific information after the authorisation

MAJOR CHANGES[1]

No	Scope	Opinion issued on	Commission Decision Issued/ amended on	Product Information affected[2]	Summary
II/0018	Update of Summary of Product Characteristics Update of SPC sections 2, 4.2, 4.3, 4.8, 5.1 and 6.5 in order to align the Product Information of Irbesartan BMS with the Product Information of the reference product Karvea.	19/03/2009	07/04/2009	SPC	The SPC of Irbesartan BMS has been aligned with the Product Information of the reference product Karvea as approved with the renewal procedure.
II/0017	Update of Summary of Product Characteristics and Package Leaflet The MAH applied for an update of the SPC sections 4.3 and 4.6 as well as PL section 2 to implement the CHMP recommendation on a harmonised labelling relating to the use of Angiotensin II Receptor Antagonists during pregnancy and lactation. Furthermore, minor typographical changes have been introduced to SPC section 4.4.	19/02/2009	23/03/2009	SPC, PL	Available data regarding use of AIIRAs during lactation have been assessed. There are no concrete data to support the contraindication of use of AIIRAs during breast-feeding. All AIIRA agents were found in the milk of lactating rats but no human data about their transfer into breast milk are available. There is only a theoretical presumption of low transport according to their high plasma protein binding and low oral availability. A harmonised wording recommending an alternative treatment with better established safety profiles during breast-feeding, especially while nursing a newborn or preterm infant, has been included in the section 4.6 of the SPC and section 2 of the PL. Consequently, the existing contraindication for lactation has been deleted.
II/0016	Changes to QPPV Update of DDPS (Pharmacovigilance) Update of Detailed Description of the Pharmacovigilance System	22/01/2009	02/03/2009	Annex II	The Detailed Description of the Pharmacovigilance System has been updated (Version 3.0) to reflect the change of the Qualified Person for Pharmacovigilance (QPPV) as well as to notify other changes to the DDPS performed since the last approved version. Consequently, Annex II has been updated using the standard text including the new version number of the agreed DDPS.
II/0010	Update of Summary of Product	24/04/2008	10/06/2008	SPC, PL	Cooper's study published in the NEJM in June 2006 identified a signal

[1] Major changes e.g. Type II variations, Annex II applications, Renewals and Annual Reassessments
[2] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet)

No	Scope	Opinion issued on	Commission Decision Issued/ amended on	Product Information affected[2]	Summary
	Characteristics and Package Leaflet The MAH applied for an update of the SPC sections 4.3, 4.4, and 4.6 as well as PL section 2 to implement the CHMP recommendation on a harmonised labelling relating to the use of ACE inhibitors and Angiotensin II Receptor Antagonists during pregnancy.				of increased risk of congenital malformations, particularly cardiac defects after exposure to ACE inhibitors during the first trimester of pregnancy. Since the role of confounding factors such as diabetes and hypertension cannot be accurately defined based on the available data, the teratogenic potential of ACE inhibitors is not demonstrated, even though data suggest that such exposure cannot be considered as safe and should be avoided. There are fewer data regarding the risks associated with first trimester exposure to Angiotensin II receptor antagonists (AIIRAs) than for ACE inhibitors. Nevertheless, there is no evidence that the risk is lower for AIIRAs, and it is considered that any conclusions on ACE inhibitors are also valid for AIIRAs. Therefore, the existing contraindication for the 2nd and 3rd trimester of pregnancy remained, but a harmonised wording regarding pregnancy across the class was introduced.

MINOR CHANGES[3]

No	Scope	Product Information affected[2]	Date[4]
IB/0019	10_Minor change in the manufacturing process of the active substance		17/04/2009
IB/0015	10_Minor change in the manufacturing process of the active substance 11_a_Change in batch size of active substance or intermediate - up to 10-fold		18/08/2008
N/0013	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	PL	04/08/2008
IA/0014	11_a_Change in batch size of active substance or intermediate - up to 10-fold		29/07/2008
IB/0012	10_Minor change in the manufacturing process of the active substance 11_a_Change in batch size of active substance or intermediate - up to 10-fold		25/04/2008
IA/0011	09_Deletion of manufacturing site		03/04/2008
IA/0009	09_Deletion of manufacturing site		13/02/2008
N/0007	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	PL	20/12/2007

[3] Minor changes e.g. Type I variations and Notifications
[4] Date of entry into force of the change

No	Scope	Product Information affected[2]	Date[4]
IB/0006	42_b_Change in storage conditions of the finished/diluted/reconstituted product	SPC, Labelling, PL	20/12/2007
IA/0008	09_Deletion of manufacturing site		14/12/2007
IB/0004	10_Minor change in the manufacturing process of the active substance		21/09/2007
IA/0005	11_a_Change in batch size of active substance or intermediate - up to 10-fold		20/09/2007
N/0003	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	PL	15/06/2007
IA/0002	32_a_Change in batch size of the finished product - up to 10-fold		23/03/2007
IA/0001	11_a_Change in batch size of active substance or intermediate - up to 10-fold		23/03/2007