EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PANTECTA Control

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion / Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
IG/0634	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	25/11/2015		SmPC and PL	
IG/0586/G	This was an application for a group of variations. B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	08/07/2015	n/a		

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer A.7 - Administrative change - Deletion of manufacturing sites B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer				
T/0020	Transfer of Marketing Authorisation	11/06/2015	08/07/2015		
N/0019	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	16/02/2015	08/07/2015	PL	
IG/0425	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	24/03/2014	n/a		
IG/0416/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.II.d.1.i - Change in the specification parameters and/or limits of the finished product - Ph. Eur. 2.9.40 uniformity of dosage units is introduced to replace the currently registered method, either Ph. Eur. 2.9.5 or Ph. Eur. 2.9.6 B.II.d.1.h - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated	24/03/2014	n/a		

	general monograph of the Ph. Eur. for the finished product B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV				

	(including contact details) and/or changes in the PSMF location				
R/0016	Renewal of the marketing authorisation.	19/12/2013	21/02/2014	SmPC and PL	Based on the CHMP review of the available information and on the basis of a re-evaluation of the benefit risk balance, the CHMP is of the opinion that the quality, safety and efficacy of non-prescription Pantoprazole continues to be adequately and sufficiently demonstrated and therefore considered that the benefit risk profile of non-prescription Pantoprazole continues to be favourable in the treatment of short-term reflux symptoms (e.g. heartburn, acid regurgitation) in adults. The CHMP was of the opinion that the renewal could be granted with unlimited validity.
WS/0341	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. The Worksharing Applicant (WSA) proposed the update of section 4.5 of the SmPC in order to add an interaction between pantoprazole and methotrexate following the assessment of cases of interaction and published literature in FUMs 13, 12, 12, 18, 13. The Package Leaflet was updated accordingly. Furthermore, the WSA used this opportunity to bring the PI in line with the latest QRD template version 9. C.I.3.b - Implementation of change(s) requested following the assessment of an USR, class labelling, a PSUR, RMP, FUM/SO, data submitted under Article 45/46, or amendments to reflect a Core SPC - Change(s) with new additional data submitted by the MAH	25/04/2013	27/05/2013	SmPC, Annex II, Labelling and PL	In a cumulative review of cases of interaction between pantoprazole and methotrexate, including published literature it was shown that concomitant use of PPIs with methotrexate may elevate and prolong serum levels of methotrexate possibly leading to methotrexate toxicities. Current evidence supporting reduced methotrexate elimination in patients receiving PPIs is primarily based on studies conducted in patients receiving high dose treatment, which is usually carried out in a specialist medical setting. Nevertheless, considering the evidence available to date a mention of these facts was added to 4.5 of the SmPC of OTC pantoprazole.

IG/0284	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	18/03/2013	n/a		
IG/0268/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH A.5.a - Administrative change - Change in the name and/or address of a manufacturer responsible for batch release A.5.b - Administrative change - Change in the name and/or address of a manufacturer of the finished product, including quality control sites (excluding manufacturer for batch release) A.5.b - Administrative change - Change in the name and/or address of a manufacturer of the finished product, including quality control sites (excluding manufacturer for batch release)	08/02/2013	27/05/2013	SmPC, Annex II, Labelling and PL	
IG/0255/G	This was an application for a group of variations. B.III.1.a.2 - Submission of a new or updated Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.2 - Submission of a new or updated Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	12/12/2012	n/a		
IG/0212	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	22/08/2012	n/a		

IG/0157/G	This was an application for a group of variations. B.III.1.a.1 - Submission of a new or updated Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer B.III.1.a.1 - Submission of a new or updated Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer	09/03/2012	n/a		
IG/0134/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS B.III.1.a.3 - Submission of a new or updated Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition)	09/12/2011	n/a		
WS/0122	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update of section 4.8 of the SPC to add Agranulocytosis, Pancytopenia, Hypomagnesaemia, Taste disorders and Gynaecomastia as new adverse drug reactions based on post-marketing data and literature references. Section 4 of the PL is updated accordingly. Furthermore the MAH took the opportunity to bring	20/10/2011	07/12/2011	SmPC and PL	Following post marketing surveillance data section 4.8. of the SPC was updated: Agranulocytosis, taste disorder and gynaecomastia were listed as rare side effects. Pancytopenia was added as a very rare side effect and hypomagnesaemia was listed as a side effect of not known frequency. The evidence with regard to hypomagnesaemia in short term use was not deemed sufficient to add an additional safety warning in 4.4. of the SPC for the OTC which are indicated for short-term use only.

	the Product Information in line with QRD template vs. 7.3.1. and to update the list of local representatives. C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data				
IG/0079/G	This was an application for a group of variations. C.I.9.h - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the back-up procedure of the QPPV	24/06/2011	n/a		
IG/0070	B.II.a.1.a - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings	26/05/2011	n/a	SmPC, Annex II, Labelling and PL	
IG/0043/G	This was an application for a group of variations. B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch	02/02/2011	n/a		

	control/testing takes place				
IG/0006	A.7 - Administrative change - Deletion of manufacturing sites	19/05/2010	n/a		