EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Preotact

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/0421	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	21/03/2014	n/a		
II/0023/G	This was an application for a group of variations. Changes to the testing arrangements for active substance and finished product.	20/03/2014	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.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure				
T/0022	Transfer of Market Authorisation from Nycomed Danmark ApS to NPS Pharma Holdings Limited. Transfer of Marketing Authorisation	24/10/2013	29/11/2013	SmPC, Labelling and PL	Transfer of the Marketing Authorisation to NPS Pharma Holdings Limited.
IA/0021	B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s)	27/06/2013	29/11/2013	SmPC, Labelling and PL	
IG/0293	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	23/04/2013	n/a		
IG/0219	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	25/09/2012	n/a		
II/0017	To register a new presentation: cartridge in a pre-filled pen. B.IV.1.c - Change of a measuring or administration device - Addition or replacement of a device which is an integrated part of the primary packaging	15/03/2012	20/04/2012	SmPC, Labelling and PL	

IB/0018	B.I.d.1.b.3 - Stability of AS - Change in the storage conditions - Change in storage conditions of the AS	29/11/2011	n/a		
IA/0016	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		
R/0015	Renewal of the marketing authorisation.	17/02/2011	14/04/2011	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 this medicinal product continues to be adequately and sufficiently demonstrated and therefore considered that the benefit/risk profile of Preotact continues to be favourable. The CHMP is of the opinion that the renewal can be granted with unlimited validity. The MAH will switch to a 3-yearly PSUR cycle. During the renewal procedure, changes were made to the Product Information to bring it in line with the current EMEA/QRD template, SmPC guideline and other relevant guideline(s), which were reviewed by QRD and accepted by the CHMP. Currently there are two parathyroid hormone products marketed: Preotact (parathyroid hormone) and Forsteo (teriparatide). Both have identical mechanisms of action: stimulation of bone formation by direct effects on bone forming cells (osteoblasts) and indirectly increases the intestinal absorption of calcium and increases the tubular reabsorption of calcium and excretion of phosphate by the kidney. In section 4.3 of the Forsteo SmPC, there is a contraindication in patients with skeletal malignancies or bone metastases. So far, Preotact has not been contraindicated in these patients and therefore, for

					consistency, the Preotact product information has been updated in line with Forsteo as part of this renewal procedure.
IA/0014	C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV	27/10/2010	n/a	Annex II	
II/0009	Changes to the manufacturing process of the active substance B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological medicinal product and is not related to a protocol	23/09/2010	04/10/2010		
IB/0010	B.II.e.3.b - Change in test procedure for the immediate packaging of the finished product - Other changes to a test procedure (including replacement or addition)	21/07/2010	n/a		
IA/0011	B.II.b.z - Change in manufacture of the Finished Product - Other variation	16/07/2010	n/a		
IA/0012	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	12/07/2010	n/a		
II/0008	New site for the control of the drug substance and drug product 01_Change in or addition of manufacturing site(s) for part or all of the manufacturing process	18/03/2010	24/03/2010		

IB/0007	IB_17_b_Change in the storage conditions for the active substance	31/03/2009	n/a		
II/0006	Changes to release testing of PTH reference standard Change(s) to the test method(s) and/or specifications for the active substance	25/09/2008	02/10/2008		
II/0005	Change(s) to the manufacturing process for the active substance	24/04/2008	29/04/2008		
N/0004	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	27/11/2007	n/a	PL	
II/0003	Change(s) to the manufacturing process for the active substance	24/05/2007	24/07/2007	Annex II	The CHMP adopted a positive opinion on the replacement of the facility for the manufacture of the drug substance and the consequential scale-up of the fermentation process.
IB/0002	IB_17_b_Change in the storage conditions for the active substance	10/04/2007	n/a		
II/0001	Quality changes	22/03/2007	29/03/2007		