VANTAVO

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
N/0039	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	27/10/2021		PL	
PSUSA/79/20 2101	Periodic Safety Update EU Single assessment - alendronic acid / colecalciferol, alendronic acid / calcium / colecalciferol	02/09/2021	n/a		PRAC Recommendation - maintenance

[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).

T/0037	Transfer of Marketing Authorisation	17/03/2021	13/04/2021	SmPC, Labelling and PL	
IG/1353	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	11/02/2021	n/a		
N/0035	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	18/01/2021	13/04/2021	PL	
N/0034	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	11/12/2020	13/04/2021	PL	
WS/1857	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	04/09/2020	13/04/2021	SmPC, Labelling and PL	
IG/1266	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	14/07/2020	n/a		
N/0031	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	28/11/2018	13/04/2021	PL	
T/0030	Transfer of Marketing Authorisation	13/06/2018	09/07/2018	SmPC, Labelling and	

				PL	
IG/0780	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	15/03/2017	15/02/2018	SmPC, Annex II, Labelling and PL	
IG/0764	B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State	31/01/2017	n/a		
PSUSA/79/20 1601	Periodic Safety Update EU Single assessment - alendronic acid / colecalciferol, alendronic acid / calcium / colecalciferol	02/09/2016	n/a		PRAC Recommendation - maintenance
WS/0862	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	01/04/2016	19/09/2016	SmPC and PL	
IG/0632	A.7 - Administrative change - Deletion of manufacturing sites	03/12/2015	n/a		
N/0024	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	28/11/2015	19/09/2016	Labelling and PL	
WS/0752	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.	24/09/2015	19/09/2016	SmPC and PL	

	Update of the SmPC section 4.4 to add 'angiogenesis inhibitors' as another example of a risk factor for ONJ. The Package leaflet is updated accordingly. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
IG/0516	A.7 - Administrative change - Deletion of manufacturing sites	21/01/2015	n/a		
WS/0657/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Type IB (B.I.a.2.e) – To introduce a minor change in the manufacturing process of the active substance to the restricted part of an Active Substance Master File. Type IA (B.I.b.1.c) – To introduce a specification parameter of a reagent used in the manufacturing process of the active substance Type IA (A.4) – To change the company name of the drug substance manufacturer from BASF Health & Nutrition A/S to BASF A/S Type IAIN (B.III.1.a.3) – To submit a new Ph. Eur. certificate of suitability from a new manufacturer for cholecalciferol. B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an	18/12/2014	n/a		

	ASMF B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient B.III.1.a.3 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition)				
IG/0481	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	29/09/2014	n/a		
R/0019	Renewal of the marketing authorisation.	24/07/2014	18/09/2014	SmPC, Annex II and PL	Based on the review of available information, the CHMP is of the opinion that the quality, safety and efficacy of Vantavo continues to be adequately and sufficiently demonstrated and considers that the benefit/risk profile of this medicinal product continues to be favourable. The product information has been updated to align with QRD templates, including paediatric information. The CHMP recommends that the renewal be granted with unlimited validity.

IG/0366	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	08/11/2013	n/a		
N/0017	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	18/07/2013	18/09/2014	PL	
IG/0182	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	20/08/2012	n/a		
WS/0238	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update of the SmPC, Annex II, Labelling and Package leaflet to align with the Product Information approved in the context of the first renewal of ADROVANCE (EMEA/H/C/0759/R/013). In addition the MAH took the opportunity to update the list of local representatives in the Package Leaflet and to include linguistic corrections in Annex A. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	19/04/2012	25/05/2012	SmPC, Annex II, Labelling and PL	This type IB variation concerns an update of the SmPC, Annex II, Labelling and Package leaflet (PL) to align them with the Product Information approved in the context of the first renewal of ADROVANCE; the changes resulted from implementation of the Agency QRD template version 8.0. In addition, the list of local representatives in the PL has been revised to amend contact details for the local representatives; linguistic corrections of Annex A were also accepted. This application was submitted following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.
WS/0212/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.1.z - Change in the manufacturer of AS or of a	19/04/2012	19/04/2012		

	starting material/reagent/intermediate for AS - Other variation B.I.a.3.b - Change in batch size (including batch size ranges) of AS or intermediate - Downscaling				
IG/0112	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	11/10/2011	n/a		
N/0006	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	06/09/2011	n/a	PL	
A20/0005	Pursuant to Article 20 of Regulation (EC) No 726/2004, the European Commission requested on 19 October 2010, the opinion of the CHMP on measures necessary to ensure the safe use of the above mentioned medicinal product further to the CHMP review on the currently available data in relation to the incidence of atypical stress fractures and its impact on the risk-benefit balance.	14/04/2011	29/06/2011	SmPC, Annex II and PL	Please refer to the Assessment Report: H-1180-RAR-A20-0005-en
IG/0060/G	This was an application for a group of variations. B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s) B.II.e.6.a - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that affects the product information	27/04/2011	n/a	SmPC, Labelling and PL	

WS/0095	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update of SPC to re-structure section 4.8 (and corresponding section in the PL) in accordance with the current SPC Guideline and QRD guidance, as agreed during the assessment of the FOSAVANCE Renewal. In addition the MAH requested changes in Section 6 of the PL in the details of local representatives and a minor change in Annex II (deletion of DDPS version number). This application was submitted as a Type II variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data	17/02/2011	24/03/2011	SmPC, Annex II and PL	The information in section 4.8 of the SPC is restructured according to QRD guidance and the Guideline on Summary of Product Characteristics Rev.2 (September 2009). The previous separate tables for adverse reactions reported during clinical studies and/or post-marketing use with defined frequency, and adverse reactions reported during post-marketing experience with unknown frequency, have been consolidated into one single tabulated list of adverse reactions. Additionally, the frequency category for the adverse reactions that had been added to the label based on post-marketing data was re-assessed according to EU SmPC Guideline. In addition the MAH details of the local representatives in Section 6 of the PL were amended and the version number of the DDPS was deleted from Annex II .
IG/0040	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	18/01/2011	n/a		
WS/0038	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.4 - Variations related to significant modifications	21/10/2010	29/11/2010	SmPC and PL	This variation concerns an update of the SPC, further to a cumulative review by the MAH of spontaneous reports describing osteonecrosis of the jaw (ONJ), to add "smoking" as a risk factor for ONJ in section 4.4 of the SPC. The application was submitted as a Type II variation

	of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data				following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. As the information about ONJ in the Product Information did not fully reflect the key messages regarding the risk minimisation measures for ONJ as identified in the Article 5(3) Referral on bisphosphonates and ONJ, additional wording fully reflecting those key messages were implemented in SPC section 4.4. The description of ONJ in SPC section 4.8 was shortened. The PL was amended accordingly, informing patients about the symptoms of ONJ and what action to take; advising on the need for patients to maintain good oral hygiene, to receive routine dental check ups and to report any oral symptoms such as dental mobility, pain or swelling; advising on the possible need for patients to have a dental check- up before starting treatment with the medicinal product. In addition, the PL section 2 was reformatted for FOSAVANCE/ADROVANCE/VANTAVO to make it consistent with FOSAMAX; the details of the Dutch local representative in Section 6 were amended; the ADROVANCE and VANTAVO annexes were harmonised with the annexes of Fosavance as agreed during the Fosavance Renewal (QRD changes).
IG/0027/G	This was an application for a group of variations. C.I.9.g - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the site undertaking pharmacovigilance activities C.I.9.h - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s)	10/11/2010	n/a	Annex II	

	to the DDPS that does not impact on the operation of the pharmacovigilance system				
IG/0020	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	14/09/2010	n/a		
N/0004	Update of the Italian and Spanish local representatives' details in the Package Leaflet. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	21/05/2010	n/a	PL	
IG/0003	B.II.b.2.b.1 - Change to batch release arrangements and quality control testing of the FP - Not including batch control/testing	06/05/2010	n/a	Annex II and PL	
IA/0002	A.2.a: administrative change - Change in the (invented) name of the medicinal product for Centrally Authorised products. A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs	26/03/2010	n/a	SmPC, Labelling and PL	
II/0001	Update of section 4.4 'Special warnings and precautions for use' of the SPC to list Barrett's oesophagus as one of the oesophageal diseases requiring caution when alendronate therapy is administered, following a request from the CHMP. Update of section 2 of the PL accordingly. The marketing authorisation numbers and date of first authorisation were also included in the SPC and	21/01/2010	15/03/2010	SmPC, Labelling and PL	Following the assessment of the MAH's cumulative review of alendronate and oesophageal carcinoma, the CHMP concluded that Barrett's oesophagus is a potentially premalignant condition of the oesophagus and a significant marker for the development of oesophageal cancer. Although the data are currently inconclusive and further investigation is required, the possibility that alendronate use may be associated with an increased risk of

	labelling. Update of Summary of Product Characteristics and Package Leaflet				oesophageal cancer can not be excluded. Therefore Barrett's oesophagus was included as a warning in section 4.4 of the SPC.