Voncento

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
IB/0052/G	This was an application for a group of variations. B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation B.II.d.2.a - Change in test procedure for the finished	25/11/2021	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).

	product - Minor changes to an approved test procedure				
IB/0050	B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product	19/11/2021		SmPC and PL	Section 6.3 in the SmPC and section 5 of the Package Leaflet have been updated. The information for local representatives in section 6 of the Product leaflet has also been updated and a linguistic correction is proposed to the French translation in section 4.6
IG/1429	B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP	20/08/2021	n/a		
IA/0049	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	22/06/2021	n/a		
II/0047/G	This was an application for a group of variations. B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products	15/04/2021	n/a		

IG/1356	B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP	16/02/2021	n/a		
IB/0046	B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier	13/01/2021	n/a		
II/0045	B.II.b.3.c - Change in the manufacturing process of the finished or intermediate product - The product is a biological/immunological medicinal product and the change requires an assessment of comparability	03/12/2020	n/a		
IG/1269	B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP	15/07/2020	n/a		
II/0042	Submission of an updated RMP version 7 in order to: - align with the revision of the GVP module V - reflect the completion of the post-marketing study (PMS) in patients with Von Willebrand Disease (VWD) - request a waiver to the post-authorisation safety study (category 3 study) in patients with haemophilia A due to feasibility reasons. C.I.11.b - Introduction of, or change(s) to, the	11/06/2020	n/a		The safety specifications of the RMP have been updated as part of this variation to align with the revised GVP module V, study CSLCT-BIO-12-83 in patients with Von Willebrand Disease (VWD) has been reflected as completed in the RMP. In addition, it was agreed to remove the post approval commitment to conduct the post-authorisation safety study Biostate_4001 in patients with haemophilia A. For more information, please refer to the Summary of Product Characteristics.

	obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required				
IG/1209	B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP	25/02/2020	n/a		
II/0041/G	This was an application for a group of variations. B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	12/09/2019	n/a		
IB/0040/G	This was an application for a group of variations. B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	27/05/2019	n/a		
IG/1074	B.V.a.1.d - PMF - Inclusion of a new, updated or	01/04/2019	n/a		

	amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP				
PSUSA/10102 /201808	Periodic Safety Update EU Single assessment - human coagulation factor viii / human von willebrand factor (centrally authorised product only)	14/03/2019	n/a		PRAC Recommendation - maintenance
IB/0038	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	04/03/2019	28/02/2020	SmPC and PL	
N/0037	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	28/11/2018	28/02/2020	PL	
II/0035/G	This was an application for a group of variations. B.II.b.3.c - Change in the manufacturing process of the finished or intermediate product - The product is a biological/immunological medicinal product and the change requires an assessment of comparability B.II.e.1.a.3 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/immunological medicinal products	15/11/2018	n/a		
R/0032	Renewal of the marketing authorisation.	22/02/2018	26/04/2018	SmPC, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Voncento in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.

IB/0034	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	04/04/2018	n/a		
PSUSA/10102 /201708	Periodic Safety Update EU Single assessment - human coagulation factor viii / human von willebrand factor (centrally authorised product only)	08/03/2018	n/a		PRAC Recommendation - maintenance
IG/0885	B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP	29/01/2018	n/a		
A31/0022	Pursuant to Article 31 of Directive 2001/83/EC, Germany initiated a procedure on 6 July 2016 based on concerns resulting from the evaluation of data from pharmacovigilance activities. The PRAC was requested to assess the potential impact of the results of the SIPPET study (which concluded that recombinant factor VIII medicines had a higher incidence of inhibitor development than plasma-derived medicines), and to issue a recommendation as to whether the marketing authorisations of these products should be maintained, varied, suspended or revoked. The EMA concluded in September 2017 that there is no clear and consistent evidence of a difference in the incidence of inhibitor development between the two classes of factor VIII medicines: those derived from plasma and those made by recombinant DNA	14/09/2017	15/11/2017	SmPC and PL	Please refer to the assessment report: human coagulation factor VIII - EMEA/H/A-31/1448

	technology. Due to the different characteristics of individual products within the two classes, EMA concluded that the risk of inhibitor development should be evaluated individually for each medicine, regardless of class. The risk for each product will continue to be assessed as more evidence becomes available.				
II/0017/G	This was an application for a group of variations. Sections 4.1, 4.2, 4.4, 4.8, 5.1, and 5.2 of the SmPC have been updated to reflect the final clinical study data from study CSLCT-BIO-08-53 (a phase III, open-Label, multicentre study to evaluate efficacy, pharmacokinetics, and safety in paediatric subjects with haemophilia A) to the Guideline on the SPC (European Commission "Notice to Applicants") in accordance to the EMA guideline on the Core SPC for human plasma derived and recombinant coagulation factor VIII products (CPMP/BPWG/1619/99 Rev.1 December 2012). C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	22/06/2017	25/07/2017	SmPC and PL	

IB/0029	B.IV.1.a.1 - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device with CE marking	22/07/2017	15/11/2017	SmPC, Labelling and PL	
IG/0788	B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP	12/04/2017	n/a		
IA/0027	B.II.d.2.f - Change in test procedure for the finished product - To reflect compliance with the Ph. Eur. and remove reference to the outdated internal test method and test method number	22/03/2017	n/a		
PSUSA/10102 /201608	Periodic Safety Update EU Single assessment - human coagulation factor viii / human von willebrand factor (centrally authorised product only)	09/03/2017	n/a		PRAC Recommendation - maintenance
IG/0757	B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP	26/01/2017	n/a		
II/0021/G	This was an application for a group of variations. B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a	10/11/2016	25/07/2017	SmPC	As a consequence of the change in assay for vWF from a Ristocetin Cofactor assay to an Activity assay that was the subject of this variation, a minor editorial change to the Voncento SmPC was made in order to change the reference to the Ristocetin Cofactor (RCo) assay in the footnote in

	biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate B.II.d.2.c - Change in test procedure for the finished product - Substantial change to or replacement of a biol/immunol/immunochemical test method or a method using a biol. reagent or replacement of a biol. reference preparation not covered by an approved protocol B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)				Section 2 – 'Qualitative And Quantitative Composition' by removing the abbreviation "RCo".
PSUSA/10102 /201602	Periodic Safety Update EU Single assessment - human coagulation factor viii / human von willebrand factor (centrally authorised product only)	02/09/2016	n/a		PRAC Recommendation - maintenance
IA/0023/G	This was an application for a group of variations.	18/08/2016	n/a		

	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process				
IA/0024/G	This was an application for a group of variations. 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) B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information	10/08/2016	n/a		
IG/0676/G	This was an application for a group of variations. B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP	27/04/2016	n/a		

	B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP				
PSUSA/10102 /201508	Periodic Safety Update EU Single assessment - human coagulation factor viii / human von willebrand factor (centrally authorised product only)	17/03/2016	n/a		PRAC Recommendation - maintenance
PSUSA/10102 /201502	Periodic Safety Update EU Single assessment - human coagulation factor viii / human von willebrand factor (centrally authorised product only)	10/09/2015	n/a		PRAC Recommendation - maintenance
IA/0016/G	This was an application for a group of variations. 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	31/07/2015	n/a		
II/0008/G	This was an application for a group of variations. Extension of indication to include prophylactic	25/06/2015	31/07/2015	SmPC, Annex II, Labelling and PL	

	treatment of patients with Von Willebrand Disease (VWD); in addition, the product information has been updated to provide data on the treatment of paediatric patients with VWD. As a consequence, sections 4.1, 4.2, 4.4, 4.9, 5.1 and 5.2 of the SmPC have been updated. The package leaflet is updated accordingly. Moreover, the MAH took the opportunity to correct the manufacturing sites addresses in Annex II and to make editorial changes to the product information. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
IA/0015/G	This was an application for a group of variations. B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the	06/07/2015	n/a		

	dossier) - Replacement or addition of a supplier B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure				
IAIN/0013	B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP	24/04/2015	n/a		
PSUSA/10102 /201408	Periodic Safety Update EU Single assessment - human coagulation factor viii / human von willebrand factor (centrally authorised product only)	12/03/2015	n/a		PRAC Recommendation - maintenance
IA/0012	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)	22/01/2015	n/a		
IA/0011/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 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 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)	08/12/2014	05/05/2015	Annex II	

	B.III.2.z - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation				
IAIN/0009	C.I.3.a - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Implementation of wording agreed by the competent authority	04/11/2014	05/05/2015	SmPC and PL	
PSUV/0007	Periodic Safety Update	11/09/2014	n/a		PRAC Recommendation - maintenance
IB/0004/G	This was an application for a group of variations. 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 B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	22/05/2014	n/a		
IB/0006	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	04/04/2014	05/05/2015	SmPC	
IAIN/0005	B.V.a.1.d - PMF - Inclusion of a new, updated or	28/02/2014	n/a		

	amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP				
IAIN/0003	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	18/11/2013	n/a		
IB/0001	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	14/11/2013	n/a		
IAIN/0002/G	This was an application for a group of variations. B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - Inclusion of an updated/amended PMF when changes do not affect the properties of the FP C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV and/or QPPV contact details and/or back-up procedure	27/09/2013	n/a		