Zutectra

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/0064	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	12/02/2024		PL	
IAIN/0063	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) -	29/11/2023	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).

	Inclusion of an updated/amended PMF when changes do not affect the properties of the FP				
N/0062	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	06/11/2023		PL	
IAIN/0061	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	13/10/2023	n/a		
II/0058	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	14/04/2023	n/a		
IAIN/0059	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	14/03/2023	n/a		
IAIN/0057	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	29/11/2022	n/a		

IA/0056	B.II.d.2.e - Change in test procedure for the finished product - Update of the test procedure to comply with the updated general monograph in the Ph. Eur.	25/11/2022	n/a		
IB/0055/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.b - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier of a medicinal product. (PMF 2nd step procedure) - First-time inclusion of a new PMF NOT affecting the properties of the FP	31/10/2022	n/a		
N/0054	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	29/08/2022	24/04/2023	PL	
IAIN/0053	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	17/05/2022	n/a		
IB/0052	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	04/03/2022	24/04/2023	SmPC, Labelling and PL	PI has been aligned with the latest QRD template (version 10.2, rev. 1)
II/0050	B.II.e.1.a.3 - Change in immediate packaging of the finished product - Qualitative and quantitative	10/02/2022	n/a		

	composition - Sterile medicinal products and biological/immunological medicinal products				
II/0051	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	13/01/2022	n/a		
IAIN/0049	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	10/08/2021	n/a		
PSUSA/1631/ 202011	Periodic Safety Update EU Single assessment - human hepatitis B immunoglobulin	08/07/2021	n/a		PRAC Recommendation - maintenance
IAIN/0048	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	17/03/2021	n/a		
IAIN/0046	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	09/07/2020	n/a		

IAIN/0045	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	13/03/2020	n/a		
IB/0044	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	10/03/2020	n/a		
IB/0043	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	07/10/2019	n/a		
IAIN/0041	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	01/08/2019	n/a		
N/0042	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	31/07/2019	24/04/2023	PL	
IAIN/0040/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.V.a.1.d - PMF - Inclusion of a new, updated or	15/03/2019	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				
N/0039	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	05/10/2018	11/04/2019	PL	
IAIN/0038	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	26/07/2018	n/a		
PSUSA/1631/ 201711	Periodic Safety Update EU Single assessment - human hepatitis B immunoglobulin	12/07/2018	n/a		PRAC Recommendation - maintenance
WS/1360	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.3.z - 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 - Other variation	17/05/2018	11/04/2019	SmPC, Annex II, Labelling and PL	
IAIN/0037	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	20/03/2018	n/a		

IAIN/0034	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	12/10/2017	n/a		
IA/0033/G	This was an application for a group of variations. B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - 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 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	28/07/2017	n/a		
PSUSA/1631/ 201611	Periodic Safety Update EU Single assessment - human hepatitis B immunoglobulin	06/07/2017	n/a		PRAC Recommendation - maintenance
IAIN/0032	B.V.a.1.d - PMF - Inclusion of a new, updated or amended PMF in the marketing authorisation dossier	10/03/2017	n/a		

	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/0030	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	03/08/2016	n/a		
N/0029	Update of the package leaflet with revised contact details of the local representative for Slovenia. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	01/08/2016	11/04/2019	PL	
PSUSA/1631/ 201511	Periodic Safety Update EU Single assessment - human hepatitis B immunoglobulin	07/07/2016	n/a		PRAC Recommendation - maintenance
IAIN/0028	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	09/03/2016	n/a		
IB/0026	B.II.d.2.e - Change in test procedure for the finished product - Update of the test procedure to comply with the updated general monograph in the Ph. Eur.	11/01/2016	n/a		
II/0024	Extension of Indication to Prevention of hepatitis B virus (HBV) re-infection in HBsAg and HBV-DNA	19/11/2015	16/12/2015	SmPC, Annex II and PL	For further information please refer to the published Assessment Report: Zutectra H-1089-II-24-AR.

	negative patients at least one week – instead of the approved at least 6 months - after liver transplantation for hepatitis B induced liver failure. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity of this procedure to update the Annex II in compliance with the QRD template version 9.1. An updated RMP version 2 has been agreed. The variation leads to amendments to the Summary of Product Characteristics, Annex II and Package Leaflet and to the Risk Management Plan (RMP). C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
IAIN/0025	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	16/10/2015	n/a		
PSUSA/1631/ 201411	Periodic Safety Update EU Single assessment - human hepatitis B immunoglobulin	09/07/2015	n/a		PRAC Recommendation - maintenance
IAIN/0023	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	13/03/2015	n/a		

	do not affect the properties of the FP				
IB/0021	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	25/02/2015	n/a		
N/0020	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/01/2015	16/12/2015	PL	
IA/0019/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.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - 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 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	12/12/2014	n/a		
R/0015	Renewal of the marketing authorisation.	24/07/2014	16/09/2014	SmPC, Labelling and	Based on the CHMP review of data on quality, safety and efficacy, the CHMP considered by consensus that the risk-

				PL	benefit balance of Zutectra in the prevention of hepatitis B virus re-infection in HBV-DNA negative patients ≥ 6 months after liver transplantation for hepatitis B induced liver failure remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IAIN/0018	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	01/09/2014	n/a		
PSUSA/1631/ 201311	Periodic Safety Update EU Single assessment - human hepatitis B immunoglobulin	10/07/2014	n/a		PRAC Recommendation - maintenance
IAIN/0016	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	05/03/2014	n/a		
PSUSA/1631/ 201305	Periodic Safety Update EU Single assessment - human hepatitis B immunoglobulin	09/01/2014	n/a		PRAC Recommendation - maintenance
IA/0014/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites	18/12/2013	06/06/2014	Annex II	
II/0011	Submission of validation data regarding the removal of thrombosis generating agents during the	24/10/2013	n/a		

	manufacturing process to comply with the revised Eur. Ph. monograph of Human Normal Immunoglobulin (0338). B.III.2.z - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation				
N/0012	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	19/09/2013	06/06/2014	PL	Inclusion of an additional local representative of the MAH for the new Member State, Croatia.
II/0008	Update of sections 4.8 and 5.1 of the SmPC and consequential changes to section 4 of the PIL to include the final results from study 974 and study 978, a PASS, in order to fulfil MEA 002.2. Furthermore, the PI is being brought in line with the latest QRD template. C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data	27/06/2013	06/06/2014	SmPC, Annex II, Labelling and PL	In study 974, an open, prospective, single-arm clinical study investigating the feasibility of home self-administration, efficacy and safety of SC Zutectra in a population of stable patients, no re-infection was observed and no serious adverse events treatment related were reported. In study 978, a non-interventional post-authorisation study evaluating compliance of patients using SC Zutectra as home self-treatment, compliance according to anti-HBs serum levels was shown for 93% of patients, no treatment failure was observed and no serious adverse events treatment related were reported. Information regarding the results of these two studies was therefore added to the product information.
II/0009	Change in 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	30/05/2013	n/a		

	product and is not related to a protocol				
IAIN/0010	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	26/03/2013	n/a		
N/0007	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	20/11/2012	06/06/2014	PL	Update of the list of local representatives for Greece, France and Romania.
IAIN/0006	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	22/06/2012	n/a		
N/0005	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	13/10/2011	n/a	PL	Update of the local representatives contact details for Denmark, France, Island, Norway, Portugal, Finland, Sweden and the United Kingdom.
IA/0004/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.c - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the back-up procedure of the QPPV C.I.9.h - Changes to an existing pharmacovigilance	12/08/2011	n/a	Annex II	

	system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system				
IA/0003/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 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	17/12/2010	n/a		
N/0002	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	15/12/2010	n/a	PL	Update of the list of the local representatives for Belgium, Spain, Luxembourg, Malta, the Netherlands and Portugal. A minor linguistic change was also made in the Italian package leaflet.
IB/0001	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Extension of storage period of a biological/immunological medicinal product in accordance with an approved stability protocol	29/07/2010	n/a	SmPC	
