VeraSeal

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)	11/09/2024		PL	
IB/0038	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	28/08/2024	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).

IG/1776	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	24/07/2024	n/a		
IB/0035	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	14/06/2024	n/a		
IG/1755	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	28/05/2024	n/a		
IB/0034	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	08/05/2024	n/a		
IG/1729	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	11/03/2024	n/a		
II/0027	Extension of indication to include treatment of children for VeraSeal, based on final results from study IG1405; this is a prospective, randomized, active-controlled, single-blind, parallel group clinical trial to evaluate the safety and efficacy of VeraSeal	14/12/2023	25/01/2024	SmPC and PL	Please refer to Scientific Discussion 'VeraSeal-H-C-004446-II-0027'

	as an adjunct to haemostasis during surgery in paediatric subjects. As a consequence, sections 4.1, 4.2 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 7.0 of the RMP has also been submitted. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
PSUSA/10297 /202306	Periodic Safety Update EU Single assessment - human fibrinogen / human thrombin	11/01/2024	n/a		PRAC Recommendation - maintenance
IG/1687	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	27/11/2023	n/a		
IG/1673	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	02/10/2023	n/a		
IA/0028	B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	12/06/2023	n/a		
IB/0025/G	This was an application for a group of variations. B.II.b.3.a - Change in the manufacturing process of	26/05/2023	n/a		

	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 B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size				
IG/1602	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	13/03/2023	n/a		
IB/0023/G	This was an application for a group of variations. B.II.f.1.b.z - Stability of FP - Extension of the shelf life of the finished product - Other variation B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	11/01/2023	25/01/2024	SmPC, Annex II and PL	
IG/1578	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		

IG/1563	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	05/10/2022	n/a		
R/0018	Renewal of the marketing authorisation.	21/07/2022	19/09/2022	SmPC, Annex II, Labelling and PL	
IG/1536	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	13/07/2022	n/a		
IB/0020	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	29/06/2022	n/a		
IG/1500/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) -	25/03/2022	n/a		

	Inclusion of an updated/amended PMF when changes do not affect the properties of the FP				
N/0017	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	20/12/2021	19/09/2022	PL	
IG/1402	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	09/06/2021	n/a		
N/0015	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	06/04/2021	19/09/2022	PL	
PSUSA/10297 /202006	Periodic Safety Update EU Single assessment - human fibrinogen / human thrombin	14/01/2021	n/a		PRAC Recommendation - maintenance
IG/1328	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	07/01/2021	n/a		
IG/1298	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	08/10/2020	n/a		
N/0011	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	30/09/2020	18/11/2020	Labelling and	

				PL	
IG/1252	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	11/05/2020	n/a		
PSUSA/10297 /201906	Periodic Safety Update EU Single assessment - human fibrinogen / human thrombin	16/01/2020	n/a		PRAC Recommendation - maintenance
IG/1188	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	05/12/2019	n/a		
II/0006/G	This was an application for a group of variations. 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 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 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	14/11/2019	18/11/2020	SmPC, Annex II, Labelling and PL	

	product information B.IV.1.a.3 - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Spacer device for metered dose inhalers or other device which may have a significant impact on the delivery of the AS				
IG/1161	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	08/10/2019	n/a		
IG/1048	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	07/03/2019	n/a		
PSUSA/10297 /201806	Periodic Safety Update EU Single assessment - human fibrinogen / human thrombin	17/01/2019	n/a		PRAC Recommendation - maintenance
PSUSA/10297 /201712	Periodic Safety Update EU Single assessment - human fibrinogen / human thrombin	12/07/2018	n/a		Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Evicel in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IG/0937	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) -	16/05/2018	n/a		

	Inclusion of an updated/amended PMF when changes do not affect the properties of the FP				
IG/0902	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	12/02/2018	n/a		