Parsabiv

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/0023	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	06/06/2024	n/a		
II/0021	Submission of the final report from study 20170561 listed as a category 3 study in the RMP. This is an	06/07/2023	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).

	observational PASS to evaluate the potential association between Parsabiv and gastrointestinal bleeding. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority				
IA/0022	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	09/06/2023	n/a		
IA/0020	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	05/07/2022	n/a		
PSUSA/10533 /202111	Periodic Safety Update EU Single assessment - etelcalcetide	10/06/2022	n/a		PRAC Recommendation - maintenance
IA/0019	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	12/05/2022	n/a		
R/0017	Renewal of the marketing authorisation.	22/07/2021	16/09/2021	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Parsabiv in the approved indication remains favourable and therefore recommended the renewal of the marketing

					authorisation with unlimited validity. Product Information was updated to incorporate changes introduced during the assessment of the renewal and to align with QRD template version 10.2. The updated RMP has been also submitted (version 3.0).
PSUSA/10533 /202011	Periodic Safety Update EU Single assessment - etelcalcetide	10/06/2021	n/a		PRAC Recommendation - maintenance
II/0015	Update of the SmPC section 4.4 to remove anti-etelcalcetide antibodies testing, minor editorial changes and update of the Product information in line with QRD template v10.1. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	10/12/2020	16/09/2021	SmPC and Annex II	n/a
PSUSA/10533 /201911	Periodic Safety Update EU Single assessment - etelcalcetide	11/06/2020	n/a		PRAC Recommendation - maintenance
PSUSA/10533 /201811	Periodic Safety Update EU Single assessment - etelcalcetide	14/06/2019	n/a		PRAC Recommendation - maintenance
II/0010	Update of sections 4.8 to add convulsions secondary to hypocalcaemia as uncommon adverse reactions and further information on reports related to hypersensitivity reactions. Editorial correction is made to section 7. The Package Leaflet is updated accordingly. Consequentially, RMP (version 2.1) has been submitted to reclassify some of the existing safety concerns.	14/02/2019	23/09/2019	SmPC and PL	Update of section 4.8 of the SmPC, in line with the other calcimimetic agent cinacalcet, by including the Undesirable effect “convulsions” in SOC nervous system disorders with the frequency uncommon and with a reference to section 4.4. In section 4.4 a reference is made to section 4.8. The Package Leaflet has been updated accordingly.

	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
IB/0012/G	This was an application for a group of variations. B.I.c.2.b - Change in the specification parameters and/or limits of the immediate packaging of the AS - Addition of a new specification parameter to the specification with its corresponding test method B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products 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 B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation 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.5.b - Change to in-process tests or limits applied during the manufacture of the finished	20/12/2018	n/a		

	product - Addition of a new test(s) and limits B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)				
PSUSA/10533 /201805	Periodic Safety Update EU Single assessment - etelcalcetide	29/11/2018	n/a		PRAC Recommendation - maintenance
IB/0011	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	05/10/2018	23/09/2019	SmPC	
IB/0009	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	07/09/2018	n/a		
PSUSA/10533 /201711	Periodic Safety Update EU Single assessment - etelcalcetide	28/06/2018	23/08/2018	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10533/201711.
IG/0946	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	04/06/2018	23/07/2018	PL	
PSUSA/10533 /201705	Periodic Safety Update EU Single assessment - etelcalcetide	30/11/2017	n/a		PRAC Recommendation - maintenance
IG/0853	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP -	10/11/2017	23/07/2018	Annex II and PL	

	Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing				
IA/0003	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)	07/09/2017	n/a		
IB/0001	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	20/07/2017	23/07/2018	SmPC	