



## Terrosa

### Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification <sup>1</sup> issued on	Commission Decision Issued <sup>2</sup> / amended on	Product Information affected <sup>3</sup>	Summary
IB/0027/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	03/02/2023	n/a		

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).



	<p>manufacturer of a novel excipient</p> <p>B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation</p> <p>B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation</p> <p>B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation</p> <p>B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS</p>				
II/0026/G	<p>This was an application for a group of variations.</p> <p>Please refer to the Recommendations section</p> <p>B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes</p> <p>B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method</p> <p>B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits</p> <p>B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished</p>	10/11/2022		SmPC, Labelling and PL	<p>The SmPC sections 1, 2, 4.2, 6.4, 6.5 and 6.6 have been updated to reflect the addition of the new pre-filled pens presentations (EU/1/16/1159/004-005) or adapted to address the specific features of the pre-filled pen presentation.</p> <p>The Labelling and PL have been updated accordingly. The package leaflet contains a Pen user manual for the Terrosa 20 micrograms (µg)/80 microliters solution for injection, in pre-filled pen.</p>

	<p>product - Addition of a new test(s) and limits</p> <p>B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process</p> <p>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site</p> <p>B.IV.1.c - Change of a measuring or administration device - Addition or replacement of a device which is an integrated part of the primary packaging</p>				
PSUSA/2903/202109	Periodic Safety Update EU Single assessment - teriparatide	05/05/2022	n/a		PRAC Recommendation - maintenance
IB/0024/G	<p>This was an application for a group of variations.</p> <p>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</p> <p>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</p>	13/12/2021	n/a		
IB/0023	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	02/12/2021	n/a		
R/0020	Renewal of the marketing authorisation.	22/07/2021	16/09/2021	SmPC, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Terrosa in the approved indication remains favourable and

					therefore recommended the renewal of the marketing authorisation with unlimited validity. The RMP has been also updated (version 2.2).
IA/0021/G	<p>This was an application for a group of variations.</p> <p>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure</p> <p>B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits</p>	06/08/2021	n/a		
IB/0019/G	<p>This was an application for a group of variations.</p> <p>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</p> <p>B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS</p>	07/01/2021	n/a		
II/0018	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	17/09/2020	16/09/2021	SmPC, Annex II, Labelling and PL	
IB/0016/G	<p>This was an application for a group of variations.</p> <p>B.I.a.2.a - Changes in the manufacturing process of</p>	17/04/2020	n/a		

	<p>the AS - Minor change in the manufacturing process of the AS</p> <p>B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation</p> <p>B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits</p>				
IAIN/0017	B.IV.1.a.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	10/04/2020	n/a		
IB/0014	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	09/01/2020	n/a		
N/0013	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	30/12/2019	09/03/2020	Labelling and PL	
IA/0012	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	26/06/2019	n/a		
II/0009	Submission of the final clinical study report from Study RGB1023O31; a Phase III, multi-centre, randomised, active-controlled, parallel-group, comparative efficacy/safety study. An updated RMP version 1.4 was agreed during the procedure.	14/06/2019	n/a		n/a

	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority				
IA/0011	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)	24/05/2019	n/a		
II/0010	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	23/05/2019	n/a		
PSUSA/2903/201809	Periodic Safety Update EU Single assessment - teriparatide	16/05/2019	n/a		PRAC Recommendation - maintenance
IB/0006	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	26/03/2019	09/03/2020	SmPC, Labelling and PL	
IA/0007	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	18/12/2018	n/a		
IB/0005/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	30/10/2018	n/a		

	<p>intermediate used in the manufacture of the AS or manufacturer of a novel excipient</p> <p>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</p> <p>B.I.z - Quality change - Active substance - Other variation</p> <p>B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place</p> <p>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure</p> <p>B.III.2.a.2 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material</p>				
IB/0004	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	23/02/2018	07/02/2019	SmPC, Annex II and PL	
IA/0003	A.z - Administrative change - Other variation	05/04/2017	05/03/2018	SmPC, Labelling and	

				PL	
IB/0001/G	<p>This was an application for a group of variations.</p> <p>B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation</p> <p>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</p>	05/04/2017	n/a		