



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Raloxifene Teva

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/0029	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	08/09/2021		PL	
IA/0028	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	12/02/2021	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).



IA/0027	A.7 - Administrative change - Deletion of manufacturing sites	21/12/2020		Annex II and PL	
IA/0026	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	04/11/2020	n/a		
PSUSA/2603/201812	Periodic Safety Update EU Single assessment - raloxifene	11/07/2019	n/a		PRAC Recommendation - maintenance
N/0024	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	20/11/2018		Labelling and PL	
IAIN/0023	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	15/06/2017	n/a		
IAIN/0022	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	07/09/2016	06/07/2017	Annex II and PL	
IB/0021/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.II.a.1.a - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings B.II.b.1.a - Replacement or addition of a	08/08/2016	06/07/2017	SmPC, Labelling and PL	

<p>manufacturing site for the FP - Secondary packaging site</p> <p>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site</p> <p>B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site</p> <p>B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products</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.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</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.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</p> <p>B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test</p> <p>B.II.b.5.c - Change to in-process tests or limits</p>				
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applied during the manufacture of the finished product - Deletion of a non-significant in-process test
B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test
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B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation
B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation
B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation
B.II.c.1.b - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method
B.II.c.1.c - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)
B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation
B.II.c.2.b - Change in test procedure for an excipient - Deletion of a test procedure if an alternative test

	<p>procedure is already authorised</p> <p>B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation</p> <p>B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation</p> <p>B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation</p> <p>B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation</p> <p>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</p> <p>B.II.f.1.e - Stability of FP - Change to an approved stability protocol</p> <p>B.II.c.1.c - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)</p>				
IB/0020/G	<p>This was an application for a group of variations.</p> <p>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)</p> <p>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</p>	25/07/2016	n/a		

	<p>an obsolete parameter)</p> <p>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)</p> <p>B.III.1.a.1 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer</p> <p>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</p>				
IA/0019	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	10/11/2015	n/a		
N/0018	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	29/07/2015	06/07/2017	Labelling	
T/0017	Transfer of Marketing Authorisation	10/04/2015	27/05/2015	SmPC, Labelling and PL	
IA/0016	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	19/02/2015	n/a		

IA/0015	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	19/02/2015	n/a		
IA/0014	B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits	10/02/2015	n/a		
R/0013	Renewal of the marketing authorisation.	20/11/2014	06/02/2015	SmPC, Annex II, Labelling and PL	Based on the CHMP review of data on quality, safety and efficacy, including all variations introduced since the marketing authorisation was granted, the CHMP considered that the risk-benefit balance of Raloxifene Teva for the treatment and prevention of osteoporosis in postmenopausal women remains favourable and therefore recommends the renewal of the marketing authorisation. The CHMP recommended that the renewal be granted with unlimited validity.
PSUSA/2603/201312	Periodic Safety Update EU Single assessment - raloxifene	11/09/2014	n/a		PRAC Recommendation - maintenance
IA/0012/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) A.7 - Administrative change - Deletion of manufacturing sites	01/08/2014	06/02/2015	Annex II and PL	
IB/0011	B.II.c.2.d - Change in test procedure for an excipient - Other changes to a test procedure (including	26/06/2014	n/a		

	replacement or addition)				
N/0009	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	12/03/2014	06/02/2015	PL	
IAIN/0008	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	31/05/2013	n/a		
N/0007	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	14/12/2012	06/02/2015	PL	
IB/0006	B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation	03/09/2012	n/a		
IB/0005	B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product	11/05/2012	29/10/2012	SmPC, Annex II, Labelling and PL	
IA/0004	A.5.b - Administrative change - Change in the name and/or address of a manufacturer of the finished product, including quality control sites (excluding manufacturer for batch release)	26/09/2011	n/a		
IA/0003/G	This was an application for a group of variations. B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	14/02/2011	n/a	Annex II and PL	

	B.II.b.2.b.1 - Change to batch release arrangements and quality control testing of the FP - Not including batch control/testing				
II/0002/G	<p>This was an application for a group of variations.</p> <p>Alternative manufacturing process. Alternative batch size of the finished product.</p> <p>B.II.b.3.b - Change in the manufacturing process of the finished product - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product</p> <p>B.II.b.4.d - Change in the batch size (including batch size ranges) of the finished product - The change relates to all other pharmaceutical forms manufactured by complex manufacturing processes</p>	20/01/2011	02/02/2011		
IB/0001/G	<p>This was an application for a group of variations.</p> <p>B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products</p> <p>B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site</p> <p>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging</p>	21/01/2011	n/a		

site

B.II.b.2.a - Change to batch release arrangements and quality control testing of the FP - Replacement or addition of a site where batch control/testing takes place