Zoledronic acid Hospira

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/0045	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	01/10/2021		PL	
PSUSA/3149/ 202008	Periodic Safety Update EU Single assessment - zoledronic acid (indicated for cancer and fractures)	09/04/2021	n/a		PRAC Recommendation - maintenance
IA/0044	A.7 - Administrative change - Deletion of	12/02/2021		Annex II and	

[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).

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	manufacturing sites			PL	
IB/0042/G	This was an application for a group of variations. 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 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 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 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	28/09/2020	22/10/2020	SmPC and PL	
IA/0041/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name	27/08/2020	n/a		

	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 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 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 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				
PSUSA/3149/ 201908	Periodic Safety Update EU Single assessment - zoledronic acid (indicated for cancer and fractures)	17/04/2020	n/a		PRAC Recommendation - maintenance
N/0039	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	02/12/2019	12/02/2020	PL	
IA/0038	A.7 - Administrative change - Deletion of manufacturing sites	16/05/2019	n/a		
PSUSA/3149/ 201808	Periodic Safety Update EU Single assessment - zoledronic acid (indicated for cancer and fractures)	11/04/2019	n/a		PRAC Recommendation - maintenance

N/0037	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	09/04/2019	12/02/2020	PL	
IA/0036	A.7 - Administrative change - Deletion of manufacturing sites	05/02/2019	12/02/2020	Annex II and PL	
N/0034	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	24/10/2018	12/02/2020	PL	
T/0033	Transfer of Marketing Authorisation	06/08/2018	20/09/2018	SmPC, Labelling and PL	
PSUSA/3149/ 201708	Periodic Safety Update EU Single assessment - zoledronic acid (indicated for cancer and fractures)	12/04/2018	n/a		PRAC Recommendation - maintenance
IB/0032	B.II.e.4.c - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products	21/03/2018	n/a		
IAIN/0031/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.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	12/02/2018	20/09/2018	Annex II and PL	

IAIN/0030	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	07/12/2017	20/09/2018	Annex II and PL	
N/0028	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	13/11/2017	20/09/2018	PL	
R/0026	Renewal of the marketing authorisation.	22/06/2017	24/08/2017	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 Zoledronic acid Hospira in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IB/0027/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol	10/08/2017	n/a		
PSUSA/3149/ 201608	Periodic Safety Update EU Single assessment - zoledronic acid (indicated for cancer and fractures)	21/04/2017	16/06/2017	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for

					PSUSA/3149/201608.
N/0025	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	16/02/2017	16/06/2017	Labelling and PL	
IB/0023	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	19/08/2016	16/06/2017	SmPC and PL	
N/0022	Update of the package leaflet with revised contact details of the local representatives for Belgium, Germany, Spain, Ireland, Luxembourg, the Netherlands, Austria and Portugal. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/06/2016	16/06/2017	PL	
IG/0693	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	02/06/2016	n/a		
IG/0645	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	17/12/2015	n/a		
IAIN/0019/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name	10/12/2015	24/06/2016	SmPC, Labelling and PL	

	and/or address of the MAH C.I.3.a - 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 - Implementation of wording agreed by the competent authority				
IB/0018	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	27/10/2015	24/06/2016	Annex II	
IB/0017/G	This was an application for a group of variations. 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 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	01/07/2015	24/06/2016	SmPC, Annex II and PL	
IG/0555	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the	22/05/2015	n/a		

	PSMF location				
IB/0015	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	19/12/2014	11/02/2015	SmPC and PL	
IB/0014/G	This was an application for a group of variations. B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	12/12/2014	n/a		
IG/0477	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	03/09/2014	n/a		
IB/0012	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	25/07/2014	11/02/2015	SmPC	

PSUSA/3149/ 201308	Periodic Safety Update EU Single assessment - zoledronic acid (indicated for cancer and fractures)	10/04/2014	n/a		PRAC Recommendation - maintenance
IB/0010	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	01/04/2014	11/02/2015	SmPC and PL	
IG/0382	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	02/12/2013	n/a		
IB/0008/G	This was an application for a group of variations. 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 C.I.6.b - Change(s) to therapeutic indication(s) - Deletion of a therapeutic indication	21/11/2013	31/01/2014	SmPC, Annex II and PL	Update of SmPC section 4.4 Special warnings and precautions for 5mg/100 ml strength as requested by the CHMP further to assessment of Aclasta PSUR 9 to include observation of acute renal failure after a single administration, and to advise calculation of creatinine clearance based upon actual body weight using the Cockroft -Gault formula prior to each dose. Deletion of reference to osteoporosis indication in SmPC section 4.1, 4.2 and 5.1 and PL sections 1 and 3 due to the patent situation and as per legal advice. Accordingly update of physician educational material, also reflecting increased risk in subjects of advanced age.
IAIN/0007	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	03/09/2013	n/a		

IG/0317	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	23/07/2013	n/a		
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 are submitted by the MAH	16/07/2013	31/01/2014	SmPC, Annex II and PL	
IAIN/0006	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	12/07/2013	n/a		
IAIN/0003	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	13/05/2013	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)	19/04/2013	31/01/2014	SmPC	
IG/0286	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	12/04/2013	n/a		