Posatex

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued / amended on	Product Information affected[2]	Summary[3]
II/0028/G	This was an application for a group of variations. B.I.a.1.g - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a new manufacturer of the AS that is not supported by an ASMF and requires significant update to the relevant AS section in the dossier B.I.a.1.g - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a new manufacturer of the AS that is not supported by an ASMF and requires significant update to the relevant AS section in the dossier B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation 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)	16/07/2020	n/a		n/a

[1] Notifications are issued for type I variations (unless part of a group including a type II variation or higher procedure or a worksharing application). Opinions are issued for all other procedures.
[2] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).
[3] Since October 2019 summary information is no longer published for variations that do not impact upon the product information

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	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.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites				
II/0027/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.I.a.1.g - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a new manufacturer of the AS that is not supported by an ASMF and requires significant update to the relevant AS section in the dossier B.I.a.1.g - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a new manufacturer of the AS that is not supported by an ASMF and requires significant update to the relevant AS section in the dossier 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	12/09/2019	n/a		The variation is to register a new manufacturing site (Katayama Seiyakusyo Co. Ltd.) for the active substance orbifloxacin and its intermediate AT-3807 and to increase the batch size of the active substance orbifloxacin as a consequence; additionally to delete registered manufacturing site (Dainippon Sumitomo Pharma Co. Ltd.) and process the name change of intermedia AS manufacturer for orbifloxacin.
IA/0026	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	08/10/2018	n/a		The Agency accepted the variation to introduce a new testing site for the active substance posaconazole.
IG/0967/G	This was an application for a group of variations. C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) in the safety database and/or major contractual arrangements for the fulfilment of PhV obligations, and/or change of the site undergoing PhV activities C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of	26/07/2018	n/a		n/a

	the PhV system				
IB/0024/G	This was an application for a group of variations. B.II.e.1.a.2 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Semi-solid and non-sterile liquid pharmaceutical forms B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products	08/06/2018	n/a		The Agency accepted the group of variations to change the dimensions of the bottles and to introduce minor changes in the composition of the immediate packaging material.
IG/0718/G	This was an application for a group of variations. C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) in the safety database and/or major contractual arrangements for the fulfilment of PhV obligations, and/or change of the site undergoing PhV activities C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the PhV system	22/09/2016	n/a		n/a
IA/0022	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	20/10/2015	n/a		The Agency accepted the variation to make a minor change in the name of the manufacturer responsible for the micronization of the active substance while the manufacturing site and all manufacturing operations remain the same.
IB/0020/G	This was an application for a group of variations. B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method	08/10/2014	n/a		The Agency accepted a grouped variation to make quality changes.
IG/0464	C.I.9.d - Changes to an existing pharmacovigilance	20/08/2014	n/a		The Agency accepted the variation to implement the

	system as described in the DDPS - Change(s) to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH				company's updated detailed description of the pharmacovigilance system (DDPS).
IA/0019	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	18/12/2013	n/a		The Agency accepted a variation to make a changes in the manufacturing process of the active substance.
R/0018	Renewal of the marketing authorisation.	07/03/2013	14/05/2013	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for Posatex.
IA/0017	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	09/11/2012	n/a		The European Medicines Agency accepted a variation for a minor change in the manufacturing process of the active substance
IB/0016	C.II.6 - Changes to the labelling or the package leaflet which are not connected with the SPC	10/05/2012	25/10/2012	SPC, Labelling and PL	The European Medicines Agency accepted a variation to make minor changes in the packaging information
IAIN/0015	B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer	20/01/2012	n/a		The European Medicines Agency accepted a Type IA(IN) variation to change a manufacturer used in the manufacture of the active substance.
IA/0014	A.4 - Administrative change - Change in the name and/or address of a manufacturer or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS	09/12/2011	n/a		The European Medicines Agency accepted a Type IA variation for a change of name of a distributor of the active substance
II/0012	C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data	10/11/2011	08/12/2011	SPC and PL	The European Commission adopted a type II variation to change the section 4.8 of the SPC.
IA/0013	B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure	27/10/2011	27/10/2011		The European Medicines Agency accepted a type IA variation for minor changes to an approved test procedure.
IA/0009/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 of the finished product, including quality control sites (excluding manufacturer for batch release) A.5.a - Administrative change - Change in the name and/or address of a manufacturer responsible for batch release	25/11/2010	20/07/2011	Annex II and PL	The European Medicines Agency accepted a grouping of Type IA variations to indicate the name change for the manufacturer of the finished product. The respective site is responsible for batch release (A.5.a) and for all other manufacturing steps (A.5.b).
IA/0011	A.4 - Administrative change - Change in the name and/or address of a manufacturer or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS	28/04/2011	28/04/2011		The European Medicines Agency accepted a variation to change the name of the manufacturer of the active substance from Schering Plough LTD to MSD International GmbH. There was no change of address.
IA/0010/G	This was an application for a group of variations. B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test	14/12/2010	14/12/2010		The European Medicines Agency accepted a group of two Type IA variations to make minor changes to approved test procedures.

	procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure				
IB/0008	C.I.8.b - Introduction of a new Pharmacovigilance system - which has been assessed by the relevant NCA/EMA for another product of the same MAH	26/11/2010	26/11/2010		The European Medicines Agency accepted a Type IB variation C.I.8.b to introduce a new pharmacovigilance system, which had already been assessed by the EMA for another product of the same MAH.
IB/0007	C.II.6 - Changes to the labelling or the package leaflet which are not connected with the SPC	08/07/2010	14/10/2010	SPC, Labelling and PL	The European Medicines Agency accepted a variation (Type IB, No. C.II.6) concerning miscellaneous amendments to the product information, including minor editorial changes to the wording, reduction of text for the smallest pack size (8.8 ml) due to space restrictions and addition of (erroneously omitted) warnings to the package leaflet for consistency with the SPC.
IB/0005/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site 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 B.II.b.2.b.2 - Change to batch release arrangements and quality control testing of the FP - Including batch control/testing	26/03/2010	14/10/2010	Annex II and PL	The European Medicines Agency accepted a grouped variation to change the manufacturing sites for bulk manufacture (Type IB, B.II.b.1.e), primary packaging (Type IAIN, B.II.b.1.b), secondary packaging (Type IAIN, B.II.b.1.a) and batch release, including control testing (Type IAIN, B.II.b.2.b.2). Annexes II and IIIB will be amended accordingly.
IB/0006/G	This was an application for a group of variations. 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 B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.III.2.a.1 - Change of specification('s) of a former non Pharmacopoeial substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - AS B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products	23/07/2010	23/07/2010		The European Medicines Agency accepted a grouped variation concerning quality changes to two of the active substances (Type IB No. B.I.d.1-a-4.: variation re-test period to 5 years - orbifloxacin: from 3 years (36 months) to 5 years (60 months) Type IA No. B.I.a.2-a: variation minor change in manufacturing process - posaconazole Type IAin No. B.III.2-a: variation to comply with Ph.Eur. - orbifloxacin) and to the primary packaging (Type IA No. B.II.e.4-a: minor change in dimension of primary packaging). No annexes are affected by this change.
IB/0004	1B-13-b Change in test procedure for active substance or starting material-other changes test procedure	16/10/2009	16/10/2009		The European Medicines Agency accepted a Type 1B no. 13b variation regarding the change to a test procedure for one of the active substances of Posatex, mometasone

					furoate monohydrate. No annexes are affected by this change.
II/0002	II - Other quality changes	15/07/2009	08/09/2009	SPC, Labelling and PL	The CVMP adopted a positive Opinion on a Type II variation to add lauric acid to the approved formulation to improve the stability of the finished product and enable storage without any special storage conditions.
T/0003	Transfer of Marketing Authorisation	03/06/2009	30/06/2009	SPC, Labelling and PL	The European Commission transferred the marketing authorisation from 'S-P Veterinary' to 'Intervet International BV'.