EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Easotic

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]
IG/1409	C.II.6.a - Changes to the labelling or the PL which are not connected with the SPC - Administrative information concerning the holder's representative	07/10/2021		PL	The Agency accepted the variation to update the list of local representatives.
IB/0023/G	This was an application for a group of variations. 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 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	06/11/2020	n/a		n/a
IA/0022	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	18/12/2019	n/a		n/a
IB/0021	C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR	21/06/2019	25/10/2019	SPC and PL	The Agency accepted the variation to update section 4.6 of the SPC and section 6 of the package leaflet following

[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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					assessment of a PSUR.
IG/0808	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	29/05/2019	n/a		n/a
IA/0019	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)	08/02/2019	n/a		The Agency accepted the variation to delete an obsolete specification parameter for the odour of the excipient
IG/0984	C.II.6.a - Changes to the labelling or the PL which are not connected with the SPC - Administrative information concerning the holder's representative	26/10/2018	25/10/2019	PL	The Agency accepted the variation to update the local representatives in the package leaflet.
IB/0016/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.c.1.a - Change in immediate packaging of the AS - Qualitative and/or quantitative composition 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.d.1.b.1 - Stability of AS - Change in the storage conditions - Change to more restrictive storage conditions of the AS	06/09/2018	n/a		The Agency accepted the group of variations to process the minor changes in the manufacturing process of the active substance; to change the immediate packaging of the active substance; to accept changes in the storage conditions of the active substance and to accept the extension of the re-test period.
IA/0017	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	12/07/2018	n/a		The Agency accepted the variation to update the Ph. Eur. Certificate of Suitability from an approved manufacturer of the active substance for gentamicin.
IA/0015	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	09/04/2018	n/a		The Agency accepted the variation to update the Ph. Eur. Certificate of Suitability from an approved manufacturer of the active substance for gentamicin.
II/0012	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	07/12/2017	n/a		The Agency accepted the variation to widen the specifications at shelf-life for the degradation products of gentamicin in the finished product, in order to harmonise with the specification of the Ph. Eur monograph for gentamicin sulfate.
IB/0013	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	21/11/2017	n/a		The Agency accepted the variation to change a test procedure for the active substance miconazole nitrate.
IAIN/0014	B.III.1.a.3 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition)	15/11/2017	n/a		The Agency accepted the variation to register a new manufacturer of Miconazole nitrate.

IB/0011	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	06/10/2017	n/a		The Agency accepted the variation to change the conditions of a test method for the determination of degradation products of the active substance in the finished product.
IB/0010	C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR	06/10/2017	20/12/2017	SPC, Labelling and PL	The Agency accepted the variation to update the SPC and product information following assessment of a PSUR. Some editorial changes are also included.
IG/0724	C.II.6.a - Changes to the labelling or the PL which are not connected with the SPC - Administrative information concerning the holder's representative	21/12/2016	20/12/2017	PL	The Agency accepted the variation to update the list of local representatives in the package leaflet.
WS/0925	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.1.b - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a manufacturer of the AS supported by an ASMF	10/11/2016	n/a		The Agency accepted the variation to add a manufacturer for the active substance hydrocortisone aceponate, supported by an ASMF.
II/0006/G	This was an application for a group of variations. B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product B.II.d.1.h - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur. for the finished product B.II.d.2.e - Change in test procedure for the finished product - Update of the test procedure to comply with the updated general monograph in the Ph. Eur.	11/12/2014	02/12/2015	SPC, Labelling and PL	The Agency accepted the group of variations regarding changes to the finished product (end of shelf life specification regarding active substance, release and end of shelf life specification parameters regarding microbiological quality, test procedure for microbiological quality and storage conditions).
IAIN/0007	B.III.1.a.3 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition)	30/10/2014	n/a		The Agency accepted the variation to add a new manufacturer of the active substance.
R/0005	Renewal of the marketing authorisation.	12/09/2013	11/11/2013	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for Easotic.
IB/0004/G	This was an application for a group of variations. B.III.1.a.2 - Submission of a new or updated Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.I.b.2.a - Change in test procedure for AS or starting	06/08/2012	n/a		The Agency accepted the variation on submission of a new updated Ph. Eur. Certificate of Suitability for the active substance gentamicin sulphate, addition of an alternative identification test for the active substance gentamicin sulphate and change in the test procedure for the active substance.

	material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate				
II/0003/G	This was an application for a group of variations. B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data	12/01/2012	02/03/2012	SPC, Labelling and PL	The Agency accepted the group of variations to amend the product information following addition of new quality data and to add single-dose containers (5 presentations in total).
IA/0002	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	14/01/2011	14/01/2011		The Agency accepted the variation to make minor changes to an approved test procedure.
IB/0001	1B-42-a-1 Change in shelf life of finished product-as packaged for sale	23/04/2009	20/10/2009	SPC	The Agency accepted the variation to extend the shelf-life of the finished product from 18 months to 2 years.