Veraflox

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/1213	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	31/03/2020		PL	The Agency accepted the group of variations to delete the list of local representatives from the package leaflet.
IB/0020	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	12/10/2018	n/a		The Agency accepted the variation to implement the test items "Trans-Pradofloxacin" and "Total degradation products" in the test and release specification.
IG/0963/G	This was an application for a group of variations. C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV and/or QPPV contact details and/or back-up procedure 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	16/07/2018	n/a		The Agency accepted the group of variations to update the detailed description of pharmacovigilance system (DDPS).
IAIN/0018	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	27/03/2018	11/06/2018	PL	The Agency accepted the variation to update the administrative details of the local representatives for BE

[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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IAIN/0017	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	28/11/2017	11/06/2018	PL	The Agency accepted the variation to update the list of the local representatives in the package leaflet. The product information was simultaneously aligned with the latest QRD template.
IA/0016	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	19/09/2017	n/a		The Agency accepted the variation to make minor changes to an approved test procedure. Minor editorial amendments were also made.
IA/0015	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	26/07/2017	n/a		The Agency accepted the variation to change the name of the manufacturer of the active substance.
IAIN/0014	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	06/06/2017	11/06/2018	PL	The Agency accepted the variation to update the list of local representatives in the package leaflet.
IB/0013/G	This was an application for a group of variations. B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation	22/12/2016	n/a		The Agency accepted the group of variations to revise the product specifications following availability of commercial batch results and stability data.
IAIN/0012	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	09/11/2016	13/06/2017	PL	The Agency accepted the variation to update the list of local representatives in the package leaflet.
IB/0011	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	19/08/2016	n/a		The Agency accepted the variation to a change in the immediate packaging of the finished product.
IAIN/0010	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	14/06/2016	13/06/2017	PL	The Agency accepted the variation to update the list of local representatives in the package leaflet.
IAIN/0009	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	27/05/2016	13/06/2017	SPC, Labelling and PL	The Agency accepted the variation to update the list of local representatives in the package leaflet.
II/0008/G	This was an application for a group of variations. B.I.b.1.h - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition or replacement (excl. Biol. or immunol. substance) of a specification parameter as a result of a safety or quality issue B.I.b.1.g - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Widening of the approved specs for starting mat./intermediates, which may have a significant effect on the quality of the AS	19/05/2016	n/a		The Agency accepted the variation to add R,S-Pradofloxacin-Diastereomer limit of no more than 0.4% and to lower assay limit of 97.7%. Also the sum of all impurities has been changed.

	and/or the FP				
IG/0663/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	25/02/2016	n/a		The Agency accepted the variation to update the Detailed Description of the Pharmacovigilance System (DDPS).
R/0006	Renewal of the marketing authorisation.	06/11/2015	07/01/2016	SPC, Labelling and PL	The European Commission renewed the marketing authorisation for Veraflox.
IAIN/0005	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	26/07/2013	n/a		The Agency accepted the variation to add a secondary packaging site
IB/0004/G	This was an application for a group of variations. B.II.b.3.f - Change in the manufacturing process of the finished product - Minor change in the manufacturing process of an aqueous oral suspension B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new tests and limits	17/05/2013	n/a		The Agency accepted the group of variations relating to quality changes.
IA/0003	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	22/06/2012	10/09/2012	SPC	The Agency accepted the variation to change the ATC code from QJ01MA to QJ01MA97
IB/0001	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	28/10/2011	28/10/2011		The Agency accepted the variation for a change in the re-test period of the active substance.
IA/0002	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	21/10/2011	21/10/2011		The Agency accepted the variation for a change in the name of the manufacturer of the active substance.