



Quinsair

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
IB/0035	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	23/11/2022	n/a		
IB/0034	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing	23/11/2022		Annex II	

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).



	authorisation, including the RMP - Other variation				
IB/0032/G	<p>This was an application for a group of variations.</p> <p>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</p> <p>B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits</p> <p>B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation</p> <p>B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation</p> <p>B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation</p> <p>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure</p> <p>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</p> <p>A.7 - Administrative change - Deletion of manufacturing sites</p> <p>A.4 - Administrative change - Change in the name</p>	03/05/2022	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				
IB/0030	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	05/01/2022	08/07/2022	Annex II	
IA/0031	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)	29/10/2021	n/a		
IB/0029	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	06/08/2021	08/07/2022	SmPC and PL	
IB/0027/G	This was an application for a group of variations. 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.c - Change in the specification parameters and/or limits of an AS, starting	13/01/2021	n/a		

	<p>material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method</p> <p>B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting</p> <p>material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method</p> <p>B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting</p> <p>material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method</p> <p>B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting</p> <p>material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method</p> <p>B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting</p> <p>material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method</p> <p>B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting</p> <p>material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method</p> <p>B.I.b.2.c - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure for a reagent, which does not have a significant effect on the overall quality of the AS</p> <p>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure</p> <p>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an</p>				
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<p>approved test procedure</p> <p>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure</p> <p>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure</p> <p>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure</p> <p>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure</p> <p>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure</p> <p>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure</p> <p>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure</p> <p>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure</p> <p>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure</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.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</p>				
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	<p>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</p> <p>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</p> <p>B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits</p> <p>B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF</p>				
IA/0028	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	07/01/2021	n/a		
IAIN/0026	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	12/11/2020	21/05/2021	SmPC and PL	
IB/0025/G	<p>This was an application for a group of variations.</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.5.b - Change to in-process tests or limits</p>	29/05/2020	21/05/2021	SmPC, Labelling and PL	

	<p>applied during the manufacture of the finished product</p> <ul style="list-style-type: none"> - Addition of a new test(s) and limits 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 				
IA/0024	A.7 - Administrative change - Deletion of manufacturing sites	23/03/2020	n/a		
R/0022	Renewal of the marketing authorisation.	12/12/2019	13/02/2020	SmPC, Annex II, Labelling and PL	
PSUSA/10429 /201905	Periodic Safety Update EU Single assessment - levofloxacin (Inhalation use)	16/01/2020	n/a		PRAC Recommendation - maintenance
IAIN/0021/G	<p>This was an application for a group of variations.</p> <ul style="list-style-type: none"> A.7 - Administrative change - Deletion of manufacturing sites 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) 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 B.III.2.b - Change to comply with Ph. Eur. or with a 	06/06/2019	n/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				
N/0020	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/02/2019	13/02/2020	Labelling and PL	
A31/0010	Pursuant to Article 31 of Directive 2001/83/EC, the German National Competent Authority on 1 February 2017 triggered a referral resulting from pharmacovigilance data, and requested the PRAC to review and assess the risk of long-lasting, disabling, and potentially permanent serious adverse drug reactions associated with the use of (luoro)quinolones. Furthermore, the PRAC was requested to assess the impact of this safety concern on the overall benefit-risk balance of quinolones and fluoroquinolones for systemic and inhalation use and the need for adequate risk minimisation measures and issue a recommendation on whether the products should be maintained, varied, suspended or revoked. As the request resulted from the evaluation of data resulting from pharmacovigilance activities, the PRAC issued a recommendation to the Committee for Medicinal Products for Human Use (CHMP).	15/11/2018	14/02/2019	SmPC and PL	Please refer to the assessment report: Quinsair EMEA/H/A-31/1452/C/002789/0010
PSUSA/10429 /201805	Periodic Safety Update EU Single assessment - levofloxacin (Inhalation use)	17/01/2019	n/a		PRAC Recommendation - maintenance

IAIN/0019	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	13/11/2018	n/a		
IAIN/0018	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	24/10/2018	14/02/2019	SmPC and PL	
T/0016	Transfer of Marketing Authorisation	18/05/2018	07/06/2018	SmPC, Labelling and PL	
PSUSA/10429 /201705	Periodic Safety Update EU Single assessment - levofloxacin (Inhalation use)	11/01/2018	n/a		PRAC Recommendation - maintenance
IAIN/0015	A.1 - Administrative change - Change in the name and/or address of the MAH	09/01/2018	07/06/2018	SmPC, Labelling and PL	
IAIN/0013	A.1 - Administrative change - Change in the name and/or address of the MAH	29/08/2017	07/06/2018	SmPC, Labelling and PL	
PSUSA/10429 /201611	Periodic Safety Update EU Single assessment - levofloxacin (Inhalation use)	09/06/2017	n/a		PRAC Recommendation - maintenance
IA/0011/G	This was an application for a group of variations. 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	07/04/2017	n/a		

	<p>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)</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.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>				
PSUSA/10429 /201605	Periodic Safety Update EU Single assessment - levofloxacin (Inhalation use)	12/01/2017	n/a		PRAC Recommendation - maintenance
IAIN/0008	A.1 - Administrative change - Change in the name and/or address of the MAH	16/12/2016	16/02/2017	SmPC, Labelling and PL	
PSUSA/10429 /201509	Periodic Safety Update EU Single assessment - levofloxacin (Inhalation use)	13/05/2016	n/a		PRAC Recommendation - maintenance
IAIN/0006/G	<p>This was an application for a group of variations.</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.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing</p>	29/02/2016	16/02/2017	Annex II and PL	
T/0002	Marketing Authorisation Transfer from Regintel Ltd to Raptor Pharmaceuticals Europe B.V.	16/11/2015	27/11/2015	SmPC, Labelling and	

	Transfer of Marketing Authorisation			PL	
IB/0003	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	12/11/2015	n/a		
T/0001	Marketing Authorisation Transfer from Aptalis Pharma SAS to Regintel Limited. Transfer of Marketing Authorisation	26/08/2015	14/09/2015	SmPC, Labelling and PL	