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/0039	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	01/04/2025		SmPC, Labelling and PL	To update the existing information under the Description of selected adverse drug reactions in section 4.8 of the SmPC, adding new aspects of prolonged, disabling and potentially irreversible adverse drug reactions and reference to section 4.4. The Package leaflet is updated accordingly (section 4). The Applicant take this opportunity to apply some Minor

[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).

					corrections to Slovenia, Czech R., Spain, Portugal, Greece and Latvia translations.
SW/0038	Post Authorisation Safety Study results - EMEA/H/C/PSR/S/0046 – Variation	30/05/2024	26/07/2024	SmPC, Annex II and PL	In view of the available data from the PASS final study report, the PRAC considers that changes to the product information and the conditions of the marketing authorisation are warranted. This study is a condition of the authorisation and Annex II should therefore be updated, as the study has been completed. The information about additional monitoring, including the black triangle, should also be removed. The footnote in section 4.8 of the SmPC referencing the statement "adverse events with uncertain relatedness to Quinsair but which are known to be associated with systemic administration of levofloxacin and/or are plausibly associated with Quinsair and were reported more frequently than with placebo in clinical studies" is no longer considered applicable for haemoptysis. Therefore, the asterisk next to haemoptysis referring to this statement should be deleted. In addition, the RMP has been updated to reflect the PRAC conclusions and version 3.2 of the Quinsair RMP is agreed.
IA/0037	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	29/02/2024	n/a		
IA/0036	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)	27/11/2023	n/a		

PSUSA/10429 /202205	Periodic Safety Update EU Single assessment - levofloxacin (Inhalation use)	12/01/2023	n/a		PRAC Recommendation - maintenance
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 authorisation, including the RMP - Other variation	23/11/2022	19/10/2023	Annex II	
IB/0032/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.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits 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.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation	03/05/2022	n/a		

	B.I.b.2.a - Change in test procedure for AS or starting 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 A.7 - Administrative change - Deletion of manufacturing sites 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				
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 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 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 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 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 material/intermediate/reagent - Addition of a new specification parameter to the specification with its	13/01/2021	n/a		

	corresponding test method 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 B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor				

	changes to an approved test procedure 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.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 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 material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method 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.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF				
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	This was an application for a group of variations. B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - 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	29/05/2020	21/05/2021	SmPC, Labelling and PL	
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	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.I.b.1.d - Change in the specification parameters	06/06/2019	n/a		

	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 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	15/11/2018	14/02/2019	SmPC and PL	Please refer to the assessment report: Quinsair EMEA/H/A-31/1452/C/002789/0010

	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).				
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 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.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process 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	07/04/2017	n/a		
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	This was an application for a group of variations.	29/02/2016	16/02/2017	Annex II and	

	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing			PL	
T/0002	Marketing Authorisation Transfer from Regintel Ltd to Raptor Pharmaceuticals Europe B.V. Transfer of Marketing Authorisation	16/11/2015	27/11/2015	SmPC, Labelling and 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	