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
N/0020	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/02/2019		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	15/11/2018	14/02/2019	SmPC and PL	Please refer to the assessment report: Quinsair EMEA/H/A-31/1452/C/002789/0010

[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).

	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).				
PSUSA/10429 /201805	Periodic Safety Update EU Single assessment - levofloxacin (centrally authorised product only)	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 (centrally authorised product only)	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 (centrally authorised product only)	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 (centrally authorised product only)	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 (centrally authorised product only)	13/05/2016	n/a		PRAC Recommendation - maintenance
IAIN/0006/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.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing	29/02/2016	16/02/2017	Annex II and 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	