Cholib

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
IA/0038	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)	29/02/2024	n/a		

[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).

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N/0037	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	29/02/2024		PL	
IB/0036	B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place	11/12/2023	n/a		
T/0035	Transfer of Marketing Authorisation	18/07/2023	23/08/2023	SmPC, Labelling and PL	
IAIN/0034	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	08/06/2023	n/a		
IAIN/0033	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	19/04/2023	23/08/2023	SmPC and PL	
IB/0032	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	22/03/2023	n/a		
IAIN/0031/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.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch	19/12/2022	n/a		

	control/testing takes place 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.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place				
PSUSA/10096 /202202	Periodic Safety Update EU Single assessment - fenofibrate / simvastatin	29/09/2022	n/a		PRAC Recommendation - maintenance
II/0029/G	This was an application for a group of variations. Update of section 4.4 of the SmPC in order to amend the existing warning on immune-mediated necrotizing myopathy (IMNM) and section 4.5 of the SmPC to add drug-drug interaction information with cobicistat, following the update of the company's core data sheet (CCDS) due to new data. Section 4.3. of the SmPC was consequently amended, also to include the necessary cross-references. Section 4.8 of the SmPC was also amended to add immune-mediated necrotizing myopathy with a rare frequency. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the list the UK (Northern Ireland) local representative in the Package Leaflet. C.I.4 - Change(s) in the SPC, Labelling or PL due to	03/06/2021	14/06/2022	SmPC and PL	Information on autoimmune necrotizing myopathy was updated in the section 4.4. of the SmPC and new data on the interaction between the fixed combination fenovibrate/simvastatin and cobistat was published in the scientific literature, triggering an update of the section 4.5 of the SmPC. For more information, please refer to the Summary of Product Characteristics.

	new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
IA/0028	A.7 - Administrative change - Deletion of manufacturing sites	23/10/2020	n/a		
IAIN/0027/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.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site 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	23/10/2020	22/01/2021	Annex II and PL	
IA/0026/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites 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	28/08/2020	n/a		

	Member State				
IAIN/0025	C.I.3.a - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Implementation of wording agreed by the competent authority	17/03/2020	22/01/2021	SmPC and PL	
IAIN/0024	B.II.a.1.a - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings	07/02/2020	22/01/2021	SmPC and PL	
PSUSA/10096 /201902	Periodic Safety Update EU Single assessment - fenofibrate / simvastatin	05/09/2019	n/a		PRAC Recommendation - maintenance
IB/0022	C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation	18/02/2019	21/02/2020	SmPC, Labelling and PL	
IA/0021/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.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	19/12/2018	n/a		

	B.III.1.a.4 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Deletion of certificates (in case multiple certificates exist per material)				
PSUSA/10096 /201802	Periodic Safety Update EU Single assessment - fenofibrate / simvastatin	06/09/2018	n/a		PRAC Recommendation - maintenance
T/0020	Transfer of Marketing Authorisation	30/07/2018	20/08/2018	SmPC, Labelling and PL	
R/0017	Renewal of the marketing authorisation.	22/03/2018	16/05/2018	SmPC, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Cholib in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity. The product information concerning simvastatin has been updated according to the latest product information of the originator Zocor.
IAIN/0018	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)	28/02/2018	n/a		
PSUSA/10096 /201702	Periodic Safety Update EU Single assessment - fenofibrate / simvastatin	28/09/2017	n/a		PRAC Recommendation - maintenance
T/0015	Transfer of Marketing Authorisation from BGP Products Ltd UK to Mylan Products Ltd.	27/09/2016	21/10/2016	SmPC, Labelling and PL	

	Transfer of Marketing Authorisation				
PSUSA/10096 /201602	Periodic Safety Update EU Single assessment - fenofibrate / simvastatin	02/09/2016	n/a		PRAC Recommendation - maintenance
N/0013	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	15/10/2015	13/04/2016	PL	
PSUSA/10096 /201502	Periodic Safety Update EU Single assessment - fenofibrate / simvastatin	08/10/2015	n/a		PRAC Recommendation - maintenance
IAIN/0012	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	27/07/2015	13/04/2016	Annex II and PL	
IB/0010	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	21/04/2015	13/04/2016	SmPC and PL	
PSUSA/10096 /201408	Periodic Safety Update EU Single assessment - fenofibrate / simvastatin	12/03/2015	n/a		PRAC Recommendation - maintenance
T/0009	Transfer of Marketing Authorisation	10/02/2015	10/03/2015	SmPC, Labelling and PL	
IA/0008	A.7 - Administrative change - Deletion of manufacturing sites	19/01/2015	n/a		
PSUV/0005	Periodic Safety Update	11/09/2014	n/a		PRAC Recommendation - maintenance
IB/0006	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	22/08/2014	15/01/2015	SmPC	

IB/0004	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	30/04/2014	n/a		
IAIN/0003	A.1 - Administrative change - Change in the name and/or address of the MAH	03/02/2014	15/01/2015	SmPC, Labelling and PL	
IB/0001	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	20/12/2013	n/a		
IB/0002/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	19/12/2013	15/01/2015	SmPC, Labelling and PL	