Yellox

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
II/0036/G	This was an application for a group of variations. B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range B.II.d.1.a - Change in the specification parameters	14/11/2024	19/12/2024	SmPC	

[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).

	and/or limits of the finished product - Tightening of specification limits				
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	19/11/2024	n/a		
PSUSA/436/202305	Periodic Safety Update EU Single assessment - bromfenac	11/01/2024	n/a		PRAC Recommendation - maintenance
IA/0035/G	This was an application for a group of variations. B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	25/08/2023	n/a		
IB/0033/G	This was an application for a group of variations. B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	26/05/2023	n/a		
IA/0032	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	06/09/2022	n/a		

T/0031	Transfer of Marketing Authorisation	10/01/2022	04/02/2022	SmPC, Labelling and PL	
PSUSA/436/202105	Periodic Safety Update EU Single assessment - bromfenac	13/01/2022	n/a		PRAC Recommendation - maintenance
IA/0030	B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits	02/12/2021	n/a		
IB/0028/G	This was an application for a group of variations. 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 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 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	01/09/2021	n/a		

	an obsolete parameter)				
IA/0027/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 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	11/05/2021	n/a		
IB/0026	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	27/10/2020	15/11/2021	SmPC, Annex II, Labelling and PL	
T/0024	Transfer of Marketing Authorisation	23/04/2020	14/05/2020	SmPC, Labelling and PL	
PSUSA/436/201905	Periodic Safety Update EU Single assessment - bromfenac	16/01/2020	n/a		PRAC Recommendation - maintenance
IA/0022	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	04/06/2018	n/a		
PSUSA/436/201705	Periodic Safety Update EU Single assessment - bromfenac	11/01/2018	n/a		PRAC Recommendation - maintenance

IA/0020	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	04/05/2017	n/a		
N/0019	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	05/04/2017	26/07/2017	Labelling and PL	
PSUSA/436/201605	Periodic Safety Update EU Single assessment - bromfenac	12/01/2017	n/a		PRAC Recommendation - maintenance
IA/0017	A.7 - Administrative change - Deletion of manufacturing sites	24/08/2016	26/07/2017	Annex II and PL	
IA/0016	A.7 - Administrative change - Deletion of manufacturing sites	21/07/2016	n/a		
IA/0015	B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits	05/07/2016	n/a		
PSUSA/436/201505	Periodic Safety Update EU Single assessment - bromfenac	14/01/2016	n/a		PRAC Recommendation - maintenance
R/0014	Renewal of the marketing authorisation.	19/11/2015	11/01/2016	SmPC, Annex II, Labelling and PL	The renewal has been granted with unlimited validity.
II/0013/G	This was an application for a group of variations. B.II.e.1.b.2 - Change in immediate packaging of the	24/09/2015	n/a		

	finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier				
PSUV/0010	Periodic Safety Update	18/12/2014	26/02/2015	SmPC and PL	Please refer to Yellow PSUV-0010 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation
T/0011	Transfer of Marketing Authorisation	06/11/2014	27/01/2015	SmPC, Labelling and PL	
IB/0009	B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size	07/08/2014	n/a		
PSUV/0007	Periodic Safety Update	13/06/2014	n/a		PRAC Recommendation - maintenance
IAIN/0008	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	08/05/2014	n/a		
IAIN/0006	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	14/08/2013	27/01/2015	SmPC and PL	
IAIN/0005	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	15/05/2013	n/a		

IAIN/0004	C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the back-up procedure of the QPPV	15/10/2012	n/a		
IAIN/0003	C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV	21/09/2012	n/a		
IB/0002	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	07/12/2011	06/02/2012	SmPC and Labelling	
IB/0001	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	18/07/2011	n/a	SmPC and PL	