Azopt

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/0077	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	16/03/2023		SmPC and PL	Editorial changes in the text in the SmPC section "5.3 Pre-clinical Safety Data". In addition, the MAH took the opportunity to remove the term "Drop-tainer" from Section 6.5 of the SmPC. The package leaflet has been updated accordingly.

[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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IB/0076	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	14/10/2022	n/a		
PSUSA/432/202108	Periodic Safety Update EU Single assessment - brinzolamide	22/04/2022	24/06/2022	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/432/202108.
IAIN/0074/G	This was an application for a group of variations. 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.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 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) A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	12/10/2021	24/06/2022	Annex II and PL	
IAIN/0073	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	12/02/2021	n/a		

IB/0072	B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation	12/03/2020	n/a		
IB/0071/G	This was an application for a group of variations. A.z - Administrative change - Other variation B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation B.II.e.4.c - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	13/05/2019	n/a		
IA/0070	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	22/06/2018	06/06/2019	SmPC, Annex II, Labelling and PL	

T/0069	Transfer of Marketing Authorisation	20/03/2018	12/04/2018	SmPC, Labelling and PL	
IB/0068	B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	26/02/2018	n/a		
IB/0067	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	08/01/2018	n/a		
T/0066	Transfer of Marketing Authorisation	06/04/2017	31/05/2017	SmPC, Labelling and PL	
II/0064/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.2.b - Changes in the manufacturing process of the AS - Substantial change to the manufacturing process of the AS which may have a significant impact on the quality, safety or efficacy of the medicinal product	18/05/2017	n/a		

	B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size 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.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits 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.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.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)				

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	material/intermediate/reagent - Other variation 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 B.I.c.1.a - Change in immediate packaging of the AS - Qualitative and/or quantitative composition B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data				
PSUSA/432/201608	Periodic Safety Update EU Single assessment - brinzolamide	05/05/2017	n/a		PRAC Recommendation - maintenance
N/0065	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	21/02/2017	31/05/2017	PL	
IB/0063/G	This was an application for a group of variations. B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation 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.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	13/01/2017	n/a		

	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.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				
IG/0452	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	28/07/2014	n/a		
II/0059	Update of sections 4.2, 4.4, 4.6, 4.7 and 4.8 of the SmPC following a review of the available clinical and post-marketing data. The Package Leaflet and Labelling were updated accordingly. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	25/04/2014	13/04/2015	SmPC, Annex II, Labelling and PL	The MAH undertook a review of the available data supporting the safety profile of Azopt eye drops. No new clinical trial data were evaluated for the purpose of this review, which was based on data from previously reported clinical studies and post-marketing experience with the product. Practical instructions about the tamper evident snap collar were also included ("After the cap is removed, if the tamper evident snap collar is loose, remove before using product").
PSUV/0060	Periodic Safety Update	10/04/2014	n/a		PRAC Recommendation - maintenance
IG/0324	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	22/07/2013	n/a		

N/0056	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	01/07/2013	05/03/2014	PL	
IA/0054	A.5.b - Administrative change - Change in the name and/or address of a manufacturer of the finished product, including quality control sites (excluding manufacturer for batch release)	21/03/2013	n/a		
IG/0274	A.1 - Administrative change - Change in the name and/or address of the MAH	19/03/2013	05/03/2014	SmPC, Labelling and PL	
IG/0149/G	This was an application for a group of variations. C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV C.I.9.h - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system	06/03/2012	15/06/2012	Annex II	
IG/0145	B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer	09/02/2012	n/a		
IG/0107/G	This was an application for a group of variations. C.I.9.h - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s)	19/09/2011	n/a		

	to the DDPS that does not impact on the operation of the pharmacovigilance system C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the contact details of the QPPV C.I.9.e - Changes to an existing pharmacovigilance system as described in the DDPS - Changes in the major contractual arrangements with other persons or organisations involved in the fulfilment of pharmacovigilance obligations and described in the DD				
IB/0045	B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the currently approved batch size	25/03/2011	n/a		
WS/0075	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. To replace the current resin which is used for the closures for the drop-trainer packaging system, with two new resins. B.II.e.1.a.3 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/immunological medicinal products	20/01/2011	04/02/2011		
IG/0039	C.I.9.i - Changes to an existing pharmacovigilance	17/01/2011	n/a	Annex II	

	system as described in the DDPS - Change(s) to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH				
N/0044	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	01/12/2010	n/a	PL	
IB/0043/G	This was an application for a group of variations. B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data 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.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	15/09/2010	n/a		

	specification parameter to the specification with its 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				
IB/0042	B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products	21/05/2010	n/a		
R/0039	Renewal of the marketing authorisation.	19/11/2009	29/01/2010	SmPC, Annex II, Labelling and PL	Based on the CHMP review of the available information and on the basis of a re-evaluation of the benefit risk balance, the CHMP was of the opinion that the quality, safety and efficacy of this medicinal product continued to be adequately and sufficiently demonstrated and therefore considered that the benefit risk profile of Azopt continued to be favourable. The CHMP was also of the opinion that the renewal could be granted with unlimited validity.
II/0036	Additional site for sterilisation of the closures used to manufacture Azopt eye drops. Change(s) to the manufacturing process for the	29/05/2009	16/06/2009		

	finished product				
II/0035	Additional site for sterilisation Azopt eye drops. Change(s) to the manufacturing process for the finished product	29/05/2009	16/06/2009		
IA/0038	IA_11_a_Change in batch size of active substance or intermediate - up to 10-fold	29/05/2009	n/a		
IA/0037	IA_11_a_Change in batch size of active substance or intermediate - up to 10-fold	29/05/2009	n/a		
II/0034	The Marketing Authorisation Holder applied for the redefinition of the starting material for the active substance. Change(s) to the manufacturing process for the active substance	22/01/2009	26/01/2009		
N/0033	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	19/01/2009	n/a	Labelling and PL	
II/0030	Extension of the approved indication to include use of Azopt as 'adjunctive therapy' with prostaglandin analogues. Extension of Indication	24/04/2008	20/06/2008	SmPC, Annex II and PL	Please refer to Assessment Report: Azopt-H-C-267-II-30
IA/0032	IA_11_a_Change in batch size of active substance or intermediate - up to 10-fold	04/06/2008	n/a		

II/0029	Update of section 4.8 of the Summary of Product Characteristics (SPC) based on safety review in the light of the full clinical study experience to-date. The Package Leaflet (PL) is updated accordingly.The opportunity is also taken to change the SPC in order to comply with the current SPC guidelines and MedDRA terminology. Additionally, the product information is amended to reflect current QRD requirements. Update of Summary of Product Characteristics, Labelling and Package Leaflet	18/10/2007	30/11/2007	SmPC, Labelling and PL	This variation application was submitted in order to update section 4.8 (Undesirable effects) of the SPC to reflect the data from 8 clinical trials completed since the approval of Azopt. In addition, the product information was updated in accordance with the current QRD requirements.
II/0031	Quality changes	18/10/2007	23/10/2007		
II/0026	Change(s) to the manufacturing process for the active substance	21/06/2007	22/06/2007		
II/0025	Update of Summary of Product Characteristics and Package Leaflet to include information on the limited paediatric data of Azopt. Amendments have been made to sections 4.2, 4.4, 4.8 and 5.1 of the SPC and to the Package Leaflet as appropriate. Update of Summary of Product Characteristics and Package Leaflet	26/04/2007	13/06/2007	SmPC, Annex II and PL	A clinical trial was conducted with AZOPT in 32 paediatric patients less than 6 years of age, diagnosed with glaucoma or ocular hypertension Results from the study show that in children not previously treated, the efficacy of Azopt is similar to the one in adults. However, in children who received prior treatment with Intra Ocular Pressure (IOP) lowering medication, the mean IOP changes from baseline did not decrease, and in fact a slight increase was observed in Azopt group.
IA/0028	IA_11_a_Change in batch size of active substance or intermediate - up to 10-fold	11/04/2007	n/a		

IA/0027	IA_04_Change in name and/or address of a manuf. of the active substance (no Ph. Eur. cert. avail.)	11/04/2007	n/a		
II/0024	Update of or change(s) to the pharmaceutical documentation	24/01/2007	20/02/2007	Annex II and PL	
IA/0023	IA_11_a_Change in batch size of active substance or intermediate - up to 10-fold	16/08/2006	n/a		
IA/0022	IA_11_a_Change in batch size of active substance or intermediate - up to 10-fold	16/08/2006	n/a		
IA/0021	IA_11_a_Change in batch size of active substance or intermediate - up to 10-fold	16/08/2006	n/a		
IA/0020	IA_11_a_Change in batch size of active substance or intermediate - up to 10-fold	31/07/2006	n/a		
IA/0019	IA_11_a_Change in batch size of active substance or intermediate - up to 10-fold	31/07/2006	n/a		
IA/0018	IA_11_a_Change in batch size of active substance or intermediate - up to 10-fold	31/07/2006	n/a		
IA/0017	IA_11_a_Change in batch size of active substance or intermediate - up to 10-fold	31/07/2006	n/a		
IA/0016	IA_11_a_Change in batch size of active substance or intermediate - up to 10-fold	31/07/2006	n/a		
IA/0015	IA_11_a_Change in batch size of active substance or	31/07/2006	n/a		

	intermediate - up to 10-fold				
IA/0014	IA_11_a_Change in batch size of active substance or intermediate - up to 10-fold	31/07/2006	n/a		
IA/0013	IA_11_a_Change in batch size of active substance or intermediate - up to 10-fold	31/07/2006	n/a		
IB/0012	IB_14_b_Change in manuf. of active substance without Ph. Eur. certificate - new manufacturer	06/06/2006	n/a		
R/0011	Renewal of the marketing authorisation.	17/02/2005	02/06/2005	SmPC, Annex II, Labelling and PL	
N/0008	MAH applied for the inclusio of additional local representatives of the MAH for all new Members States and of an electronic contact address for the Swedish local representative. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	13/05/2004	n/a	Labelling and PL	
N/0007	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	07/10/2002	12/11/2002	PL	
I/0006	16_Change in the batch size of finished product	24/06/2002	28/06/2002		
I/0005	12_Minor change of manufacturing process of the active substance	08/05/2002	23/05/2002		

I/0004	12_Minor change of manufacturing process of the active substance	14/03/2002	18/03/2002		
I/0003	12_Minor change of manufacturing process of the active substance	12/11/2001	15/02/2002		
I/0002	11b_Change in supplier of an intermediate compound used in manufacture of the active substance	12/11/2001	15/02/2002		
I/0001	30_Change in pack size for a medicinal product	05/04/2000	16/11/2000	SmPC, Annex II, Labelling and PL	