EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Vaniqa

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/0057	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	26/09/2022		PL	
II/0056	B.I.z - Quality change - Active substance - Other variation	22/09/2022	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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IB/0055	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	27/10/2021		SmPC, Annex II, Labelling and PL	
IA/0054	A.7 - Administrative change - Deletion of manufacturing sites	31/05/2021	n/a		
PSUSA/1202/ 201807	Periodic Safety Update EU Single assessment - eflornithine (topical use)	14/03/2019	n/a		PRAC Recommendation - maintenance
N/0053	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	06/03/2019		PL	
II/0051	B.I.a.1.b - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a manufacturer of the AS supported by an ASMF	19/07/2018	n/a		
IB/0050	B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	05/04/2017	16/03/2018	SmPC, Annex II, Labelling and PL	
IB/0048/G	This was an application for a group of variations. B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an	17/05/2016	n/a		

	ASMF B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits 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				
N/0049	Update of the package leaflet with revised contact details of the local representative for Belgium. In addition, the MAH took the opportunity to make minor linguistic and editorial amendments in the package leaflets for some of the EEA languages (BG, DE, EL, FI, FR, IS, IT, LT, LV, NO and PL). Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	12/04/2016	16/03/2018	PL	
PSUSA/1202/ 201507	Periodic Safety Update EU Single assessment - eflornithine (topical use)	17/03/2016	n/a		PRAC Recommendation - maintenance
IAIN/0046	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	11/07/2014	08/07/2015	SmPC and PL	
IB/0045/G	This was an application for a group of variations.	08/05/2014	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.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF 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.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure				
N/0044	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	09/04/2014	22/05/2014	PL	
IAIN/0043	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	19/12/2013	n/a		

IA/0042	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	25/09/2013	n/a		
IAIN/0041	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	13/08/2013	n/a		
IB/0040/G	This was an application for a group of variations. 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 B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS 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.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.2.a - Change in test procedure for AS or	18/07/2013	n/a		

	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.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.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) 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)				

II/0035/G	This was an application for a group of variations. Change in the specifications of the finished product. 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 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 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 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 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 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 B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change	25/04/2013	25/04/2013		

	outside the approved specifications limits range B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range				
IB/0038	Update of the SmPC, labelling and the package leaflet according to the latest QRD template. The MAH also took the opportunity to amend an incorrect statement regarding age range introduced at the time of the latest renewal and to update the contact details of the local representatives for the United Kingdom, Ireland, the Netherlands and Italy. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	10/04/2013	22/05/2014	SmPC, Labelling and PL	
IB/0036/G	This was an application for a group of variations. B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits B.II.b.3.z - Change in the manufacturing process of the finished product - Other variation	22/03/2013	n/a		
IA/0039/G	This was an application for a group of variations. B.II.c.1.b - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method B.II.c.1.b - Change in the specification parameters	18/03/2013	n/a		

	and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method B.II.c.1.b - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method B.II.c.1.b - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method B.II.c.1.b - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method B.II.c.1.b - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method B.II.c.1.b - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method B.II.c.1.b - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method B.II.c.1.b - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method B.III.2.a.2 - Change of specification(s) of a former				

	non Pharmacopoeial substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material				
IA/0037/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites B.II.c.1.b - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method B.III.2.a.2 - Change of specification(s) of a former non Pharmacopoeial substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material B.II.c.1.a - Change in the specification parameters and/or limits of an excipient - Tightening of specification limits B.II.c.1.b - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure	06/03/2013	n/a		
R/0034	Renewal of the marketing authorisation.	16/12/2010	04/03/2011	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 is of the opinion that the quality, safety and

					efficacy of Vaniqa continues to be adequately and sufficiently demonstrated and therefore considered that the benefit risk profile of Vaniqa continues to be favourable.
IA/0033	A.1 - Administrative change - Change in the name and/or address of the MAH	30/09/2010	n/a	SmPC, Labelling and PL	
IB/0032	IB_33_Minor change in the manufacture of the finished product	25/11/2009	n/a	SmPC, Labelling and PL	
IB/0031	IB_31_b_Change to in-process tests/limits during manufacture - addition of new tests/limits	25/11/2009	n/a		
IA/0030	IA_09_Deletion of manufacturing site	14/08/2009	n/a	Annex II and PL	
IA/0029	IA_05_Change in the name and/or address of a manufacturer of the finished product	14/08/2009	n/a	Annex II and PL	
T/0028	Transfer of Marketing Authorisation	13/05/2008	06/06/2008	SmPC, Labelling and PL	
IA/0027	IA_09_Deletion of manufacturing site	08/11/2007	n/a		
II/0026	Update of Summary of Product Characteristics and Package Leaflet Update of Summary of Product Characteristics and Package Leaflet	24/05/2007	27/06/2007	SmPC and PL	Following the assessment of the Periodic Safety Update Report 9 covering the period 27 October 2005 -26 July 2006, the CHMP endorsed the MAH's proposal to replace the term 'hair disorder' with the more descriptive terms 'abnormal hair texture and abnormal hair growth' in Section 4.8 of the SPC and Section 4 of the PL.

N/0025	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	23/05/2007	n/a	PL	
IB/0024	IB_37_a_Change in the specification of the finished product - tightening of specification limits	07/12/2006	n/a		
IB/0023	IB_29_a_Change in qual./quant. composition of immediate packaging - semi-solid/liquid ph. forms	09/11/2006	n/a		
IB/0022	IB_33_Minor change in the manufacture of the finished product	28/09/2006	n/a		
IB/0021	IB_18_Replacement of an excipient with a comparable excipient	28/06/2006	n/a		
R/0020	Renewal of the marketing authorisation.	23/02/2006	18/04/2006	SmPC, Annex II, Labelling and PL	Based on the review of the available information, the CHMP was of the opinion that the quality, the safety and the efficacy of Vaniqa continues to be adequately and sufficiently demonstrated and that the benefit/risk profile of Vaniqa continues to be favourable in the treatment of facial hirsutism in women. However the CHMP has concerns regarding the Phamacovigilance monitoring of Vaniqa by the MAH, in particular related to the low level of reporting of adverse events, the incorrect classification of such events according to System Organ Class and the methodology used to calculate patient exposure. Although the overall risk/benefit remains positive, due to the limited exposure of the product (marketed since August

					2004), and the above-mentioned Pharmacovigilance concerns, the CHMP is of the opinion that one additional renewal is required. Based on the CHMP review of the available information and on the basis of a re-evaluation of the benefit risk balance the CHMP is of the opinion that the quality, the safety and the efficacy of Vaniqa continues to be adequately and sufficiently demonstrated and therefore considered the benefit/risk profile of Vaniqa continues to be favourable. However the CHMP has concerns regarding the Phamacovigilance monitoring of Vaniqa by the MAH, in particular related to the low level of reporting of adverse events, the incorrect classification of such events according to System Organ Class and the methodology used to calculate patient exposure. Although the overall risk/benefit remains positive, due to the limited exposure of the product (marketed since August 2004), and the above-mentioned Pharmacovigilance concerns, the CHMP is of the opinion that one additional renewal is required.
IA/0019	IA_09_Deletion of manufacturing site	09/12/2005	n/a		
IA/0018	IA_05_Change in the name and/or address of a manufacturer of the finished product	30/09/2005	n/a		
N/0017	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	10/08/2005	n/a	PL	

IB/0016	The MAH applied for Hermal Kurt Herrmann GmbH & Co - Scholtztrasse 3, D-21465 Reinbeck - Germany as an alternative manufacturer responsible for the manufacturing of the dosages form, primary packaging for the finished product, batch Control and testing. IA_08_a_Change in BR/QC testing - repl./add. of batch control/testing site IB_07_c_Replacement/add. of manufacturing site: All other manufacturing operations ex. batch release IB_07_b_02_Replacement/add. of manufacturing site: Primary packaging site - Semi-solid ph. forms	19/07/2005	n/a		
IB/0014	IB_10_Minor change in the manufacturing process of the active substance	02/06/2005	n/a		
IA/0015	IA_07_a_Replacement/add. of manufacturing site: Secondary packaging site	26/05/2005	n/a		
IA/0013	IA_08_b_01_Change in BR/QC testing - repl./add. manuf. responsible for BR - not incl. BC/testing	04/03/2005	n/a	Annex II and PL	
IA/0012	IA_07_a_Replacement/add. of manufacturing site: Secondary packaging site	04/03/2005	n/a		
N/0011	Further to your letter of Notification received on 7 February 2005 concerning the change in Italian outer carton in accordance with article 61(3) of Directive 2001/83/EC, as amended, the EMEA would like to	02/03/2005	n/a	Labelling	

	inform you that the change in relation to the addition of the reimbursement price in the blue box area as proposed by Shire Pharmaceutical Contracts Ltd is acceptable. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)				
N/0010	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	06/01/2005	n/a	PL	
IB/0009	IB_42_a_01_Change in shelf-life of finished product - as packaged for sale	22/10/2004	n/a	SmPC	
IA/0008	IA_08_a_Change in BR/QC testing - repl./add. of batch control/testing site	25/03/2004	n/a		
IA/0007	IA_08_b_01_Change in BR/QC testing - repl./add. manuf. responsible for BR - not incl. BC/testing	17/03/2004	n/a	Annex II and PL	
T/0006	Transfer of Marketing Authorisation	22/01/2004	04/03/2004	SmPC, Labelling and PL	
T/0005	Transfer of Marketing Authorisation	08/07/2003	05/08/2003	SmPC, Labelling and PL	
I/0004	25_Change in test procedures of the medicinal product	21/12/2001	11/02/2002		
I/0003	03_Change in the name and/or address of the	16/11/2001	n/a	SmPC,	

	marketing authorisation holder			Labelling and PL	
I/0002	12_Minor change of manufacturing process of the active substance	17/07/2001	n/a		
I/0001	11b_Change in supplier of an intermediate compound used in manufacture of the active substance	24/04/2001	n/a		