Grepid

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/0057/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO	15/12/2023	11/01/2024	SmPC and PL	

[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).

	new additional data is required to be submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH				
IB/0056/G	This was an application for a group of variations. B.III.1.a.1 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer 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	02/08/2023	n/a		
IA/0055	A.7 - Administrative change - Deletion of manufacturing sites	10/07/2023	n/a		
II/0054	As a consequence of this variation, presentations packaged in PA/ALL/PVC-aluminium foil container are removed from the marketing authorisation. The following EU numbers are removed from the marketing authorisation: EU/1/09/535/008-14. B.II.a.3.b.5 - Changes in the composition (excipients) of the finished product - Other excipients	26/04/2023	15/09/2023	SmPC, Labelling and PL	The following statement has been included in the SmPC Section 4.3: This medicinal product contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'. The SmPC section 6.1 has been updated as follows: Talc is replaced by Sodium Stearyl Fumarate The SmPC section 6.4 has been updated as follows: storage precautions for 'aluminium blisters' (PA/ALL/PVC-aluminium

	- Change that is supported by a bioequivalence study				foil) have been deleted. The SmPC section 6.5 has been updated as follows: references to PA/ALL/PVC-aluminium foil presentations have been deleted. The SmPC section 8 has been updated as follows: EU numbers EU/1/09/535/008-14, corresponding to PA/ALL/PVC-aluminium foil presentations, have been deleted. The PL has been updated accordingly.
IB/0053	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	26/07/2022	15/09/2023	SmPC and PL	
IB/0052/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.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF 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.III.2.a.1 - Change of specification(s) of a former	08/06/2022	n/a		

	non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - AS				
IB/0051	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	03/11/2021	16/12/2021	SmPC and PL	
N/0050	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	29/09/2021	16/12/2021	PL	
IB/0049	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	03/05/2021	19/05/2021	SmPC and PL	
IB/0048	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	27/11/2020	19/05/2021	SmPC and PL	
IB/0047	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference	24/02/2020	04/05/2020	SmPC and PL	

	product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH				
IA/0046	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	25/07/2019	04/05/2020	SmPC and PL	
IB/0045/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	23/05/2019	04/05/2020	SmPC and PL	
IB/0044	B.II.b.4.e - Change in the batch size (including batch size ranges) of the finished product - More than 10-fold increase compared to the originally approved batch size for immediate release (oral) pharmaceutical form	07/02/2019	n/a		
N/0043	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	09/11/2018	06/06/2019	PL	

IB/0042	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	31/05/2018	06/06/2019	SmPC and PL	
N/0041	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/11/2017	06/06/2019	PL	
IB/0040/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	13/06/2017	19/07/2017	SmPC, Labelling and PL	
IB/0039	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	15/12/2016	n/a		
N/0038	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	19/10/2016	19/07/2017	PL	

IB/0037/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	09/12/2015	24/06/2016	SmPC and PL	
II/0033	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	24/09/2015	n/a		
N/0036	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	02/07/2015	24/06/2016	Labelling	
IB/0035	C.I.2.a - Change in the SPC, Labelling or PL of a	04/06/2015	24/06/2016	SmPC and PL	

	generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH				
IAIN/0034	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	12/05/2015	n/a		
PSUSA/820/201311	Periodic Safety Update EU Single assessment - acetylsalicylic acid / clopidogrel, clopidogrel	10/07/2014	n/a		PRAC Recommendation - maintenance
R/0029	Renewal of the marketing authorisation.	20/02/2014	11/04/2014	SmPC, Annex II, Labelling and PL	The safety and efficacy of clopidogrel have been demonstrated by several large clinical studies. A literature review was performed and no significant new efficacy or effectiveness information was identified that could possibly alter the effectivess of this agent for the authorized indications and treatment regimen. The beneficial effect of clopidogrel remains in line with that of the originator product, and is considered positive. The CHMP therefore recommended that the Marketing Authorisation for Grepid can be renewed with unlimited validity.
IA/0032	A.7 - Administrative change - Deletion of manufacturing sites	08/04/2014	n/a		
IB/0030	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference	09/01/2014	11/04/2014	SmPC	

	product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH				
IB/0028/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	10/10/2013	11/04/2014	SmPC and PL	
IB/0027/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data are submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data are submitted by the MAH	05/08/2013	11/04/2014	SmPC, Annex II, Labelling and PL	

N/0025	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	16/05/2013	11/04/2014	PL	
N/0024	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	08/02/2013	11/04/2014	PL	
IAIN/0023/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	07/02/2013	n/a		
II/0021	To add an alternative manufacturer of clopidogrel besilate B.I.a.1.b - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a new manufacturer of the AS that is supported by an ASMF	15/11/2012	n/a		
N/0022	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	05/11/2012	11/04/2014	PL	
N/0020	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	20/03/2012	26/07/2012	PL	
IB/0019/G	This was an application for a group of variations.	10/01/2012	n/a	SmPC,	

	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) B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product			Labelling and PL	
IB/0017/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data are submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data are submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data are submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data are submitted by the MAH C.I.2.a - Change in the SPC, Labelling or PL of a	12/08/2011	n/a	SmPC and PL	

	generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data are submitted by the MAH				
IA/0018/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.c - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the back-up procedure of the QPPV C.I.9.d - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the safety database 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 C.I.9.i - Changes to an existing pharmacovigilance 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	27/07/2011	n/a		
IB/0016	B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation	12/07/2011	n/a		
IB/0015	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following	07/04/2011	n/a	SmPC, Annex II, Labelling	

	assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data are submitted by the MAH			and PL	
II/0014	To add an alternative route of synthesis of the active substance (clopidogrel besylate) at the already approved manufacturing site. B.I.a.1.c - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer uses a substantially different route of synthesis or manufacturing conditions	18/11/2010	08/12/2010		
IB/0013	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data are submitted by the MAH	28/07/2010	n/a	SmPC and PL	
N/0006	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/01/2010	n/a	PL	
IB/0005	IB_41_a_02_Change in pack size - change in no. of units outside range of appr. pack size	25/11/2009	24/11/2009	SmPC, Labelling and PL	
IB/0004	To add an alternative manufacturer for the finished product, including batch testing and batch release. IA_07_a_Replacement/add. of manufacturing site: Secondary packaging site IB_07_c_Replacement/add. of manufacturing site:	25/11/2009	n/a	Annex II and PL	

	All other manufacturing operations ex. batch release IA_07_b_01_Replacement/add. of manufacturing site: Primary packaging site - Solid forms IA_08_b_02_Change in BR/QC testing - repl./add. manuf. responsible for BR - incl. BC/testing				
IB/0003	To add an alternative manufacturer for all manufacturing operations except batch release IA_07_a_Replacement/add. of manufacturing site: Secondary packaging site IB_07_c_Replacement/add. of manufacturing site: All other manufacturing operations ex. batch release IA_07_b_01_Replacement/add. of manufacturing site: Primary packaging site - Solid forms	25/11/2009	n/a		
IA/0012	IA_41_a_01_Change in pack size - change in no. of units within range of appr. pack size	24/11/2009	24/11/2009	SmPC, Labelling and PL	
IA/0011	IA_08_b_02_Change in BR/QC testing - repl./add. manuf. responsible for BR - incl. BC/testing	24/11/2009	n/a	Annex II and PL	
IA/0010	IA_07_a_Replacement/add. of manufacturing site: Secondary packaging site	24/11/2009	n/a		
IA/0009	IA_07_a_Replacement/add. of manufacturing site: Secondary packaging site	24/11/2009	n/a		
IA/0008	IA_07_a_Replacement/add. of manufacturing site: Secondary packaging site	24/11/2009	n/a		

IA/0007	IA_07_a_Replacement/add. of manufacturing site: Secondary packaging site IA_07_b_01_Replacement/add. of manufacturing site: Primary packaging site - Solid forms	24/11/2009	n/a		
IA/0002	IA_07_a_Replacement/add. of manufacturing site: Secondary packaging site IA_07_b_01_Replacement/add. of manufacturing site: Primary packaging site - Solid forms	05/10/2009	n/a		
N/0001	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	25/09/2009	n/a	PL	