Clopidogrel Teva

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/0061/G	This was an application for a group of variations. B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information	26/02/2024	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).

	B.II.e.1.a.1 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms				
IB/0059/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	09/01/2024	08/02/2024	SmPC, Labelling and PL	
IA/0060/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 B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the	20/11/2023	n/a		

	relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer				
IB/0057	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	03/06/2022	15/09/2023	SmPC, Labelling and PL	Section 4.5 of the SmPC was updated to add the drug-drug interaction between clopidogrel and rosuvastatin following the same update for the reference product. The package leaflet was updated accordingly.
IG/1508	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)	23/05/2022	n/a		
IB/0056	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	04/10/2021	26/11/2021	SmPC and PL	
IB/0055	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	
IA/0054/G	This was an application for a group of variations.	02/03/2021	n/a		

	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 B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure				
IAIN/0053/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 A.7 - Administrative change - Deletion of manufacturing sites	04/02/2021	19/05/2021	Annex II and PL	
IB/0052	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	24/11/2020	19/05/2021	SmPC, Labelling and PL	
IB/0051/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	21/02/2020	04/05/2020	SmPC, Annex II and PL	

	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				
IAIN/0050	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	22/08/2019	04/05/2020	SmPC and PL	
IA/0048	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	31/05/2019	n/a		
IB/0049/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	28/05/2019	04/05/2020	SmPC, Labelling and PL	

IAIN/0047/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites 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	21/11/2018	n/a		
IB/0046	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	25/09/2018	n/a		
IB/0045	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	13/04/2018	31/01/2019	SmPC and PL	
IAIN/0044	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	04/12/2017	31/01/2019	Annex II and PL	
IA/0043/G	This was an application for a group of variations.	21/09/2017	n/a		

	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process				
IB/0042/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	22/05/2017	23/06/2017	SmPC, Labelling and PL	
IA/0041/G	This was an application for a group of variations. 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.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the	06/03/2017	n/a		

	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				
IA/0040/G	This was an application for a group of variations. B.II.e.1.a.1 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms B.II.e.1.a.1 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products	16/12/2016	n/a		
IAIN/0039	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	14/09/2016	23/06/2017	Annex II and PL	
IB/0038/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	10/12/2015	26/05/2016	SmPC and PL	

	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				
IAIN/0037	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	27/11/2015	26/05/2016	Annex II and PL	
IB/0036	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	01/06/2015	26/05/2016	SmPC and PL	
T/0034	Transfer of Marketing Authorisation	09/01/2015	30/01/2015	SmPC, Labelling and	

				PL	
IAIN/0035	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	21/01/2015	n/a		
IB/0033	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	28/11/2014	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.	20/03/2014	16/05/2014	SmPC, Labelling and PL	The safety and efficacy of clopidogrel have been demonstrated by several large clinical studies. The MAH has submitted an Addendum to Clinical Overview (ACO) to provide details of the efficacy and safety of Clopidogrel Teva since its approval. In the CHMP's view the provided data do not change the overall knowledge about the beneficial effect and safety profile of clopidogrel when used in the approved indications. The beneficial effect of Clopidogrel Teva remains in line with that of the originator product (Plavix), and is considered positive.
IB/0032/G	This was an application for a group of variations. Following an assessment of safety updates for the reference product, the MAH applied to update section 4.4 'Special Warning and Precautions for use' and 4.5	23/04/2014	30/01/2015	SmPC, Labelling and PL	

	'Interaction with other medicinal products' of the SmPC in order to add information on Core Data Sheets linked to clopidogrel INN: - Addition of an interaction with the selective serotonin reuptake inhibitors (SSRIs) in section 4.5. - Addition of a consequential information concerning this interaction in section 4.4. The Section 2 of the Package leaflet has been updated accordingly. To update section 4.8 'Undesirable effects – System Organ Class: Skin and subcutaneous tissue disorders' of the SmPC to add information on Core Data Sheet linked to clopidogrel INN: - Addition of a new undesirable effect 'Rash exfoliative'. Finally, minor editorial changes have been proposed in section 5 of labelling of the outer carton. The contact details of the local representatives for Luxembourg, Malta, Iceland and Cyprus were updated. Also, the Danish, Italian and French Package Leaflet were brought in line with the innovator text as some editorial differences were detected. 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				
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 product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	10/02/2014	16/05/2014	SmPC and PL	
IB/0028	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	03/12/2013	n/a		
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 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	06/11/2013	16/05/2014	SmPC and PL	

	new additional data is required to be submitted by the MAH				
IAIN/0026/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 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 A.7 - Administrative change - Deletion of manufacturing sites B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	17/10/2013	n/a		
IB/0024/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	15/08/2013	16/05/2014	SmPC, Annex II, Labelling and PL	

	new additional data are submitted by the MAH				
IAIN/0023	B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes	14/08/2013	16/05/2014	SmPC, Labelling and PL	
IAIN/0022	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	17/07/2013	n/a		
IB/0021	B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products	18/04/2013	n/a		
IA/0020/G	This was an application for a group of variations. 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) A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites	16/04/2013	16/05/2014	Annex II and PL	
IB/0019	B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary	13/03/2012	n/a		

	packaging, for non-sterile medicinal products				
IB/0018	B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products	16/02/2012	n/a		
IB/0017/G	This was an application for a group of variations. B.III.2.a.1 - 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 - AS 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 A.7 - Administrative change - Deletion of manufacturing sites	09/01/2012	n/a		
IB/0016/G	This was an application for a group of variations. 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.3.b - Change in test procedure for the immediate packaging of the AS - Other changes to a	23/09/2011	n/a		

	test procedure (including replacement or addition) B.I.c.2.c - Change in the specification parameters and/or limits of the immediate packaging of the AS - 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 non Pharmacopoeial substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - AS				
IB/0015/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	08/08/2011	n/a	SmPC, Annex II and PL	
IB/0014	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	13/07/2011	n/a		
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	11/04/2011	n/a	SmPC, Annex II, Labelling and PL	The MAH wishes to amend the SmPC and PL to put it in line with the recently adopted text of the innovator product Plavix. The sections to be updated are the following: 4.2 'Posology and method of administration', 4.4 'Special

	new additional data are submitted by the MAH				warnings and precautions for use', 4.5 'Interaction with othet medicinal products and other forms of interaction' and 5.2 'Phamakokinetics properties'. In addition the PhV system in Annex II has been amended and local representatives in Austria, Germany and Spain have been updated. Finally minor amendments have been introduced in the Annexes of the following languages: DA, NL, FI, HU, LV, LT, MT, PL, SL
IA/0012/G	This was an application for a group of variations. B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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)	16/11/2010	n/a		
IB/0011	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	16/07/2010	n/a	SmPC, Labelling and PL	
IB/0010	To add a desiccant as an intermediate packaging component for the active substance. B.I.c.z - Container closure system of the AS - Other	24/06/2010	n/a		

	variation				
IA/0009	IA_07_a_Replacement/add. of manufacturing site: Secondary packaging site	09/12/2009	n/a		
IA/0001	IA_29_b_Change in qual./quant. composition of immediate packaging - all other pharm. forms	30/09/2009	n/a	SmPC, Labelling and PL	
IA/0008	IA_41_a_01_Change in pack size - change in no. of units within range of appr. pack size	24/09/2009	24/09/2009	SmPC, Labelling and PL	
IA/0007	IA_41_a_01_Change in pack size - change in no. of units within range of appr. pack size	24/09/2009	24/09/2009	SmPC, Labelling and PL	
IA/0006	IA_41_a_01_Change in pack size - change in no. of units within range of appr. pack size	24/09/2009	24/09/2009	SmPC, Labelling and PL	
IA/0005	IA_41_a_01_Change in pack size - change in no. of units within range of appr. pack size	24/09/2009	24/09/2009	SmPC, Labelling and PL	
IA/0004	IA_41_a_01_Change in pack size - change in no. of units within range of appr. pack size	24/09/2009	24/09/2009	SmPC, Labelling and PL	
IA/0003	IA_41_a_01_Change in pack size - change in no. of units within range of appr. pack size	24/09/2009	24/09/2009	SmPC, Labelling and PL	
IA/0002	IA_41_a_01_Change in pack size - change in no. of units within range of appr. pack size	24/09/2009	24/09/2009	SmPC, Labelling and	

				PL	