Clopidogrel Taw Pharma

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/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	07/12/2023	18/12/2023	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/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	29/06/2022	23/06/2023	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 product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	07/02/2022	21/02/2022	SmPC, Labelling and PL	
T/0045	Transfer of Marketing Authorisation	20/10/2021	15/11/2021	SmPC, Labelling and PL	
IAIN/0046	A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs	01/10/2021	25/10/2021	SmPC, Labelling and PL	
IB/0044	C.I.2.a - Change in the SPC, Labelling or PL of a	22/04/2021	10/05/2021	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				
IB/0043	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	10/05/2021	SmPC and PL	
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	26/02/2020	04/05/2020	SmPC and PL	
IB/0041	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	06/09/2019	04/05/2020	SmPC and PL	

IA/0040	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	25/06/2019	n/a		
IB/0039/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 and PL	
N/0038	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	11/03/2019	04/05/2020	PL	
IA/0037/G	This was an application for a group of variations. 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 B.II.b.2.a - Change to importer, batch release	28/06/2018	n/a		

	arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place				
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	13/04/2018	25/03/2019	SmPC, Labelling and PL	
IB/0035/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	15/06/2017	SmPC, Labelling and PL	
IB/0034/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	07/12/2015	12/05/2016	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/0033	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	16/11/2015	n/a		
IB/0032	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	22/05/2015	12/05/2016	SmPC and PL	
IB/0031/G	This was an application for a group of variations. B.I.a.2.e - Changes in the manufacturing process of	27/11/2014	n/a		

	the AS - Minor change to the restricted part of an ASMF 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.3.d - Change in batch size (including batch size ranges) of AS or intermediate - More than 10-fold increase compared to the originally approved batch size 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				
PSUSA/820/201311	Periodic Safety Update EU Single assessment - acetylsalicylic acid / clopidogrel, clopidogrel	10/07/2014	n/a		PRAC Recommendation - maintenance
R/0027	Renewal of the marketing authorisation.	20/03/2014	22/05/2014	SmPC, Labelling and PL	The safety and efficacy of clopidogrel have been demonstrated by several large clinical studies. No literature review on the efficacy/effectiveness has been submitted by the MAH within this application. Since the clinical efficacy of clopidogrel in the approved indications is well established and evidence of clinical efficacy has been discussed at time of approval the CHMP finds acceptable the MAH approach of not performing a literature review on the efficacy/effectiveness of clopidogrel. The beneficial effect of Clopidogrel Mylan remains in line with that of the originator product (Plavix), and is considered positive.

IB/0030/G	This was an application for a group of variations. To update sections 4.4 and 4.5 of the SmPC to add information on an interaction with the selective serotonin reuptake inhibitors (SSRIs) in section 4.5 and consequential information concerning this interaction in section 4.4. The Package leaflet has been updated accordingly. To update 4.8 of the SmPC to add "Rash exfoliative" as a new undesirable effect. Furthermore minor editorial correction to DE, HR, NO and PL text were introduced. These changes have been previously approved for the reference medicinal product Plavix in WS/476 and WS/477 respectively 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	23/04/2014	09/04/2015	SmPC and PL	
IB/0029/G	This was an application for a group of variations.	11/03/2014	10/04/2014	SmPC, Annex II and PL	

	Update of SmPC section 4.4 following CHMP adoption of WS/409 to "Special warnings and precautions for use" for the originator. In addition the MAH also adds the two indications of the originator that have come off patent to the annexes. 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.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation				
IB/0025/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	14/11/2013	10/04/2014	SmPC	
IB/0023/G	This was an application for a group of variations.	21/08/2013	10/04/2014	SmPC, Annex	

	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			II, Labelling and PL	
IAIN/0024	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	08/08/2013	n/a		
IB/0022/G	This was an application for a group of variations. 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.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State	21/05/2013	10/04/2014	SmPC	
IB/0021	B.II.a.3.z - Changes in the composition (excipients) of the finished product - Other variation	09/04/2013	10/04/2014	SmPC and PL	

IB/0020/G	This was an application for a group of variations. 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.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	08/03/2013	n/a		
IA/0019/G	This was an application for a group of variations. 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 A.7 - Administrative change - Deletion of manufacturing sites	18/01/2013	n/a		
IB/0018	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	
IA/0017	A.7 - Administrative change - Deletion of manufacturing sites	13/04/2011	n/a		

IB/0016	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	12/04/2011	n/a	SmPC, Annex II and PL	To update the Summary of Product Characteristics (SmPC) and Package Leaflet to update sections 4.2 "Posology and method of administration", 4.4 "Special warnings and precautions for use", 4.5 "Interaction with other medicinal products and other forms of interaction" and 5.2 "Pharmacokinetic properties" of clopidogrel/acetylsalicylic acid (ASA) SPC to include new information on the variability of response to clopidogrel due to either genetic variations of the CYP2C19 enzyme or concomitant use of drugs that inhibit the CYP2C19 enzyme such as proton pump inhibitor (PPI). In addition, section 4.8 has been amended with minor details on the CURE study. Additional changes have been added to the SmPC and Package Leaflet in order to bring it in line with the revised QRD template (version 7.3) In addition, the deletion of DDPS number 1.3 and dated 21 April 2008 was introduced in Annex IIB as requested by the EMA with the procedural announcement in October and November 2010.
N/0015	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	14/12/2010	n/a	PL	
IB/0014	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	11/08/2010	n/a	SmPC and PL	
IB/0012/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other	08/06/2010	n/a		

	variation B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation				
IA/0013	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	04/06/2010	n/a		
IB/0011	IB_18_Replacement of an excipient with a comparable excipient	25/01/2010	n/a	SmPC and PL	
II/0001	addition of alternative manufcture for an intermediate and change in manufacturer process of intermediate Change(s) to the manufacturing process for the active substance	17/12/2009	04/01/2010		
IA/0009	IA_07_a_Replacement/add. of manufacturing site: Secondary packaging site	23/11/2009	n/a		
IA/0008	IA_41_a_01_Change in pack size - change in no. of units within range of appr. pack size	04/11/2009	04/11/2009	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	04/11/2009	04/11/2009	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	04/11/2009	04/11/2009	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	04/11/2009	04/11/2009	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	04/11/2009	04/11/2009	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	04/11/2009	04/11/2009	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	04/11/2009	04/11/2009	SmPC, Labelling and PL	