Myfenax

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/0048/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	23/06/2022		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 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				
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		
PSUSA/10550 /202105	Periodic Safety Update EU Single assessment - mycophenolate mofetil, mycophenolic acid	16/12/2021	17/02/2022	PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10550/202105.
IB/0047	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following	08/10/2021	17/02/2022	SmPC	

	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				
N/0046	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/09/2021	17/02/2022	PL	
IA/0044	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	13/04/2021	n/a		
PSUSA/10550 /202005	Periodic Safety Update EU Single assessment - mycophenolate mofetil, mycophenolic acid	10/12/2020	19/02/2021	SmPC	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10550/202005.
IA/0043	A.7 - Administrative change - Deletion of manufacturing sites	01/02/2021	17/02/2022	Annex II and PL	
IA/0041	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	17/06/2020	n/a		
IAIN/0040/G	This was an application for a group of variations. 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 B.II.e.5.a.1 - Change in pack size of the finished	12/06/2020	18/11/2020	SmPC, Labelling and PL	

	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				
IB/0039	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	16/03/2020	18/11/2020	SmPC, Annex II and PL	
IAIN/0038/G	This was an application for a group of variations. 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 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	11/12/2019	18/11/2020	SmPC, Labelling and PL	
IB/0035	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	04/12/2019	n/a		
PSUSA/10550 /201905	Periodic Safety Update EU Single assessment - mycophenolate mofetil, mycophenolic acid	28/11/2019	n/a		PRAC Recommendation - maintenance

IB/0036	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	22/10/2019	n/a		
IA/0037	B.II.e.3.a - Change in test procedure for the immediate packaging of the finished product - Minor changes to an approved test procedure	27/09/2019	n/a		
PSUSA/10550 /201805	Periodic Safety Update EU Single assessment - mycophenolate mofetil, mycophenolic acid	29/11/2018	n/a		PRAC Recommendation - maintenance
IB/0033/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	14/09/2018	04/10/2019	SmPC, Labelling and PL	
IA/0031	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	22/06/2018	n/a		

N/0030	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	19/03/2018	04/10/2019	Labelling and PL	
PSUSA/10550 /201705	Periodic Safety Update EU Single assessment - mycophenolate mofetil, mycophenolic acid	14/12/2017	05/03/2018	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10550/201705.
IA/0028	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	22/05/2017	n/a		
IA/0027	A.7 - Administrative change - Deletion of manufacturing sites	13/04/2016	12/04/2017	Annex II and PL	
IB/0026	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	28/01/2016	18/02/2016	SmPC, Annex II and PL	
IAIN/0025	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	02/12/2015	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	10/08/2015	18/02/2016	SmPC 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 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/0023	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	22/04/2015	18/02/2016	SmPC and PL	
T/0022	Transfer of Marketing Authorisation	09/01/2015	27/01/2015	SmPC, Labelling and PL	

IB/0021	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)	13/10/2014	30/10/2014	SmPC, Labelling and PL	
IB/0020	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	30/10/2013	30/10/2014	SmPC, Annex II, Labelling and PL	
IAIN/0019	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	24/05/2013	n/a		
IA/0018	B.III.1.a.2 - Submission of a new or updated Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	01/02/2013	n/a		
IA/0017	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)	21/11/2012	n/a		
R/0015	Renewal of the marketing authorisation.	20/09/2012	19/11/2012	SmPC, Annex II, Labelling and PL	Based on the review of the available information, the CHMP is of the opinion that the quality, the safety and the efficacy of this medicinal product continues to be adequately and sufficiently demonstrated and therefore considers the benefit/risk profile of Myfenax continues to be favourable. The CHMP is also of the opinion that the renewal can be granted with unlimited validity.

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	13/09/2012	19/11/2012	SmPC and PL	Update of Section 4.5 of the SmPC to include information regarding the interaction with proton pump inhibitors following the outcome of PSUR 18 assessment (covering period: 01.05.08-30.04.11) of the Reference Product. The Package Leaflet has been updated accordingly.
IAIN/0014/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.II.b.2.b.1 - Change to batch release arrangements and quality control testing of the FP - Not including batch control/testing	16/03/2012	11/06/2012	Annex II and PL	
IA/0013	B.III.1.a.2 - Submission of a new or updated Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	15/09/2011	n/a		
IB/0012	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	10/02/2011	n/a	SmPC, Annex II and PL	Changes to the PIL section 2 (Pregnancy and breast-feeding) recommended by the CHMP following the assessment of the originator product. The MAH also took the opportunity to: - Delete the version number of the DDPS from Annex IIB of the Marketing Authorisation. - Change the name of the active ingredient from "mycophenolate" to "mycophenolate mofetil" throughout the SmPC and PIL. - Make minor linguistic changes to comply with QRD requirements.

N/0010	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	12/11/2010	n/a	PL	
IA/0011/G	This was an application for a group of variations. 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 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	21/10/2010	21/10/2010	SmPC, Labelling and PL	
N/0008	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	13/07/2010	n/a	PL	
II/0007	Update of section 4.8 of the SPC to include information on isolated reports of interstitial lung disease and pulmonary fibrosis. This change was made to bring Myfenax's product information in line with the reference medicinal product CellCept. Update of Summary of Product Characteristics	21/01/2010	23/03/2010	SmPC	In September 2009, a variation (EMEA/H/C/82/II/93) to the marketing authorisation for CellCept was approved to update section 4.8 of the SPC to include information on isolated reports of ILD and pulmonary fibrosis. In November 2009, the Marketing Authorisation Holder for Myfenax submitted a Type II variation to bring the product information for Myfenax in line with CellCept's product information.
II/0004	Update of section 4.4 and 4.8 of the SPC to include information on pure red cell aplasia. Update of sections 4.8 of the SPC to include information on acquired Pelger-Huet anomaly and to include the term "gingival hyperplasia". Update of section 4.5 of the SPC to include possible drug-drug interaction of	23/07/2009	21/08/2009	SmPC and PL	In April 2009, a variation (EMEA/H/C/82/II/86) to the marketing authorisation for CellCept was approved to update sections 4.4 and 4.8 of the SPC to include information on pure red cell aplasia; to update section 4.8 of the SPC to include information on acquired Pelger-Huet anomaly and to include the term "gingival hyperplasia"; to

	Myfenax in combination with ciprofloxacin or amoxicillin plus clavulanic acid. The Package Leaflet was updated accordingly. These changes were made to bring Myfenax's product information in line with its reference medicinal product CellCept. Update of Summary of Product Characteristics and Package Leaflet				update of section 4.5 of the SPC to include possible drug-drug interaction of Myfenax in combination with ciprofloxacin or amoxicillin plus clavulanic acid. The Package Leaflet was updated accordingly. On 27 April 2009, the Marketing Authorisation Holder (MAH) for Myfenax was requested the submission of a Type II variation, within two months, to match the changes introduced by CellCept variation II/0086. In June 2009, the MAH submitted the requested Type II variation to bring the product information for Myfenax in line with CellCept's product information.
IB/0006	IB_17_a_Change in re-test period of the active substance	15/07/2009	n/a		
IA/0005	IA_15_a_Submission of Ph. Eur. certificate for active substance - approved manufacturer	01/07/2009	n/a		
II/0003	Inclusion (following adoption by the CHMP of a safety variation to the Marketing Authorisation of the Innovator product, CellCept) of a new warning in sections 4.4 and 4.8 of the Myfenax's (mycophenolate mofetil) summary of product characteristics (SPC) related to cases of BK virus-associated nephropathy, as well as cases of JC virus-associated progressive multifocal leukoencephalopathy (PML) reported in patients treated with mycophenolate mofetil. Update of Summary of Product Characteristics	22/01/2009	26/02/2009	SmPC	In October 2008, a variation (EMEA/H/C/82/II/84) to the marketing authorisation for CellCept was approved to update sections 4.4 and 4.8 of the SPC to implement the warning on BK virus associated nephropathy (BKVN) and JC virus associated progressive multifocal leukoencephalopathy (PML) requested by the CHMP in July 2008. In 08 October 2008, the Marketing Authorisation Holder (MAH) for Myfenax was requested the submission of a Type II variation, within two months, to match the changes introduced by CellCept variations II/0084. In November 2008, the MAH submitted the requested Type II variation to bring the SPC for Myfenax in line with CellCept's product

					information.
IB/0002	IB_34_b_01_Change in colour/flavour - Increase or addition: colouring system	02/12/2008	n/a	SmPC, Labelling and PL	
II/0001	Update of sections 4.4 and 4.8 of the Summary of product Characteristics (SPC) to include information that cases of Progressive Multifocal Leukoencephalopathy (PML), sometime fatal, have been reported in Myfenax treated patients. Section 4.6 of the SPC was also updated to include that cases of spontaneous abortion have been reported in patients exposed to Myfenax. The Package Leaflet was updated accordingly. These changes were made to bring the Myfenax's product information in line with CellCept (reference medicinal product for Myfenax). In addition, the MAH corrected the contact details for Hungary and France in the "Marketing Authorisation Holder and Manufacturer" section of the Package Leaflet. Update of Summary of Product Characteristics and Package Leaflet	26/06/2008	25/07/2008	SmPC and PL	The reference medicinal product for Myfenax is CellCept (which was first granted marketing authorisation in the EU on 14 February 1996 for the prevention of renal transplant rejection when used in combination with ciclosporin and corticosteroids, and subsequently for prevention of cardiac and hepatic transplant rejection). On 28 February 2008, two variations (EMEA/H/C/000082/II/0082 and EMEA/H/C/000082/II/0083) to the Marketing Authorisation for CellCept were approved to update sections 4.4, and 4.8 of the SPC to include information that cases of Progressive Multifocal Leukoencephalopathy (PML), sometimes fatal, have been reported in CellCept treated patients, and to update section 4.6 of the SPC to include that cases of spontaneous abortions have been reported in patients exposed to CellCept. On 11 March 2008, the Marketing Authorisation Holder (MAH) for Myfenax was requested the submission of a Type II variation, within two months, to match the changes introduced by CellCept variations II/0082 and II/0083. On 29 May 2008, the MAH submitted the requested Type II variation to bring the SPC and PL for Myfenax in line with CellCept's product information.