Trumenba

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/0043	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	23/11/2022	n/a		
IA/0044	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test	09/11/2022	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).

	procedure				
II/0037	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	22/09/2022		SmPC	Please refer to Scientific Discussion Trumenba/H/C/004051/II/0037
IB/0041	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	09/08/2022	n/a		
II/0040	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	10/06/2022	n/a		
PSUSA/10607 /202110	Periodic Safety Update EU Single assessment - meningococcal group B vaccine (recombinant, adsorbed)	10/06/2022	n/a		PRAC Recommendation - maintenance
R/0036	Renewal of the marketing authorisation.	24/02/2022	25/04/2022	SmPC and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Trumenba in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity. Trumenba is removed from the additional monitoring list. Therefore, the statement that this medicinal product is subject to additional monitoring is removed from the summary of product characteristics and the package leaflet.
IB/0039	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	06/04/2022	n/a		

N/0035	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	24/09/2021	25/04/2022	PL	
PSUSA/10607 /202010	Periodic Safety Update EU Single assessment - meningococcal group B vaccine (recombinant, adsorbed)	10/06/2021	n/a		PRAC Recommendation - maintenance
II/0032	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	06/05/2021	25/04/2022	SmPC and PL	
N/0033	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	27/11/2020	25/04/2022	PL	
PSUSA/10607 /202004	Periodic Safety Update EU Single assessment - meningococcal group B vaccine (recombinant, adsorbed)	26/11/2020	n/a		PRAC Recommendation - maintenance
II/0027/G	This was an application for a group of variations. C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH	01/10/2020	n/a		

	where significant assessment is required				
IB/0030/G	This was an application for a group of variations. B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	11/09/2020	n/a		
IB/0029/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.I.a.1.k - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - New	06/07/2020	n/a		

	storage site of MCB and/or WCB				
IB/0028/G	This was an application for a group of variations. B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits	06/07/2020	n/a		
II/0013	Update of sections 4.2, 4.4, 4.8 and 5.1 of the SmPC based on the results from two paediatric studies: B1971017 and B1971035. The MAH took the opportunity to carry out typographical and linguistic improvements throughout the PI. The Package Leaflet is updated in accordance. The RMP version 2.0 has also been submitted. In addition, the Marketing authorisation holder (MAH) took the opportunity to submit a corrected version of the final report of study B1971016, which was included in the initial marketing authorisation application. C.I.6.a - Change(s) to therapeutic indication(s) -	28/05/2020	05/11/2020	SmPC, Annex II, Labelling and PL	Please refer to Scientific Discussion Trumenba-H-C-4051-II-13

	Addition of a new therapeutic indication or modification of an approved one				
PSUSA/10607 /201910	Periodic Safety Update EU Single assessment - meningococcal group B vaccine (recombinant, adsorbed)	14/05/2020	n/a		PRAC Recommendation - maintenance
II/0023	Update of sections 4.8 and 5.1 of the SmPC in order to update the safety and immunogenicity information based on final results from study B1971033 listed as a category 3 study in the RMP (MEA007); this is a duration of immunity study to assess persistence of hSBA response for up to 48 months after completion of vaccination with Trumenba and the immunogenicity, safety, and tolerability of a booster dose of Trumenba. The RMP version 3.0 has also been submitted, including changes related to this variation, changes agreed during another ongoing variation (II-13) and editorial changes. In addition, the Marketing authorisation holder (MAH) took the opportunity to include editorial changes in Annex II, in the labelling and in the Package Leaflet. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	14/05/2020	05/11/2020	SmPC, Annex II, Labelling and PL	The results of a phase 3 study (B1971033) confirmed the duration of immunity and persistence of hSBA response for up to 48 months after completion of vaccination with Trumenba. The MAH has updated the information contained about persistence of immune and booster responses in Tables 6 and 7. For more information, please refer to the Summary of Product Characteristics.
IB/0026	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor	29/04/2020	n/a		

	changes to an approved test procedure				
IB/0025	B.II.z - Quality change - Finished product - Other variation	16/03/2020	n/a		
II/0020/G	This was an application for a group of variations. 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 B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test	06/02/2020	05/11/2020	Annex II	

	method at the site is a biol/immunol method B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS 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.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.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				
PSUSA/10607 /201904	Periodic Safety Update EU Single assessment - meningococcal group B vaccine (recombinant, adsorbed)	28/11/2019	n/a		PRAC Recommendation - maintenance
IA/0022	A.7 - Administrative change - Deletion of manufacturing sites	25/11/2019	05/11/2020	Annex II and PL	
IB/0021	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	20/11/2019	n/a		

PSUSA/10607 /201810	Periodic Safety Update EU Single assessment - meningococcal group B vaccine (recombinant, adsorbed)	16/05/2019	n/a		PRAC Recommendation - maintenance
II/0016/G	This was an application for a group of variations. B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	16/05/2019	n/a		
IB/0018	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	18/02/2019	n/a		
IB/0014/G	This was an application for a group of variations. B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test	07/01/2019	n/a		
IB/0015	C.I.11.z - Introduction of, or change(s) to, the	17/12/2018	n/a		

	obligations and conditions of a marketing authorisation, including the RMP - Other variation				
PSUSA/10607 /201805	Periodic Safety Update EU Single assessment - meningococcal group B vaccine (recombinant, adsorbed)	29/11/2018	n/a		PRAC Recommendation - maintenance
II/0011	Update of section 4.4 of the SmPC in order to add a warning about an increased risk of invasive disease caused by Neisseria meningitidis serogroup B in persons with complement deficiencies or using concomitant treatments inhibiting terminal complement activation C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	08/11/2018	18/06/2020	SmPC	The CHMP considered that the post marketing data provided by the MAH strongly suggest that after successful vaccination with a meningococcal vaccine, the risk of meningococcal disease is increased during the use of eculizumab. The product information has therefore ben updated to reflect that persons with familial complement deficiencies (for example, C5 or C3 deficiencies) and persons receiving treatments that inhibit terminal complement activation (for example, eculizumab) are at increased risk of invasive disease caused by Neisseria meningitidis serogroup B, even if they develop antibodies following vaccination with Trumenba.
IB/0012	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	16/10/2018	18/06/2020	SmPC	
T/0009	Transfer of Marketing Authorisation	11/07/2018	27/09/2018	SmPC, Labelling and PL	
II/0008	B.II.d.2.c - Change in test procedure for the finished product - Substantial change to or replacement of a	05/07/2018	n/a		

	biol/immunol/immunochemical test method or a method using a biol. reagent or replacement of a biol. reference preparation not covered by an approved protocol				
PSUSA/10607 /201711	Periodic Safety Update EU Single assessment - meningococcal group B vaccine (recombinant, adsorbed)	14/06/2018	n/a		PRAC Recommendation - maintenance
IAIN/0007/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.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	11/04/2018	27/09/2018	Annex II, Labelling and PL	
IB/0006	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	09/04/2018	n/a		
IB/0004	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	15/02/2018	n/a		
II/0002/G	This was an application for a group of variations.	14/12/2017	27/09/2018	SmPC and PL	A cumulative review of cases of syncope occurring in association with administration of Trumenba showed that

	Update of section 4.4 of the SmPC in order to add a warning on syncope based on review of post-marketing data. Update of section 4.8 of the SmPC in order to update the safety information regarding booster vaccination based a review of adverse events data reported in the interim clinical study report (B1971033). The package leaflet is updated accordingly. In addition, the MAH took the opportunity to make a clarification on interchangeability of Trumenba in section 4.2 of the SmPC and to update the list of local representatives in the package leaflet. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				as with other injectable vaccines, syncope (fainting) can occur in association with administration of Trumenba. Procedures should be in place to avoid injury from fainting. The review of adverse events data reported in the interim clinical study report (B1971033) showed that adverse reactions following booster vaccination in 268 subjects aged 15 to 23 years were similar to adverse reactions during the primary Trumenba vaccination series approximately 4 years earlier. Additionally, the MAH took the opportunity to clarify that there are no data available on the interchangeability of Trumenba with other meningococcal group B vaccines to complete the vaccination series.
IB/0003	B.II.c.4.a - Change in synthesis or recovery of a non-pharmacopoeial or novel excipient - Minor change	14/11/2017	n/a		
IA/0001	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	08/09/2017	n/a		