



Qdenga

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
PSUSA/11034 /202308	Periodic Safety Update EU Single assessment - dengue tetravalent vaccine (live, attenuated) [Dengue virus, serotype 2, expressing Dengue virus, serotype 1, surface proteins, live, attenuated / Dengue virus, serotype 2, expressing Dengue virus, serotype 3, surface proteins, live, attenuated /	21/03/2024	17/05/2024	SmPC	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s) for PSUSA/11034/202308.

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).



	Dengue virus, serotype 2, expressing Dengue virus, serotype 4, surface proteins, live, attenuated / Dengue virus, serotype 2, live, attenuated.]				
WS/2618	<p>This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.</p> <p>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)</p>	18/04/2024	n/a		
WS/2575	<p>This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.</p> <p>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</p>	14/12/2023	n/a		
IG/1669/G	<p>This was an application for a group of variations.</p> <p>B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process</p> <p>B.II.c.3.z - Change in source of an excipient or reagent with TSE risk - Other variation</p> <p>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test</p>	25/10/2023	n/a		

	<p>procedure</p> <p>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure</p>				
WS/2522/G	<p>This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.</p> <p>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</p> <p>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</p>	19/10/2023	n/a		
PSUSA/11034 /202302	<p>Periodic Safety Update EU Single assessment - dengue tetravalent vaccine (live, attenuated) [Dengue virus, serotype 2, expressing Dengue virus, serotype 1, surface proteins, live, attenuated / Dengue virus, serotype 2, expressing Dengue virus, serotype 3, surface proteins, live, attenuated / Dengue virus, serotype 2, expressing Dengue virus, serotype 4, surface proteins, live, attenuated / Dengue virus, serotype 2, live, attenuated.]</p>	28/09/2023	n/a		PRAC Recommendation - maintenance

IB/0009	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	09/08/2023	n/a		
IB/0006	B.II.f.1.e - Stability of FP - Change to an approved stability protocol	06/07/2023	n/a		
IB/0005/G	This was an application for a group of variations. B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation B.II.b.4.f - Change in the batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased/decreased without process change (e.g. duplication of line)	23/06/2023	n/a		
IB/0003	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	28/04/2023	n/a		
IB/0002/G	This was an application for a group of variations. B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation 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	12/04/2023	n/a		

	<p>intermediate used in the manufacture of the AS or manufacturer of a novel excipient</p> <p>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</p> <p>B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS</p>				
IB/0001/G	<p>This was an application for a group of variations.</p> <p>B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process</p> <p>B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size</p>	15/03/2023	n/a		