



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Dengue Tetravalent Vaccine (Live, Attenuated) Takeda

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency's update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification ¹ issued on	Commission Decision Issued ² / amended on	Product Information affected ³	Summary
Change of Scientific Opinion	Change of Scientific Opinion Holder (Art. 58)	28/11/2025		SmPC, Labelling 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).



Holder - EMA/T/0000310352	of Regulation (EC) No 726/2004)				
Variation type IA / EMA/VR/0000290025	B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.b Addition of a new test(s) and limits - Refused	14/11/2025	N/A		
Variation type IB / EMA/VR/0000265582	<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.II.b.4 Change in the batch size (including batch size ranges) of the finished product - B.II.b.4.a Up to 10-fold compared to the originally approved batch size - Accepted</p> <p>B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.a Minor change in the manufacturing process - Accepted</p> <p>B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.a Minor change in the manufacturing process - Accepted</p> <p>B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.a Minor change in</p>	04/09/2025	N/A		

	<p>the manufacturing process - Accepted</p> <p>B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.a Minor change in the manufacturing process - Accepted</p> <p>B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.a Minor change in the manufacturing process - Accepted</p> <p>B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.a Minor change in the manufacturing process - Accepted</p> <p>B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.z Other changes - Accepted</p>				
Variation type IA / EMA/VR/0000268247	A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release -	27/05/2025	N/A		

	Accepted				
Variation type IB / EMA/VR/0000258002	<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.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.k New storage site of Master Cell Bank and/or Working Cell Banks - Accepted</p> <p>B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.k New storage site of Master Cell Bank and/or Working Cell Banks - Accepted</p>	08/05/2025	N/A		
Variation type IA_IN / EMA/VR/0000246644	B.I.b.1 Change in the specification parameters and/or limits of an active	26/03/2025	N/A		

	substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.a Tightening of specification limits for medicinal products subject to Official Control Authority Batch Release - Accepted				
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