



BIMERVAX

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
II/0010	Submission of the final report from study HIPRA-HH-5, "A phase III, open label, single arm, multi-center, trial to assess the safety and immunogenicity of a booster vaccination with a recombinant protein RBD fusion heterodimer candidate (PHH-1V) against SARS-COV-2, in adults vaccinated against COVID-19". The RMP version 1.4 has also been submitted.	11/04/2024	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).



	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority				
II/0007/G	<p>This was an application for a group of variations.</p> <p>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</p> <p>B.II.e.5.c - Change in pack size of the finished product - Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, including biological/immunological medicinal products</p> <p>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</p> <p>B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes</p>	07/03/2024		SmPC, Labelling and PL	Section 2, 6.3, 6.4, 6.5 and 6.6 of the SmPC have been updated. The Labelling and PL have also been updated accordingly.
II/0006	Submission of the final report from study HAN-01 listed as a category 3 study in the EU-RMP. This is a phase IIb, randomised, controlled, observer-blinded	18/01/2024	n/a		

	<p>study to evaluate safety and immunogenicity of a recombinant protein RBD fusion dimer candidate vaccine (PHH-1V) against SARS-CoV-2 in adult healthy volunteers.</p> <p>C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority</p>				
IB/0011/G	<p>This was an application for a group of variations.</p> <p>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</p> <p>A.3 - Administrative change - Change in name of the AS or of an excipient</p>	20/12/2023		SmPC, Labelling and PL	
II/0005/G	<p>This was an application for a group of variations.</p> <p>B.I.b.1.f - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Change outside the approved specifications limits range for the AS</p> <p>B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation</p>	23/11/2023	n/a		
II/0002	<p>Submission of the final study report HIPRA-HH-1 listed as a category 3 study in the RMP. This is a phase I/IIa study to evaluate safety and</p>	09/11/2023	n/a		<p>Not applicable</p> <p>For more information, please refer to the Summary of Product Characteristics.</p>

	<p>immunogenicity of PHH-1V against SARS-COV-2 in adult healthy volunteers.</p> <p>C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority</p>				
II/0008	<p>Submission of the final report from study HIPRA-HH-10 listed as a category 3 study in the RMP. This is a phase 2b, double-blind, randomised, active-controlled, multi-centre, non-inferiority trial to assess immunogenicity and safety of a booster vaccination with a recombinant protein RBD fusion dimer candidate (PHH-1V) against SARS-CoV-2, in adults fully vaccinated with adenovirus vaccine against COVID-19.</p> <p>C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority</p>	12/10/2023	n/a		
IB/0003	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	18/08/2023	n/a		
IB/0001	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	29/06/2023		SmPC and PL	To extend the shelf-life of the biological finished product, in accordance with the approved stability protocol, from 1 year to 15 months when stored at 2 °C – 8 °C.