HIPRA HUMAN HEALTH, S.L.U
Avda. la Selva. 135, 17170 Amer (Girona), Spain
Tel.: (34) 972 43 06 60 · hipra@hipra.com · www.hipra.com

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Amer, 5th February 2025

SUBJECT: Withdrawal of Type II variation B.I.a.6.a – Changes to the active substance of a vaccine against human coronavirus - for **BIMERVAX JN.1**, adapted PHH-1V101 vaccine.
Product reference number: H0006058
Procedure number: EMEA/H/C/006058/II/0016

Dear Sir/Madam,

I would like to inform you that, at this time, the Marketing Authorisation Holder (MAH), HIPRA Human Health, S.L.U., has decided to withdraw the application for the Type II variation concerning changes to the active substance of a vaccine against human coronavirus - for BIMERVAX JN.1, adapted PHH 1V101 vaccine.

This decision to withdraw is based on the following reasons:

The technical information required to address the queries raised in the 3rd Request for Supplementary Information issued on November 14, 2024, requires the manufacturing of new drug substance (DS) and drug product (DP) batches, as well as the generation of extensive data and additional information, which would entail several months of work. Since this variant was recommended for the autumn of 2024 vaccination campaign, there is no longer commercial interest in pursuing it for the upcoming campaign. Consequently, the decision has been made to focus efforts on the future recommended variant rather than on the previous one.

Should you require any further information, please do not hesitate to contact us.

Yours sincerely,