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Date: 1 September 2023

Harald Enzmann
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

**Subject:** Withdrawal of SKYCovion, 25 micrograms/dose, emulsion and suspension for emulsion for injection - **EMEA/H/C/005998** 

Dear Dr. Harald Enzmann,

I would like to inform you that, at this point of time, SK Chemicals GmbH (Applicant on behalf of SK bioscience Co., Ltd.) has taken the decision to withdraw the application for Marketing Authorisation of SKYCovion, which was intended to be used for active immunisation to prevent Coronavirus disease (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

This withdrawal is based on commercial reasons.

The withdrawal will have no impact on ongoing clinical trials with SKYCovion, and the follow-up activities will continue as planned.

We would like to take this opportunity to thank the (Co-)Rapporteurs, Committee for Medicinal Products for Human Use (CHMP) and European Medicines Agency (EMA) for their time and consideration for this application.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

I agree for this letter to be published on the EMA website.

Yours sincerely,

SK Chemicals GmbH Mergenthalerallee 77 65760 Eschborn