Janssen Pharmaceutica NV
Turnhoutseweg 30
B-2340 Beerse, Belgium

Removal of COVID-19 Janssen vaccine lot XD955

NOTIFICATION LETTER

Dear Customer,

We like to bring to your attention that Janssen (a company of Johnson & Johnson) has announced the removal of COVID-19 vaccine lot XD955, which was released within the European Union and contains drug substance (active ingredient) manufactured at the Emergent Manufacturing Operations Baltimore LLC, Maryland, US, facility.

Batch number	Manufacturing date	Expiry Date (dd/mm/yyyy)	Market of destination
XD955	Mar/21	28/02/2023	EEA

The above decision has been taken supporting the class II Rapid Alert instructions, generated by the Belgian Authorities (FAGG) on 12APR2022, proposing a recall of the COVID-19 Janssen vaccine, which used drug substance from the Emergent site. This Rapid Alert is following the issuance of a Statement of Non-Compliance with GMP for the site involved (Emergent). Although there have been no changes to the quality, safety and efficacy of the vaccines, given the current reduced demand and broader availability of COVID-19 vaccines in Europe, we have decided to remove the specified batch containing Emergent drug substance from the market. We continue to communicate with our Health Authorities and other stakeholders to provide sufficient information and guidance.

In this context, we would appreciate immediate action on this letter by returning the completed appendices 1 & 2, as soon as possible.
Please confirm the receival of the briefing package of the COVID-19 Janssen vaccine removal including the notification to all involved governmental handlers and vaccine handlers (ref Appendix 1).
Please inform us of the quantity of the subject batch received from us and the quantity of the subject batch removed and quarantined from the involved governmental handlers and vaccine handlers (ref Appendix 2).

We sincerely thank you for your assistance in this matter.

Kind regards,

GENEVIEVE MEEUS

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Geneviève Meeus, Site Quality Head
Janssen Pharmaceutica NV, Beerse, Belgium