

FOI 23/033

1st February 2022

Dear

Thank you for your recent FOI request received 12 January 2023, where you asked for the following:

“Do you have an iDAP report for the smallpox vaccine? We require information regarding the Jynneos”

The Jynneos vaccine helps protect against monkeypox, smallpox, and other diseases caused by orthoropoxviruses.

Further to your request, please find attached Vaccine Analysis Print (VAP) for Jynneos. Please note that this VAP relates only to reports where the specific brand name has been provided by the reporter and is inclusive of any indication, brand names and indications for use are not mandatory for Yellow Cards and are not always provided. This VAP contains complete data for all UK spontaneous suspected adverse reactions, or side effects, including those which are associated with a fatal outcome. Please refer to the attached information sheet for guidelines on how to interpret this VAP.

When considering the attached spontaneous ADR data, it is important to be aware of the following points:

- A reported reaction does not necessarily mean it has been caused by the vaccine, only that the reporter had a suspicion it may have. Each year, millions of doses of vaccinations are given in the UK alone, and when any vaccine is administered to large numbers of people, some recipients will inevitably experience illness following vaccination. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.
- Additionally, the number of reports received via the Yellow Card scheme does not directly equate to the number of people who suffer adverse reactions and therefore cannot be used to determine the incidence of a reaction or compare the safety profile of different vaccines.

I hope the information provided is helpful, but if you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team,

Vigilance and Risk Management of Medicines Division