Medicines & Healthcare products Regulatory Agency

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

[redacted]

20th January 2024

Dear [redacted]

FOI 24/083

Thank you for your Freedom of Information request dated 24 January 2024, where you asked for:

1. Adverse reactions to the Vaxelis Vaccine which is now included as one of the two 6-1 vaccines since it has been included as part of the schedule.
2. Deaths reported from the Vaxelis Vaccine.
3. The clinical trial data/ reports that were used for it to be accepted as a suitable vaccine.

Requests 1 and 2

I can confirm that the MHRA does hold this information. Currently, the MHRA has received 6 UK spontaneous suspected adverse reaction reports associated with the Vaxelis vaccine up to and including the 12th February 2024, none of which include a fatal outcome. Please find attached a Vaccine Analysis Print (VAP) which lists all the reactions reported to the MHRA where the Vaxelis vaccine has specifically been reported. Also attached is a guidance sheet which provides you with further information on how to interpret the print.

As these data do not necessarily refer to proven side effects, you should refer to the product information leaflet (PIL) and the Summary of Product Characteristics (SPC) which can be found here: https://www.medicines.org.uk/emc/product/12264 for details on the known possible side effects of the Vaxelis vaccine.

When considering the attached spontaneous 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 routine 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. The fact that symptoms occur after use of a vaccine or medicine, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by it. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.

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- 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. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular medicine or vaccine and may be stimulated by promotion and publicity.

Request 3
Vaxelis suspension for injection in pre-filled syringe, PLGB 50692/0001
Vaxelis suspension for injection in vial, PLGB 50692/0002

The Marketing Authorisations for these products were converted from EC Centralised authorised products (CAP) to GB marketing authorisations on 01 January 2021.

The European Public Assessment report (EPAR) has been published. The clinical trial data that were assessed as part of the Marketing Authorisation applications are detailed in the EPAR, which is available using the following link Vaxelis, Common name: diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and haemophilus type b conjugate vaccine (adsorbed) (europa.eu).

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