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United Kingdom

Ms Neethling
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Ref: FOI 19/322 - Safety assessments and clinical trials of Hepatitis B vaccine for infants

Dear Ms Neethling,

Many thanks for your Freedom of Information request dated 17th July 2019 where you requested:

- Clinical trials conducted to assess the short- and long-term safety of administering the Hepatitis B vaccine to infants under 16 weeks old and the rationale behind this decision - this may include minutes of meetings, for example with the Joint Committee on Vaccination and Immunisation (JCVI)
- Statistics on the adverse effects documented since the introduction of this vaccine to the UK infant immunisation schedule

Further to your request, please follow the link below to find information regarding the assessment decisions made in the grant of Infanrix Hexa. The application for Infanrix Hexa was assessed by the European Medicines Agency (EMA) via the centralised procedure. The centralised procedure essentially allows applicants to obtain a licence that is valid throughout the EU. This involves submitting an application directly to the European Medicines Agency (EMA) where it is assessed by the Committee for Medicinal Products for Human Use (CHMP). We have attached the initial European Public Assessment Report (EPAR) provided by the EMA in 2005 for your convenience: https://www.ema.europa.eu/en/medicines/human/EPAR/infanrix-hexa

We have also attached both the Joint Committee on Vaccination and Immunisation (JCVI) minutes from 2014 where the inclusion of Infanrix Hexa into the immunisation schedule was discussed, and a guidance document from Public Health England regarding the inclusion of hepatitis B vaccine in the routine immunisation schedule.

Regarding your request for reports of the adverse effects, it is important to be aware of the following points, which you may be familiar with from previous requests:

- The inclusion of a report on our Adverse Drug Reaction (ADR) database does not necessarily mean that the events described were caused by the vaccination, only that the reporter had a suspicion it may have or it had a close temporal relationship to the administration of the vaccine. Each year, millions of doses of vaccines are given in the UK alone and when any vaccine is administered to very large numbers of people, some recipients will inevitably experience illness following vaccination. The fact that symptoms occur after use of a vaccine and are reported via the Yellow Card Scheme does not in itself mean that they are proven to have been caused by the vaccine. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.

- Furthermore, the number of reports received should not be used as a basis for determining incidence of a reaction as neither the total number of reactions occurring, nor the number of patients receiving the vaccine is included within the data. These reports should also be considered in the context that such vaccinations are widely used when part of the routine schedule. ADR reporting rates are influenced by the seriousness

of ADRs, their ease of recognition, the extent of use of a particular medication, and may be stimulated by promotion and publicity.

Any emerging evidence relating to possible risks associated with vaccines and medicines is carefully reviewed and if appropriate, regulatory action would be taken if any serious risks were confirmed.

As this data does not necessarily refer to proven side effects, you should refer to the product information for details on the possible side effects of the vaccine here: https://www.medicines.org.uk/emc/product/2586.

The MHRA have received a total of 309 UK spontaneous suspected ADR reports in association with DTaP/IPV/Hib/HepB vaccine, otherwise known as the 6 in 1 vaccine or Infanrix Hexa, up to and including 18th July 2019. Please find attached a drug analysis print (DAP) for the 6 in 1 vaccine which provides all spontaneous suspected ADRs which have been reported for this vaccine to the MHRA, via the Yellow Card Scheme. Please refer to the attached guidance sheet for further instructions on how to interpret the DAP. Please note that these reports may contain more than one suspect vaccination/medication. Furthermore, whilst the 6 in 1 vaccine may be reported as suspect, this does not necessarily mean the vaccination was given as part of the routine schedule as the vaccine is available privately.

If you have a query about the information provided, please reply to this email.

Yours sincerely,

FOI Team,
Vigilance and Risk Management of Medicines Division