EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Dr Loretta Bolgan
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3 March 2017
EMA/148469/2017
Deputy Executive Director

Dear Dr Bolgan,

Subject: **Infanrix hexa (diphtheria (d), tetanus (t), pertussis (acellular, component) (pa), hepatitis b (rdna) (hbv), poliomyelitis (inactivated) (ipv) and haemophilus influenzae type b (hib) conjugate vaccine (adsorbed)), ASK-27205 – Release letter to the requester – batch 1**

Thank you for your request for access to documents received on 6th February 2017, for which the procedure was initiated on 7th February 2017, in which you apply for copies of the following documents concerning the above mentioned product, in particular:

- Infanrix Hexa PSUR 2011-2014 appendices and tables.

Your request has been handled in accordance with Article 7 of Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents (the Regulation)[1] and Article 6 of the Rules for the Implementation of Regulation (EC) No 1049/2001 on access to European Medicines Agency documents (the Agency rules)[2]. Moreover, it has been assessed pursuant to Article 4 of the Regulation, Article 3 of the Agency rules and the European Medicines Agency policy on access to documents related to medicinal products for human and veterinary use (the Agency policy)[3].

As it concerns a large number of documents, and the Agency has to examine each document individually to ensure that no private or public interests are being compromised, we are not in a position to fulfil your request immediately. Therefore the Agency endeavours to provide you with sets of documents at certain intervals. This decision is in line with the principle set out in our policy which states the Agency will apply the principle of proportionality in order to avoid the core business tasks of the Agency and its performance being jeopardised by the administrative workload related to activities conducted by the Agency in accordance with the Regulation.

The **first batch** includes the following document:

- • Infanrix Hexa PSUR 2011-2014 appendices_Part1.

Based on the above assessment, the Agency considers that access to the requested document in the first batch should be granted.

However, the document has been redacted as follows:

1 OJ L 145, 31.5.2001, P. 43-48
2 EMEA/MB/203359/2006 Rev 1 Adopted
3 EMA/110196/2006 of 30 November 2010

- In accordance with Article 4(1)(b) of the Regulation and the European Union legislation regarding the protection of personal data, all protected personal data was redacted in order to avoid that the disclosure of the document would undermine the privacy and integrity of any individual;
- In accordance with Article 4(2) 1st indent of the Regulation, commercially confidential information, such as sales per country, was redacted in order to avoid that the disclosure of the document would undermine the protection of commercial interests of a natural or legal person, including intellectual property.

You may submit a confirmatory application in writing against this decision to the European Medicines Agency, within 15 working days of the release of the document. Should you wish to do so, you are kindly invited to provide your reasons against our decision to redact parts of the document at this stage, or detail any other considerations in terms of public interest, which you believe should be taken into account by the Agency in adopting a final decision.

Once your confirmatory application has been received, you will be informed of the outcome within 15 working days (extendable in exceptional circumstances), either granting you access to redacted parts of the document or confirming refusal of access. In the latter case, you will also be informed of any further appeal routes open to you to consider.

The confirmatory application should be submitted using the on-line request form, available on the European Medicines Agency website, under the following location:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/landing/ask_ema_landing_page.jsp&mid=WC0b01ac05806499f0

Please use the ASK Procedure Number mentioned in the subject line in any correspondence related to this request.

The document concerned will be sent to you via Eudralink no sooner than 10 working days after the legal consultation stage with the Marketing Authorisation Holder has been finalised. Please note that this document is made available to you in order to provide you with access in accordance with the Regulation and the Agency rules.

In that regard, please visit the Agency's public website to know more about the applicable copyright and limited reproduction notices.

Please note that, according to Article 16 of the Regulation, the release of the requested document in accordance with this Regulation is without prejudice to any existing rules on copyright which may limit a third party's right to reproduce or exploit released documents. The European Medicines Agency shall assume no liability for any unlawful or unauthorised use, disclosure or reproduction of these documents.

If you have any queries on the enclosed, please do not hesitate to contact the Access to Documents Coordinator for this request, Sonia Espejo Brea, e-mail: Sonia.brea@ema.europa.eu, using the ASK Procedure Number mentioned in the subject line.

Yours sincerely,

Dr Anne-Sophie Henry-Eude
Head of Documents Access and Publication Service
Office of the Deputy Executive Director

Ruben Pita
Legal Administrator
Legal Department