Direct Healthcare Professional Communication

<Date>

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*)]: Packaging issue potentially impacting the sterility of needle softpacks of *Infanrix hexa.*

Dear Healthcare Professional,

GlaxoSmithKline Biologicals SA in agreement with the European Medicines Agency and *<the National Competent Authority>* would like to inform you of the following:

SUMMARY

- **A packaging issue potentially impacting the sterility of needle softpacks provided with pediatric vaccine *Infanrix hexa*.**
- **Neither the syringe nor its content are impacted by this packaging defect.**
- **In scope of the packaging issue are needles supplied with the 10x dose presentation pack of *Infanrix hexa* (10 vials + 10 pre-filled syringes + 20 needles).**
- **The identified defect is a minor hole with a diameter of 1 mm, found on the paper section of the needle softpack.**
- **This hole could compromise the sterility of the enclosed needle. Because the defect is not easily detectable, and as a precautionary measure, GSK recommends that the Healthcare Professionals to:**
  - **Discard the needle packs from all the boxes of the affected batches to exclude any potential safety issues for patients**
  - **Use other available needles for vaccine administration, of the same gauge and length as the discarded ones**
  - **Share the information with relevant healthcare personnel under your supervision**

BACKGROUND

Infanrix hexa is indicated for primary and booster vaccination of infants from the age of 6 weeks and toddlers against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and disease caused by *Haemophilus influenzae* type b.

GSK have identified a packaging issue potentially impacting the sterility of needle packs in vaccine batches listed below. Neither the syringe nor its content are impacted by this packaging defect and there is no impact on product efficacy.

The identified defect is a minor hole, with a diameter of 1 mm, found on the paper section of the needle softpack. Typically, this impacts one needle out of 20 from an affected pack. Not all packs are impacted.

This hole could compromise the sterility of the enclosed needle, and because the defect is not easily detectable, as a precautionary measure GSK recommends that HCPs:

- Discard the needle packs from all the boxes of the affected batches to exclude any potential safety issues for patients. Carefully check the impacted batch numbers listed below.
- Use other available needles for vaccine administration, of the same gauge *(<add market specific details: 23G or 25G>*) and length *(<add market specific details: 5/8 inch or 1 inch (16mm or 25mm)*) as the discarded ones.

  <the National Competent Authority> may also provide guidance on needle selection based on patient age, weight, medical assessments, route of administration, and product availability.>

- Share the information with relevant healthcare personnel under your supervision.

The situation is expected to last until the consumption of the impacted batch with the latest expiry date: *<add market specific detail - batch number and expiry date of the last market specific batch>.*

The root cause of the packaging defect has been identified and the issue has been corrected for future batches.

Call for reporting

Healthcare Professionals are reminded to report any suspected adverse reactions in accordance with the national spontaneous reporting system *<include the details (e.g. name, postal address, fax number, website address>*, including batch/Lot number if available.

Company contact point

For further information or questions, or if you require compensation for replacement needles, please contact *<local contact point details, including telephone number and/or email>.*

List of batches

<include the details of market specific batches >

Vaccine	Batch number	Batch Expiry date	Presentation details

DHPC COMMUNICATION PLAN	
Medicinal product(s)/active substance(s)	**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) Note: This packing defect also impacts products registered in EU via Mutual Recognition Procedure (*Boostrix, Boostrix IPV, Infanrix, Infanrix Polio and Infanrix Polio Hib*). For your information, a list of the impacted vaccines and markets is provided in Annex 1 to this Communication plan
Marketing authorisation holder(s)	GlaxoSmithKline Biologicals S.A
Safety concern and purpose of the communication	To make healthcare professionals aware of a packaging issue potentially impacting the sterility of needle packs in batches of *Infanrix hexa* (10x dose presentation packs – 10 vials + 10 pre-filled syringes + 20 needles). The purpose of the communication is to advise HCP to discard all the needle packs from impacted batches and to use replacement needles of the same specification as the discarded needles.
DHPC recipients	*A specific local distribution target will be defined and agreed with the National Authority.* This DHPC is targeted for distribution to all identified physicians/ physicians and pharmacists / specialists / physician assistants / nurse practitioners / other healthcare staff. - Other healthcare staff includes <<list>>.
Member States where the DHPC will be distributed	For vaccine *Infanrix hexa* registered via EU Centralised Procedure: in markets Czechia, Ireland, Italy, Norway, Slovakia and Spain. A list is provided in Annex 2 to this communication plan. GSK also propose to distribute the EMA approved DHPC for MRP products *Boostrix, Boostrix IPV, Infanrix, Infanrix Polio and Infanrix Polio Hib* in markets Spain, Denmark, Norway, Slovakia, Italy, Portugal. A list is provided in Annex 1 to this communication plan

Timetable	Date
DHPC and communication plan (in English) agreed by CHMP	23 September 2024
Submission of translated DHPCs to the national competent authorities for review	26 September 2024
Agreement of translations by national competent authorities	3 October 2024
Dissemination of DHPC	10 October 2024