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PLEASE READ
IMPORTANT MEDICINE SAFETY INFORMATION
APPROVED BY THE HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

GlaxoSmithKline (Ireland) Limited
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Direct Healthcare Professional Communication

10th October 2024

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 Health Products Regulatory Authority would like to inform you of the following:

SUMMARY

- A packaging issue potentially impacting the sterility of needle softpacks provided with paediatric 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 Healthcare Professionals:
  - 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
  - There is no action recommended for vaccines already administered
  - Share the contents of this communication 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 Healthcare Professionals:

- 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 (*25G)* and length (25mm) as the discarded ones (25G1).
- There is no action recommended for vaccines already administered.
- Share the contents of this communication 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: A21CE469C 31-Oct-2027.

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

Call for reporting
Adverse events should be reported directly to the Health Products Regulatory Authority (HPRA) on their website: www.hpra.ie. Adverse events should also be reported to GlaxoSmithKline on 1800 244 255.

A copy of this Dear Healthcare Professional letter may be found on the website of the HPRA and on www.medicines.ie/dhpc.

Company contact point
Please contact GSK Customer Services for replacement needles on 01-2571423 or gskpharmacs@prl.ie.
Please contact GSK Medical Information on 1800 244 255 with any medical information queries.

List of batches

Vaccine	Presentation details	Batch number	Batch Expiry date
Infanrix hexa (EU/1/00/152/006)	Powder and Suspension for Suspension for Injection, 10 doses (0.5ml)	A21CE469C	31-Oct-2027
		A21CE460C	30-Sep-2026
		A21CE458B	31-May-2027
		A21CE376A	28-Feb-2027
		A21CE437A	31-May-2027

Yours sincerely,

Electronically signed by: Eavan Daly
Reason: I am signing for the reasons as stated in the document.
Date: Oct 8. 2024 09:44 GMT+1

Eavan Daly BSc(Hons), PhD, Dip MP, PG Cert PH
Country Medical Director

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