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30 April 2015

Late implementation of Patient Information Leaflet (PIL) safety update in the locally available *Infanrix hexa* presentation

Dear Healthcare Professional,

This letter is being sent in agreement with the Medicines Authority to inform you of the following:

SUMMARY

- **A Patient Information Leaflet (PIL) safety update will be implemented late in the locally available *Infanrix hexa* presentation**
- **The pending PIL safety update includes an additional statement in the Warnings & Precautions for parents to seek advice from their doctor if their child becomes unresponsive or experiences seizures after vaccination with *Infanrix hexa***
- **Late implementation of this safety update is in view of supply issues. Supply of the presentation with the older version of the PIL will continue to be available on the local market. Updated pack is expected to be available in Malta by end of 2015**

A Patient Information Leaflet (PIL) safety update will be implemented late in the locally available *Infanrix hexa* presentation. The safety update in scope (European Medicines Agency Reference: EMEA/H/C/296/II/154) had already been implemented in the local Summary of Product Characteristics (SPC) and includes information regarding observed increased reporting rates of convulsions (with or without fever) and hypotonic hyporesponsive episode (HHE) with concomitant administration of *Infanrix hexa* and Prevenar 13.

In view of this safety update, the PIL was due to be updated with the following information in the Warnings & Precautions section:
If your child should become unresponsive or experience seizures (fits) after the vaccination, please contact your doctor immediately. See also Section 4: 'Possible Side Effects'.

As per local legislative requirements, the deadline of implementation of the new PIL was due on the 24th of April 2015. However, in view of supply issues of the updated *Infanrix hexa* presentation and to ensure continuity of supply to patients in Malta, it has been agreed with the Medicines Authority to continue to supply the *Infanrix hexa* presentation with the older version of the PIL. The updated pack is expected to be available in Malta by end of 2015.

FURTHER INFORMATION

Full prescribing information can be obtained from representatives of GlaxoSmithKline at:
GlaxoSmithKline (Malta) Limited, 1, 1st floor, de la Cruz Avenue, Qormi QRM 2458, Malta (Tel. 21 238131) or can be accessed through the European Medicines Website (http://www.ema.europa.eu/ema/).

CALL FOR REPORTING

Please do not forget to report any suspected adverse events to GlaxoSmithKline (Malta) Limited, 1, 1st floor, de la Cruz Avenue, Qormi, QRM 2458; by phone to 21238131. Any suspected adverse reaction and medication errors can also be reported via the national Adverse Drug Reactions (ADRs) reporting system. Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and posted to Medicines Authority Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gżira GŻR 1368, MALTA, or sent by email to postlicensing.medicinesauthority@gov.mt. When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset and treatment dates.

Yours sincerely

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