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GLAXOSMITHKLINE INFORMATION ADVISORY

Title: Potential fading of lot-specific information on syringe and vials of all GSK vaccine products

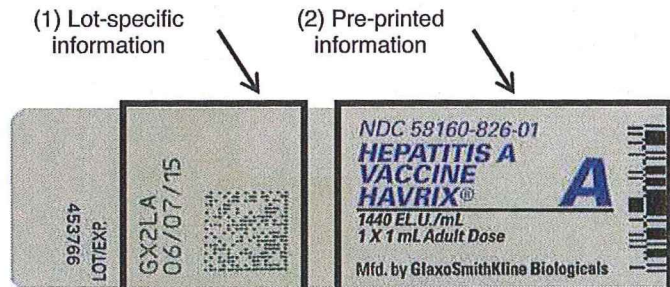
Date: September 9, 2014

Dear Health Care Provider,

GlaxoSmithKline (GSK) would like to inform you that there is a potential for fading of the 2D datamatrix code, lot number and expiration date on syringe and vial vaccine labels for all GSK vaccines over time.

The labels on syringes and vials consist of two areas:

- (1) Lot-specific information, which may fade over the shelf-life of the product.
- (2) Pre-printed information, which is not impacted by this issue.



Please note that, although a Havrix label is used in the above illustration, this issue may affect all GSK vaccine labels in the US.

Key Messages

Fading over time of the lot-specific information on syringe and vial labels has been observed upon routine inspection of vaccine containers retained by GSK. A low rate of nonscannable 2D bar codes and only one instance of an unreadable (by the human eye under normal lighting conditions) lot number has been observed in GSK retained samples. In contrast, GSK has not received any reports of illegibility on visual inspection and has received only one report of non-scannable 2D bar code, in the approximately 42 million doses of potentially affected product on the US market to date.

Syringes and vials are distributed in cartons that contain the same lot-specific information. The information printed on cartons is not impacted by this issue

Given the typical re-order schedule and current supply considerations, most products affected are likely to be used before fading leads to illegible or non-scannable labels.

However, GSK is providing this alert so that you have the contact information to receive immediate support, in the event you do encounter this issue.

Importantly, this labeling issue has no impact on the quality of the vaccine product (stability, potency, efficacy, or purity).

Action Being Taken by GlaxoSmithKline

GSK is taking no action with products on the market at this time, but is developing a new label for future products that will be implemented as soon as possible. GSK Vaccine Service Center will be available to address concerns. The hours of operation are 8AM - 6PM EST.

Action required from Health Care Providers

GSK recommends that you continue to inspect the lot number and expiry date on each vaccine syringe or vial prior to use as would normally be done in the course of routine practice. Please contact the GSK Vaccine Service Center at 1-866-475-8222 if you note any labels that have become unreadable by visual inspection or 2D bar code scanner.

Contact(s) for Further Information/Questions

For all questions, please contact:

Vaccine Service Center at 1-866-475-8222



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