GlaxoSmithKline
Scientific Office

جلاكسو سميث كلاين
المكتب العلمي

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December 10th , 2013

Subject: Mencevax ACWY™ and antibody persistence

Dear Healthcare Professional:

The current Prescriber Information for Mencevax ACWY™ states an antibody persistence of at least 3 years. New data suggest that among individuals 11-55 years of age who were vaccinated two years earlier with Mencevax ACWY™, immunity to serogroups W-135 and Y persists only in 24.0% and 44.0%, respectively.

Summary:

- New persistence data for *Mencevax ACWY™* are now available
- The immunity to serogroups W-135 and Y in individuals 11-55 years of age who were vaccinated two years earlier with *Mencevax ACWY™* is 24.0% and 44.0%, respectively.
- Limited data showed a waning of serum bactericidal antibody titres against serogroup A one year post-vaccination when using human complement in the assay (hSBA).
- Individuals remaining at high risk of exposure to serogroups A, W-135 and Y should be considered for revaccination according to local recommendations.

Further information on the safety concern:

GlaxoSmithKline (GSK) Vaccines would like to inform you about available clinical data relevant to the antibody persistence of *Mencevax ACWY™*.

During the clinical development of another meningococcal vaccine manufactured by GSK, *Mencevax ACWY™* was used as a comparator vaccine. New antibody persistence data for *Mencevax ACWY™* are now available. Previously, there was only limited antibody persistence data available showing persistence of two years post vaccination with *Mencevax ACWY™*, and vaccine effectiveness data up to three years post vaccination for a related meningococcal vaccine containing serogroup A and C.
These new data indicate that among individuals 11-55 years of age who were vaccinated two years earlier with Mencevax ACWY™, immunity to serogroups W-135 and Y persists in 24.0% and 44.0%*, respectively, where antibody persistence is defined as the presence of serum bactericidal antibodies using rabbit complement (rSBA) titres ≥1:8.

In addition, limited data showed a waning of serum bactericidal antibody titres against serogroup A one year post-vaccination when using human complement in the assay (hSBA). The clinical relevance of the waning of hSBA-MenA antibody titres is unknown and data now suggest that earlier revaccination may be appropriate for individuals who remain at high risk of exposure to meningococcal disease.

The current Prescriber Information for *Mencevax ACWY™* states an antibody persistence of at least 3 years in the 'Pharmacodynamics' section. In several countries the posology section also includes the statement that: "In adults and children over 5 years of age immunity will persist for up to 3 years. Children who were aged less than 5 years when first vaccinated should be considered for revaccination after 2-3 years if they remain at high risk".
General guidance on earlier revaccination across a broader age group is now considered appropriate and the company intends to update the product information for *Mencevax ACWY™*, including these new antibody persistence data.

Recommendations to healthcare professionals:

- *Mencevax ACWY™* is generally well tolerated and immunogenic. These new data provide updated information regarding the persistence of immunity
- Individuals remaining at high risk of exposure to serogroups A, W-135 and Y should be considered for revaccination according to local recommendations
- Alternatively conjugate vaccines can be used for the immunization against invasive meningococcal diseases caused by *Neisseria meningitidis* group A, C, W-135 and Y according the local recommendations.

About Mencevax ACWY™:

Mencevax ACWY™ is a preparation of polysaccharides from *Neisseria meningitidis* (meningococcus) of serogroups A, C, W-135 and Y. Each 0.5 ml dose of reconstituted vaccine contains 50 micrograms of each of the polysaccharide of serogroups A, C, W-135 and Y.
Mencevax ACWY™ is indicated for the active immunisation of children from 2 years of age, adolescents and adults against meningococcal disease caused by meningococci of serogroups A, C, W-135 and Y.

The letter is sent in agreement with the Saudi Food and Drug Authority

Further Information

GlaxoSmithKline will continue to monitor the safety of *Mencevax ACWY*™ and update SFDA of any serious adverse event for evaluation. You can assist us in monitoring the safety of *Mencevax ACWY*™ by reporting adverse reactions to GlaxoSmithKline Fax: +966 12 6536660 or by email to safety email: faisal.m.shujrah@gsk.com or to national Pharmacovigilance and Drug Safety Center at Fax: +966 11 2057662 or by email to: npc.drug@sfda.gov.sa or through online reporting system: http://ade.sfda.gov.sa/

If you have any question about the new information, please contact GSK medical information department at GlaxoSmithKline Saudi Arabia by phone: +966 12 6536666 or fax: +966 12 6536660.

Best regards;

Mohammed Hany Soliman

Country Medical Director

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Saudi Arabia

Reference:

Ref *: Replacement of the current antibody-persistence data with new data generated during the MenACWY-TT development studies (MenACWY-TT-015, -016, -017, -017, -018, -019 AND -020) + removal of existing statement statements related to the 3-year persistence.