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The current Prescriber Information for ACWY Vax[®] states an antibody persistence of at least 3 years. Available data suggest that individuals remaining at high risk of exposure to serogroups A, W-135 and Y should be considered for earlier revaccination

Dear Healthcare Professional,

Summary

- Study findings demonstrate a waning of antibody titres after ACWY Vax[®] vaccination between one and two years after vaccination
- Individuals who remain at high risk of exposure to *Neisseria meningitidis* should be considered for revaccination earlier than currently recommended
- Conjugate vaccines are recommended when revaccination within 2 years after administration of the previous ACWY Vax[®] dose is considered

Further information on the safety concern

GlaxoSmithKline (GSK) Vaccines would like to inform you about available clinical data relevant to the antibody persistence of ACWY Vax[®].

During the clinical studies for another meningococcal vaccine manufactured by GSK, ACWY Vax[®] was used as a comparator vaccine. Antibody persistence data for ACWY Vax[®] vaccine from these studies are now available. Previously, there was only limited antibody persistence data available showing persistence of two years post vaccination with ACWY Vax[®], and vaccine effectiveness data up to three years post vaccination for a related meningococcal vaccine containing serogroup A and C.

New data indicate that among individuals 11-55 years of age who were vaccinated two years earlier with ACWY Vax[®], 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 $\geq 1:8$. Therefore according to local recommendations, revaccination two years after receipt of ACWY Vax[®] may be appropriate for individuals who remain at high risk of exposure to *Neisseria meningitidis*.

The current Prescriber Information for ACWY Vax[®] 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 ACWY Vax[®], including these antibody persistence data.



Recommendations to healthcare professionals:

- ACWY Vax[®] is generally well tolerated and immunogenic. New data provide updated information regarding the persistence of immunity
- These data do not impact the current recommendation for travellers who travel in high risk areas for a short period
- Individuals remaining at high risk of exposure to serogroups A, W-135 and Y should be considered for revaccination two years after receipt of ACWY Vax[®] according to local recommendations. This include:
 - Residents in endemic area, staying longer than two years exposed to *Neisseria meningitidis* and previously vaccinated with ACWY Vax[®].
 - Travellers leaving for a short period journey and previously vaccinated with ACWY Vax[®] longer than 2 years ago
- Conjugate vaccines are recommended when revaccination within 2 years after administration of the previous ACWY Vax[®] dose is considered.

Please do not forget to report any suspected adverse events at GlaxoSmithKline (Malta) Limited, 1, 1st floor, de la Cruz Avenue, Qormi, QRM 2458; by phone to 21238131; or e-mail at mt.info@gsk.com, as appropriate. 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.

If you need additional information or have any questions, please contact representative of GlaxoSmithKline at GlaxoSmithKline (Malta) Limited, 1, 1st floor, de la Cruz Avenue, Qormi QRM 2458, Malta (Tel. 21 238131).

About ACWY Vax[®]

ACWY Vax[®] 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.

ACWY Vax[®] 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.

Yours sincerely

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