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23rd December 2022

Rotarix Dosing and Administration Wheel – discrepancy in date estimate

Dear Healthcare Professional,

GSK is committed to providing resources to healthcare professionals (HCPs) to support the quality use of our medicines and vaccines. Rotarix (human rotavirus, live attenuated oral vaccine) is indicated for the prevention of rotavirus gastroenteritis.

It has come to GSK's attention that discrepancies have been noticed in some copies of the Rotarix Dosing and Administration Wheel (Rotarix Wheel). An image of the Rotarix Wheel is included on the following page for reference. **GSK recommends that HCPs immediately cease use of the Rotarix Wheel and discard any copies currently in their possession.** In 2023, GSK intends to refresh the aids it provides to immunisers to assist with dosing and administration of Rotarix.

Please note: **There is no impact to the quality of the Rotarix vaccine**, this letter relates solely to the Rotarix Wheel, which is collateral distributed separately from the Rotarix vaccine.

As stated in the Rotarix Product Information, the vaccination course consists of two doses. The first dose should be given between 6 and 14 weeks of age. The interval between the two doses should not be less than 4 weeks. The vaccine course should be completed by the age of 24 weeks as safety has not been assessed in older children. This dosing schedule aligns with the current National Immunisation Program (NIP) schedule with the first dose being administered at 2 months of age and the second dose being administered at 4 months of age. Dosing schedule recommendations from both the Rotarix Product Information and NIP have been correctly printed on the Rotarix Wheel for the HCP's reference.

For information on GSK products or to report an adverse event involving a GSK product, please contact GSK Medical Information on 1800 033 109.

Yours Sincerely,

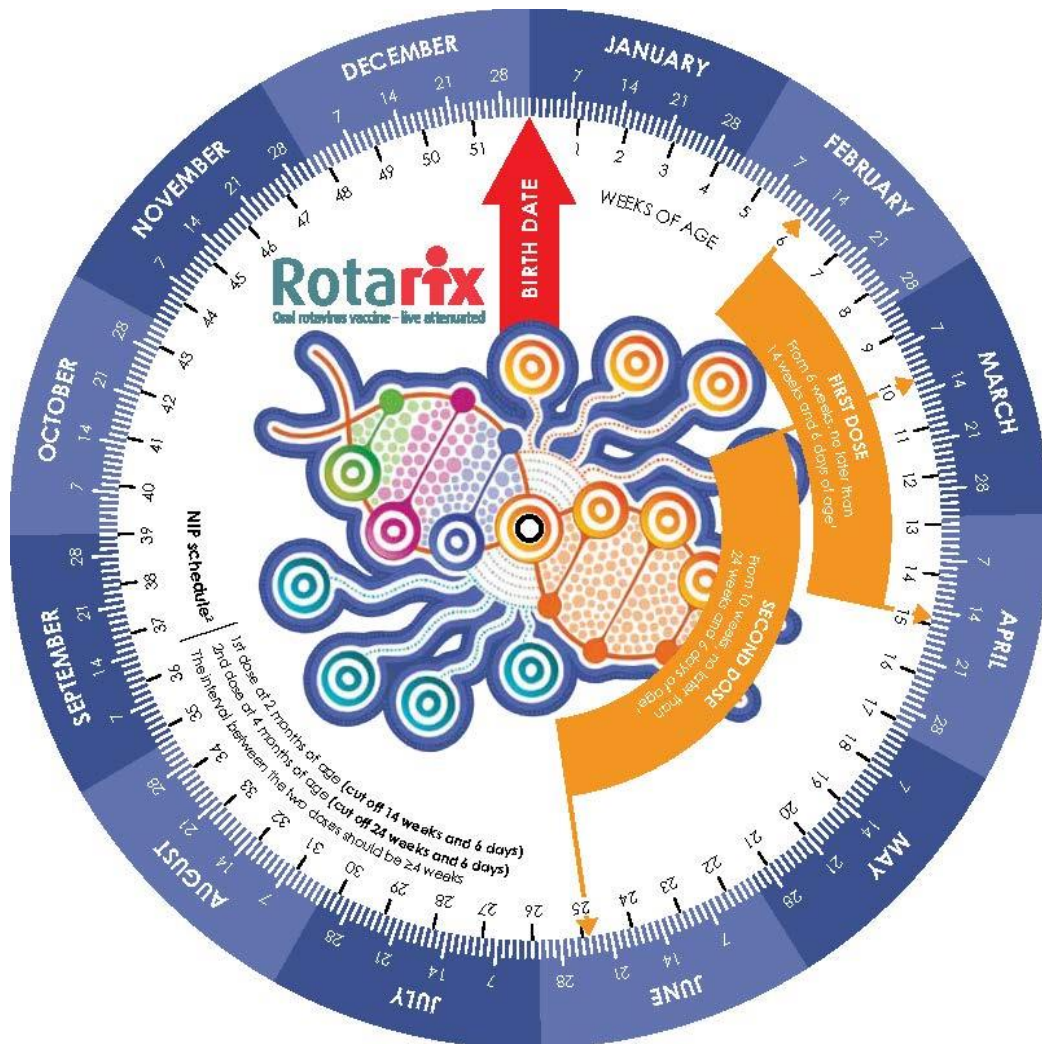
Vincent So
Head of NIP Vaccines Business
GSK

References:

Rotarix Product Information can be accessed at: www.gsk.com.au/rotarix

National Immunisation Program schedule can be accessed at: [NIP Schedule](#)

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Rotarix is presented as 1.5 mL ready-to-use, oral suspension in a squeezable tube.¹

The tube has a membrane, and a spike cap to pierce the membrane.



STEP 1

Check the liquid is clear and particle free, and the tube is intact.

Pull off the cap. Keep the cap to pierce the membrane.



STEP 2

Hold the tube upright. Repeatedly flick the top of the tube until it is clear of any liquid.



STEP 3

Turn the cap upside down and use the spike to pierce the membrane.



STEP 4

Seat the infant leaning slightly backwards. Squeeze the liquid gently into the side of their mouth, towards the inside of their cheek.

It is OK if a drop remains in the tip of the tube.



PBS Information: This Product is listed on the National Immunisation Program (NIP). Refer to the NIP Schedule.

Please review Rotarix Product Information before prescribing. Full Product Information is available at www.au.gsk.com

References: 1. Rotarix Approved Product Information. 2. Australian Technical Advisory Group on Immunisation (ATAGI). Australian Immunisation Handbook, Australian Government Department of Health, Canberra, 2018, immunisationhandbook.health.gov.au. (Accessed May 2019).

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