

## Summary of Key Characteristics of WHO Prequalified Rotavirus Vaccines\*

Characteristics		<i>Rotarix</i> <sup>TM</sup> (GSK)	<i>Rotateq</i> <sup>TM</sup> (Merck)	<i>Rotavac</i> <sup>TM</sup> (Bharat)	<i>Rotasiil</i> <sup>TM</sup> (Serum Institute)
Efficacy for severe rotavirus gastroenteritis, at 2 years follow-up*, by child mortality rate stratum of country of study site <sup>1</sup>	Low Mortality	<b>90%</b> (95% CI, 86-93%)	<b>94%</b> (95% CI, 61-99%)	No data available	No data available
	Medium Mortality	<b>78%</b> (95% CI, 70-83%)	<b>81%</b> (95% CI, 66-89%)	No data available	No data available
	High Mortality	<b>54%</b> (95% CI, 9-77%)	<b>44%</b> (95% CI, 23-59%)	<b>54%</b> (95% CI, 40-65%)	<b>44%</b> (95% CI, 26-58%)
	Study sites	Multiple countries at different income and mortality levels.		3 sites in India	6 sites in India; 1 center, multiple sites in Niger
Date of WHO prequalification		March 2009	October 2008	January 2018	September 2018
Safety		<ul style="list-style-type: none"> <li>WHO has concluded that the prequalified rotavirus vaccines (RVVs) are safe and should be among the vaccine options to prevent severe rotavirus gastroenteritis globally.<sup>1,2,3</sup> Continued monitoring of the risk for intussusception is recommended.<sup>3</sup></li> </ul>			
Mixed schedules & interchangeability of products <sup>4</sup>		<ul style="list-style-type: none"> <li>If the product used for a prior dose is unavailable or unknown, the series should be completed with any available licensed product. Restarting the vaccine series is not recommended.</li> <li>If any dose in the series was from a product that has a 3-dose schedule, or if the vaccine product is unknown for any dose, a total of 3 doses of rotavirus vaccine should be administered for a complete vaccination series.</li> <li>The published safety and efficacy data on mixed schedules or interchangeability that exist for <i>Rotarix</i><sup>TM</sup> and <i>Rotateq</i><sup>TM</sup> are reassuring;<sup>5,6</sup> No published data yet exist on performance of any mixed vaccine courses that include <i>Rotavac</i><sup>TM</sup> or <i>Rotasiil</i><sup>TM</sup>.</li> </ul>			

\* One year follow-up efficacy estimates for severe rotavirus gastroenteritis diarrhea were reported in the 2020 Cochrane review and are similar to those for 2 year follow-up.

### References:

<sup>1</sup> Systematic review and meta-analysis of the safety, effectiveness and efficacy of childhood schedules using Rotavirus Vaccines – Cochrane Response. October 2020 SAGE Meeting, Rotavirus Vaccines – Session 6. Background documents ; [https://www.who.int/immunization/sage/meetings/2020/october/SAGE\\_eYB\\_Oct2020final.pdf?ua=1](https://www.who.int/immunization/sage/meetings/2020/october/SAGE_eYB_Oct2020final.pdf?ua=1); SAGE Meeting slide deck. Rotavirus Vaccines - Session 6. October 2020. [https://www.who.int/immunization/sage/meetings/2020/october/SAGE\\_Slidedeck\\_Oct2020-Web.pdf?ua=1](https://www.who.int/immunization/sage/meetings/2020/october/SAGE_Slidedeck_Oct2020-Web.pdf?ua=1)

<sup>2</sup> Report of the WHO Global Advisory Committee on Vaccine Safety, 6-7 December 2017. <http://apps.who.int/iris/bitstream/handle/10665/259874/WER9303.pdf?sequence=1>

<sup>3</sup> Report of the WHO Global Advisory Committee on Vaccine Safety, 4-5 December 2019. <https://apps.who.int/iris/bitstream/handle/10665/330607/WER9504-eng-fre.pdf?ua=1>

<sup>4</sup> WHO Programmatic Guidance Note Use of more than one rotavirus vaccine product to complete the vaccination series. November 12, 2019. [https://www.who.int/immunization/diseases/rotavirus/Rota\\_mixed\\_schedules\\_interchangeability.pdf?ua=1](https://www.who.int/immunization/diseases/rotavirus/Rota_mixed_schedules_interchangeability.pdf?ua=1)

<sup>5</sup> Libster R, et al. Safety and Immunogenicity of Sequential Rotavirus Vaccine Schedules. *Pediatrics*. 2016 Feb;137(2).

<sup>6</sup> Payne DC, Sulemana I, Parashar UD, for the New Vaccine Surveillance Network. Evaluation of Effectiveness of Mixed Rotavirus Vaccine Course for Rotavirus Gastroenteritis. *JAMA Pediatrics*. 2016;170(7):708-710.

\* For the rotavirus vaccines discussed in this document, the following disclaimer applies: WHO does not approve or endorse the use of specific branded products over others; this publication may not be used for any commercial or promotional purposes.

### Appendices:

- For current information and additional details, please visit: <https://www.who.int/immunization/diseases/rotavirus/en/>
- Gavi's detailed product profiles for rotavirus vaccines: <https://www.gavi.org/about/market-shaping/detailed-product-profiles/>

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