

**Memo – October 2016**

## **WHO AND GLOBAL PARTNERS HELP SAFEGUARD THIMEROSAL SUPPLY FOR VACCINES**

WHO and its global health partners are helping safeguard a continuous supply of thimerosal to vaccine manufacturers. Thimerosal is used in trace amounts as a vaccine preservative with antimicrobial properties, primarily in multi-dose presentations of pentavalent, hepatitis B, tetanus and other vaccines.<sup>1</sup> Over the last five years, health economists estimate these vaccines have averted over 10.5 million deaths globally.<sup>2</sup>

GIHON Laboratorios Químicos is an established quality producer of the current Good Manufacturing Practices (cGMP) pharmaceutical grade thimerosal, supplying manufacturers of medicinal products globally for decades. For vaccines, acceptable alternative preservatives (e.g., 2-phenoxyethanol) qualifying for the WHO multi-dose open vial policy or novel small single container presentations may reduce dependencies on thimerosal in the future.<sup>3</sup> However, in the near term, thimerosal is the best option for preserving multi-dose vaccine presentation, such as pentavalent (DTP-HepB-Hib); thus, WHO and UNICEF work to mitigate any supply interruption.

WHO and partners worked with GIHON and its global distributor, Cfm Oskar Tropitzsch GmbH, to support equipment improvements at GIHON's thimerosal manufacturing site in Mar del Plata, Argentina, and to create an 18-month (2,000-kilogram) stockpile of finished product, half stored in Mar del Plata and half at Oskar Tropitzsch's warehouse in Marktrechwitz, Germany.<sup>4</sup>

In order to accomplish this, the equipment improvements enable and commit GIHON to operating a stable manufacturing platform for at least the next 20 years. The thimerosal stockpile provides additional insurance against vaccine manufacturing issues impacting vaccine supplies.

WHO acted expeditiously following the United Nations Environment Programme's 2013 Minamata Convention on Mercury to ensure thimerosal for human and veterinary vaccines were not impacted by regulatory changes enacted.<sup>5</sup> This commitment to GIHON builds on WHO and UNICEF's advocacy efforts to further reduce the risks of interrupting access to life-saving vaccines where they are needed most, since thimerosal-containing vaccines remain the preferred presentation of developing countries.

The Bill & Melinda Gates Foundation is providing \$1.5 million in grant funding to GIHON for equipment improvements to support the generation of a thimerosal stockpile. PATH will continue to provide technical support to GIHON on thimerosal supply issues as needed.

WHO's question and answer sheet on thimerosal is available at [http://www.who.int/immunization/newsroom/thiomersal\\_questions\\_and\\_answers/en/](http://www.who.int/immunization/newsroom/thiomersal_questions_and_answers/en/)

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<sup>1</sup> Note: Thimerosal is a preservative used to prevent bacterial and microbial growth in vaccines. Vaccines contain 0.01 percent or lower concentrations of thimerosal, if used.

<sup>2</sup> Gavi, Health Impact modeling, April 2016.

<sup>3</sup> Note: Manufacturers of new vaccines are encouraged to consider novel or low dose presentations that do not require preservative, or consider alternative preservatives for multi-dose containers.

<sup>4</sup> Note: World thimerosal production was 2.5 metric tons in 2014 (down from 10 metric tons in 1993). Vaccines account for 64% of thimerosal production, with other medicinal products such as immunoglobulin preparations, skin test antigens, antivenins, ophthalmic and nasal products using the remainder. A 2 metric ton stockpile is anticipated to meet global vaccine production needs for 12-18 months.

<sup>5</sup> Note: Thimerosal used as a preservative in vaccines has been excluded from the United Nations Environment Programme's 2013 Minamata Convention ban on mercury.