





New Collaboration Aims to Reduce Infant Mortality in

Developing Countries by Making Life-Saving Antiseptic More Widely Available

Chlorhexidine gel can help prevent umbilical cord infections, a leading cause of newborn deaths

September 24, 2018 – GSK, USP and the U.S. Agency for International Development (USAID) today announced a collaboration to help increase the availability of quality-assured chlorhexidine in developing countries through technology-sharing. Chlorhexidine is a life-saving antiseptic that is specifically recommended by the World Health Organization to prevent umbilical cord infections in newborns who are delivered at home in areas with a high neonatal mortality rate.

Through this new collaboration, GSK will share manufacturing expertise and specifications for Umbipro in order to stimulate local production and sustainable access to this critically needed medicine in developing countries. USP will be supported by USAID to provide technical assistance in the form of training and technology transfer to local manufacturers interested in producing quality assured chlorhexidine.

"This initiative is an important step towards driving sustainable access to quality chlorhexidine gel" said Pauline Williams, SVP Global Health R&D at GSK. "The focus of GSK's approach to addressing Global Health challenges is the application of our scientific and technical expertise, and to work closely with partners offering complementary expertise to maximise the impact of the medicines and vaccines we develop. This collaboration with USP and USAID is a great example of that in practice."

Umbipro (chlorhexidine digluconate gel 7.1%, equivalent to 4% chlorhexidine) was developed by GSK in 2016 in partnership with international children's charity, Save the Children. This was in response to a 2012 call from the United Nations for pharmaceutical manufacturers to develop chlorhexidine products for newborn umbilical cord care, with the aim of saving up to 422,000 lives over five yearsⁱ. GSK continues to work with Save the Children and other organisations to help reach some of the most vulnerable and marginalised children with life saving interventions, including chlorhexidine. Umbipro remains the only chlorhexidine product developed specifically for umbilical cord care that has undergone stringent regulatory review.

The involvement of USAID and USP in this collaboration builds on more than 25 years of partnership between the two organizations to expand access to quality-assured medicines. In an effort to end preventable newborn deaths, USAID supports the local manufacture and use of quality-assured chlorhexidine.

Through the USAID-funded Promoting the Quality of Medicines (PQM) Program, USP will strengthen the capacity of interested local manufacturers to increase the supply of high quality chlorhexidine. Working with partners, such as PATH and the Chlorhexidine Working Group, USP has undertaken a number of activities to enhance access to quality-assured chlorhexidine. This includes developing a quality

standard for chlorhexidine gel in 2016 and providing technical assistance to manufacturers, as part of our work to improve public health.

Since 2011, the USP PQM program has provided technical assistance to over 100 manufacturers globally to produce quality-assured essential medicines, with over 30 products successfully achieving WHO prequalification or stringent regulatory authority approval. PQM has successfully supported 10 local manufacturers to produce and gain local approval for chlorhexidine in Nepal, Ethiopia, Kenya, Nigeria, Pakistan, and Bangladesh.

"Technology transfer can help facilitate local manufacturing of critical essential medicines, helps build a reliable and affordable source of life-saving essential medicines," said Emily Kaine, M.D., USP's Senior Vice President of global health. "This collaboration can help save the lives of thousands of newborn babies." Since 2002, USAID and its partners have been working to scale up the use of chlorhexidine products as part of its new born health program, which aims to ensure that all children have the same chance of a healthy life, regardless of where they are born. These efforts contributed to the 18.5% reduction in the neonatal mortality rate observed in USAID priority countries from 2008 to 2015.^{III}

About GSK

GSK is a science-led global healthcare company with a special purpose: **to help people do more, feel better, live longer.** We have 3 global businesses that research, develop and manufacture innovative pharmaceutical medicines, vaccines and consumer healthcare products. For further information please visit <u>www.gsk.com</u>.

About USAID

USAID is the world's premier international development agency and a catalytic actor driving development results. USAID's work advances U.S. national security and economic prosperity, demonstrates American generosity, and promotes a path to recipient self-reliance and resilience. USAID partners with governments to save and improve lives around the world. For more information please visit <u>www.usaid.gov</u>.

About USP

USP is an independent scientific organization that collaborates with the world's top experts in health and science to develop quality standards for medicines, dietary supplements, and food ingredients. Through our standards, advocacy and education, USP helps increase the availability of quality medicines, supplements and food for billions of people world-wide. For more information about USP, visit www.usp.org.

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ⁱ 2012 UN Report on Lifesaving Commodities for Mothers and babies in developing countries <u>https://www.unfpa.org/publications/un-commission-life-saving-commodities-women-and-children</u>

ⁱⁱ USAID.gov Newborn Health website [last updated:February 24, 2017] <u>https://www.usaid.gov/what-we-do/global-health/maternal-and-child-health/technical-areas/newborn-health</u>