For immediate release

PATH develops technology that protects hepatitis B vaccine from heat and freeze damage

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Breakthrough formulation methods recently published in Human Vaccines and Vaccine help to stabilize hepatitis B vaccine when temperatures rise and fall

Seattle, WA, August 3, 2009—PATH scientists and collaborators have developed formulation methods that protect hepatitis B vaccine from heat and freeze damage, helping to ensure the potency of hepatitis B vaccine in areas of the world where the cold chain is insufficient.

In partnership with Arecor and the University of Colorado Denver School of Pharmacy, PATH published findings in this month’s issue of Human Vaccines (volume 5, issue 8) that describe a new hepatitis B vaccine formulation exhibiting nine week stability at 55°C and at least six month stability at both 37°C and 45°C. The data indicate that the new hepatitis B vaccine formulation will be better able to withstand disruption in the cold chain and could potentially be stored at room temperature for a significant part of its shelf life.

Additionally, PATH scientists and partners combined the heat-stable hepatitis B vaccine formulation with the freeze-protection technology developed earlier this year. In collaboration with Arecor and the University of Colorado Denver School of Pharmacy, PATH tested this new hepatitis B vaccine formulation and found it to be heat-stable for 12 months at 37°C in addition to proving freeze-stable at −20°C. According to research findings recently published in Vaccine (volume 27, issue 34), this freeze- and heat-stable formulation was found to be well tolerated in animal models without any significant local or systemic side effects.
The development of these formulation methods and the research described in both published studies were conducted in conjunction with PATH’s broad project work in vaccine stabilization, funded by the Bill & Melinda Gates Foundation.

**Strengthening cold chain capacity to ensure vaccine potency**

World Health Organization guidelines recommend that all vaccines (except oral polio vaccine) be stored at 2°C to 8°C. These temperature requirements necessitate use of a vaccine cold chain—a global distribution network of refrigeration equipment and procedures for maintaining vaccine quality during transport and storage.

Cold chain storage facilities in many developed and developing countries are insufficient to handle the increasing number of vaccines that are being introduced in immunization programs. The ability to remove the more heat-stable vaccines to storage kept at higher temperatures with appropriate controls could provide space for less heat-stable vaccines and thus expand cold chain storage capacities in many countries where cold chains are frequently at, or over, capacity.

A heat-stable hepatitis B vaccine could be kept in alternate storage facilities (such as air-conditioned rooms) and under alternative transport conditions (such as insulated packaging without ice packs) for potentially its entire shelf life without compromising the effectiveness of the vaccine. The added heat stability can also facilitate outreach to remote areas and enable better health outcomes when health care providers, for example, travel to remote areas to deliver the necessary birth dose of hepatitis B vaccine to hard-to-reach populations.

Altogether, the heat- and freeze-stabilization of common vaccines, like hepatitis B vaccine, has the potential to help to extend immunization coverage by simplifying the logistics and reducing the costs associated with transport and storage of vaccines in regions of the world where the cold chain is insufficient, impractical, or otherwise constrained.

**Applying technology to second-generation products**

To date, PATH and collaborators have completed additional laboratory and preclinical studies validating the science and technology behind the new heat- and freeze-stable hepatitis B vaccine formulations. A commercial vaccine producer is in the process of applying the formulation methods to the development of a second-generation hepatitis B vaccine. Key clinical trials of this new product are scheduled for early 2010.

The Technologies and Logistics Advisory Committee of the World Health Organization's Department of Immunization, Vaccines and Biologicals also recently proposed within its 2008-2009 report to focus on hepatitis B vaccine as a pioneer antigen to define the regulatory, policy, and programmatic pathways for higher temperature storage of this and other vaccines.
About PATH

PATH is an international nonprofit organization that creates sustainable, culturally relevant solutions, enabling communities worldwide to break longstanding cycles of poor health. By collaborating with diverse public- and private-sector partners, PATH helps provide appropriate health technologies and vital strategies that change the way people think and act. PATH’s work improves global health and well-being.

About Arecor

Arecor collaborates with pharmaceutical and biotech companies who are developing recombinant proteins and vaccines for application in drugs, medical devices or diagnostics. Arecor has developed ArestatT, a proprietary stabilization technology, which enables the formulation of labile proteins and vaccines as stable aqueous preparations at elevated storage temperatures, even at high concentrations. As a simple reformulation, the technology can be readily integrated into existing manufacturing processes. ArestatT does not involve the covalent modification of biologics and uses only GRAS (Generally Regarded As Safe) excipients approved by relevant regulatory authorities.

About the University of Colorado Denver School of Pharmacy

The University of Colorado Denver School of Pharmacy is one of the top-ranked pharmacy schools in the nation. Consistently among the top 10 U.S. pharmacy schools in federal research funding, the school's internationally renowned faculty conduct basic and clinical research in a variety of scientific fields. Committed to pharmaceutical education, research and patient care, the School of Pharmacy educates students in the properties of medicinal agents, the biology of disease, the pharmacological and toxicological actions of drugs and the current best practices for clinical and therapeutic uses of drugs. For more information, visit the UC Denver School of Pharmacy online.