

## **2<sup>nd</sup> Meeting of Stop TB Partnership Working Group on New TB Vaccines: Task Force on Economics and Target Product Profiles, October 5-6, 2009**

The Task Force on Economics and Product Profiles of the Stop TB Partnership Working Group on New TB Vaccines held its second meeting, at the Fondation Merieux in Veyrier du Lac, France, chaired by Gerard Cunningham of the Bill & Melinda Gates Foundation. Two presentations on the epidemiology and cost-effectiveness of TB vaccines were given; Brian Williams from the South African Centre for Epidemiological Modeling & Analysis focused on the impact and importance of HIV control on TB control while Kevin Schwartzman from McGill University presented on cost-effectiveness modeling and related scenarios in various publications with strong emphasis on synergistic approaches. Marc LaForce of the Meningitis Vaccine Project spoke on development and regulatory lessons from experience with the new Meningitis A conjugate vaccine. Some of the lessons learned were: “Don’t let the perfect be the enemy of the good,” expect the unexpected, face-to-face time is critical, and estimated resources needed for regulatory affairs should be doubled.

Lew Barker of Aeras and Jacqui Shea from OETC provided a product development overview and an update of MVA85A, where questions regarding priming by environmental mycobacteria and also CD4 correlates in HIV positive and negative patients arose. This was followed by a discussion led by Gerard Cunningham of the progress in Critical Pathway Analysis to define timelines to licensure and Target Product Profiles (TPPs) to provide explicit insight into desired and actual product attributes (these are essential for market research). Questions were raised regarding TPPs of latency vs. boosting vaccines, vaccines for new infections vs. reactivation, and how to adjust TPPs for multiple indications and/or various target populations. Mark Chataway from Baird’s CMC presented an overview of an upcoming market research project for new TB vaccines. The Task Force brainstormed criteria for country selection and selection of countries for the project itself. Joris van de Putte of TBVI then discussed achievements in communication and advocacy but also questioned what more could be done with today’s information. The meeting closed with a summary of current gaps and plans forward given by Andrew Farlow from the University of Oxford. He emphasized importance in cost-effectiveness work of getting very good cost and effectiveness data, especially including all kinds of costs saved. Ray Hutubessy from WHO indicated need to include country and scaled-up budget impacts per WHO CEA guidelines.

The Task Force agreed upon several areas that are worth discussing more and further research. Integrating cost-effectiveness and other economic data collection with phase III clinical trials may help improve data quality of mathematical models. Talks regarding prices and paying mechanisms should continue in the future with more discussion on affordability considering current financial constraints. Another topic for consideration is how to use currently available evidence effectively to raise awareness and what new avenues and channels could be used to improve advocacy.

For the next meeting, the Task Force will continue to address TPPs by refining them, adding flexibility to TPPs where needed, and integrating TPPs with cost-effectiveness work and other TB interventions such as drugs and diagnostics. Also, the Task Force will continue to explore regulatory pathways and policy issues, and it will discuss the market research project findings and their applications as product development progresses. Participants in future meetings of the Task Force from FIND and MVI can add value based on their various knowledge and experiences.