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The International Collaboration Unit of the Biologics and Genetic Therapies Directorate's (BGTD) Office of Policy and International Collaboration (OPIC) is proud to present the second edition of their Canadian HIV Vaccine Initiative (CHVI) Regulatory Capacity Building newsletter. An update on current exciting projects will be provided. The next issue of the Newsletter can be expected in Spring 2013. Stay tuned!

## 2012 HPFB International Regulatory Forum

After a rewarding and busy September, Health Canada's fourth annual Health Products & Food Branch (HPFB) International Regulatory Forum and regulatory capacity building satellite workshops (Sept. 22-29) have finally come to a close! Having hosted over a hundred participants from at least forty countries, the Forum was extremely successful and received glowing reviews from the delegates on the core program and satellite workshops.

The core program provided a comprehensive and detailed overview of Canadian regulatory processes for biologics, pharmaceuticals and medical devices, throughout the pre- and post-market product lifecycle. To align the program with CHVI regulatory capacity building objectives, a two-day course was offered during the Forum on vaccine and clinical trial regulation along with case studies on lot release as a special topic.

With CHVI funding, Health Canada sponsored forty representatives from twenty-four emerging national regulatory authorities (NRAs) to participate. These NRAs were selected in consultation with our CHVI partners and international stakeholders to complement current international regulatory capacity building initiatives. Delegates included members of the African Vaccines Regulatory Forum (AVAREF), the Pan American Network for Drug Regulatory Harmonization Vaccine Working Group, the Pharmacy, Medicines and Poisons Board of Malawi as part of the on-going CHVI Regulatory Capacity Mentorship Program, as well as other countries whom have demonstrated a commitment to building regulatory capacity via interactions with them at the Developing Country Vaccine Regulators' Network.

The two satellite workshops were CHVI-sponsored and targeted specific audiences. One workshop was held in partnership with the Pan American Health Organization and discussed considerations for implementing the Common Technical Document for vaccines in the Latin American region. The other was delivered by the Mapping African Research Ethics Committees (MARC) project from the Council on Health Research for Development and focussed on building effective collaboration between NRAs and Research Ethics Committees in the ethical review of clinical trials.

Health Canada is extremely pleased with the outcomes of the Forum and will continue to expand and develop the core program for future years. The 2013 Forum will likely take place in September or October; it is advised that if you wish to be considered for sponsorship opportunities in the **vaccines stream**, please e-mail one of the CHVI program associates listed in the contact information section by April 2013.



## Featured below are some testimonials from our CHVI-sponsored participants on the Forum:

*"Thank you to Health Canada, which opened up its doors selflessly. There were very many interesting sessions in the Forum. The presenters were extremely knowledgeable and I truly saw a lot of excellence in operation at these sessions. The case studies helped me to quickly evaluate my work back home and I have planned to share my experiences with my colleagues in a series of in-house seminars. I was also glad to connect the presentations with a visit to the Health Canada labs. Thank you to everyone who was willing to spare their time in showing us around and answering my questions way beyond expectations. In summary, I was impressed."* – Helen Byomire Ndagije, AVAREF Co-Chair, National Drug Authority, Uganda

*"I was grateful to have this educational and practical learning opportunity from Health Canada. I was deeply impressed and inspired with the professionalism and knowledge of staff members from Health Canada. The International Regulatory Forum enabled me to have a broad and profound perspective and build international networks as a reviewer."* – Kyung Hee Sohn, Korea Food & Drug Administration

*"I have benefitted immensely from attending the International Regulatory Forum by the sponsorship of CHVI. I attended all the vaccine sessions at the Forum and for me it is indeed a refresher course with great quality of information and acquisition of new knowledge. Of particular note was the lecture on Biostatistics which de-mystified understanding the application of statistics to clinical trials. This surely aids me in the review of statistical analysis of trial reports. Also of great interest was the Ethics Satellite Workshop in which I learnt of great opportunities to use on-line resources available for vaccine trials. I am truly grateful to Health Canada and CHVI for such a great opportunity."* – Chinyere Ilonze, National Agency for Food and Drug Administration and Control, Nigeria

## Health Canada's Participation at Partner-Led Workshops/Conferences

In June 2012, Health Canada participated in the World Health Organization-led Developing Countries' Vaccine Regulators Network (DCVRN) and led a discussion on issues regarding vaccine clinical trials in paediatric populations. Health Canada also seized this opportunity to connect with colleagues from the World Health Organization (WHO) to identify areas for collaboration under the CHVI.

In September 2012, Health Canada participated in the 7<sup>th</sup> annual meeting of AVAREF. Health Canada capitalized on this opportunity to engage AVAREF members on our virtual collaborative platform project as well as our CHVI Regulatory Capacity Mentorship Program. Updates on these two projects can be found in the last two sections of this newsletter.

Health Canada also attended the AIDS Vaccine 2012 conference and participated in the CHVI satellite session by discussing the quality and regulatory requirements in relation to clinical trials from the perspective of a researcher. This will be addressed via the "Draft Guidance for the Development of Vaccines" which is currently in development by Health Canada. The conference also provided Health Canada with the opportunity to identify upcoming HIV vaccine clinical trials within Africa. As HIV vaccine clinical trials are expected to have some challenges, with the potential of having trials using a combination of drug preventative measures, Health Canada may be able to assist in the coordination of regulatory support for these countries at a more regional level in collaboration with AVAREF.

In October 2012, Health Canada participated in the WHO's International Conference of Drug Regulatory Authorities (ICDRA). Health Canada contributed to a discussion on international capacity building for vaccine regulation.



## AVAREF Virtual Collaborative Platform

The proposed AVAREF Virtual Collaborative Platform is intended to bridge geographic and financial challenges to regular and increased collaboration amongst AVAREF members. The platform would enable members to interact, exchange information, discuss issues of interest, access relevant information, participate in training sessions and video-conferences, and seek input from others on emerging issues.

AVAREF and WHO have expressed ardent support for Health Canada's proposal to develop a working prototype for the virtual collaborative platform. It is anticipated that the prototype will be eventually transitioned to AVAREF ownership and management. Subsequently, during the summer, Health Canada engaged a number of stakeholders on feedback for this project and is currently pursuing the procurement of professional services to develop a working prototype to pilot with the AVAREF community. The working prototype will serve to demonstrate functionality, usage and viability, collect user feedback, as well as build momentum amongst AVAREF members. It is Health Canada's hope to have a working prototype up and running in 2013, with AVAREF members providing on-going input and feedback prior to the launch.

## CHVI Regulatory Capacity Mentorship Program

The Mentorship Program with the Pharmacy, Medicines and Poisons Board (PMPB) of Malawi commenced in February 2012 in Lilongwe, Malawi. The training component of the Mentorship Program, which has been underway since, continued at the 2012 Health Products & Food Branch International Regulatory Forum.

The National Agency for Food and Drug Administration of Control (NAFDAC) of Nigeria recently submitted a proposal for mentorship. Health Canada discussions with NAFDAC and other international stakeholders are currently underway.

A presentation jointly prepared by Health Canada and PMPB on the Mentorship Program was presented at the 7<sup>th</sup> annual AVAREF meeting in September, where both parties identified lessons learned and experiences thus far as well as developments made by PMPB in the areas of clinical trial and vaccine regulatory processes, strengthening of accountability, and building operational capacity to meet regulatory commitments. Feedback was also requested by Health Canada, from the AVAREF community, regarding a regional approach to mentorship. Based on the positive feedback, Health Canada will proceed on collaborations under the Mentorship Program with a regional approach in mind, in collaboration and consultation with the World Health Organization and AVAREF.

## Contact Us

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