EDCTP Stakeholder Meeting on Regulatory Affairs

Friday, 29 November 2013
Aula P. G. Janssens, Institute of Tropical Medicine
Antwerp, Belgium

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08:30-09:15	Registration
09:00-09:15	Coffee/Tea
09:15-09:30	**Opening addresses** **Professor Bruno Gryseels**, Director, Institute for Tropical Medicine **Professor Charles Mgone**, EDCTP Executive Director
09:30-09:45	**Introduction by Chairpersons** **Professor Christian Burri**, Swiss Tropical and Public Health Institute and **Dr Opokua Ofori-Anyinam**, GSK *Objectives of meeting and expected outcomes*
09:45-10:15	**Dr Michael Makanga**, EDCTP *Background on EDCTP1 regulatory programme and progress towards EDCTP2*
10:15-10:45	**Keynote address** **Mr Lahouari Belgharbi**, World Health Organization *Regulatory landscape in Africa over the last decade and future outlook*
10:45-11:15	Coffee/Tea
11:15-11:45	**Mrs Margareth Ndomondo-Sigonda**, African Union NEPAD Agency *African regulators' perspective on strengthening regulatory capacity and overview of the African regulatory harmonization process*
11:45-12:15	**Ms Emer Cooke**, European Medicines Agency (EMA) *How to support regulatory capacity strengthening in sub-Saharan Africa – European perspective*
12:15-13:00	**Discussion and recommendations**
13:00-14:00	Lunch
14:00-14:30	**Dr Samba Cor Sarr**, Senegal National Health Research Council (CNRS) *AVAREF experience on strengthening regulatory pathway capacity in Africa*
14:30-15:00	**Dr Delva Shamley**, University of Cape Town *Clinical trials sponsorship by academic and research institutions: Challenges and opportunities - African experience* **Ms Christine Mathieu**, Clinical Trial Center *Clinical trials sponsorship by academic and research institutions: Challenges and opportunities - European experience*
15:00-15:30	**Discussion and recommendations**
15:30-16:00	Tea/Coffee
16:00-17:15	**Discussion and final recommendations on regulatory priorities in EDCTP2**
17:15-17:30	**Closing remarks**

Speaker Biographies

Chairpersons

Professor Christian Burri is the Head of the Department of Medicines Research at the Swiss Tropical & Public Health Institute (Swiss TPH) and Professor of Pharmacy and Clinical Pharmacology at the Department of Pharmaceutical Sciences, University of Basel. From 2000 to 2011 he directed the Institute's academic CRO (PMU), specialised in the management of clinical trials on drugs and vaccines against tropical and poverty related diseases. He was also a member of the EDCTP Partnership Board from 2007-2011. Since 2011 he has been responsible for the Department's Research Cluster, which is active in translational research projects in drug development, epidemiology and public health, and in clinical trial methodology. Prof Burri was trained as a pharmacist at the University of Bern, holds a PhD in medical parasitology from the University of Basel and received post-doctoral training in molecular pharmacology at Johns Hopkins University, Baltimore.

Dr Opokua Ofori-Anyinam is a clinical researcher with over 20 years' experience in clinical development. She is a Director, Global Clinical Development at GSK Vaccines, Belgium. She has led and worked with cross functional teams across Africa, Asia, US and Europe. She has worked on various development programmes including among others malaria, tuberculosis and more recently influenza vaccines. She has been involved in various training and capacity building programmes for African scientists in collaboration with NACCAP, EDCTP and WHO-TDR. She runs the GSK /WHO-TDR trainee fellowship programme at GSK Vaccines.

Keynote address speaker

Mr Lahouari Belgharbi is an Algerian and French National born in Algeria, working as a Scientist for the World Health Organization in the area of immunization and vaccines since he joined WHO in 1987. He studied at the French Universities of Paris Vincennes Paris VIII (Sciences de l 'Education), Jussieu Paris VI (Sciences de la Terre and Biochimie) and Grenoble (Nursing and General Medicine), France, then in Libreville (Gabon) where he graduated respectively in behavioural sciences, education, management, biochemistry, nursing and later Chinese traditional medicines including acupuncture. He then had opportunities to attend several post graduate training courses in the area of international public health and epidemiology, vaccinology, statistics, immunization, clinical research and ethics, vaccine regulation and quality with different international institutions and universities, such as Atlanta CDC and Emory University, WHO CIESPAC Brazzaville, University of Medical Sciences of Libreville and Vienna School of Medicines.

Session speakers

Mrs Margareth Ndomondo-Sigonda served as Chief Pharmacist and Registrar of the Pharmacy Board, Ministry of Health, Tanzania, since 1998 before being appointed as the First Director General of the Tanzania Food and Drugs Authority from 2003-2010. She then joined the African Union - NEPAD Agency as the Pharmaceutical Coordinator where she is responsible for coordinating the pharmaceutical development programmes including the African Medicines Regulatory Harmonization (AMRH) initiative. She holds a MSc degree in pharmaceutical services and medicines control from University of Bradford in the United Kingdom, an MBA from the Eastern and Southern Africa Management Institute (ESAMI) Tanzania and Maastricht School of Management in The Netherlands, and a Bachelor's degree in Pharmacy from the University of Dar es Salaam, Tanzania.

Ms Emer Cooke has worked in a number of management roles for the European Medicines Agency for over ten years. Currently, she is Head of International Affairs (formally the International and European Cooperation Sector) responsible for liaison activities with the European institutions and EU and non EU regulators; she previously worked in the European Commission, a national regulatory authority and spent seven years as head of scientific and regulatory affairs for the European Pharmaceutical Industry Association. Since 1991, she has lived and worked in four different European countries and all of her roles have had a strong international component, working closely with FDA as well as other international partners.

Dr Samba Cor Sarr is a health research expert in ethics of health research. He is the coordinator of the Senegalese National Ethical Committee and Chief of Health Research Department in the Ministry of Health and Prevention. In Senegal, Dr Sarr has been responsible for the health research system since 2002, after his training in health research management from Laval University in Quebec. He is the vice-Chair of AVAREF.

Dr Delva Shamley has worked in academia for over 20 years and in academic clinical trials for seven years. She has worked in Oxford and set up and run an academic Clinical Trials Unit in Dorset, UK. Her research interest is the latent effects of adjuvant therapies for cancer. She is currently Deputy Director at the University of Cape Town's Clinical Research Centre, which aims to support rigorous academic studies run nationally and internationally.

Ms Christine Mathieu studied law and graduated in 1995 at the Catholic University of Leuven. After 6 years as a lawyer at the bar of Leuven and 10 years as legal counsel in the financial sector, she joined the Clinical Trial Center of the University Hospitals Leuven in 2011 as a legal advisor. Currently she is the legal coordinator of this Clinical Trial Center. The legal team mainly amplifies contracts between the University Hospitals Leuven on the one hand and the pharmaceutical industry or other academic partners on the other hand. The team also provides legal advice to the Ethics Committee of the University of Leuven. Christine is also a member of the Ethics Committee of the University of Leuven.