DNDi at the World Health Summit – Oct 21-24, 2012

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DNDi – MMV Partner Symposium - 23.10.2012
14:30-16:00h     Room: Langenbeck

Overcoming Regulatory Barriers to Meet Priority Health Needs in Developing Countries - Putting Theory into Practice

A recent shift in the drug product environment for Africa has seen a score of new products being developed specifically for diseases in developing countries, creating new challenges for regulators in Africa and elsewhere. However, it is not certain that all African regulatory authorities have equal resources to meet these new demands. The growing need to assess novel neglected disease (ND) products for African use has generated a range of responses. Policymakers have responded to these shortcomings by developing regulatory pathways tailored to ND products, including the EMA’s Article 58, WHO drug prequalification, and FDA “tentative approval”. In addition, the African Medicines Regulatory Harmonisation (AMRH) Initiative aims to support African countries to improve public health by increasing access through harmonizing medicines regulations, and expediting registration.

The symposium will focus on experiences with EMA’s Art. 58 and discuss how the AMRH initiative functions. It will assess how international regulatory procedures can be translated into practice and discuss the perspective of a country affected.

Chairs:

- Nathalie Strub Wourgaft, Medical Director | Drugs for Neglected Diseases initiative (DNDi) | Switzerland
- David Ubben, Director, Clinical Development | Medicines for Malaria Venture (MMV) | Switzerland

Speakers:

- **Regulatory Routes for Drugs in the Field of Neglected Diseases**: Nathalie Strub Wourgaft, Medical Director | Drugs for Neglected Diseases initiative (DNDi) | Switzerland
• **Introducing Art. 58 – History, Experiences and Challenges:** Marie-Hélène Pinheiro, Principal Regulatory Advisor | EMA | United Kingdom

• **Practical Experiences of Product Development Partnerships with Regulatory Procedures – Case Studies:** Carla Botting, Director, Product Development and Access | PATH Malaria Vaccine Initiative (MVI) | United States

• **Experiences of the Pharmaceutical Industry in the Field of Novel Neglected Disease Products:** Valérie Faillat-Proux, Regulatory Affairs Director | Sanofi | France

• **The African Medicines Regulatory Harmonisation Initiative – Set Up And First Steps:** Nditonda B. Chukilizo, Manager - Medicines and Cosmetics Evaluation and Registration | Tanzania Food and Drugs Authority (TFDA) | Tanzania

• **Conclusions and Outlook: The Bigger Policy Framework:** David Ubben, Director, Clinical Development | Medicines for Malaria Venture (MMV) | Switzerland

Federal Ministry of Economic Cooperation and Development – Sanofi
Partner Symposium 22.10.2012 14:30-16:00 Room: Virchow

**Bringing Medicines to Low-Income Markets**

The symposium introduces the results of the research project “Bringing Medicines to Low-income Markets” which was supported by the German Federal Ministry for Economic Cooperation and Development (BMZ) and will provide room to discuss the opportunities and challenges of inclusive business models that serve low-income patients with quality medicines.

**Chairs:**

• Hans-Jürgen Beerfeltz, Secretary of State | Federal Ministry for Economic Cooperation and Development (BMZ) | Germany

• Ibrahim Faisal, Deputy Vice Chancellor | Upper Nile University, Khartoum | Sudan

**Welcome Address:**

• Hans-Jürgen Beerfeltz, Secretary of State | Federal Ministry for Economic Cooperation and Development (BMZ) | Germany

**Speakers:**

• **Partnership as Success Factor for Improving Global Health:** Ibrahim Faisal, Deputy Vice Chancellor | Upper Nile University, Khartoum | Sudan

• **Moderation of Panel Discussion:** Constanze Helmchen, Senior Manager | Deutsche Gesellschaft für internationale Zusammenarbeit (GIZ) | Germany

• **Introduction of the Study “Bringing Medicines to Low Income Markets”:** Solveig Haupt, Associated Expert | enterprise solutions for development (endeva) | Germany

• **Experience of NGOs:** Nathalie Strub Wourgaft, Medical Director | Drugs for Neglected Diseases initiative (DNDi) | Switzerland
- **Enabling Inclusive Business through Development Politics**: Nicole Maldonado, Desk Officer, Division on Economic Policy; Financial Sector | Federal Ministry for Economic Cooperation and Development (BMZ) | Germany
- **Contribution of Health Industry to Global Health**: Robert Sebag | Vice President Access to Medicines | Sanofi | France

**University of Heidelberg - McMaster University Partner Symposium**

22.10.2012  14:30-16:00  Room: Koch

**Do We Need a Global Convention for R&D?**

**Policy Brief: Why an Essential R&D Convention is Needed**

**Chairs:**
- Albrecht Jahn, University of Heidelberg | Germany
- Steven J. Hoffman, McMaster University | Canada

**Speakers:**
- John-Arne Rottingen, Visiting Professor of Global Health and Population | Harvard University School of Public Health | United States
- Odile Leroy | European Vaccine Initiative (EVI) | Germany
- Carlos Correa | South Center | Switzerland
- Petra Keil | Novartis | Germany
- Bernard Pécout, Executive Director | Drugs for Neglected Diseases initiative (DNDi) | Switzerland

**GIZ on behalf of Federal Ministry of Economic Cooperation and Development - Sanofi Workshop**

23.10.2012  09:00-11:00h  Room: Langenbeck

**Bringing Medicines to Low-Income Markets**

How can pharmaceutical companies more effectively serve low-income patients in developing and emerging countries with quality medicines? A brief introductory speech at the beginning of the workshop will discuss this question, pointing to critical challenges and promising approaches along four “As”: Acceptance, Awareness, Availability, Affordability. During a subsequent, interactive session, participants of the workshop are invited to discuss the fifth “A” of the 4A+1 formula, which stands for “Actors” or strategic partners, in a World Café format. The discussion will revolve around the role of business, governments and NGOs in bringing medicines to low-income markets – potential for cooperation between these actors.
Chairs:

- Nathalie Strub Wourgaft, Medical Director | Drugs for Neglected Diseases initiative (DNDi) | Switzerland
- Robert Sebba, Vice President Access to Medicines | Sanofi | France

Introductory Statements:

- Solveig Haupt, Associated Expert | enterprise solutions for development (endeva) | Germany
- Aline Krämer, Managing Director | Endeva UG | Germany
- Nathalie Strub Wourgaft, Medical Director | Drugs for Neglected Diseases initiative (DNDi) | Switzerland
- Robert Sebba, Vice President Access to Medicines | Sanofi | France
- Susan Seifert, Communications | Planet Finance Germany | Germany