DNDi
Drugs for Neglected Diseases *initiative*

Strengthening Capacity in Africa for the Registration of New Drugs for Neglected Diseases

DNDi Workshop
24 June 2009
Nairobi, Kenya

At present, there is a quasi global standard for securing the registration of pharmaceuticals and related products with well-resourced regulatory authorities seen as setting the benchmark. The reliance on well-resourced regulatory approaches has made it difficult for developing countries regulators to appropriately assess new products for national use and has led to slow approvals and other inefficiencies. There is therefore an interest in understanding how the registration of new medicines currently developed for neglected diseases might be handled in a way that better reflects the African realities, health environment and priorities.

The workshop will look into present regulatory approaches and mechanisms, how they interact with each other and what are the advantages and disadvantages of each in supporting the registration process in Africa. Case studies with different registration strategies will be presented to inform the broader discussion. The workshop will aim at addressing what would be the best regulatory approach to secure, in Africa, the registration of:

- new chemical entities developed specifically to respond to African public health needs and which have not been previously registered by well-resourced regulatory authorities (e.g. fexinidazole for human African trypanosomiasis);

- known chemical entities, already registered in other countries, but which were not initially developed to address African public health needs (e.g. paromomycin).

Agenda

9.00 Introduction by Chair – Dr Bernard Pécoul, DNDi

9.15 *"Pharmaceutical regulatory system in Africa – how to move forward?"* – Javier Guzman, George Institute for International Health

9.45 Comments from regulatory experts (15 mn each)
- Hiiti Sillo, Tanzania Food and Drug Authority
- Matthias Dormeyer, expert in European regulatory systems

10.15 Questions and discussion

10.45 Coffee break

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11.15 Case studies in innovative regulatory strategies (10 mn each)

- *The need to get neglected disease drugs promptly to neglected patients* – Tido von Schoen-Angerer, MSF Campaign for Access to Essential Medicines
- *Lessons learnt from the registration of paromomycin in India* - Philippe Desjeux, Institute for One World Health
- *Lessons learnt from the registration of ASAQ* – Mireille Cayreyre, Sanofi-Aventis
- *DNDi needs: future registration of fexinidazole for human African trypanosomiasis and of paromomycin for visceral leishmaniasis in Africa* – Els Torreele & Manica Balasegaram, DNDi

12.00 Discussion

12.45 Conclusions