

AGENDA:

WHO PREQUALIFICATION OF DIAGNOSTICS AND MEDICINES 2ND CONSULTATIVE STAKEHOLDER MEETING

Thursday, 11 January 2007, Salle A, WHO Headquarters, Geneva

- 09:00–09:15** **Welcome and introductions**
*Dr Howard Zucker, Assistant Director-General
Health Technology and Pharmaceuticals*
- 09:15–09:45** **WHO Prequalification Programme for Diagnostics and Medicines: in context**
*Dr Hans Hogerzeil, Director
Department of Medicines Policy and Standards (PSM)*
Brief overview of the development of the Programme, including its objectives, principles and structure
- 09:45–10:15** **Update and future directions for prequalification of medicines**
Dr Lembit Rägo, Coordinator, Quality and Safety: Medicines, PSM
Focusing on operational procedures, activities and outputs, financial status
- 10:15–10:45** **Questions and discussion on prequalification of medicines**
Chaired by WHO Member State (Norway): Mrs Kari Bremer
- 10:45–11:15** **Coffee/tea break**
- 11:15–11:25** **WHO prequalification of diagnostics: in context**
*Dr Steffen Groth, Director
Department of Essential Health Technologies (EHT)*
Brief overview of the development of the Programme, including its objectives, principles and structure
- 11:25–11:45** **Update and future directions for prequalification of diagnostics**
*Dr Gaby Vercauteren, Coordinator, Diagnostics and Laboratory
Technology, EHT*
Focusing on operational procedures, activities and outputs, financial status
- 11:45–12:30** **Questions and discussion on prequalification of diagnostics**
Chaired by WHO Member State (Canada): Mr Peter Oldham
- 12:30–14:00** **Lunch**

- 14:00–14:45** **Building capacity to produce medicines of assured quality**
Dr Lembit Rägo, Coordinator, Quality and Safety: Medicines, PSM,
Mr Rutendo Kuwana, Medicines Control Authority, Zimbabwe
Mr Olivier Gross, Inspector, Quality and Safety: Medicines, PSM
Overview of technical assistance provided to regulators and manufacturers
to improve regulatory and manufacturing standards
- 14:45–15:30** **Building capacity to produce diagnostics of assured quality**
Dr Gaby Vercauteren, Coordinator, Diagnostics and Laboratory
Technology, EHT
Dr Jiang Yan, National AIDS Reference Laboratory, People's Republic of
China
Dr Youchun Yan, National Institute for the Control of Pharmaceuticals and
Biological Products, People's Republic of China
Dr Robyn Wood, Therapeutic Goods Administration, Australia,
Overview of capacity-building requirements for target products and
services
- 15:30–16:00** **Coffee/tea break**
- 16:00–17:00** **Related issues: Neglected public health needs: prequalification of
therapeutic sera**
Chaired by WHO Member State
Dr David Warrell, Oxford University, UK.
Other issues for discussion will include: fees for prequalification;
prioritizing of medicines and diagnostics for prequalification;
prequalification of non-medicine items; post-marketing surveillance for
diagnostics
- 17:00–17:30** **Questions of clarification**
- 17:30–17:45** **Closure**