

AGENDA:
UN PREQUALIFICATION OF DIAGNOSTICS, MEDICINES & VACCINES
3RD CONSULTATIVE STAKEHOLDER MEETING

Monday, 4 February 2008, Salle A, WHO Headquarters, Geneva

- 09:00–09:15** **Welcome and introductions**
Dr Hans Hogerzeil, Director, Department of Medicines Policy and Standards (PSM)
Dr J-M. Okwo-Bele, Director, Department of Immunizations, Vaccines and Biologicals (IVB)
Dr Steffen Groth, Director, Department of Essential Health Technologies (EHT)
- 09:15–09:45** **Prequalification by WHO, in cooperation with other UN family members and WHO Member States**
Dr Hans Hogerzeil, Director, Department of Medicines Policy and Standards (PSM)
- 09:45–10:15** **WHO prequalification of vaccines and vaccine delivery devices**
Dr. Nora Dellepiane, Scientist, Immunization, Vaccines and Biologicals (IVB); Quality Safety and Standards (QSS); Department of Family and Community Health (FCH)
- 10:15–10:30** **Update and future directions for prequalification of medicines**
Dr Lembit Rägo, Coordinator, Quality Assurance and Safety: Medicines; Department of Medicines Policy and Standards (PSM)
- 10:30–11:00** **Questions and discussion on prequalification of medicines and vaccines**
Chaired by Mr. Peter Oldham, Counsellor, Permanent Mission of Canada
- 11:00–11:30** **Coffee/tea break**
- 11:30–11:45** **Update for prequalification of diagnostics**
Dr Steffen Groth, Director, Department of Essential Health Technologies (EHT)
- 11:45–12:15** **Future directions for prequalification of diagnostics**
Dr Gaby Vercauteren, Coordinator, Diagnostics and Laboratory Technology, Department of Essential Health Technologies (EHT)
- 12:15–12:45** **Questions and discussion on capacity building for prequalification of diagnostics**
Chaired by Mr. Peter Oldham, Counsellor, Permanent Mission of Canada
- 12:45–14:15** **Lunch**

- 14:15–15:00** **Building capacity for regulatory oversight and quality manufacture**
Technical assistance for manufacturers
Dr Olivier Gross, Quality Assurance and Safety: Medicines; Department of Medicines Policy and Standards (PSM)
- Regulatory capacity building**
Mr Rutendo Kuwana (Medicines Control Authority, Zimbabwe)
- Prequalification of quality control laboratories**
Dr Jitka Sabartova, Quality Assurance and Safety: Medicines; Department of Medicines Policy and Standards (PSM)
- 15:00–15:30** **Review - 10 years of strengthening vaccines regulatory capacity/**
Dr David Wood, Coordinator, Immunization, Vaccines and Biologicals (IVB) / Quality Safety and Standards (QSS); Department of Family and Community Health (FCH)
- Questions and discussions on capacity building**
Dr Raul Kiivet, Manager of the WHO Prequalification Programme, Quality Assurance and Safety: Medicines; Department of Medicines Policy and Standards (PSM)
- 15:30–16:00** **Coffee/tea break**
- 16:00–16:30** **Building capacity to regulate clinical trials for vaccines**
Dr. Liliana Chocarro, Scientist, Immunization, Vaccines and Biologicals (IVB) / Quality Safety and Standards (QSS); Department of Family and Community Health (FCH)
- 16:30–17:15** **General discussions and final considerations**
Chaired by Mr Ze Zhang, Third Secretary, Permanent Mission of China
- 17:15** **Reception**