

**UN Medicines & Diagnostics Prequalification Programme:  
Future Needs and Strategic Options**

**Monday, 26 September 2005  
Salle D, WHO Headquarters, Geneva**

- 09:00–09:15**      **Welcome and introductions**  
*Mr Denis Aitken, Director, Office of the Director-General*  
*Dr Hans V. Hogerzeil, Director, Medicines Policy and Standards*
- 09:15–10:00**      **Update on prequalification of medicines**  
*Dr Lembit Rägo, Coordinator, Quality and Safety (Medicines)*  
Objectives, principles, basic procedures and structure of medicines prequalification; products listed and in the pipeline; scope of the programme and plans for expansion; spin-offs for WHO, national regulatory agencies and the pharmaceutical industries; current and future challenges.
- 10:00–10:20**      **Update on prequalification of diagnostics**  
*Dr Gaby Vercauteren, Scientist, Diagnostics and Laboratory Technology*  
Increased demand for validated diagnostics; objectives, principles, basic procedures and structure of diagnostics prequalification; consolidating technical and legal basis of validation.
- 10:20–10:50**      **Discussion**  
Questions of clarification and general issues
- 10:50–11:10**      **Coffee break**
- 11:10–11:40**      **The Prequalification of Medicines Business Plan: optimizing current resources and projecting future needs**  
*Anil Soni, Clinton Foundation*  
In May–June 2005, four consultants seconded by the Clinton Foundation, assisted WHO in preparing a business plan for the prequalification of medicines programme. Key questions addressed are: projected needs in the next four years; cost of current procedures, and possible efficiencies; and funding options to ensure sustainability of the programme in the near and medium term.
- 11:40–12:00**      **The Validation of Diagnostics Business Plan: projecting future needs**  
*Kate Condliffe, Clinton Foundation*  
This month, two consultants seconded by the Clinton Foundation assisted WHO in preparing a business plan for scaling up WHO activities to validate selected diagnostics. Key questions addressed by the plan are: projected needs in the next five years; management of current procedures; and cost of current procedures.

<p><b>12:00–12:30</b> 12:00</p>	<p><b>Discussions on policy and technical issues</b>  <b>1. Trends and future needs</b>  Do we agree with the projections made in the business plans?  Can any other trends or developments to foreseen?</p>
<p><b>12:30–14:00</b></p>	<p><b>Lunch</b>  Crystal Restaurant</p>
<p><b>14:00–14:45</b> 14:00</p>	<p><b>Discussions on policy and technical issues</b> (<i>continued</i>)  <b>2. Selection of products for prequalification</b>  Presentation of current methods and criteria for inclusion; suggested criteria for future expansion (diseases, therapeutic classes, medicines, laboratories, diagnostics, etc.).</p>
<p>14:15</p>	<p><b>3. Possibilities for managerial efficiencies</b>  How can we best promote good-quality applications and prevent waste of resources?  How can we increase the pool of experts participating in prequalification activities?  How can we maximize cost-efficiency in managing prequalification activities?</p>
<p>14:30</p>	<p><b>4. Prequalification in the long-term: programme vision and sustainability</b>  Projection of long-term needs and direction; management of prequalification of medicines and diagnostics; possibilities for decentralization, burden-sharing or hand-over to other organizations; projections of future political and financial support.</p>
<p><b>15:00–15:30</b></p>	<p><b>Summary of discussion and recommendations</b></p>
<p><b>15:30–16:00</b></p>	<p><b>Tea break</b></p>
<p><b>16:00–16:30</b></p>	<p><b>Is the prequalification programme meeting the scale-up needs of treatment programmes?:</b>  Comments by external stakeholders</p>
<p><b>16:30–17:00</b></p>	<p><b>Is the prequalification programme meeting the scale-up needs of treatment programmes?:</b>  Comments by internal stakeholders</p>
<p><b>17:00–17:15</b></p>	<p><b>Next steps</b></p>
<p><b>17:15</b></p>	<p><b>Closure</b></p>