

Technical Briefing Seminar
Quality Assurance and Safety of Medicines:
Promoting Global Collaboration
12 - 16 September 2011, Room M 605, WHO Headquarters, Geneva

Provisional Programme

Monday, 12 September 2011

Facilitators: *Dr S Azatyan, Dr R Balocco*

08:45 - 09:00	Registration
09:00 - 09:30	Welcome - Objectives of the Seminar <i>Dr L Rágo, Coordinator, QSM</i>
09:30 - 10:30	Introduction of participants <i>Dr S Azatyan, Mrs P Guillot, Mrs K Kalmaru</i>
10:30 - 11:00	Coffee/tea break
11:00 - 12:00	International Nonproprietary Names (INN): the process, its value, lists, database, expert committee <i>Dr R Balocco, Dr S Lasseur, Dr J Dong</i>
12:00 - 12:30	Discussion
12:30 - 14:00	Lunch
14:00 - 14:45	Anatomical Therapeutic Chemical (ATC) Classification and the Defined Daily Dose (DDD) for medicines <i>Speaker to be confirmed</i>
14:45 - 15:00	Discussion
15:00 - 15:30	Overview on Medicines Regulation <i>Dr L Rágo, Dr S Azatyan, Dr A Prat</i>
15:30 - 16:00	Coffee/tea break
16:00 - 17:00	Overview on Medicines Regulation (Continued)

17:00 - 17:30 Discussion
17:30 - 19:00 Reception (WHO Main Restaurant)

Tuesday, 13 September 2011

Facilitators: *Dr L Rāgo, Mr R Kuwana*

09:00 - 09:30 Review of previous day

09:30 - 10:45 Introduction and details of the Prequalification
of Medicines Programme
Dr L Rāgo

10:45 - 11:15 Coffee/tea break

11:15 - 12:00 Dossiers and assessments
Mr R Kuwana

12:00 - 12:30 Questions/discussion

12:30 - 13:45 Lunch

13:45 - 14:00 Introduction to the Prequalification of Medicines
Programme Website
Ms A Lopes

14:00 - 14:45 Good Manufacturing Practices and inspections
Mr D Mubangizi

14:45 - 15:00 Questions/discussion

15:00 - 15:30 Prequalification of laboratories and quality
control testing
Dr J Sabartova

15:30 - 16:00 Coffee/tea break

16:00 - 16:45 Capacity building and training
Dr M Šmid

16:45 - 17:30 Questions/discussion

Wednesday, 14 September 2011

Facilitators: *Dr S Kopp, Dr A Padilla*

09:00 - 09:30	Review of previous day
09:30 - 10:15	WHO standard setting and normative functions in the field of pharmaceuticals: general principles <i>Dr S Kopp, Dr H Schmidt</i>
10:15 - 10:30	Discussion
10:30 - 11:00	Coffee/tea break
11:00 - 12:30	WHO Standards for Quality Assurance: Medicines; Quality Control: The International Pharmacopoeia <i>Dr H Schmidt, Ms C Mendy</i>
12:30 - 12:45	Discussion
12:45 - 14:00	Lunch
14:00 - 15:30	Quality Assurance and Safety of Blood Products: WHA Resolution63.12: on availability, safety and quality of blood products. WHO Guidelines on Good Manufacturing Practices for Blood Establishments. Regulation of blood products: Assessment criteria for national blood regulatory systems. <i>Dr A Padilla</i>
15:30 - 16:00	Coffee/tea break
16:00 - 17:00	Impact of the WHO Biological Reference Preparations on the control of quality and safety of blood products at global level. WHO website on snake antivenoms. <i>Dr A Padilla</i>
17:00 - 17:30	Discussion

Thursday, 15 September 2011

Facilitators: *Dr S Pal, Dr W Scholten*

09:00 - 9:30	Review of previous day
09:30 - 10:15	Pharmacovigilance: Overview <i>Dr S Pal</i> <ul style="list-style-type: none">- Importance of PV- WHO Programme for International Drug Monitoring- WHO Collaborating Centre for Drug Monitoring (UMC)- Pharmacovigilance in Public Health Programmes- Pharmacovigilance & Patient Safety
10:15 - 10:30	Discussion
10:30 - 11:00	Coffee/tea break
11:00 - 12:15	Methodologies & Tools in Pharmacovigilance <ul style="list-style-type: none">- Spontaneous Reporting- Reporting forms- Causality <i>Speaker to be confirmed</i>
12:15 - 12:30	Discussion
12:30 - 13:30	Lunch
13:30 - 15:15	Methodologies & Tools in Pharmacovigilance (continued) <ul style="list-style-type: none">- Data Management (WHO-ART, Vigiflow, Database, Vigisearch)- Cohort Event Monitoring- Communication and Crisis Management
15:15 - 15:30	Discussion
15:30 - 16:00	Coffee/tea break
16:00 - 17:00	International control of substances of abuse Access to controlled medicines <i>Dr W Scholten</i>

17:00 - 17:30 Discussion

Friday, 16 September 2011

Synthesis

Facilitators: *Dr L RÄgo, Dr S Azatyan*

09:00 - 9:30 Review of previous day

09:30 - 11:30 (Including 15 minutes coffee break)
Collaborations/Partnerships/Hot topics
(participants to choose)

11:30 - 12:00 Summary and Closure

14:00 Individual appointments with WHO technical staff