1st GENERAL MEETING OF THE WHO GLOBAL NETWORK OF NATIONAL QUALITY CONTROL LABORATORIES FOR PHARMACEUTICALS (WHO-GNP)

Date: 1 to 3 October 2024
Venue: Pestana Rio Atlântica, Rio de Janeiro, Brazil
In collaboration with of INCQS/FIOCRUZ and PAHO

DAY 1. Tuesday 1 October 2024

Chairs:
Rutendo Kuwana, Team Lead, Incidents, Substandard and Falsified Medicines Team (ISF), WHO Headquarters (WHO-HQ)

8:30 - 9:00	**Registration**
9:00 - 9:45	**Session 1. Opening session**
9:45 - 10:00	**Session 2. Official presentation of the WHO Global Network of Quality Control Laboratories for Pharmaceuticals (WHO-GNP)** **Objectives of the Network and Membership** Natércia Guerra Simões, Technical Officer, Laboratory Networks and Services (LNS), Regulation and Safety Unit (REG), WHO Headquarters (WHO-HQ) **Sharing of information: the Sharepoint of the WHO-GNP** Natércia Guerra Simões, Technical Officer, Laboratory Networks and Services (LNS), Regulation and Safety Unit (REG), WHO Headquarters (WHO-HQ)
10:00 – 10:30	**Coffee / tea break**
10:30 – 12:00	**Session 3. Expectations of potential members of the WHO-GNP (10 min/country)** **Moderator:** Monica Hirschhorn, Head of Quality and Chemistry Section, Comisión para el Control de Calidad de Medicamentos (CCCM), Uruguay The current participants and potential members of WHO-GNP will provide presentations for introduction of their National Quality Control Laboratory, as well as needs and expectations from the WHO-GNP. - **Egypt** - **Peru** - **Thailand** - **Tanzania** - **Ukraine** - **Vietnam** **Discussion**
12:00 – 13:30	**Lunch break**
13:30 – 15:00	**Session 4. Updates from WHO** **Moderator:** Thiago Santana Novotny, Medicines Technical Unit Coordinator, INCQS/FIOCRUZ

	The WHO will provide presentations on updates of activities related with regulatory strengthening activities and Good Practices for Pharmaceutical Quality Control Laboratories and the host country will provide updates of the current activities related with the laboratory testing function. **WHO Good Practices for Pharmaceutical Quality Control Laboratories (GPPQCL, WHO TRS 1052 Annex 4): updates on the new version, current activities and impacts on QCLs and other WHO guidances (15 min)** Natalia Volovyk, Senior Researcher, Deputy Director for Quality, Ukrainian Scientific Pharmacopoeial Center for Quality of Medicines, Ukraine **WHO Prequalification: impact of the new version of the GPPQCL in inspections (15 min)** Dimitrios Catsoulacos, Inspection Services Team (INS), WHO Headquarters (WHO-HQ), Geneva **Laboratory Networks and Services (LNS): updates on regulatory strengthening activities and capacity building (15 min)** Natércia Guerra Simões, Technical Officer, Laboratory Networks and Services (LNS), Regulation and Safety Unit (REG), WHO Headquarters (WHO-HQ) **WHO Global Benchmarking Tool and WHO Listed Authorities (15 min)** Alireza Khadeem, Team Lead, Regulatory Strengthening Systems Team (RSS), Regulation and Safety Unit (REG), WHO Headquarters (WHO-HQ) **Questions and Answers**
15:00 – 15:30	**Coffee / tea break**
15:30 – 17:00	**Session 5. Challenges to NQCLs: networking, reliance and recognition mechanisms** **Moderator:** Natalia Volovyk, Senior Researcher, Deputy Director for Quality, Ukrainian Scientific Pharmacopoeial Center for Quality of Medicines, Ukraine In this session the speakers will provide an overview of current practices in regulatory networks, as well as examples of international recognition of competence, as well as reliance mechanisms, and how to share best practices. **Current experience in networking: the European OMCL network, SEARN and AMQF (30 min)** General European OMCL Network (GEON): Richard Wanko, Biological Standardisation, OMCL Network and HealthCare Department (DBO), European Directorate for the Quality of Medicines (EDQM) South East Asia Regulatory Network (SEARN): Md. Shaikh Ahsan, Assistant Director, Drug Testing Laboratory, Bangladesh African Medicines Quality Forum (AMQF): Bonaventure Chilinde, Director Laboratory Services, National Drug Control Laboratory, Zambia Medicines Regulatory Authority (ZAMRA) **Health Surveillance Laboratories Network: Official Q.C. Laboratories (10 min)** Graziela Costa Araújo, Public Health Laboratories General Manager, Agência Nacional de Vigilância Sanitária (ANVISA) **International recognition of competence: challenges and benefits of WHO Prequalification and ISO17025 accreditation (20 min)** Annette Ssenkindu, Quality Manager, National Drug Authority (NDA), Uganda Thiago Santana Novotny, Medicines Technical Unit Coordinator, INCQS/FIOCRUZ **WHO audit system for NQCLs: preparation for WHO Prequalification and reliance mechanism between members of the WHO networks (10 min)** Natércia Guerra Simões, Technical Officer, Laboratory Networks and Services (LNS), Regulation and Safety Unit (REG), WHO Headquarters (WHO-HQ) **Panel discussion (15 min)**
17:00 – 17:15	**Closing remarks for day 1**

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DAY 2. Wednesday 2 October 2024

Chairs:

Thiago Santana Novotny, Medicines Technical Unit Coordinator, INCQS/FIOCRUZ

9:00 – 10:30	**Session 6. Market surveillance** **6.1. Updates from WHO and participants**
	Moderator: Natércia Guerra Simões, Technical Officer, Laboratory Networks and Services (LNS), Regulation and Safety Unit (REG), WHO Headquarters (WHO-HQ) The WHO and participants will provide presentations on the activities related with post-market surveillance. **WHO Post-market surveillance: updates (10 min)** Rutendo Kuwana, Team Lead, Incidents, Substandard and Falsified Medical Products Team (ISF), Regulation and Safety Unit (REG), WHO-HQ **WHO Guideline on Market Surveillance and Control (15 min)** Rian Extavour, Consultant, Incidents, Substandard and Falsified Medical Products Team (ISF), Regulation and Safety Unit (REG), WHO-HQ **Examples of National Market Surveillance Programs (60 min, 10 min each country)** - **Kazakhstan** - **Nigeria** - **Pakistan** - **Indonesia** - **Uruguay** - **China** **Questions and Answers**
10:30 – 11:00	**Coffee / tea break**
11:00 – 12:30	**Session 6.2. Challenges in testing substandard and falsified medical products** **Moderator:** Monica Hirschhorn, Head of Quality and Chemistry Section, Comisión para el Control de Calidad de Medicamentos (CCCM), Uruguay The participants will provide insights on recent experiences in testing substandard and falsified medical products. **The nitrosamines case in Brazil (20 min)** Mychelle Alves Monteiro, Head of the Medicines, Cosmetics and Sanitizers Laboratory, FIOCRUZ/INCQS **The Ethyleneglycol/Diethylenglicol contamination in Indonesia (20 min)** Nia Yuniarti, Food and Drug Supervisory Agency BPOM, Indonesia **Challenges with substandard and falsified medicines in the Caribbean (20 min)** Sydonna Tugwell, Caribbean Public Health Agency (CARPHA) **Questions and answers**
12:30 – 14:00	**Lunch break**
14:00 – 15:30	**Session 7. Capacity building** **Moderator:** Rutendo Kuwana, Team Lead, Incidents, Substandard and Falsified Medicines Team (ISF), WHO Headquarters (WHO-HQ), Geneva The participants, WHO and partners will provide presentations on current and planned activities regarding capacity building. **The Global Health Protection Program (GHPP) and LabTrain (20 min)**

	Andrea Stanglmair, GHPP LabTrain Project, Federal Institute for Drugs and Medical Devices (BfArM), Germany **USP PQM+ activities (20 min)** Souly Phanouvong, Technical Director, USP PQM+, USA **African Medicines Quality Forum (15 min)** Kervin Dzawo, Head of Chemistry Division, Medicines Control Authority of Zimbabwe (MCAZ) **Current capacity building activities in the QCL network in Brazil (15 min)** Ivano Raffaele Victorio de Filippis Capasso, Research Support Coordinator, INCQS/FIOCRUZ **Discussion and recommendations**
15:30 – 16:00	**Coffee / tea break**
16:00 – 17:00	**Session 8– Quality assurance and monitoring** **Moderator:** Natalia Volovyk, Senior Researcher, Deputy Director for Quality, Ukrainian Scientific Pharmacopoeial Center for Quality of Medicines, Ukraine This session will provide updates on useful tools to assure the quality of the results. **External quality control: the use of Proficiency Evaluation and WHO EQAAS (15 min)** Marius Brits, Associate Professor and Director of WHO Collaborating Centre for the Quality Assurance of Medicines, North-West University, South Africa **Internal Quality Control Tools (15 min)** Natércia Guerra Simões, Technical Officer, Laboratory Networks and Services (LNS), Regulation and Safety Unit (REG), WHO Headquarters (WHO-HQ) **The experience of being a Proficiency testing provider: challenges and benefits (15 min)** Armi Wanderley da Nobrega, FIOCRUZ Board Assessor and Mychelle Alves Monteiro, Head of the Medicines, Cosmetics and Sanitizers Laboratory, FIOCRUZ/INCQS
17:00 – 17:15	**Closing remarks for day 2**
18:00 – 20:00	******** SOCIAL EVENT********

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DAY 3. Thursday 3 October 2024

Chairs:
Natércia Guerra Simões, Technical Officer, Laboratory Networks and Services (LNS), Regulation and Safety Unit (REG), WHO Headquarters (WHO-HQ)

The sessions of Day 3 are training sessions, expected to be interactive. Active participation is required, using laptops and/or mobile phones.

9:00 – 10:30	**Training Session 1 – Quality Risk Management in a laboratory** **Marius Brits,** Associate Professor and Director of WHO Collaborating Centre for the Quality Assurance of Medicines, North-West University, South Africa
10:30 – 11:00	**Coffee / tea break**
11:00 – 12:30	**Training Session 2 – Uncertainty of measurement** **Natalia Volovyk,** Senior Researcher, Deputy Director for Quality, Ukrainian Scientific Pharmacopoeial Center for Quality of Medicines, Ukraine
12:30 – 14:00	**Lunch**
14:00 – 15:30	**Training Session 3 – Management of Out-of-Specification Results** **Monica Hirschhorn**, Head of Quality and Chemistry Section, Comisión para el Control de Calidad de Medicamentos (CCCM), Uruguay
15:30 – 16:00	**Coffee / tea break**
16:00 – 17:00	**Training Session 4 – Managing Nonconforming Work and Nonconformities** **Thiago Santana Novotny,** Medicines Technical Unit Coordinator, INCQS/FIOCRUZ
17:00 – 17:20	**Closing remarks** **INCQS, PAHO and WHO**

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