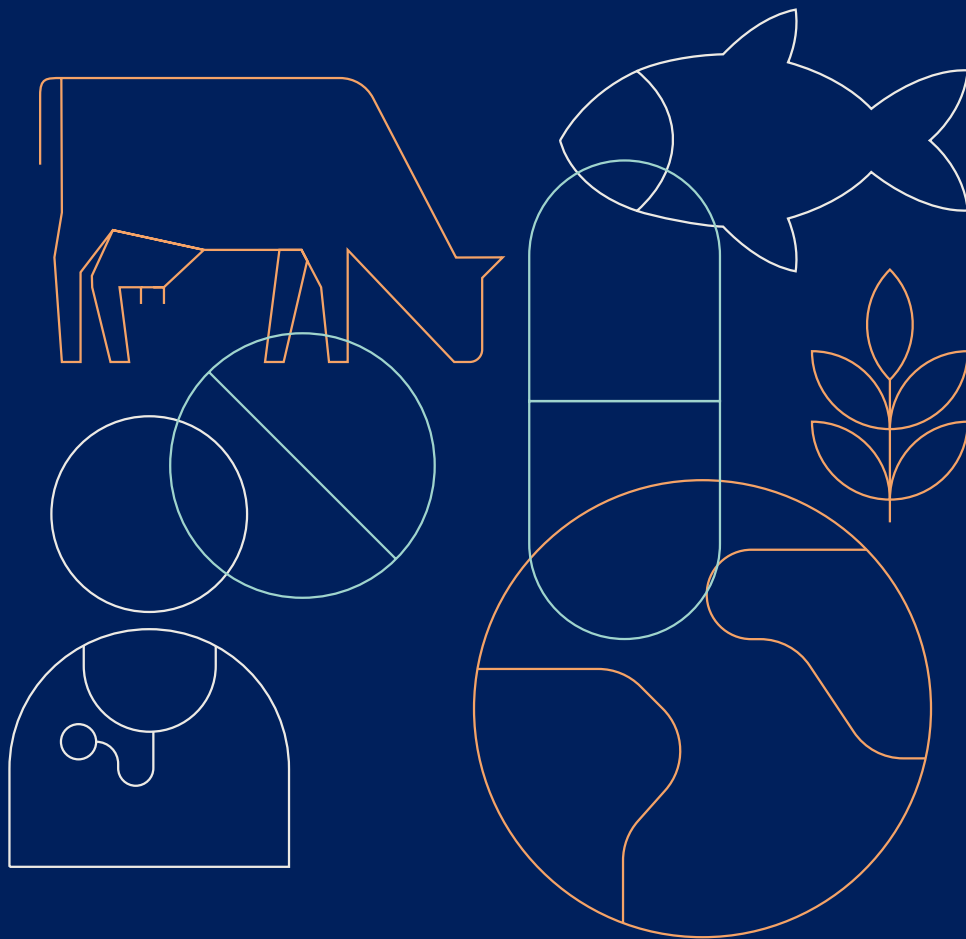


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# 1st Global Joint Summit of Human and Veterinary Medicines Regulatory Authorities to Preserve Antimicrobials

## Summit Report



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization



World Organisation  
for Animal Health  
Founded as OIE

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# Introduction

The 1st global joint summit of human and veterinary medicines regulatory authorities to preserve antimicrobials, with the theme '*Phasing out over-the-counter sales of antibiotics*,' was hosted by the Quadripartite organizations - FAO, UNEP, WHO, and WOA - on 4-5 May 2023 in Geneva, Switzerland.

The summit, conducted in a hybrid format, brought together over 200 participants from 100 countries, including human and veterinary medicines regulators, policymakers, scientists, UN agencies, international organizations, and other stakeholders from around the world. The summit agenda was informed by a series of pre-summit consultations with human and veterinary prescribers, civil society as well as industry stakeholders.

AMR is associated with a significantly high mortality and morbidity as evidenced by 4.95 million associated deaths and 1.27 million deaths attributable to bacterial AMR in 2019 with implications for public health, animal health, food security and the global economy which demands the concerted efforts of all stakeholders. The disproportionate burden of AMR borne by LMICs mostly SSA and SEA adds to the urgency for strengthening regulatory systems to address equity and prevent spread.



**Image 1** Group Photo of in-person participants at WHO Headquarters, Geneva.

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# Opening of the summit and welcome by the AMR quadrupartite leadership

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During the opening remarks of the summit, the quadrupartite leadership, consisting of Dr. Qu Dongyu, Director-General of the Food and Agriculture Organization; Dr. Tedros Adhanom Ghebreyesus, Director-General of the World Health Organization; and Dr. Monique Eloit, Director-General of the World Organisation for Animal Health, emphasized the need for enhanced regulatory capacity, enforcement mechanisms, and collaboration across sectors to control the over-the-counter sales of antibiotics, while ensuring equitable access to quality medicines for those in need.

The leaders expressed their confidence in the summit as a crucial step towards preserving the effectiveness of antimicrobials for the benefit of both human and animal health.

Speaking on behalf of the Senior Management Group of the Quadrupartite Joint Secretariat on AMR, Dr. Hanan Balkhy, Assistant Director-General of the World Health Organization for Antimicrobial Resistance, highlighted the unique role of regulators and encouraged knowledge exchange among sectors and countries at different stages of development.

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## Aim of the Summit

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The main aim of the summit was to review the current global status of over-the-counter sales of antibiotics in both human and veterinary health sectors and identify relevant intervention strategies to phase out over-the counter sales, unregulated

and unlawful online sales, as well as sub-standards and falsified medicines. The summit also aimed to define ways to enhance collaboration and coordination among human and veterinary medicines regulatory agencies and other key stakeholders.

# Regulators as critical partners in the global AMR response

The summit noted the links between AMR, the antimicrobial cycle, role of regulators, and international instruments on antimicrobial usage.

The summit also noted the possible association between the use of antimicrobials in farm animals and the development of AMR in those animals and in humans through consumption of animal foods thus underscoring the important linkage between the animal and human sectors.

## Regulator's transformative role

Dr. Haileyesus Getahun, the Director of the Quadripartite Joint Secretariat on Antimicrobial Resistance (AMR) and Director in the World Health Organization (WHO) highlighted the transformative role of regulators in strengthening national systems, focusing on the reduction of antimicrobial usage in human, animal, and agricultural sectors. The significance of this role was also linked to the recent Muscat Manifesto targets as well as early suggestions of the Global Leaders Group for consideration in the upcoming UNGA 2024 high-level meeting and the 4th Ministerial Meeting on AMR thereafter.

The Summit emphasized the importance of nationally adopting international instruments, such as the WHO Model List of Essential Medicines and the World Organisation for Animal Health (WOAH) List of Antimicrobials of Veterinary Importance, as well as the FAO-WHO Codex Alimentarius codes and WOAH International Standards to inform effective policies and strategies towards curbing over-the-counter sales of antibiotics.



The need for continuous intersectoral engagement and collaboration via a dedicated forum was also recognized especially considering that over 60% of countries having medicines regulatory agencies for animal and health sectors reporting to separate line ministries such as health and agriculture. The summit noted the opportunity to develop a collaboration mechanism or forum of regulators whose agenda could potentially inform a biennial recurring regulators' summit.

## UNGA 2024 HLM on AMR: A potential game changing opportunity?

The summit noted the upcoming high-level meeting on AMR at UNGA 2024 and the previous high-level meetings on AMR, including the [Global Leaders Group](#) and ministerial conferences that had taken place since 2014 to 2022 demonstrating existing strong political commitment. The summit noted the potential to enhance the role of regulators by integrating national systems transformation towards reducing the use of antimicrobials in human, animal, and agricultural domains into the political agenda of the Global Leaders Group and the upcoming 2024 UNGA high-level meeting on AMR.

# Over-the-counter sales of antibiotics– unveiling the realities of a growing crises

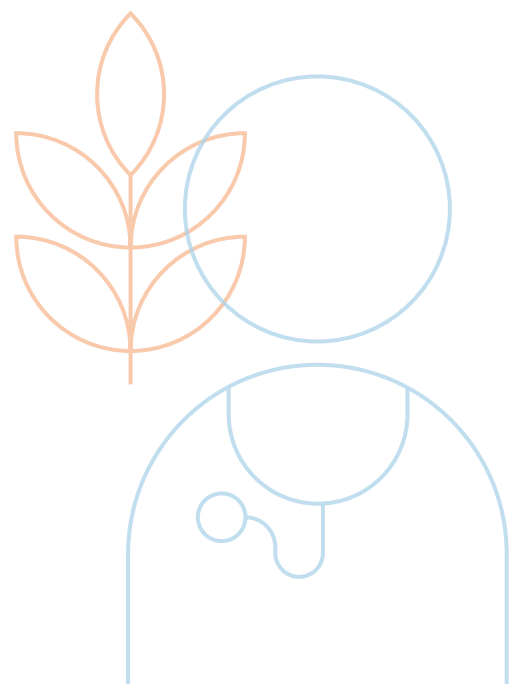
The summit addressed the growing crisis of over-the-counter sales of antibiotics and its implications. It highlighted the lack of quality data and evidence to guide policy decisions, particularly in the animal health sector.

The summit noted the global prevalence of over-the-counter antibiotic sales and the associated risks of antimicrobial resistance (AMR). It highlighted the complex transmission mechanisms of AMR among animals, humans, and through food, water, and environmental contamination as well as the potential for rapid spread of AMR across national boundaries. Over-the-counter antimicrobial usage was found to be prevalent in low-and-middle-income-countries (LMICs) particularly South America, Africa, and Asia, accounting for a significant portion of purchases in some countries. Efforts to reduce animal antimicrobial usage have shown promising results, with a 27% decrease between 2016-18. The summit acknowledged that antimicrobial overuse is not limited to LMICs, as high-income countries also faced challenges due to lack of health insurance and financial barriers.

The summit observed the role of antimicrobial overuse as a major driver of resistance, linked to health systems, demand, supply and industry factors. The summit discussed the importance of legislation in creating an enabling environment for phasing out the over-the-counter sale of antimicrobials alongside other measures such as behavior change, improved packaging and labeling, restricted drug use, and enhanced health workforce training, while noting the need for a 'just transition'.

## Taking the Bold Steps! A synopsis of country efforts in phasing out over-the-counter sales of antibiotics

The summit acknowledged both successes and challenges in phasing out over-the-counter sales, noting the contrasting legislative and regulatory actions taken by different countries. It highlighted the European Union's success in phasing out antimicrobials for growth promotion and setting reduction targets for sales in food-producing animals and aquaculture by 2030 as a model that LMICs could adopt. The need for comprehensive strategies within the framework of universal health coverage, environmental and infrastructural improvements, enhanced nutrition, vaccines and vaccination was emphasized to address the barriers to phasing out over-the-counter antimicrobial sales.



# Phasing out over-the counter sales of antibiotics: Country experiences

## South Africa: Positive results of Cross-sectoral harmonization of Antibiotic Regulation

80% of antibiotics are used in agriculture and a large number of them sold over-the-counter. Proposal adopted to manage access of antibiotics through schedules and veterinary oversight and departure from OTC antibiotics for animal use presented to Act 36/1947: Nov 2022. Cancellation of veterinary oral use preparation of Colistin as a registered medicine. Resulted in tangible migration.

## United States of America: Safeguarding Medically Important Antimicrobials through multisectoral engagement

A systematic approach based on National Antimicrobial Resistance Monitoring System Strategic Plan 2021-2025 with enhanced focus on One Health approach, and incorporation of medically important antimicrobials under vet oversight. Building consensus and

outreach proved very effective resulting in all medically important antimicrobials for animals will be under the authority of veterinarians and require a prescription as of June 2023.

## France: Cutting-edge Strategies for Veterinary antimicrobial use reduction

Remarkable success in reducing the quantity of antibiotics sales achieved (-60% on the 10 ultimate years) following implementation of a three-phase intervention applying 5 key tools including pyramidal control and traceability, implementation of an antibiotic sales; incentives, training, and market regulation. 60% reduction of antimicrobial use in veterinary sector achieved over the last ten years.

## Saudi Arabia: Effective policy reforms to curb over-the-counter sales of antibiotics

23% reduction in sales of OTC antimicrobials for human use from 2018 however injectable antibiotic usage increased by 50% in the same period.

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# International standards: Maximizing impact!

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The summit observed the role of antimicrobial overuse as a major driver of resistance, linked to health systems, demand, supply and industry factors. The summit discussed the importance of legislation in creating an enabling environment for phasing out the over-the-counter sale of antimicrobials alongside other measures such as behavior change, improved packaging and labeling, restricted drug use, and enhanced health workforce training, while noting the need for a ‘just transition’.

Technical experts from the Quadripartite and other international partners presented relevant standards aimed at enhancing the effectiveness of regulatory functions in human and animal health, as well as food safety. Notably, the summit highlighted the significance of standards such as the [WHO AWaRe Standards](#), [FAO-WHO Codex Alimentarius Standards](#), [WOAH International Standards Related to AMR](#), and the recently updated WHO [Medically Important Anti-Microbials](#) (MIA) list. Collaborative approaches that embrace these standards were emphasized to maximize synergies across sectors, ensuring the implementation of appropriate and effective regulatory strategies within the comprehensive framework of One Health.

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## Benchmarking tools: Promoting consistent standards and coherence

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The summit extensively discussed a range of benchmarking tools ([WHO global benchmarking tool](#); UK Veterinary benchmarking tool, [WOAH’s Veterinary Legislation Support Program](#), and [One Health Legislative Assessment Tool for](#)

[AMR](#)) designed to facilitate systematic assessments of the capacity, function, and quality of national regulatory systems, ultimately ensuring consistent standards, coherence, and improved outcomes.

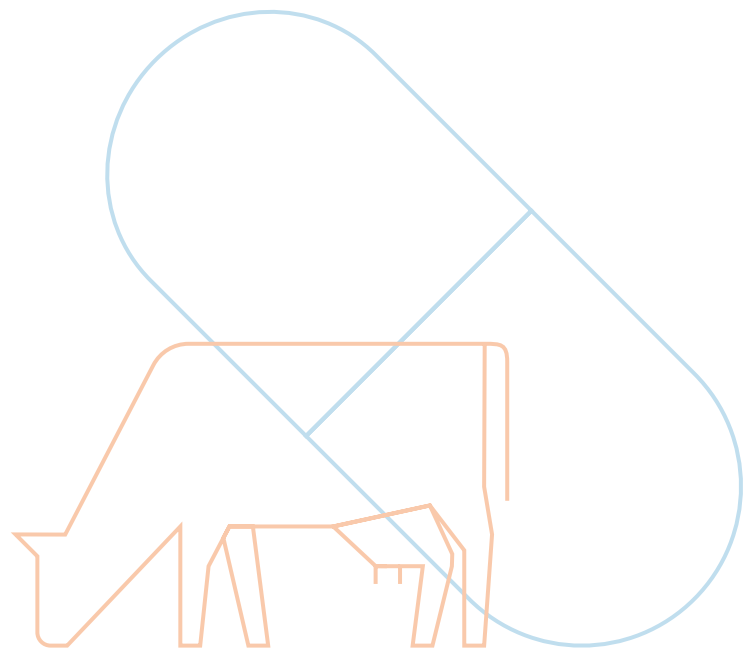
# Bolstering our defenses against antimicrobial resistance: The vital role of legislation and enforcement

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The summit emphasized the critical importance of effective legislation and robust enforcement in combating the unrestricted sale of over-the-counter (OTC) antimicrobials.

However, it was duly recognized that legislation alone is insufficient to drive substantial or desired change. To achieve meaningful progress, it is imperative to engage multiple stakeholders, including the private sector, establish efficient coordination mechanisms, allocate sufficient human and financial resources, collaborate with monitoring, and control authorities, and implement behavior change strategies. The summit acknowledged that while 147 countries had laws governing the prescription and sale of antimicrobials for human use, they are not fully aligned with international reference standards, while the number is significantly lower for terrestrial and aquatic animal use, indicating a crucial gap that needs to be urgently addressed.

To assist countries in assessing their national and regional legislation on antimicrobial resistance (AMR), the Quadripartite developed a comprehensive One Health Legislative Assessment Tool for AMR. Preliminary findings from the tool's pilot implementation revealed a lack of complete harmonization across relevant sectors, highlighting the dual necessity for sector-specific strategies and cross-sectoral solutions to effectively address AMR.



# Overcoming barriers in phasing out over-the-counter sales of antibiotics

## Madagascar: Fortifying regulatory mechanisms against the AMR Superbug Invasion

Government's 5-year plan of 2019 includes restrictions on non-veterinary medical use of antimicrobials, elimination of their unregulated use, strengthening regulation of the pharmaceutical supply chain, strengthening antimicrobial quality assurance measures, and enhancing prescriber capacity. Country efforts challenged by absence of enforcement, control, and inspection; accessibility to care, availability of products, illicit markets, self-medication; and inadequate health personnel capacity.

## Jordan: Unlocking the power of the multisectoral approach

Multi-pronged approach paying off despite challenges. Key actions include activation of existing law to control prescribing & dispensing of antimicrobials, application of the WHO AwaRe classification which modified prescription modalities, establishment of national infectious diseases treatment protocols, and the establishment of a formalized multisector coordination committee to monitor progress. Challenged by inadequate resources to maintain inspection, enforcement, and public educational campaigns. Antimicrobials added by farmers to animal feed to promote faster growth. There is also a lack of capacity to regulate and ensure prudent use of antimicrobials in healthy animals to prevent diseases.

## Mexico: Systematic approach using evidence to influence antibiotic use policy

Regular update of regulations on the list of products registered and authorized by AGRICULTURA/SENASICA based mainly on information from international organizations, especially WOA and WHO, as well as evidence from scientific publications. Country reclassified antimicrobials from group II to I (reserve) to incorporate restrictions based on AMR risks. Controlled prescriptions not required by national regulators. Systematisation Project aims to address these issues.

### Potential solutions

- Close collaboration and cooperation between medicines and veterinary drug agencies
- Financing for enforcement
- Education and public awareness campaigns
- Overall system strengthening

# Confronting substandard, and falsified medical product sales

Against the backdrop of an escalating problem of substandard and falsified (SF) medical products and their attendant consequences, the summit noted the usefulness of the various systems and activities for mitigation developed by WHO, WOAHA and FAO in supporting country efforts.

The summit also expressed concern over the increasing online purchase of over-the-counter antimicrobials, especially in LMICs, where such sales are associated with the informal sector and the common crossover usage of antimicrobials between humans and animals.

The [WHO Global Surveillance and Monitoring System \(GSMS\)](#) was acknowledged as crucial to advancing global health security. The summit observed that the problem of substandard and falsified medical products is further compounded by the rise in unregulated online purchases of antibiotics. The WHO Global Medical Product Alerts enables early detection, alerts and empower NRAs to identify SF medical products with the view to ensuring their prompt removal from the market, which in turn helps them to improve their public health outcomes. WHO confirmed the availability of the GSMS to continuously assist countries in conducting post-market surveillance activities, incident management, analytical insights, risk communication, bespoke interventions, and NRA reinforcement. The alert and reporting system also enable constructive engagements with stakeholders at national, global, and regional levels including manufacturers, customs, and telecommunication authorities. Some country examples presented demonstrated some lessons learnt and best practices in addressing the issues in diverse settings.

Similarly, the WOAHA Global Information and Alert System for substandard and falsified veterinary products currently under development for the animal health sector is expected to support mitigation within the animal health sector. This will be crucial in tackling the problem considering the sub-optimal inter-sectoral collaboration.

Additionally, WOAHA informed the summit about their ongoing effort on the development of regional laboratory networks and guidelines on post-marketing surveillance for the quality of veterinary products including antimicrobials to address this issue.

FAO supports 12 countries in the FAO Farmer Field School program, through the Fleming fund project to monitor the quality of antimicrobials in the field, enhancing policies and regulatory frameworks to minimize the role of substandard and falsified antimicrobials in food and agriculture sectors. The risk of deeper market penetration of such products increased in unregulated markets, where antibiotics were often sold without proper regulation or prescription.



**Image 2** SENASA Case Study – A Successful Experience in Argentina.

# Turning the tide against substandard and falsified (SFs) antimicrobials and online sales

## Russian Federation: Tackling Online Sales of antibiotics

Country adopted a strategy for improved measures to control the turnover of antimicrobial medicines, chemical and biological agents; and ensure interagency cooperation and development of international cooperation in the field of prevention and limitation of the spread of AMR. Tremendous success via the Information System for Monitoring the Movement of Medicines for Human Use (Traceability System) blocking over 77,000 internet resources for online sales of medicines for human use and blocked over 45,000 involved in illegal sales. Sale of unprescribed fell while online sales declined by 2%.

## Argentina: Effective regulation of online sales of antimicrobials for veterinary use

Argentina's regulation prohibits online commercialization of Antibiotics for veterinary use. A successful private-public partnership was created with the purpose of monitoring the online sale of all veterinary products subject to prescription. With this initiative, users gain trust of the platforms, and are assured of purchasing regulated products.

## Zimbabwe: Effective surveillance – enabling success against substandard and falsified medicines

Progress being made since the establishment of a surveillance system to detect substandard and falsified medical and veterinary products using Raman spectrophotometers and near-infrared spectrometers at ports of entry to Zimbabwe. Effective use of the media also to fight SF products sale. Adopted the use of WHO and WOAHA Immediate notification form to record and report product specific information on the SF resulting in at least 10 SF/illegal substance (Veterinary) reported to WOAHA in Q4 of 2022.



# Smart solutions for combating AMR

The summit provided an opportunity for countries to share valuable insights into the successful strategies and smart solutions used as adjunct to legislative and enforcement approaches. These provided ideas on measures that other countries could adapt to their specific contexts to combat AMR in both the human and animal health sectors.

## Brazil: Coordinated roll-out of a national prescription initiative

Brazil rolled out a smart and forward-thinking national prescription initiative to tackle antimicrobial based on a multisectoral (One Health) approach principally involving the Ministry of Health, ANVISA, and the Ministry of Agriculture and Livestock as well as State and municipal councils. A joint Action Plan was systematically implemented involving structural changes, IT solutions, collaboration, and effective communication initiatives which marked a significant milestone in the country's national AMR response. The establishment of a Controlled Substances National Management System (SNGPC) and the national prescription drugs management system coupled with an electronic bookkeeping system enabled comprehensive monitoring of antimicrobials in the country, which in turn promoted responsible prescription practices. Electronic Patient Information Leaflets (e-PILs) as well as campaigns such as the World Antimicrobial Awareness Week and via social media helped to reinforce public education on antimicrobial prescriptions.

## Thailand: encouraging results of integrated management and antibiotic reclassification

Thailand implemented multi-faceted smart actions to combat AMR, including antibiotic reclassification, antimicrobial stewardship, integrated AMR management in hospitals (IAM) as well as the Thai Surveillance of Antimicrobial Consumption (Thai-SAC) program. Additionally, Thailand's national drug

policy emphasized rational drug use, leading to reduced antibiotic prescription rates in cases of upper respiratory infections (URI), acute diarrhea, and fresh traumatic wounds since 2016. Overall, the country achieved a 24.8% decrease in antibiotic consumption in humans, and 36% decrease in animals between 2017 to 2020, surpassing the 30% national target. Guidelines, educational approaches, alternatives to antibiotics, and incentives collaboratively supported by the Ministry of Public Health (MOPH), the National Health Security Office (NHSO), and Health Authorities (HA) policies also played key role in the success of the program.

## Sweden: positive results from implementing a value added behaviour change strategy

The Swedish approach to combating AMR involves strong governmental commitment, active participation of stakeholders, well-functioning healthcare systems, and access to medicines, along with sufficient human and financial resources. Effective coordination, private sector commitment, and the presence of monitoring and control authorities are also crucial aspects. The country's 'Netflix model' that involves antibiotic market shaping through incentivizing pharmaceutical companies to ensuring the availability of effective antibiotics, engagement of various stakeholders achieved remarkable reduction of the inappropriate use of antimicrobials in both human and animal healthcare settings. Public education and involvement of Schools are via the "AntibiotikaSMART Sverige" program has been successful in not only reducing antibiotic demand but also shifting from "demanding" antibiotics to not anticipating prescriptions. This coupled with Health Care Professionals (HCPs) engagement, physician training using "Antibiogram" encouraged the use of access antibiotics. Public awareness and motivation are further enhanced by open publication of the results and improvements recorded. However, controlling and restricting Internet sales of antibiotics remains a significant challenge.

# Forging a resilient future against AMR

## Political

- The Summit recognized the need to continue to escalate the political prominence of antimicrobial resistance through influential platforms like the G7, G20, the Global Leaders Group, and UNGA.
- The Summit identified an opportunity to mainstream regulatory issues and give the role of regulators enhanced presence at the upcoming UN High-level meeting on AMR in 2024 by enabling regulators to feed into political processes and procedures leading up to the 2024 high level event.
- The summit recognized the urgent need for a robust financing mechanism that will leverage funds to sustainably support AMR initiatives particularly at country and regional levels.

## Technical

- The Summit requested the quadripartite to harmonize and align the Medicines Agency Self-Assessment & Evaluation Tool developed by the UK VMD with the WHO Global Benchmarking tool with the view to strengthen veterinary regulatory services and institutional development plans and establish consistent standards across regions.
- The Summit identified an opportunity to leverage data on falsified medicines and antimicrobial resistance to inform the development of national action plans and drive targeted public health interventions. Smart solutions and artificial intelligence (AI) could also be leveraged to deal with OTC sales and online sales of antimicrobials.
- The summit called on the Quadripartite to support capacity building and the provision of guidance to human and animal health national regulatory authorities with a particular focus on low-and middle-income-countries (LMICs) and Small Island Developing States (SIDS) including via North-South and South-South cooperation. This should also include establishing collaboration with Regional Economic Communities (RECs), as well as research and academia institutions.
- The Summit requested the Quadripartite to publish a policy brief on regulatory systems strengthening and expansion of surveillance from sales to actual use in recipients (for all relevant sectors).

## Collaboration

- The Summit identified an opportunity for the Quadripartite to support the establishment of a global forum for regulators as well as regional and in-country coordination mechanisms.
- Regulators expressed interest in continuing collaboration on over-the-counter products and the broader antimicrobial resistance (AMR) agenda through a recurring mechanism yet to be identified.
- The Summit identified an opportunity for the Quadripartite to facilitate sustained intersectoral collaboration of the medicines regulatory agencies via the AMR multistakeholder partnership platform to effectively maintain the momentum generated from the summit.
- The Summit requested the Quadripartite to explore how to support countries to curb unlawful and unregulated online or internet sales, including via international collaboration.

# Annex 1: Summit Agenda:

## Day 1: Thursday, 4 May 2023

### SESSION A: Welcome and global overview of the over-the-counter sales of antibiotics situation moderator:

| Time        | Session                                                                                                                                                  | Speakers                                                                    |
|-------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 08:30-09:00 | Walk-in and registration                                                                                                                                 | ALL                                                                         |
| 09:00-09:30 | Opening of the Summit and Welcome to all by the Quadripartite Leadership                                                                                 |                                                                             |
| 09:00-09:15 | FAO Welcome remarks                                                                                                                                      | Dr. QU Dongyu – DG FAO                                                      |
|             | UNEP Welcome Remarks                                                                                                                                     | Ms. Inger Andersen – ED UNEP                                                |
|             | WHO Welcome Remarks                                                                                                                                      | Dr. Tedros Adhanom Ghebreyesus -DG WHO                                      |
|             | WOAH Welcome Remarks                                                                                                                                     | Dr. Monique Eloit – DG WOAH                                                 |
|             |                                                                                                                                                          |                                                                             |
| 09:15-09:20 | Opening remarks on behalf of Senior Management Group of Quadripartite Joint Secretariat on AMR                                                           | Hanan Balkhy, Assistant Director-General, AMR Division (WHO)                |
|             |                                                                                                                                                          |                                                                             |
| 09:20-09:30 | Introduction by moderator - SLIDO                                                                                                                        |                                                                             |
| 09:30-10:00 | Setting the Scene                                                                                                                                        |                                                                             |
| 09:30-09:50 | Framing the role of Regulators and the Summit in the broader context of the global AMR response architecture and the UNGA 2024 High-Level Meeting on AMR | Haileyesus Getahun (WHO), Director, Quadripartite Joint Secretariat on AMR. |
|             |                                                                                                                                                          |                                                                             |
| 90:50-10:00 | Q&A and discussions                                                                                                                                      | ALL                                                                         |
| 10:00-10:30 | Health break                                                                                                                                             | ALL                                                                         |
| 10:30-11:30 | The global state of over-the-counter sales of antibiotics: the significance as a public health problem.                                                  |                                                                             |

## SESSION A: Welcome and global overview of the over-the-counter sales of antibiotics situation moderator:

| Time        | Session                                                                        | Speakers                                    |
|-------------|--------------------------------------------------------------------------------|---------------------------------------------|
| 10:30-10:50 | Epidemiology of over-the-counter sale of antibiotics in humans and animals.    | Daniel Morgan (University of Maryland, USA) |
| 10:50-11:10 | Over-the-counter sale of antibiotics: a societal perspective                   | Clare Chandler (LSHTM, UK)                  |
|             |                                                                                |                                             |
| 11:10-11:30 | Q&A                                                                            | ALL                                         |
| 11:30-12:30 | Country experiences with phasing out the over-the-counter sales of antibiotics |                                             |
| 11:30-11:40 | South Africa                                                                   | Alice Sigobodhla (SAHPRA)                   |
| 11:40-11:50 | United States of America                                                       | Amber McCoig (US FDA)                       |
| 11:50-12:00 | France                                                                         | Franck Foures (ANSES)                       |
|             |                                                                                |                                             |
| 12:00-12:30 | Q&A and discussions                                                            | ALL                                         |
| 12:30-14:00 | LUNCH BREAK                                                                    | ALL                                         |

## SESSION B: The role of international standards regulations and enforcement in phasing out over-the-counter sales of antibiotics

| Time         | Session                                                                               | Speakers                        |
|--------------|---------------------------------------------------------------------------------------|---------------------------------|
| 14:00- 15:30 | International standards and guidance related to over-the-counter sales of antibiotics |                                 |
| 14:00-14:15  | WHO AWaRe Standards                                                                   | Benedikt Huttner (WHO)          |
| 14:15-14:30  | FAO - Codex Alimentarius Standards                                                    | Gracia Brisco (FAO)             |
| 14:30-14:45  | WOAH - WOA Codes                                                                      | Andrés García Campos (WOAH)     |
| 14:45-15:00  | Medically Important Antimicrobials                                                    | Jorge Raul Matheu Alvarez (WHO) |
|              |                                                                                       |                                 |
| 15:00-15:30  | Q&A and discussions                                                                   | ALL                             |
| 15:30-16:00  | Health break                                                                          | ALL                             |

## SESSION B: The role of international standards regulations and enforcement in phasing out over-the-counter sales of antibiotics

| Time        | Session                                                                                                                   | Speakers                                      |
|-------------|---------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| 16:00-16:45 | Key barriers towards phasing out the over-the-counter sales of antibiotics - Country experiences                          |                                               |
| 16:00-16:10 | Madagascar                                                                                                                | Ilo Tsimok'Haja Ramahatafandry (MoA)          |
| 16:00-16:20 | Jordan                                                                                                                    | Wesal AlHaqaish (JFDA)                        |
| 16:20-16:30 | Mexico                                                                                                                    | Maria Elena Gonzalez Ruiz (SENASICA)          |
|             |                                                                                                                           |                                               |
| 16:30-16:45 | Q&A and SLIDO                                                                                                             | ALL                                           |
| 16:45-17:30 | Regulatory systems strengthening and enforcement of regulations for phasing out the over-the-counter sales of antibiotics |                                               |
| 16:45-16:50 | Strengthening regulatory and enforcement systems for phasing out the over-the-counter sales of antibiotics                | Carmen Bullon (FAO)                           |
| 16:50-17:00 | WHO Benchmarking Tool                                                                                                     | Mohamed Refaat Abdelfattah (WHO)              |
| 17:00-17:10 | UK Veterinary Benchmarking Tool                                                                                           | Noel Joseph (UKVMD)                           |
| 17:10-17:20 | Regulatory systems strengthening and enforcement strategies                                                               | Yuval Feldman (Bar-Ilan University, Tel Aviv) |
|             |                                                                                                                           |                                               |
| 17:20-17:30 | Q&A and discussions                                                                                                       | ALL                                           |
| 17:30       | RECEPTION                                                                                                                 | ALL                                           |

## Day 2: Friday, 5 May 2023

### SESSION C: Smart solutions and topics of importance in phasing out over-the-counter sales of antibiotics

| Time        | Session                                                      | Speakers                    |
|-------------|--------------------------------------------------------------|-----------------------------|
| 09:00-09:15 | Opening of Day 2 and recap of Day 1                          |                             |
| 09:15-10:30 | Issues of importance for phasing out over-the-counter sales: |                             |
| 09:15-09:20 | Online sales of medicines and health products                | Video recording (Argentina) |

## SESSION C: Smart solutions and topics of importance in phasing out over-the-counter sales of antibiotics

| Time        | Session                                                                                                   | Speakers                                           |
|-------------|-----------------------------------------------------------------------------------------------------------|----------------------------------------------------|
| 09:20-09:30 | Combating Illegal Sales of Prescription Medicines, Including Online Sales                                 | Alla Samoylova (Russian Federation)                |
| 09:30-09:40 | Substandard and falsified medicines                                                                       | Zivanai Makoni (Zimbabwe)                          |
| 09:40-10:00 | WHO and WOAHA initiatives for the Prevention, detection, and response to sub-standard, falsified products | Naseem Hudroge (WHO), Andrés García Campos (WOAH). |
|             |                                                                                                           |                                                    |
| 10:00-10:30 | Q&A and discussion                                                                                        | ALL                                                |
| 10:30-11:00 | Health break                                                                                              | ALL                                                |
| 11:00-12:00 | Smart solutions: concepts from countries around the world: success and challenge?                         |                                                    |
| 11:00-11:10 | Brazil                                                                                                    | Isabela M. A de Avila (MAPA)                       |
| 11:10-11:20 | Thailand                                                                                                  | Worasuda Yoongthong (Thai FDA)                     |
| 11:20-11:30 | Sweden                                                                                                    | Björn Eriksson (LAKEMEDELVERKET)                   |
| 11:30-11:40 | Considerations from pre-summit consultations with key stakeholders                                        | Kefas Samson (WHO)                                 |
|             |                                                                                                           |                                                    |
| 11:40-12:00 | Q&A and discussion                                                                                        |                                                    |

## SESSION D: The Communique and the Global Human and Veterinary Medicines Regulatory Authorities Summit and Forum to Preserve Antimicrobials

| Time        | Session                                                         | Speakers                                                                                                                               |
|-------------|-----------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|
| 12:00-13:00 | Moving the intersectoral collaboration agenda beyond the Summit |                                                                                                                                        |
| 12:00-12:50 | Moderated Round Table open discussion on next steps             | Regulators and Quadripartite Joint Secretariat on AMR – Haileyesus Getahun, Holy Akwar (WOAH), Samvel Azatyan (WHO), Junxia Song (FAO) |
|             | SLIDO                                                           |                                                                                                                                        |
| 12:50-13:00 | Response and feedback by Regulators                             | All                                                                                                                                    |
|             |                                                                 |                                                                                                                                        |
| 13:00       | LUNCH BREAK AND CLOSURE                                         | ALL                                                                                                                                    |

## Annex 2: List of Participants – In-person:

| No | Name                           | Country/Organization                      |
|----|--------------------------------|-------------------------------------------|
| 1  | Adeyeye MOJI                   | Nigeria                                   |
| 2  | Adi AL-NUSEIRAT                | Egypt                                     |
| 3  | Alban DHANANI                  | France                                    |
| 4  | Alla SAMOYLOVA                 | Russian Federation                        |
| 5  | Amber MCCOIG                   | USA, FDA                                  |
| 6  | Ana Cristina FERNANDES         | WHO                                       |
| 7  | Anastasiya NIKITINA            | Russian Federation                        |
| 8  | Andrea KEYTER                  | Brunei Darussalam                         |
| 9  | Andres GARCIA CAMPOS           | WOAH                                      |
| 10 | Anwar AL-SADDER                | Jordan                                    |
| 11 | Benedikt HUTTNER               | WHO                                       |
| 12 | Björn ERIKSSON                 | Sweden                                    |
| 13 | Carmen BULLON                  | FAO                                       |
| 14 | Cédric MAERCKX                 | Belgium                                   |
| 15 | Cong DUAN                      | China                                     |
| 16 | Dalel KAMOUN                   | Tunisia                                   |
| 17 | Daniel MORGAN                  | University of Maryland School of Medicine |
| 18 | Danilo LO FO WONG              | Denmark                                   |
| 19 | Delese DARKO                   | Ghana                                     |
| 20 | Dragos GUTU                    | Moldova (Republic of)                     |
| 21 | Farah Mohamed SHAWARE          | Somalia                                   |
| 22 | Franck FOURES                  | France                                    |
| 23 | Gracia Teresa BRISCO LÓPEZ     | FAO                                       |
| 24 | Hoby Sitraka RAVELOMAMPINANINA | Madagascar                                |
| 25 | Holy AKWAR                     | WOAH                                      |
| 26 | Ilo Tsimok'Haja RAMAHATAFANDRY | Madagascar                                |

| No | Name                         | Country/Organization    |
|----|------------------------------|-------------------------|
| 27 | Isabela ÁVILA                | Brazil                  |
| 28 | Jane NJIRU                   | Kenya                   |
| 29 | Jeremiah Gabriel BEECHINOR   | Ireland                 |
| 30 | Jorge Raul Matheu Alvarez    | WHO                     |
| 31 | Junxia SONG                  | FAO                     |
| 32 | Marju SAMMUL                 | Estonia                 |
| 33 | Md Mostafizur RAHMAN         | Bangladesh              |
| 34 | Meheret MELLES-BREWER        | WHO                     |
| 35 | Melchior Athanase J.C. AÏSSI | ECOWAS                  |
| 36 | Mohamed Reffat ABDELFATTAH   | WHO                     |
| 37 | Naseem HUDROGE               | WHO                     |
| 38 | Olumuyiwa SIGBEKU            | Nigeria                 |
| 39 | Philippe DOO KINGUE          | Congo, Republic of      |
| 40 | Rebecca BARKSBY              | United Kingdom          |
| 41 | Ricardo SOMARRIBA REYES      | Nicaragua               |
| 42 | S M Sabrina YESMIN           | Bangladesh              |
| 43 | Samvel AZATYAN               | WHO                     |
| 44 | Seima DIJENG                 | Botswana                |
| 45 | Shorouq ALFAWARA             | ministry of agriculture |
| 46 | Siniša TOMIĆ                 | Croatia                 |
| 47 | Sulaiman M. ALAJEL ALOTAIBI  | Saudi Arabia, FDA       |
| 48 | Valeria GIGANTE              | WHO                     |
| 49 | Vijith GUNASEKERA            | Sri Lanka               |
| 50 | Wangdi GYELTSHEN             | Bhutan                  |
| 51 | Werner KNOESS                | Germany                 |
| 52 | Wesal ALHAQAISH              | Jordan                  |
| 53 | Yvonne Korkoi NKRUMAH        | Ghana                   |
| 54 | Zanatul Aini ZAININ          | Brunei Darussalam       |

## Annex 2: Participants List - Virtual (ZOOM):

| No | Name                     | Country/Organization |
|----|--------------------------|----------------------|
| 1  | Abdourahmane MAREGA      | Country Participant  |
| 2  | Abeer Elbehairy          | Country Participant  |
| 3  | Abi Seager               | Country Participant  |
| 4  | Abigail Artiga           | Country Participant  |
| 5  | Adelaide Ayoyi           | Country Participant  |
| 6  | Advenia Sáenz            | Country Participant  |
| 7  | AEMPS Ministry of Health | Country Participant  |
| 8  | Agnes Abashaba           | Country Participant  |
| 9  | AHAMADA MSA MLIVA        | Country Participant  |
| 10 | Ahmad Hussen Tareq       | Country Participant  |
| 11 | Aitziber Echeverria      | Country Participant  |
| 12 | Alaaeldin Elkady         | Country Participant  |
| 13 | Alberto Chambe           | Country Participant  |
| 14 | Alejandro Platt Orzáez   | Country Participant  |
| 15 | Alexandra Cameron        | Quadripartite        |
| 16 | Alifah Ismail            | Country Participant  |
| 17 | Amanda Zepeda            | Country Participant  |
| 18 | Amina Achaibou           | Country Participant  |
| 19 | Ana Mateus               | Quadripartite        |
| 20 | Andre Abreu              | Country Participant  |
| 21 | Angela Schug             | Country Participant  |
| 22 | Anita Bottger            | Country Participant  |
| 23 | Anitha TUYISHIME         | Country Participant  |
| 24 | Ansshu Butani            | Quadripartite        |
| 25 | Antonio Radoev           | Country Participant  |
| 26 | Aqsa Hashmi              | Country Participant  |

| No | Name                                           | Country/Organization |
|----|------------------------------------------------|----------------------|
| 27 | Arno Muller                                    | Quadripartite        |
| 28 | ASSOUMANI MAHAMOUD                             | Quadripartite        |
| 29 | Bandar Alhammad                                | Country Participant  |
| 30 | Bassem Zayed                                   | Quadripartite        |
| 31 | Benedikt Huttner                               | Quadripartite        |
| 32 | Berta Chelle Uruguay                           | Country Participant  |
| 33 | Biljana Strojmanovska                          | Country Participant  |
| 34 | Boubacar BAH                                   | Country Participant  |
| 35 | BURHANI SIMAI                                  | Country Participant  |
| 36 | Camille Loi                                    | Quadripartite        |
| 37 | CANDELA                                        | Country Participant  |
| 38 | Carlos Alves                                   | Country Participant  |
| 39 | Carlos Enrique Jasso Villazul                  | Country Participant  |
| 40 | Cédric Maerckx                                 | Country Participant  |
| 41 | Cedric Muentener                               | Country Participant  |
| 42 | Chaiporn Pumkam                                | Country Participant  |
| 43 | Charlotte Vilstrup Castle                      | Country Participant  |
| 44 | Charunee Krisanaphan_TH (Charunee Krisanaphan) | Country Participant  |
| 45 | Chelsey Shivley                                | Country Participant  |
| 46 | Chhorvoin Om                                   | Country Participant  |
| 47 | Chinyere Okoro                                 | Quadripartite        |
| 48 | Clare Chandler                                 | Guest Speaker        |
| 49 | Claudia Tzompantzi                             | Country Participant  |
| 50 | Constanze Boenig                               | Country Participant  |
| 51 | Consuelo RUBIO MONTEJANO                       | Country Participant  |
| 52 | Dalel Kamoun                                   | Country Participant  |
| 53 | Deborah Tong                                   | Quadripartite        |
| 54 | Deon Poovan                                    | Country Participant  |
| 55 | Dharma Purushothaman                           | Country Participant  |
| 56 | dimbinavela RAOBELISON                         | Country Participant  |
| 57 | Diriba Mosissa                                 | Quadripartite        |

| No | Name                       | Country/Organization |
|----|----------------------------|----------------------|
| 58 | Dr Alice Tsitsi Sigobodhla | Country Participant  |
| 59 | Dr Carine Ngadi            | Country Participant  |
| 60 | Dr Mbadinga                | Country Participant  |
| 61 | Dr Memiaghe Vanessa        | Country Participant  |
| 62 | Dr moussidath memiaghe     | Country Participant  |
| 63 | Dr Sandrine OUEDRAOGO      | Country Participant  |
| 64 | Dr Tolla Laticiae          | Country Participant  |
| 65 | Dr.ESSYMBA Elvis           | Country Participant  |
| 66 | Elizabeth Artiga           | Country Participant  |
| 67 | Ellen Hart                 | Country Participant  |
| 68 | elvis ESSYMBA              | Country Participant  |
| 69 | Eseru                      | Country Participant  |
| 70 | Estelle Hamelin            | Quadripartite        |
| 71 | Ester Oliveira             | Country Participant  |
| 72 | Eszter Dr. Kollár-Nagy     | Country Participant  |
| 73 | fajer AlSalloom            | Country Participant  |
| 74 | Fanny Carrillo             | Country Participant  |
| 75 | Fanta SYLLA                | Country Participant  |
| 76 | Ferry (Ferry Tri Aryati)   | Country Participant  |
| 77 | Fransina Nambahu           | Country Participant  |
| 78 | Gabriela Ibarra            | Country Participant  |
| 79 | Gabriele Rothmüller        | Country Participant  |
| 80 | Gerard Mahloane            | Country Participant  |
| 81 | Gisela Papaleo Mahle       | Country Participant  |
| 82 | Gonca ÖZTAP ÖZEN           | Country Participant  |
| 83 | Gustavo Rivera             | Country Participant  |
| 84 | Helena Panayiotopoulou     | Country Participant  |
| 85 | HKSAR-Frank Chan           | Country Participant  |
| 86 | Ibrahim DJAMA ISMAEL       | Country Participant  |
| 87 | Ilse Boekhoud              | Country Participant  |
| 88 | iPhone (Stasya) (2)        | Country Participant  |

| No  | Name                                         | Country/Organization |
|-----|----------------------------------------------|----------------------|
| 89  | Irhamahayati hayati                          | Country Participant  |
| 90  | Iris Matos                                   | Country Participant  |
| 91  | Isabel Claros (Stephany Isabel López Claros) | Country Participant  |
| 92  | ISINGIZWE MARIE ANGE                         | Country Participant  |
| 93  | Jahad Alghamdi                               | Country Participant  |
| 94  | Jahad Alghamdi                               | Country Participant  |
| 95  | Javier Y. Marcos                             | Quadripartite        |
| 96  | Jean Pierre Nyemazi                          | Quadripartite        |
| 97  | Jeanne Bukeka Muhindo                        | Country Participant  |
| 98  | Jennifer Dow                                 | Country Participant  |
| 99  | Jennifer Doyle                               | Country Participant  |
| 100 | Jinho Shin                                   | Quadripartite        |
| 101 | Jonatas Lima                                 | Country Participant  |
| 102 | Joseph Aldrin Ferre                          | Country Participant  |
| 103 | Josephine Nyanzi                             | Country Participant  |
| 104 | Juline Chua                                  | Country Participant  |
| 105 | Justyna Kozik-Jaromin                        | Country Participant  |
| 106 | Karamba DIABY                                | Country Participant  |
| 107 | Katrin Schlager                              | Country Participant  |
| 108 | Kelsey Galantich                             | Quadripartite        |
| 109 | Kirill Gorelov                               | Country Participant  |
| 110 | Kitty Healey                                 | Country Participant  |
| 111 | KOMLAN AKODA                                 | Country Participant  |
| 112 | Kouadjo Théodore DOMAGNI                     | Country Participant  |
| 113 | Lamees Albawaneh                             | Country Participant  |
| 114 | Larissa Zanotto                              | Country Participant  |
| 115 | Laura Villar - NAP Spain                     | Country Participant  |
| 116 | lei shi                                      | Country Participant  |
| 117 | Lenah Mukhtar                                | Country Participant  |
| 118 | Ling Fung Chan                               | Country Participant  |
| 119 | Liz Tayler                                   | Quadripartite        |

| No  | Name                       | Country/Organization |
|-----|----------------------------|----------------------|
| 120 | Lkhagva Vanchinsuren       | Quadripartite        |
| 121 | Iora Alsawalha             | Quadripartite        |
| 122 | Lorena Reyes Guerra        | Country Participant  |
| 123 | Lot Chan                   | Country Participant  |
| 124 | Luiz Henrique Costa        | Country Participant  |
| 125 | Malik Asad                 | Country Participant  |
| 126 | Malika Sarr                | Quadripartite        |
| 127 | MARIA ELENA GONZALEZ       | Country Participant  |
| 128 | Maria Martynova            | Country Participant  |
| 129 | Maria Trainer              | Country Participant  |
| 130 | Mariana Santillán COFEPRIS | Country Participant  |
| 131 | Marie-Lyvie Oulabou        | Country Participant  |
| 132 | Marina Sokolova            | Country Participant  |
| 133 | Marius M. Bunea ROvet      | Country Participant  |
| 134 | Mark Schipp                | Country Participant  |
| 135 | Martin Josheski            | Country Participant  |
| 136 | Martina Escher             | Country Participant  |
| 137 | Mathias Lukwago            | Country Participant  |
| 138 | MHAZA Hassane              | Country Participant  |
| 139 | Mi Sh                      | Country Participant  |
| 140 | Michel Rouamba             | Country Participant  |
| 141 | Mimi Melles-Brewer         | Quadripartite        |
| 142 | Mirela Eidt                | Country Participant  |
| 143 | Mohammad Yousuf            | Country Participant  |
| 144 | Momir Radulović            | Country Participant  |
| 145 | Morgan Jeannin WOAHA       | Quadripartite        |
| 146 | Moussa Ibrahim             | Country Participant  |
| 147 | Moussa MZE                 | Country Participant  |
| 148 | Nada Hanna                 | Country Participant  |
| 149 | Nadia UWERA                | Country Participant  |
| 150 | Nadine NIYOMAHORO          | Country Participant  |

| No  | Name                                       | Country/Organization |
|-----|--------------------------------------------|----------------------|
| 151 | Natercia Caporali                          | Country Participant  |
| 152 | Nithima Sumpradit                          | Country Participant  |
| 153 | Noe Geovanni García Iraheta                | Country Participant  |
| 154 | Noel Aineplan                              | Country Participant  |
| 155 | Noel Joseph                                | Country Participant  |
| 156 | Nuwe Marina                                | Country Participant  |
| 157 | Obaidullah Malik                           | Country Participant  |
| 158 | Olga Ivanova                               | Country Participant  |
| 159 | Olivia RANAIVOARIMANANA                    | Country Participant  |
| 160 | Olivier Mureramanzi                        | Country Participant  |
| 161 | Pasi Penttinen                             | Country Participant  |
| 162 | Paul Joseph Portelli                       | Country Participant  |
| 163 | Philip Mathew                              | Quadripartite        |
| 164 | Polina Zaborkina                           | Country Participant  |
| 165 | Purnomo Siddhi                             | Country Participant  |
| 166 | Renata Peral                               | Country Participant  |
| 167 | Robert Ssekajjugo                          | Country Participant  |
| 168 | Robin Rojas                                | Quadripartite        |
| 169 | Rohaya Mohd Ali                            | Country Participant  |
| 170 | Rosine Manishimwe                          | Country Participant  |
| 171 | Rukia Saidi                                | Country Participant  |
| 172 | Said Farzullayev                           | Country Participant  |
| 173 | Saliha SADKI                               | Country Participant  |
| 174 | Samiha Toumi                               | Country Participant  |
| 175 | Samvel Azatyan WHO HQ/REG (Samvel Azatyan) | Quadripartite        |
| 176 | Sanna Gevers                               | Country Participant  |
| 177 | Sarah Paulin                               | Quadripartite        |
| 178 | Shereen Abdelgawad                         | Country Participant  |
| 179 | Silverani Padayachee                       | Country Participant  |
| 180 | Sirima Punnin                              | Country Participant  |
| 181 | Sofi Taubkina                              | Country Participant  |

| No  | Name                        | Country/Organization |
|-----|-----------------------------|----------------------|
| 182 | Soufiana KABA               | Country Participant  |
| 183 | Stéphanie Laruelle          | Quadripartite        |
| 184 | Sulaiman Alajel             | Country Participant  |
| 185 | Suzanne Young               | Quadripartite        |
| 186 | TAMAR KIRVALIDZE            | Country Participant  |
| 187 | Thanyaporn Puengpipattrakul | Country Participant  |
| 188 | Thomas Heberer              | Country Participant  |
| 189 | Thomas Joseph               | Quadripartite        |
| 190 | Tikiri Priyantha            | Quadripartite        |
| 191 | Valeria Pasarin             | Quadripartite        |
| 192 | Verica Ivanovskai           | Quadripartite        |
| 193 | Walter Fuller               | Quadripartite        |
| 194 | Wangdi Gyeltshen            | Country Participant  |
| 195 | Worasuda Yoongthong         | Country Participant  |
| 196 | Yuval Feldman               | Country Participant  |
| 197 | Zivanai Makoni              | Country Participant  |
| 198 | Zizwe Cindzi                | Country Participant  |
| 199 | Алина Попова                | Country Participant  |

