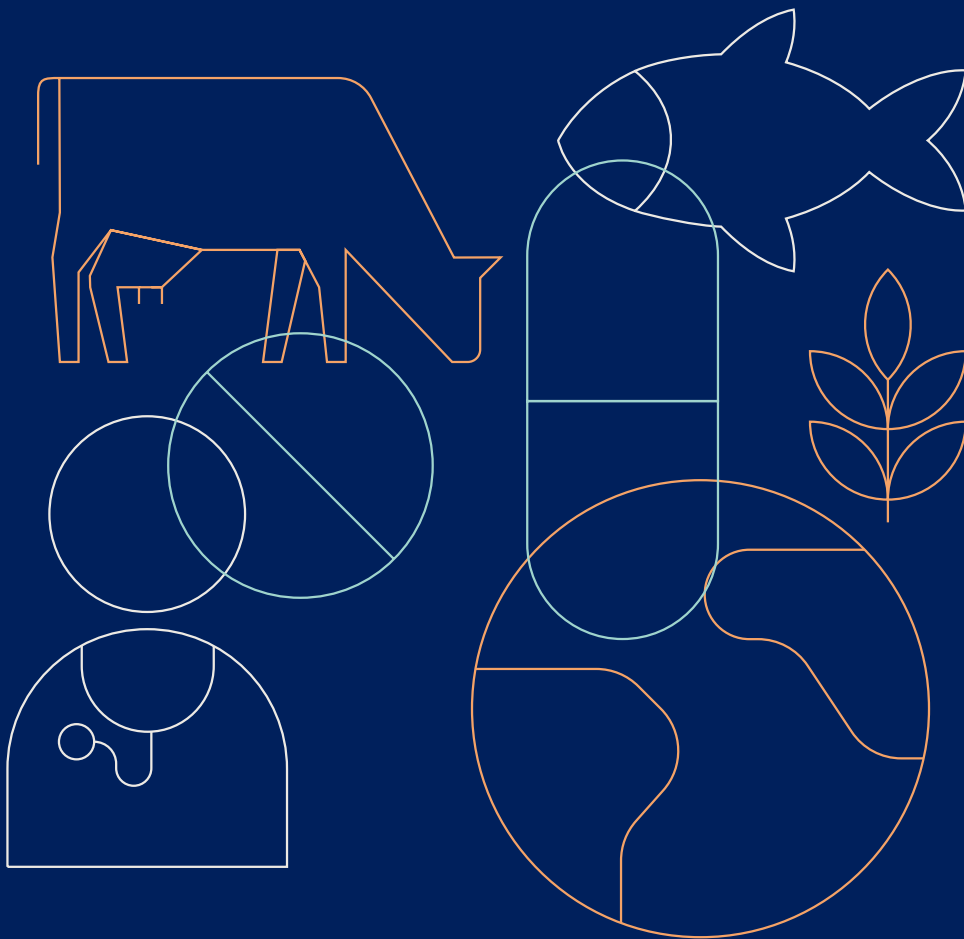

1st Global Joint Summit of Human and Veterinary Medicines Regulatory Authorities to Preserve Antimicrobials

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.

Opening of the summit and welcome by the AMR quadripartite leadership

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During the opening remarks of the summit, the quadripartite 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 Quadripartite 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.

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 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

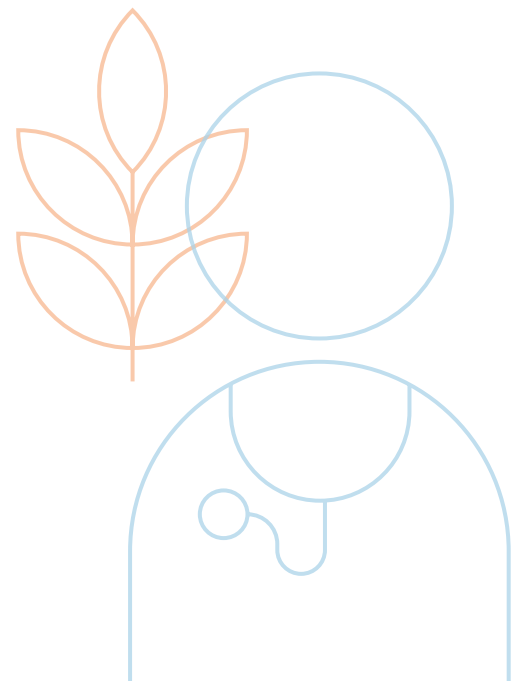
The summit addressed the growing crisis of over-the-counter sales of antibiotics and its implications. It highlighted the lack of quality data and evidence to guide policy decisions, particularly in the animal health sector.

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.

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 Antimicrobials](#) (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.

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.

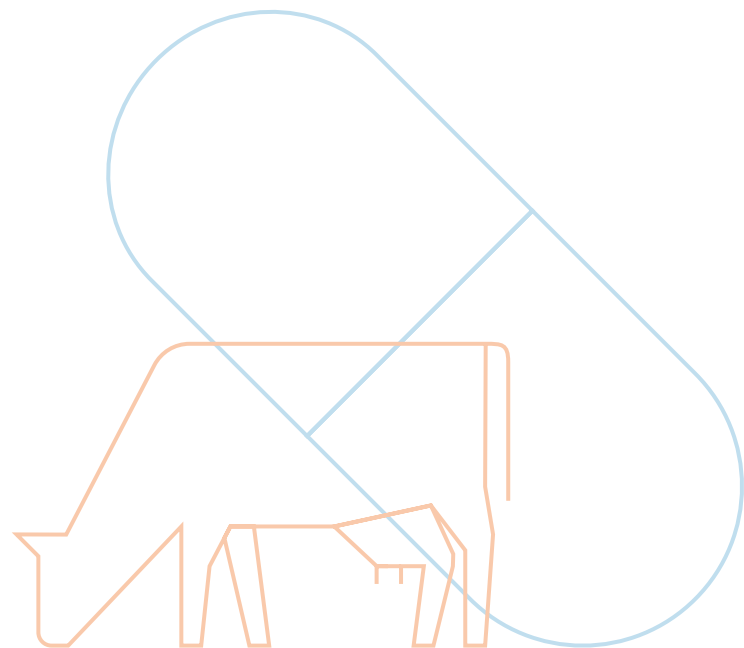
Bolstering our defenses against antimicrobial resistance: The vital role of legislation and enforcement

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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 WOH 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

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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, WOH 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 WOH 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, WOH 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 unlicensed 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 WOH Immediate notification form to record and report product specific information on the SF resulting in at least 10 SF/illegal substance (Veterinary) reported to WOH 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 MELLESE-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	lora 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	Samaha 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

