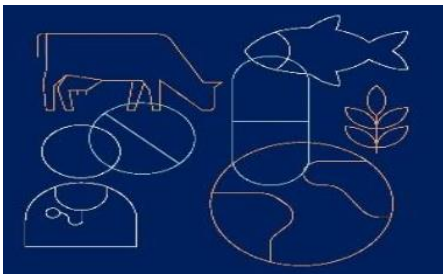
Second Global Regulatory Authorities Summit on Antimicrobial Resistance (AMR) 14-15 January 2026



CONCEPT NOTE

Theme: Strengthening Regulatory Practices on Labelling for Antimicrobials to promote Appropriate use and disposal – A One Health Perspective

Background:

The 1st Global Regulatory Summit on AMR, held in May 2023, focused on phasing out over the counter (OTC) antibiotic sales and set a clear agenda for coordinated regulatory action across sectors. Key outcomes included:

- Recognition of the role of regulators in the AMR response and launch of Regulatory Agencies Global Network against AMR (RAGNA) for stronger engagement in the global forums
- A call for adaptable regulatory tools targeted and capacity-building support for LMICs and SIDS
- Cross-sector collaboration on over-the-counter sales, falsified medicines, and environmental oversight

The first summit did not issue formal recommendations but established a shared understanding of regulatory priorities and the need for continued dialogue.

The 2024 UNGA Political Declaration[1] on AMR explicitly recognized the need to strengthen national and regional regulatory bodies, promote implementation and accountability, and provide targeted assistance to low- and middle-income countries. Responding to the Declaration, the Jeddah commitments[2], and the RAGNA call to action[3], the 2nd Global Regulatory Summit will translate high-level commitments into practical, regulator-led action through a single cross-cutting entry point:

Labelling for Antimicrobials - A One Health Perspective:

Labelling travels with every antimicrobial product. Harmonized, clearly presented labelling provides end users with essential directions on dosage, duration, withdrawal periods, and includes product information leaflets (PILs). Environmental labelling[4] is part of regulatory labelling and provides lifecycle environmental disclosures on production, risks, and disposal of medicines. This promotes sustainable environmental practices, empowers informed decision-making, and supports regulators in mitigating environmental impact. Labelling is a low-cost regulatory tool that can:

- guide responsible access and use
- flag falsified or sub-standard lots
- promote sustainable environmental practices
- embed track-and-trace digital

[1] UNGA 2024 Political Declaration

[2] Jeddah Commitments

[3] RAGNA call to action

[4] The concept of 'environmental labelling' does not have an agreed definition, however, its recognizable features have been identified by certain jurisdictions, warranting consideration by the international community, for instance the… Directive 2004/27/EC amends the EU medicinal products code (Directive 2001/83/EC), introducing key environmental provisions. It requires an Environmental Risk Assessment (ERA) as part of marketing authorization applications for new medicines; mandates inclusion of clear disposal instructions in patient leaflets to minimize environmental harm; and emphasizes safe disposal measures.

Once the OTC loopholes are closed, the label itself becomes a final regulator in every clinic, farm and household.

Real-world evidence shows labelling works:

- After 2016 U.S. boxed-warning update on fluoroquinolone labels cut [5] inappropriate UTI prescriptions dropped from 42 % to 19 % within two years
- Hospital penicillin-allergy "de-labelling"[6] programmes reduced broad-spectrum antibiotic days by 24 % while restoring first-line β-lactams.
- Retail poultry carrying an "antibiotic-free" logo [7]showed 28 % multidrug-resistant *Salmonella* versus 55 % in conventional meat – CIDRAP

Scope:

The 2nd Global Regulatory Summit will be a technical dialogue, not a normative process, among regulators from across sectors. It will:

- exchange country experiences and regulatory approaches already in use, focusing on practical implementation within existing mandates.
- deep-dive into dosage-and-indication labelling, disposal (as part of environmental labelling), product information leaflets (PILs) and language/translation strategies
- examine how antimicrobial labelling including environmental labelling, enhances equitable access, promotes responsible use, reduces environmental impact, and strengthens risk communication
- clarify the role of National Regulatory Authorities (NRAs) in advancing quality, safety, appropriate use, and reduced environmental impact through labelling.
- *Clarify that reference to environmental labelling is intended to support technical dialogue and peer exchange only. No new normative standards or definitions are proposed, the focus is on practical element already in use such as safe disposal, ERA information, and sustainability-relevant practices [4].*

S.No.	Tangible Action	PD/JC	Lifecycle link
1.	Support regulator-led labelling for human and veterinary antimicrobials - voluntary where feasible and or/compulsory where already mandated, including environmental labelling elements (e.g.: disposal and other lifecycle disclosures) where appropriate	Para 21, 45, 55, 63-64, 65, 92 and Jeddah #5, #7)	Equitable access, informed use, safe disposal, cross sector governance

Purpose:

Establish a shared regulatory pathway for integrating antimicrobial labelling including environmental labelling elements withing existing national frameworks, agree a concise set of voluntary actions for pilot implementation with priority support for LMICs/SIDS, and assign follow-up responsibilities under RAGNA and the Quadripartite Joint Secretariat.

[5] Tran PT, Antonelli PJ, Hincapie-Castillo JM, Winterstein AG. Association of US Food and Drug Administration Removal of Indications for Use of Oral Quinolones with Prescribing Trends. *JAMA Intern Med.* 2021;181(6):808–816. doi:10.1001/jamainternmed.2021.1154. (PubMed: 33871571)

[6] Penicillin-allergy de-labelling (PubMed: 32756983)

[7] Antibiotic-free logo

Objectives:

1. Share country experiences and practical tools on dosage-and-indication labelling, disposal (as part of environmental labelling), PILs, and multilingual labelling.
2. Explore how regulatory labelling, including environmental labelling can improve access, promote responsible use, increase detection of substandard and falsified products, and reduce environmental impact, especially in LMICs and SIDS contexts.
3. Facilitate cross-sector dialogue on challenges, innovations, and enabling conditions for improved antimicrobial and environmental labelling
4. Identify opportunities for collaboration on voluntary regulatory approaches such as track-and-trace, product inserts and multilingual labelling.
5. Clarify the role of regulatory authorities in ensuring quality, safety, user protection, through appropriate labelling including environmental labelling within current legal frameworks.
6. Foster harmonization in antimicrobials labelling at the supranational and regional level

Expected Outcomes:

By the end of the summit, the participants will:

1. Share a common understanding of how antimicrobial labelling and environmental labelling advance quality, safety and support sustainable environmental practices (e.g. disposal) across human, animal and environmental sectors.
2. Document national and regional regulatory best practices to inform peer learning, technical exchange, and adaptation with emphasis on LMIC/SIDS needs
3. Identify regulatory priorities and areas of future cooperation under the Quadripartite and RAGNA frameworks for stronger labelling and environmental labelling practices.
4. Outline follow-up actions and resource needs to strengthen regulator-led labelling including environmental labelling within national regulatory frameworks, particularly in resource-limited settings, and to foster supranational harmonization.

Format:

The Second Global Regulatory Summit will be delivered virtually over two 2 hour 45 minutes technical session (incl. 15 min break). The programme will move from global/regional to national perspectives and will combine framing presentations, interactive panel discussions, and multi-sectoral breakout groups to support cross-pollination of regulatory ideas and align them in country contexts.

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