Spanish Action Plan on Antibiotic Resistance

One Health high-level meeting on Antimicrobial Resistance

Briefing Note

Pamplona, 18 and 19 october 2023

MINISTERIO DE SANIDAD

agencia española de medicamentos y productos sanitarios

EU23 SPANISH PRESIDEN COUNCIL OF THE EUROPEAN UN

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CONTEXT

Antimicrobial Resistance (AMR) causes a significant impact on microbiology, epidemiology and clinical practice, and it already represents a serious social and economic burden, threatening the achievement of several of the United Nations sustainable development goals. AMR must be addressed from a single or "One Health" perspective. This approach recognises that human health and animal health are interdependent and linked to the ecosystems and environment in which they coexist.

The European Union One Health Action Plan against AMR, published in 2017, aims to address the problem of AMR. The EU Council Recommendation on stepping up EU action to combat antimicrobial resistance in the framework of the One Health approach calls on Member States to combat AMR through a joint approach. As such, the fight against antimicrobial resistance was established as a priority on the agendas of the different EU Council presidencies.

The Spanish Presidency of the EU Council during the second half of 2023 provided an excellent opportunity to lead EU recommendations giving continuity to the actions carried out in previous years, and showing the firm commitment it has always had with this serious public health problem. In this context, on October 2023, the Spanish National Action Plan against AMR (PRAN), coordinated by the Spanish Agency for medicines and Medical Devices (AEMPS), organized a One Health High-Level Meeting on AMR. This meeting was intended to respond to one of the priorities of the Spanish Presidency and brought together the highest representatives of the European and international institutions, as well as the Spanish Minister of Health. The aim of the event was to host a high-level debate among EU representatives to discuss, from a One Health perspective, the main challenges we face in this public health problem.

On October 18th, the Spanish National Action Plan against AMR (PRAN), the Spanish Agency for Medicines and Medical Devices (AEMPS) and the European Medicines Agency (EMA) organised a meeting of AMR experts to present the European Medicines Agencies Network Strategy to 2025. The working sessions focused on the new AMR 2025 strategy and the communication strategies needed to raise awareness among professionals and the general public. The recording of thePRAN-EMA-HMA expert meeting is available at the following link

Simultaneously, the Ibero-American Medicines Authorities Network (Red EAMI) gathered for a one-day plenary meeting where they had the chance to discuss their Strategic Plan, working priorities and the follow-up of ongoing activities. The meeting was attended by 14 country members.

Taking advantage of the important topic that brought them to Pamplona, a special session on AMR and the One Health approach took place. In this line, several representatives shared information on their national actions plans and the actions and activities implemented to address this global threat. This exchange of information and best practices engaged the participants in a very rich and fruitful discussion on the challenges and opportunities they face at national level. This discussion highlighted once again the key role of the One Health and international perspective in the fight against AMR.

The high-level meeting was held on October 19 and was organised in round tables to foster open discussions. It included an introduction of the Regulatory Agencies Global Network against AMR (RAGNA) as a model for a global AMR strategy, a dialog on integrated surveillance systems in Europe, and a discussion oncross-sectorial coordination between regions. A recording of the One Health High-Level Meeting is available at the following link.

PROGRAMME
18th October

PRESIDENCIA ESPAÑOLA
CONSEJO DE LA UNIÓN EUROPEA

Expert meeting

"PRAN-EMA-HMA MEETING ON ANTIMICROBIAL RESISTANCE IN EUROPE" 17th and 18th October

	17 OCTOBER
19:30-21:00	*Reception and welcome cocktail*
	18 OCTOBER
09:00-09:30	**Reception**
09:30-10:00	**Welcome and Opening remarks** María Lamas - Executive Director AEMPS Björn Eriksson - Director General, Swedish MPA Emer Cooke - Executive Director EMA
10:00-11:00	**EMA-HMA Antimicrobial Resistance Strategy 2025 – Session 1** **Presentation of EMANS 2025 / Theme 4 on AMR** • Thomas Heberer - Head of Department , Veterinary Medicines, BVL • Barbara Freischem - AMR Senior Specialist, Veterinary Division, EMA
11:00-11:30	*Coffee break*
11:30-12:30	**EMA-HMA Antimicrobial Resistance Strategy 2025 – Session 2** **Surveillance of antimicrobial consumption in humans and in animals** • Katharina Hofmann - Scientific Officer, Drug Resistance, BVL • Dominique Monnet - Head of Section, AMR and HAIs, DPR – ECDC
12:30-13:30	**EMA-HMA Antimicrobial Resistance Strategy 2025 – Session 3** **AMR diagnosis tools** • Zoltan Kunsagi - Head of Service Veterinary AMR, EMA • Boudewijn Catry - CVMP AMR Working Party, EMA • Radu Botgros - Senior Scientific Officer, EMA • Olman Elizondo - Project Manager Proyecto RaDAR PPI, AQuAS de Catalunya
13:30-15:00	*Lunch break*
15:00-16:30	**Communication strategies for improving public awareness on AMR** Moderator: Diego Pernas - Head of Communication, AEMPS and Co-chair of the Group of Communication, HMA • Danilo Lo-Fo-Wong - European Regional Adviser Control of AMR, WHO • Svenja Sander - Head of Drug Resistance, BVL • Camelia Enachioiu - Communication Officer and Social Media Coordinator, EMA • María Santacreu - Head of Communication, Spanish NAP on AMR (PRAN)
18:30	*Social event*
21:00	*Gala dinner*

PROGRAMME
19th October

UE23 PRESIDENCIA ESPAÑOLA CONSEJO DE LA UNIÓN EUROPEA

High-Level Meeting

"Antimicrobial Resistance in Europe" 19th October

	18 OCTOBER
18:30	*Social event*
21:00	*Gala dinner*
	19 OCTOBER
09:00-9:30	*Registration*
09:30-10:15	**Welcome** Fernando Domínguez – Health Counsellor of Navarra, Spain José Miñones – Minister for Health, Spain
10:15-10:30	**Opening remarks** Roser Domenech Amado - Director of One Health, EC (DG SANTE)
10:30-11:15	**Round table 1: RAGNA, a global AMR strategy: implementation, governance, and management** Moderator: Björn Eriksson - Director General, Swedish MPA • Jean Pierre Nyemazi - Healthcare Delivery Scientist, WHO • Thomas Heberer - HMA management group • Fanny Marcela Carrillo - Medical Supervisor Specialist in Medication Registration El Salvador • Pharm Okanlawon Abayomi Samuel - Deputy Director, NAFDAC
11:15-11:45	*Coffee break*
11:45-12:30	**Round table 2: Integrated surveillance systems in Europe: harmonization to succeed** Moderator: María Lamas - Executive Director, AEMPS • Ernesto Liébana Criado - Team Leader, BIOHAZ Unit, EFSA • Barbara Freischem - Head of Veterinary Surveillance and Regulatory Support, EMA • Dominique Monnet - Head of Section, AMR and HAIs, DPR – ECDC • Caroline Whalley Expert on Water Industries and Pollution, EEA
12:30-13:15	**Round table 3: Intersectoral Coordination across regions: improve synergies to face AMR.** Moderator: Danilo Lo-Fo-Wong - European Regional Adviser Control of AMR, WHO • Christine Årdal - EU Joint Action on AMR and Healthcare-Associated Infections • Javier Yugueros-Marcos - Head of the AMR & Veterinary Products, WOAH • Pilar Ramon-Pardo - Head of special AMR programme, PAHO/WHO • Daniel Beltran-Alcrudo - Technical Advisor, FAO Europe and Central Asia • Barbara Mentré – Legislative Officer Unit on AMR and Human Nutrition, DG SANTE
13:15-13:30	**Closing remarks** María Lamas – Executive Director, AEMPS
13:30	**Family photo**
13:40	*Cocktail*

ONE HEALTH HIGH-LEVEL MEETING ON AMR

1. ROUND TABLE - RAGNA, A GLOBAL AMR STRATEGY: IMPLEMENTATION, GOVERNANCE AND MANAGEMENT

Regulatory Agencies Global Network against AMR (RAGNA) is an initiative lead by Swedish Medical Products Agency (MPA), involving representatives from regulatory agencies, globally for both human and veterinary medicines. It is a good example of a One Health project to promote antimicrobial accessibility through globally coordinated initiatives, as required by the EU Council.

RAGNA's objectives are fully in line with the urgent need to effectively combat AMR. Strengthening international collaboration, identifying practical contributions and sharing best practices between regulatory agencies are fundamental pillars in order to fulfil its mission. The objective of this roundtable was d to discuss the crucial and collective role that regulatory agencies around the world play in contributing to global solutions to combat AMR.

The discussion was enriched by the diverse perspectives of esteemed speakers from two regulatory agencies, such as the National Agency for Food and Drug Administration and Control (NAFDAC, Nigeria) and the National Directorate of Medicine (El Salvador) within the EAMI network, the Head of Medicines Agency (HMA) and the World Health Organisation (WHO), as a representative of the quadripartite. The moderator was the Director of the Swedish MPA.

All panellists were asked about how their institution could encourage participation in RAGNA and they were invited to share how synergies are being sought. The panelists discussed the role of the quadripartite in RAGNA. The HMA representative noted that the current pharmaceutical legislation on human medicines was under review, with special emphasis on measures to encourage antibiotic research. This representative also provided insight on the usefulness of RAGNA in the implementation of the new legislative requirements (both human and veterinary regulations). On the other hand, the NAFDAC representative mentioned that a new African Agency of Medicines was recently founded, and reflected on how RAGNA can positively influence on its development and viceversa.

Key messages

- There is an urgency to address AMR. The escalating threat of AMR requires swift and unified action on a global scale.

- Regulatory agencies cannot simply be a network, but a platform for action. Tangible and concrete actions against AMR are deemed necessary. Surveillance data can lead to impactful change and RAGNA is well placed to translate this dialogue into action.

- The upcoming UN General Assembly high-level meeting on AMR in September 2024 presents a significant opportunity in order to propose feasible, evidence-based actions within the regulatory mandate to combat AMR globally.

- RAGNA can interconnect regulatory bodies from different countries. These partnerships broaden the scope and impact of RAGNA, promoting a more comprehensive response to AMR.

- Surveillance of consumption and resistance is key to have a better picture of the real AMR situation in each country. There is also a need for constant data sharing.

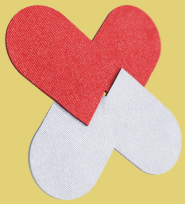
2. ROUND TABLE - INTEGRATED SURVEILLANCE SYSTEMS IN EUROPE: HARMONIZATION TO SUCCEED

The Council of the EU encourages the development of integrated surveillance systems for AMR and antimicrobial consumption covering human, animal and plant health in an interconnected environment. Integrated surveillance should enable robust conclusions to be drawn on the interconnections between humans, animals and the environment with the ultimate goal of implementing regulatory actions.

In this context, the aim of this table was to discuss the best strategies for developing integrated surveillance systems involving all European Agencies with competencies in surveillance of either consumption or/and resistance: the European Centre for Disease Prevention and Control (ECDC), the European Food Safety Authority (EFSA), the European Environment Agency (EEA) and the European Medicines Agency (EMA). The discussion focused on new opportunities and synergies arising from the integration of information and digitalisation of Member States´ health systems to strengthen the European Health Union, enhance cooperation, reinforce existing surveillance systems, and access to real-time AMR data.

All panellists provided their views on the optimal determinant(s) of integrated surveillance. Each of them also discussed specific issues related to their institution. Such was the case of the ECDC representative, who revealed that the Data Analysis and Real World Interrogation Network (DARWIN EU) plays an important role in the development of integrated surveillance systems.

In addition, the EFSA representative highlighted that its Agency was working on several projects and is planning to initiate new ones on how to generate data from different food production systems to be integrated into surveillance systems. On the other hand, the EEA representative mentioned that, in the last few years, the European Commission had proposed and adopted numerous Directives and Regulations on water in which antimicrobial resistance and antibiotic residues have a special consideration. It was also explained how these changes will affect EEA's current procedures and operations, as well as the impact of these new legislations on current environmental monitoring. Finally, the EMA representative summarised that the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project was updated to European Sales and Use of Antimicrobials for veterinary medicine (ESUAVET) to collect data on antimicrobial use in animals. In addition, there was a discussion on how to combine this data source into an integrated EU-wide surveillance system.



Key messages

- Data harmonisation is a key element in developing an integrated surveillance system that can provide answers to fill the knowledge gaps.

- Data brings together measurable indicators that can compute trends and measure risks by conducting risk assessments that can drive policies and regulations.

- Some information/data gaps still exist (eg. water in food production systems and the environment, use of antimicrobials in plants, antifungicides). Interagency collaborative projects are fundamental to fill these gaps.

- Experience with previous programs can provide us some benefits: monitoring of air quality and other markers linking health and environment, initiatives in the field of chemicals, monitoring of Sars-Cov-2 in wastewater and monitoring of fungicide resistance that integrates five European agencies.

3. ROUND TABLE - INTERSECTORAL COORDINATION ACROSS REGIONS: IMPROVE SYNERGIES TO FACE AMR

The objective of this roundtable was, as remarked by the EU Council, to highlight the importance of coordination and cooperation between different sectors to address AMR as a global One Health challenge that affects all sectors. The discussion was enriched by several sectors that are essential to tackle the AMR problem globally as a One Health issue: the European Commission (DG SANTE) as G20 representative, global institutions such as the Pan American Health Organisation's/World Health Organisation (WHO/PAHO) , the World Organisation for Animal Health (WOAH), the Food and Agriculture Organisation (FAO), and the Global AMR Hub.

The panelists were asked to deliberate on the most effective ways to formulate plans and enable information exchange to bridge the gap between the different domains (human, animal, plant and environmental) from a regional perspective. As moderator of the panel, the WHO Regional Advisor for AMR Control and Regional Office for Europe, highlighted the need for international cooperation as top research priority of One Health regarding AMR.

The panelists were invited to reveal how communication between sectors can be promoted from a One Health perspective, for example, by sharing the vision, challenges, and opportunities of each of the institutions. This question was intended to provide ideas on how to foster coordination and/or collaboration across sectors in each region based on their experience. They were also invited to reflect on how their institutions can collaborate in a global context and which challenges they encountered in developing and implementing cross-regional cooperation and/or collaboration. This question gave an opportunity to present their ideas for improving synergies in the fight against AMR across regions.

Key messages

- It is crucial to establish work plans, monitor and evaluate them to demonstrate the success of the One Health approach.

- Innovation is needed to improve the accessibility to antibiotics, taking into account the association of the supply chain and the impact on the environment.

- The creation of working groups from different regions and sectors is fundamental to share ideas, guidelines and knowledge.

- It is key to coordinate efforts and policies between institutions and organisations to prevent duplications.

- Financial support is critical in Research and Development in all sectors.

- Targets should be defined to optimise the use of antimicrobials, especially in those sectors showing a downward trend in antibiotic use.

- Collaboration between different areas of expertise should be carried out systematically, and bridges should be built between silos and sectors.

FUTURE ACTIONS

The diverse perspectives and ideas presented during the different roundtables and sessions were inspiring, and they will undoubtedly have a lasting impact on our collective efforts to combat AMR.

The main conclusions of the fruitful discussions by worldwide-renowned experts from various regulatory agencies and leading international organisations will help guide future actions to develop effective strategies to address the AMR problem.

- Strengthening international collaboration to exchange knowledge of experiences and practices across sectors will form a global strategy to effectively combat AMR, with regulatory agencies around the world playing an important role in combatting AMR and contributing to global solutions.

- Harmonisation of data collected from different surveillance networks will provide the appropriate framework to develop an integrated surveillance system with measurable indicators to assess progress that will support risk assessment to drive policy and regulation.

- Improving good communication to foster coordination and cooperation between human, animal, plant and environment sectors will facilitate the definition of strategies to tackle AMR using a One Health approach, and facilitate the flow of information to bridge the gap between the different sectors (human, animal, plant, environmental) from a regional perspective.

ABOUT THE SPANISH NAP AGAINST AMR – PRAN

The Spanish National Action Plan against AMR (PRAN) started in 2014, coordinated by the Spanish Agency for Medicines and Medical Devices (AEMPS) and approved by the Interterritorial Council for the Spanish National Health System and the Plenary Session of the Sectorial Conference of the Spanish Ministry of Agriculture.

Since then, the PRAN is resolutely committed to tackling the growing threat of antimicrobial resistance (AMR) through a multifaceted strategy that aligns with the EU action plan on AMR, the Global Action Plan on AMR and the new European Roadmap on Antimicrobial Resistance (2023-2030).

Recognising the imperative of collaboration and integration, the PRAN advocates for a One Health approach, intertwining efforts across human health, animal health, and the environment. Up to date, this strategy resulted on a high reduction of the use of antibiotics (69.5% in Veterinary and 17% in human) that placed Spain as the first Member State reducing the antibiotic consumption in animal health care and the third in human health care.

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