EN

ANNEX 22

of the Commission Implementing Decision
on the 2018 Partnership Instrument Annual Action Programme

Action Fiche for Working Together to Fight Antimicrobial Resistance (AMR)

1. IDENTIFICATION

<table>
<thead>
<tr>
<th>Title of the action</th>
<th>Working Together to Fight Antimicrobial Resistance (AMR)</th>
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</thead>
<tbody>
<tr>
<td>Country(ies)/Region</td>
<td>Argentina, Brazil, Chile, Colombia, Paraguay, Peru and Uruguay (when relevant other countries in the region will participate in the activities)</td>
</tr>
<tr>
<td>Total cost</td>
<td>Total estimated cost: EUR 9 000 000&lt;br&gt;Total amount of the EU budget contribution: EUR 9 000 000</td>
</tr>
<tr>
<td>Total duration¹</td>
<td>36 months</td>
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<tr>
<td>Method of implementation</td>
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<th>Significant objective</th>
<th>Main objective</th>
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2. RATIONALE AND CONTEXT

2.1. Summary of the action and its objectives

The EU recognises the threat of Anti-Microbial Resistance (AMR) and addresses this issue at the highest political level. Many countries outside of the EU, as well as

¹ Maximum duration of the operational implementation period of the contract(s).
international organisations, are tackling this issue. International cooperation is a key element of the AMR action plan.

The EU has been active in this field for more than 15 years. The Commission Action Plan against the rising threats from AMR (2011-2016) contained actions for implementation with EU Member States, including cooperation with international partners. The evaluation of this Action Plan showed that it had a clear added value acting as a symbol of political commitment, stimulating several actions within Member States, and reinforcing international cooperation.

The EU is strengthening its commitment against AMR with the launch in 2017 of a second Action Plan, with the aim to strengthen its leading role in global fora and contribute to regional and global action on AMR with international organisations and major trade partners.

Building upon an ongoing Partnership Instrument (PI) funded Policy Support Facility, the proposed PI action aims at engaging with the Latin American countries Argentina, Brazil, Chile, Colombia, Paraguay, Peru, and Uruguay while at the same time reinforcing the role of the relevant International Organisations, the the World Health Organisation (WHO)/the Food and Agriculture Organization of the United Nations (FAO)/the World Organisation for Animal Health (OIE) tripartite in the fight against AMR in the region by:

1. Supporting the development and evaluating the implementation of national One Health AMR action plans, in line with the WHO Global Action Plan, OIE Strategy and FAO Action Plan;
2. Strengthening surveillance and monitoring of AMR and consumption of human and veterinary antimicrobials;
3. Stimulating the private sector in the fight against AMR, with the signing of a voluntary food industry charter and technical assistance on prudent use of antimicrobials;
4. Strengthening research and innovation on AMR, and fostering international cooperation in these areas.

If successful the proposed PI action could serve as an example for possible future EU regional AMR activities in other regions e.g.in Asia or South-East Asia.

2.2. Context

Antimicrobial resistance (AMR) is nothing new. In fact, this natural phenomenon was mentioned by Alexander Fleming when he received the Nobel Prize for the discovery of penicillin in 1945. An accumulation of factors, in particular the excessive and inappropriate use of antimicrobials and poor infection control practices, have progressively turned AMR into a serious threat for humans and animals. This threat, if left unchecked, could nullify much of the medical progress of recent decades, effectively turning back the clock to the pre-antibiotic era, with massive negative consequences for people's health and the economy, not only in Europe, but across the world.

Antimicrobials: include antibiotics, antivirals, antifungals and antiprotozoals. They are active substances of synthetic or natural origin which kill or inhibit the growth of microorganisms. Used in every-day medicine (e.g. urinary tract infections, surgery
and care of premature babies), they are vital to preventing and treating infections in humans and animals.

Antimicrobial resistance (AMR) is the ability of microorganisms, such as bacteria, to become increasingly resistant to an antimicrobial to which they were previously susceptible. AMR is a consequence of natural selection and genetic mutation. Such mutation is then passed on conferring resistance. This natural selection process is exacerbated by human factors such as inappropriate use of antimicrobials in human and veterinary medicine, poor hygiene conditions and practices in healthcare settings or in the food chain facilitating the transmission of resistant microorganisms. Over time, this makes antimicrobials less effective and ultimately useless.

Fighting AMR has long been a priority for the European Commission which launched a 5-year ‘Action Plan against the rising threats from AMR’ in November 2011. The evaluation of the 2011 EU action plan identified that international activities and cooperation should be strengthened. Building on many years of extensive experience and the evaluation of the 2011 EU action plan, the EU in June 2017 has reaffirmed its commitment in tackling AMR with the new ambitious and comprehensive 'European One Health Action Plan against Antimicrobial Resistance (AMR)' having stronger EU international presence as one of its three pillars. The actions of the international pillar include stronger EU presence in normative global fora, stronger bilateral partnerships, cooperation with developing countries and developing a global research agenda.

A high level of political commitment has also been mobilised within the G7, G20, United Nations (UN) and within several international organisations, including the World Health Organization (WHO), World Organisation for Animal Health (OIE), Food and Agriculture Organization (FAO) and Organisation for Economic Co-operation and Development (OECD).

Social and economic burden of AMR

AMR is a global health threat crossing borders and causing serious social and economic burden. Internationally, the cost of inaction is projected to result in 10 million deaths annually and a cumulative loss of over EUR 88 trillion to the world economy by 2050. In addition to increased mortality and morbidity of currently treatable infectious diseases and causing additional suffering, AMR results in higher treatment costs as well as loss of productivity and income. Preventable drivers for AMR include excessive and inappropriate use of antimicrobials in both humans and animals. This together with market failures, including the slowing down of new antimicrobials emerging from research, entering the market and reaching patients have led to worrying projections, such as that of the World Bank, which has warned that, by 2050, drug-resistant infections could cause global economic damage on a par with the 2008 financial crisis. On a wider picture, AMR also threatens the achievement of several of the UN sustainable development goals, particularly the targets for good health and well-being.

Major global commitments and milestones

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Urgent action is needed and several important steps have been made, including the 2015 WHO Global Action Plan on AMR which serves as the global blueprint for AMR activities, the FAO Action Plan, and the OIE Strategy. The Political Declaration of 21 September 2016 in the 71st UN General Assembly gave high-level support to the international implementation of the WHO Global Action Plan on AMR, as did the political commitments in the G7 and G20.

EU action on AMR (international) and overarching aims

The EU and its Member States are part of an increasingly interconnected world characterized by an intensive exchange of people and commodities where policies implemented in one region can have significant impact elsewhere. The EU has gained valuable expertise and experience in relation to AMR, while some of its trading partners have taken different approaches and chosen different priorities in this regard.

The 2017 EU One Health action plan is built around three pillars for action. Having recognised that strengthened international cooperation is a key element in tackling AMR, the third pillar focuses on international action (i.e. activities outside of the EU) and aims to make a contribution towards globally addressing the threat. The 2017 EU action plan specifically sets out to 'engage with major global players and strategic countries' and 'contributing towards achieving objectives of the WHO Global Action Plan on AMR by sharing experiences, advocating best practices and stimulating actions outside the EU'. As there is common interest internationally in curbing AMR, there is scope for more collaboration and closer ties with these seven partner countries to align approaches and to build consensual activities, for the benefit of all sides. This should apply to research cooperation and activities in international standard setting bodies as well, e.g. the Codex Alimentarius and OIE.

As one of the world's largest markets for agricultural products, the EU can play a major role in promoting its AMR-related standards, measures in food production, and standards on animal welfare, e.g. through its bilateral Free Trade Agreements (FTAs). The systematic inclusion of AMR-related provisions is now a current practice for the Commission in all new FTAs. Further actions may also be considered to ensure a level playing field between EU producers and EU trading partners, e.g. so that efforts made by EU farmers are not compromised by the non-prudent use of antimicrobials in EU trading partners. This could include linking concessions made to EU trading partners with compliance with specific EU AMR policy objectives.

Areas where the EU has particular strength, experience and added value include (i) surveillance and monitoring, (ii) research and development, (iii) implementation of good practices in prevention and control (e.g. the EU-wide ban on use of antibiotics as growth promoters in feed for food-producing animals since 2006), (iv) scientific assessments and guidelines, as well as (v) trade-related aspects.

Further ongoing international activities include EU action within the Global Health Security Agenda (GHSA) under the steering group for the action packages on AMR and cooperation with the USA, Canada and Norway under the Transatlantic Taskforce on AMR (TATFAR).

EU and South American partner countries
While maintaining a global perspective, the 2017 EU action plan has specific reference to partnering with major global players (e.g. Brazil, China and India), taking into account a regional approach.

Brazil is not only a major global player as a BRIC country and an emerging economy, but it is also a major EU trade partner with regional influence. Some partner countries, such as Brazil, Uruguay, and Argentina are major exporters of products of animal origin in the international markets, representing a substantial percentage of global bovine meat production and international trade. Collaborating on human and animal health issues will help strengthen ties, as the EU continues to build the relationship with those countries as trading partners through bilateral agreements.

This PI action partnering with Argentina, Brazil, Chile, Colombia, Paraguay, Peru, and Uruguay follows up a preceding PI action funded by the Policy Support Facility, comprising of an initial AMR conference in March 2017 followed by technical seminars in cooperation with the seven South American partner countries.

**Major ongoing AMR activities in South American partner countries**

While working within the blue-print of the WHO Global Action Plan and other international commitments, the seven South American partner countries are at different stages in developing and implementing their NAPs on AMR.

Argentina was one of the first countries to approve their NAP in 2015. It defines critical actions including surveillance of AMR and antimicrobial consumption in humans and animals, pharmaceutical protocols, infection prevention and control programmes in human health and agricultural production establishments. Argentina also set 2019 as a deadline for banning the use of antibiotics for growth promotion in animal production sectors (except for poultry). Argentina is a member of the Joint Programming Initiative on AMR (JPIAMR) which supports and coordinates national research efforts.

Peru, Brazil, and Chile concluded national reviews and analyses of their individual AMR situations and developed NAPs in 2017, with Chile and Peru presenting their NAP in end 2017 and publication of the Brazilian NAP being imminent. Through multisector planning processes, these countries integrated existing national sectoral initiatives, norms and policy issues from different sectors, while developing specific integrated actions to deal with emerging AMR issues. For these countries, the next challenges are to ensure effective NAP implementation.

Colombia is in the earlier stages of developing their NAP. The Ministry of Health has initiated a national planning process that is expected to involve further government sectors in 2018.

Paraguay is in the very early stages of developing their NAP, where the government has developed and published background documents related to human and animal health.

Uruguay is also in the very early stages and has recently appointed the Ministry of Public Health as focal point for AMR to initiate the preparation of its NAP. Key national stakeholders are the ministries of health and agriculture, and NAP coordination groups, which have broad representation from national government sectors, coming from the environment, economic, education and communication.
areas. Professional associations, health-care professionals, academic institutions and the private animal sector also play an important stakeholder role.

**Ongoing regional tripartite coordination mechanism**

Noting that this PI action takes a targeted approach, partnering with seven South American countries, it is important to take stock of the major ongoing regional activities amongst the WHO/OIE/FAO tripartite, which also engage with a wider scope of Latin American countries. In line with the coordination at Headquarters level, the regional offices of the tripartite in the Americas and Caribbean have a successful coordination mechanism with meetings that include the most relevant regional international organisations including those from the private sector.

For 2018-2019, the regional tripartite plan to (i) coordinate support for countries in developing their NAPs, (ii) support countries in reporting on their NAPs and also to elaborate and implement the plans where necessary, and (iii) start a project on the evaluation of animal production systems with and without the use of antibiotics.

The tripartite have identified the following needs in the region:

a) NAP governance. Insufficient or lack of coordination at national level is one of the main constraints. Coordination requires clear knowledge of existing international standards and guidelines by all the stakeholders. Political support is also a need for the development of NAPs and sustainability in the operation of individual NAPs.

b) Member States need support in the implementation and monitoring of their NAPs. While some countries have adopted their NAPs, some need technical support for its implementation.

c) Integrated surveillance including environmental surveillance.

d) Regulatory and accreditation aspects of testing methods (both in the human health sector and agriculture) on the use of antimicrobials and on AMR.

e) Surveillance on the use of antimicrobials both in humans and in agriculture.

f) Include more countries in ongoing technical cooperation projects.

The financial support of the EU will ensure that the AMR work will increase in quantity and quality. Taking into consideration that the tripartite count now with a budget of around USD 1 740 000 per year for the whole region, the impact of this Action should be considerable.

### 2.3. Lessons learnt

This PI action builds on the experience gathered from the PI action "EU and South America: Working together on Antimicrobial Resistance", comprising of an initial AMR international conference in March 2017 followed by six technical seminars in cooperation with the seven South American partner countries. The technical seminars discussed the topics of human health, animal health, research and innovation, international cooperation and engagement with international organizations, trade aspects, and environmental aspects. The events contributed to create a momentum among the involved countries, and to increase their interest and commitment to work on AMR with the EU. All seven partner countries and the EU have endorsed the UN Political Declaration on AMR and the action plans/strategies of the WHO, OIE and FAO and have published or are developing national action plans (NAPs) on AMR,
making this PI action a timely activity. The preparatory work done with the seven countries during the workshops represent an important basis to develop the work proposed by this action which fully takes into consideration the recommendations made by the countries during the workshops.

Recommendations and lessons learnt from these seminars indicate that the PI action should consider the following:

– A smart mix approach including voluntary measures and regulatory frameworks,
– The inclusion of EU good practices in the human and animal health sectors, experiences on integrated surveillance, implementation and evaluations of NAPs,
– Awareness raising in the professional and private sectors on AMR,
– A consistent and coherent regional approach,
– Have an impact at political level,
– Consider activities on research and innovation,
– Focus on actions that can have immediate practical positive consequences on AMR issues

2.4. Complementary actions

Complementarity and coordination will be sought with relevant EU initiatives funded at bilateral and regional level, such as the current pilot project on mapping the global threat of AMR in sub-Saharan countries and ongoing relevant work of the EU in developing countries. Other projects funded by the EU in our partner countries that offer synergies include the activity on (i) environment friendly, energy efficiency and sustainable urban development in Argentina, (ii) agricultural innovation for food security in Peru and sub-Andean region, and (iii) strengthening the capacity and management of sustainable enterprises in post-conflict Colombia, each at various levels of implementation.

The PI action particularly complements the previous and ongoing AMR events in seven South American countries, funded by the EU, which promote the One Health approach for tackling AMR in humans, animals and the environment amongst our partner countries.

The PI action should also seek synergies with other ongoing and foreseen PI funded initiatives, engaging private and public sectors, namely Environmental Diplomacy in G7/G20, Responsible business conduct in Latin America and Caribbean, Public and Cultural Diplomacy as well as the EU-Brazil Sector Dialogue.

The PI action will provide technical assistance for the development and implementation of NAPs through regional and country level actions, complementing the ongoing actions in Latin America and the Caribbean Region implemented by the PAHO-WHO/FAO/OIE tripartite collaboration (overview of tripartite activities in the background section).

The Regional Team in Brasilia and the EU Delegations to the beneficiary countries will ensure complementarity with other Member State actions in those countries.
2.5. Cross-cutting issues

AMR presents a serious challenge to human and animal health, food safety and security, economy and development. The 2017 EU One Health action plan aims to link various sectors and actors in defence of human, animal and environmental health and rights.

By promoting efficient development and implementation of NAPs, the PI action will promote good governance in the human and animal health sectors as well as in the public administration as a whole. It will also reinforce capacities across other sectors to address AMR and counteract its grave social and economic burden, which have stronger consequences on less informed and educated consumers both in the EU and in Latin America. Finally it will contribute to better health and well-being.

3. Detailed Description

3.1. Objectives

The overall objective of this PI action is to tackle AMR as outlined in the 2017 EU action plan, engaging with 'major global players and strategic countries' and 'contributing towards achieving objectives of the WHO Global Action Plan on AMR by sharing experiences, advocating best practices and stimulating actions outside the EU', by working with targeted Latin American partner countries.

In order to contribute towards the overall objective, this PI action establishes four specific objectives:

1. Supporting the development and evaluating the implementation of national One Health AMR action plans, in line with the WHO Global Action Plan, OIE Strategy and FAO Action Plan;
2. Strengthening surveillance and monitoring of AMR and consumption of antimicrobials;
3. Stimulating the private sector in the fight against AMR, with the signing of a voluntary food industry charter and technical assistance on prudent use of human and veterinary antimicrobials.
4. Strengthening research and innovation on AMR, and fostering international cooperation in these areas.

3.2. Expected results and main activities

Result 1: NAPs are established and implemented. Effective evaluations of One Health NAPs are carried out.

This result will take into consideration the different stages of NAP development and implementation in the seven partner countries. Colombia, Paraguay, and Uruguay will be supported in the design and development of their NAPs, while Argentina, Brazil, Chile, and Peru will be supported by focusing on the implementation, monitoring and evaluation of their NAPs.

In order for an effective implementation of the NAPs it will be important for the PI Action to support 1) the strengthening of the governance structure of the NAPs; 2) the establishment and formalization of national inter-ministerial committees for the coordination of integrated AMR policies; and 3) the consolidation of the regulatory
capacities of the seven partner countries in human health, animal health and food safety.

Under R1 indicative activities may include:

- Technical assistance to support the countries with the finalization of the NAPs (where necessary)
- Study visits and exchange of experiences between South American and EU experts on the establishment of NAPs and their implementation
- Technical collaboration to share, discuss and support the adaptation of monitoring and evaluation methodologies and/or tools for NAPs
- Design and provision of training activities on effective evaluation of NAPs
- Technical advice on the governance structure of the NAPs
- National seminars on the regulatory framework
- Support to the creation and formalization of national inter-ministerial committees

Result 2: Integrated surveillance and monitoring of AMR trends and consumption of antimicrobials are strengthened by improved data collection, management, and analysis and reporting in the human and animal health sectors. Regional Reference Laboratories (for human health and animal health) are strengthened.

Strong and efficient integrated surveillance and monitoring systems are key for analysing the local, regional and national situation, identifying outbreaks and negative trends to enable corrective actions to be taken, monitoring and adjusting policies and reporting on evidence-based measures.

The Regional Reference Laboratories would allow for comparative analysis of national AMR data in the region and will provide support for the verification or identification of emerging resistance mechanisms in the participating countries and will maintain the coordination of the External Quality Assurance Programs. To achieve this result existing selected national reference laboratories will need to be strengthened and scaled-up, to act as Regional Reference Laboratories for all regional AMR samples and to support the accreditation process. The PI action will also support the coordination for inter-sectorial integration (human health, animal health, food, and environment). Regarding human health, the INEI ANLIS, Malbran Institute, Buenos Aires, Argentina, is serving as Regional Reference Laboratory to the Latin American Network on AMR Surveillance (ReLAVRA by its Spanish acronym) since 1996. The increasing demand to provide technical guidance, verification of emerging resistance mechanisms, and external quality control, highlight the need to strengthen its capacity to better respond to regional needs.

Regarding animal health and food safety, it will be necessary to evaluate capacities in the seven partner countries to choose and establish a reference laboratory for these sectors (maybe one for each sector). The region has the Inter American Food Analysis Laboratory Network (INFAL) since 1997 that is formed by national food
analysis laboratories that can also provide support to this PI action. This network is under PANAFTOSA/PAHO-WHO secretariat.

In this framework, the PI action would support the partner countries to acquire the laboratory and epidemiological capacities to be able (if they consider appropriate) to participate in the Global Antimicrobial Resistance Surveillance System (GLASS), including the support for adapting their information systems. GLASS is a system that enables standardised global reporting of official national AMR data and promotes the use of globally agreed and standardised methods for compiling data both locally and nationally, and the gathering of information on selected AMR indicators in a harmonised way across and within countries. This would allow the countries to strengthen their surveillance systems and enhance the capacities of their laboratories.

Misuse of antimicrobials both regarding human consumption and use in the animal sector is one of the main determinants of AMR. Several methodologies to monitor antimicrobial consumption in humans and animals have been developed to facilitate national policies to reduce it. Surveillance of antimicrobial consumption quantifies the selection pressure on microbial populations and permits benchmarking comparisons at national or healthcare facility level and evaluation of the impact of educational or regulatory interventions. The partner countries have uneven capacities to monitor antimicrobial consumption.

Surveillance of antimicrobial use tracks how and why antimicrobials are being used and misused. Monitoring antimicrobial prescription and consumption behaviour provides insights and tools needed to inform therapy decisions, to assess the public health consequences of antimicrobial misuse, and to evaluate the impact of resistance containment interventions. The point prevalence surveys on hospital antimicrobial use (PPS-HAMU) constitute a robust methodology to provide evidence that support the measures for adequate use of antimicrobials at hospital level.

As advocacy resources at local or national level, the European Surveillance of Antimicrobial Consumption Network (ESAC-net) and the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project has demonstrated that monitoring antimicrobial use patterns and costs can prove the crucial factor driving political commitment to successful campaigns to contain AMR, especially when surveillance of consumption is enhanced by surveillance of resistance.

The evaluation of the use and consumption of antimicrobials in food-producing animals is crucial as many of them are identical, or closely related, to those used in humans. Antimicrobials can be used in food-producing animals to treat and control bacterial infections in the presence of disease and for prevention and growth promotion purposes in the absence of disease. The use of antimicrobials in food-producing animals can select and disseminate resistant bacteria in food-producing animals, which can then be transmitted to humans via food, the environment and other transmission routes.

Under R2 indicative activities may include:

- Technical assistance to support the designation process and increased capacity of Regional Reference Laboratories (one for human health and one for animal health and food safety)

- Technical assistance to strengthen the capacity of countries to analyse data on AMR
- Support a pilot on integrated molecular surveillance (food, animals, humans and environment)
- Targeted support for laboratories developing capacity for detection of emerging AMR mechanisms, including molecular surveillance capacity (i.e. laboratory consumable and reagents to install new phenotypic or genotypic microbiologic methods)
- Transfer methodology for surveillance of antimicrobial consumption, and support adaptation to Latin America, using the experiences and lessons learnt of the European Surveillance of Antimicrobial Consumption Network (ESAC-net) and the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project
- Training for health professionals on AMR surveillance and monitoring
- Technical assistance to support the establishment of effective mechanisms for national laboratories to work as a network, as well as possible certification of procedures (ISO, etc.) and workers to guarantee regional and international recognition of analysis
- Exchange of experience with European Centre for Disease Prevention and Control (ECDC) on the European Antimicrobial Resistance Surveillance System (EARSS) and Point Prevalence Survey and support the implementation of Point Prevalence Survey in the different countries
- Support surveillance on AMR regarding human consumption as well as use in the animal health and agriculture sectors
- Regional and national seminars to promote exchange of experiences and horizontal technical cooperation

**Result 3: Participation of the private sector in the fight against AMR is increased, with the signing of a voluntary food industry charter and capacity building on prudent use of antimicrobials.**

For an effective strategy on AMR, the private sector is pivotal. Private sector encompasses various fields of both human and animal health, from pharmaceutical industry to food and feed production and professionals and stakeholders in the human health, animal health, academic and research sectors etc. Discussions were held at country level during the development of the NAPs to better integrate the private sector in those; however, the lack of documented experience and the different political and economic scenarios challenge the development of standardized guidelines in this regard. The tripartite is already working with some private sector organisations (e.g. pharmaceutical and animal food production) but the project will allow to strengthen and expand the engagement.

There is a strong resistance from the food-producing animal sector to adopt alternative measures as good production practices and biosecurity measures, so it is necessary to raise awareness in this sector on the importance of the adequate use of antimicrobials.

Under R3 **indicative activities** may include:
- Mapping of relevant food industries in the region
Collection of data on AMR-relevant food products
Regional and national seminars and awareness raising campaigns with the relevant industries/private sectors
Technical seminars for the drafting of a voluntary food industry charter
Collection of data on AMR-relevant food products
Create links and share experience with the AMR Industry Alliance
Regional and national seminars and awareness campaigns for the private sectors
Organization of Regional Seminar(s), to facilitate drawing and signing a voluntary private-sector “Food-industry charter” on AMR with actions they can take to act against AMR
Capacity building for private sector stakeholders on prudent use of antimicrobials in food, animal food production and feed
Exchange of experiences with the European Food Safety Authority-EFSA

Result 4: Research and innovation on AMR are strengthened, and international cooperation in these areas has improved.

A stronger, more interconnected research environment is needed. Benefits can be gained from a further coordination of efforts in this area, supporting the G20 aim to maximise the impact of existing and new antimicrobial basic and clinical research initiatives as well as product development, including therapeutics, vaccines and diagnostics.

Under R4 indicative activities may include:
- Support the establishment of AMR research networks (in collaboration with the JPIAMR Virtual research institute)
- Technical assistance to facilitate research on the environmental impacts of AMR, the development of new antimicrobials or their alternatives diagnostics, the economic impact of prudent antimicrobial use in production practices, public health systems, etc.
- Create a database of institutes performing AMR research (in collaboration with JPIAMR)
- Regional Scientific workshops
- Support existing initiatives or forums for exchange of scientific information, results or initiatives

During the inception phase, the different stage of maturity of the partner countries will be assessed and activities will be designed accordingly. Regional activities may also include representatives of other Latin American countries not targeted by the PI action. The European scientific agencies EMA, EFSA and ECDC will also be involved in the implementation of activities according to their expertise.
### 3.3. Risks and assumptions

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<tr>
<th>Risk</th>
<th>Risk level (H/M/L)</th>
<th>Mitigating measure</th>
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<tbody>
<tr>
<td><strong>Ensuring buy-in of the competent authorities during the development and/or evaluation of NAP.</strong></td>
<td><strong>L</strong></td>
<td>Previous EU and South America AMR conference and seminars have raised political awareness of EU cooperation activities on AMR. All partner countries have been consulted and involved in the conceptualization of this PI action from an early stage via an identification mission.</td>
</tr>
<tr>
<td><strong>National coordination groups that developed NAPs may not have sufficient capacity to effectively manage the implementation of key technical components which may compromise the quality of execution.</strong></td>
<td><strong>L</strong></td>
<td>Sharing of EU experience and support via the implementing international organizations will be adapted to the national situation of each of the partner countries. The tripartite have extensive experience in scaling activities according to national situation, hence mitigating this risk.</td>
</tr>
<tr>
<td><strong>Insufficient buy-in from the private sector for the 'food industry charter' due to multiple and diverse business needs and interests.</strong></td>
<td><strong>L</strong></td>
<td>The private sector is constantly looking for new opportunities to engage with government and voice their business needs. The food industry charter will operate on a voluntary basis and a key assumption is that all relevant stakeholders do their part in addressing AMR.</td>
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<tr>
<td><strong>Laboratory staff may not have sufficient capacity to conduct AMR diagnostics.</strong></td>
<td><strong>L</strong></td>
<td>The tripartite will mitigate this risk by supporting training through regional and national laboratories and assist in strengthening the capacity of laboratory professionals.</td>
</tr>
<tr>
<td><strong>Lack of political will at the national level to adopt new policies.</strong></td>
<td><strong>L</strong></td>
<td>Partner countries have affirmed their political will as outlined in the existing WHO Global Action Plan on AMR, FAO Action Plan, OIE Strategy and political commitments in the UN Declaration on AMR as well as the G20.</td>
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### 3.4. Stakeholders

The main stakeholders involved in articulating the AMR policies and implementation in the seven partner countries are:

**Argentina:** Ministerio de Salud, Ministerio de Agroindustria, Servicio Nacional de Sanidad y Calidad Agroalimentaria (SENASA), Universidad de Buenos Aires, Administración Nacional de Medicamentos, Alimentos y Tecnología Medica.
Brazil: Ministério da Saúde, Ministério da Agricultura, Pecuária e Abastecimento, Agência Nacional de Vigilância Sanitária (ANVISA)

Chile: Ministerio de Salud, Ministerio de Agricultura, Instituto de Salud Pública de Chile, Instituto de Investigaciones Agropecuarias, Servicio Nacional de Sanidad y Calidad Agroalimentaria.


Paraguay: Ministerio de Salud Pública y Bienestar Social, Ministerio de Agricultura y Ganadería, Instituto Nacional de Salud – INS.

Perú: Ministerio de Salud, Ministerio de Agricultura, Servicio Nacional de Sanidad Agraria – SENASA.


Mexican Authorities may join the initiative at a later stage.

Other important stakeholders for the implementation of the proposed PI action are the European Medicines Agency (EMA), European Food Safety Authority (EFSA), European Centre for Disease Prevention and Control (ECDC), Joint Programming Initiative on AMR (JPIAMR), Organisation for Economic Co-operation and Development (OECD) and Inter-American Institute for Cooperation on Agriculture (IICA). The academics, researchers, professionals and consumers associations working on AMR should be associated to the action as well as the pharma industry and the agroindustry.

4. IMPLEMENTATION ISSUES

4.1. Method of implementation

4.1.1. Indirect management (with an international organisation)

This action may be implemented in indirect management with the World Health Organisation (WHO)/Pan American Health Organization (PAHO)\(^3\), the Food and Agriculture Organization of the United Nations (FAO) and the World Organisation for Animal Health (OIE) in accordance with Article 62(1)(c) of Regulation (EU) No 2018/1046.

The entrusted entity would carry out the following budget implementation tasks: inter alia the provision of technical assistance\(^4\) and consultancy services, seminars/conferences/events, carrying out studies and analysis and supporting specific partnerships.

This implementation entails undertaking all necessary actions, including the main indicative activities described above in section 3, to achieve the objectives and

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\(^3\) Serving as the Regional Office for the Americas of the World Health Organization.

\(^4\) Advice, assistance and training pertaining to the fields covered by the action.
expected results of the PI action. This implementation is justified because of the specific technical competence of WHO/PAHO, FAO and OIE on matters related to AMR. The three organisations have established a Regional Tripartite group internationally recognized with the mandate to strengthen the development and implementation of the NAPs, through regional action plans and technical assistance projects.

Consequently, the WHO/PAHO, FAO and OIE are best placed and constitute a logical choice for managing this complex EU intervention, due to the unique combination of technical expertise and contacts with relevant authorities in governments of partner countries, with businesses and other stakeholders.

The Pan American Health Organization (PAHO) is the specialized international health agency for the Americas (regional office for WHO). It works with countries throughout the region to improve and protect people's health. PAHO is responsible for the human health approach and coordinates all the activities related to AMR, working with PANAFTOSA in the topics related to the interface human-animal. The Panamerican Centre of Aphtose Fever -PANAFTOSA is the specialized PAHO centre for Veterinary Public Health (VPH). Its activities are related to AMR in the interface human-animal and in the food chain. The VPH center is also responsible for PAHO coordination and communication with the other agencies. PAHO activities planned for 2018-2019 include support to countries on the development and implementation of National Action Plans to tackle AMR and on technical cooperation for integrated surveillance. PAHO has been working in many awareness campaigns related to the WHO Global Action Plan on AMR, as hand washing awareness campaigns, immunization awareness campaigns and activities, and many other activities and campaigns focused on the reduction of infections and on the adequate use of antimicrobials, development and strengthening of national AMR surveillance, and coordinates the collection of AMR data from foodborne pathogens from humans, the development of guidelines and other technical documents, the development, implementation and monitoring of NAPs from a One Health perspective and in collaboration with FAO and OIE, using M&E indicators. During 2017, several multi-country meetings/workshops were organized in the Americas to support Member States with the implementation of their NAPs. These multi-country workshops from a One Health perspective will be continued to further support the implementation and monitoring of the national action plans (including the specified countries).

WHO has a group of experts on AMR, which is called AGISAR-Advisory Group on Integrated Surveillance of AMR. Its activities include:

1. assistance to member states with development and strengthening of integrated surveillance of AMR in foodborne bacteria by providing protocols and guidance, training workshops and support countries with setting up pilot projects.
2. elaboration of guidelines as the WHO List of critically important antimicrobials (CIA list) for human medicine, the WHO guide on integrated surveillance of AMR in foodborne bacteria – One Health approach, and the WHO guidelines on use of medically important antimicrobials in food-producing animals;
3. support to FAO/OIE/WHO tripartite and Codex Alimentarius activities related to AMR and food safety. It is involved in the Codex work on draft Guidelines
on Integrated Surveillance of Antimicrobial Resistance, an electronic working group (eWG) chaired by the Netherlands and co-chaired by New Zealand, Chile and China. The draft was discussed in the 5th Codex Task Force on AMR (TFAMR5), in conjunction with WHO-AGISAR "Integrated Surveillance of Antimicrobial Resistance in foodborne bacteria".

The Food and Agriculture Organization (FAO) is specialized agency of the United Nations that leads international efforts to defeat hunger. FAO, itself a multidisciplinary organization, brings into play its expertise in aquatic and terrestrial animal health and production, food safety and crop production, and natural resources’ management, with due attention to all regulatory aspects in the fight against AMR. A focus area for FAO is critical information gaps. There are only a few networks that track data on AMR. Some countries lack laboratory facilities that can accurately identify resistant microorganisms. This impairs detection and response capabilities. Similarly, there is insufficient new research into new diagnostics to detect resistant microorganisms, and vaccines for preventing and controlling infections. FAO is already working in Latin America with a group of countries to validate and consolidate strategies and tools for integrated AMR risk management from food and agriculture approaches. Once the tools are adapted to the specific scenario of the region, they can be applicable to the rest of the countries of the region, facilitating technical interventions.

The World Organisation for Animal Health (OIE) is the intergovernmental organisation responsible for improving animal health worldwide. OIE is responsible for the intergovernmental codes for AMR for animal sector. It provides specific training on AMR to OIE National Focal Points for Veterinary Products through a global capacity-building program as well as global awareness campaigns on the topic, in line with the other international organizations forming the Tripartite Agreement. The OIE Regional Representation for the Americas participates in awareness activities reaching both technical and political levels, in many cases involving other organizations under the One Health approach. Specific yearly seminars on the topic have been organized since 2015, as well as electronic meetings providing training for the provision of information on antimicrobial usage data since 2015. The organization is responsible for the collection of information about the quantities and use of antimicrobials in all the member and non-member countries and analyses this information at global level. OIE Regional program covers the 31 OIE members from the Americas.

### 4.2. Indicative budget

<table>
<thead>
<tr>
<th>Method of Implementation</th>
<th>Amount in EUR million</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1.1. – Indirect management with international organisations</td>
<td>9</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>9</strong></td>
</tr>
</tbody>
</table>
4.3. **Organisational set-up and responsibilities**

A steering committee will be set up. It will be composed of a representative of each of the national authorities responsible for the NAP, a representative of each of the three International Organisations of the Tripartite and representatives of relevant services of the European Commission, of the European External Action Service, and of European Medicines Agency (EMA), European Food Safety Authority (EFSA) and European Centre for Disease Prevention and Control (ECDC). Private sectors representatives and civil society organizations may participate as observers. The Steering Committee will provide general political guidance and oversight of progress.

A technical committee will be established to guarantee the translation of the political guidance of the Steering Committee into practical measures. The technical committee will be composed of a representative of the three international organizations of the Tripartite, representatives of relevant services of the European Commission. When relevant, the European agencies will also be invited to take part of the technical committee.

A national committee will be formed in each of the seven partner countries, with a representative of the main institutions related to AMR, the national representative of the tripartite group and a representative of the European Union. The national committee will coordinate the activities at national level and inform the Steering Committee on the implementation of the annual action plan.

A Project Management Team (PMT) will be established to ensure: 1) the execution of the project activities, 2) a smooth project implementation with timely input and output and coordination with all the stakeholders; and 3) the management of financial, personnel and administrative affairs. The PMT shall report to the Contracting Authority.

4.4. **Performance monitoring**

The day-to-day technical and financial monitoring of the implementation of this action will be a continuous process and part of the implementing entity’s responsibilities. To this end, the implementing entity shall establish a permanent internal, technical and financial monitoring system for the action and elaborate regular progress reports (not less than annual) and final reports.

Every report shall provide an accurate account of implementation of the action, difficulties encountered, changes introduced, as well as the degree of achievement of its results. The progress and final reports shall provide quantified and qualitative data in relation to the logical framework indicators which will include relevant indicators from the list of common Partnership Instrument indicators.

The report shall be laid out in such a way as to allow monitoring of the means envisaged and employed and of the budget details for the action. The final report, narrative and financial, will cover the entire period of the action implementation.

The Commission may undertake additional project monitoring visits both through its own staff and through independent consultants recruited directly by the Commission.
for independent monitoring reviews (or recruited by the responsible agent contracted by the Commission for implementing such reviews).

4.5. **Evaluation and audit**

For this project, the Commission may carry out interim and/or final/ex-post evaluation(s) via independent consultants contracted by the Commission based on specific terms of reference.

Without prejudice to the obligations applicable to contracts concluded for the implementation of this action, the Commission may, on the basis of a risk assessment, contract independent audits or expenditure verification assignments.

As the “N+1” rule applies for contracting under this decision, external evaluations and audits, as well as additional external monitoring referred to under section 4.5 above, will be funded from sources other than those allocated to this specific action.

4.6. **Communication and visibility**

Communication and visibility of the EU is a legal obligation for all external actions funded by the EU.

Due the specific nature of this Action which pursues an improved cooperation between the EU and the targeted countries measures will be taken to make sure that implementers systematically ensure visibility of the European Union.

This action shall contain communication and visibility measures which shall be based on a specific Communication and Visibility Plan of the Action, to be elaborated at the start of implementation.

Appropriate contractual obligations shall be included in, respectively, the procurement and grant contracts, and delegation agreements.

This action must comply with the updated 'Communication and Visibility Requirements for EU External Actions' for implementing partners that came into force on 1st January 2018, and apply to all contracts signed from that date.\(^5\)

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