



Request for Proposals

Regulatory Landscape Phase 2

Overview

The [AMR Industry Alliance](#) is one of the largest private sector coalitions established to provide sustainable solutions to curb antimicrobial resistance (AMR). The AMR Industry Alliance currently includes over 100 biotech, diagnostics, generics and research-based pharmaceutical companies and associations. Through its members, the AMR Industry Alliance drives the life-sciences industry to curb AMR across four different pillars: (i) **appropriate use** of antibiotics to reduce the development of AMR with the support of vaccines and diagnostics; (ii) **access** to quality antibiotics and ensuring new ones are available to all, and improve and accelerate access to diagnostics in low- and middle-income countries; (iii) mitigating the environmental impact of **manufacturing**; and (iv) investing in **research and science** to meet public health needs with new innovative diagnostics and treatments.

As part of its Strategic Plan 2021-2025, the AMR Industry Alliance is pursuing initiatives across each of these four pillars through relevant internal Working Groups. The AMR Industry Alliance is currently seeking proposals to support the work of its Research and Science Working Group. The duration of this consultancy is defined for a period of approximately 8 months, starting 1 October 2021 (or as soon as the procurement process is completed) and ending 31 May 2022 when the deliverables have been approved by the AMR Industry Alliance Board. The consultancy will be conducted under the overall guidance of the AMR Industry Alliance Research and Science Working Group Lead and Core Team. The Consultancy will be home-based, from any country.

Background and Objectives of the Consultancy

Over the last number of years, there have been a number of significant advances toward market incentives, especially pull incentives. However, there remains a need to better understand how regulatory mechanisms can be harmonized to support pull incentives to motivate innovation for antimicrobial resistance (AMR), including the key challenges. Through its ongoing work, the AMR Industry Alliance Research and Science Working Group is seeking to:

- Increase understanding of how innovation for AMR can be fostered through better understanding of current regulations.
- Facilitate collaborations to innovate and bring critically needed antimicrobials to both developed and developing markets, in partnership with the AMR Industry Alliance's work on access.
- Leverage lessons learned from the COVID-19 pandemic to inform how regulatory science and data sharing can support an improved global regulatory climate for antimicrobials.

Within this context, the Consultant will support the AMR Industry Alliance's Research and Science Working Group to:



- Organize and facilitate a series of roundtable workshops, e.g., building on initial efforts from the Global Antibiotic Research and Development Partnership (GARDP) and the U.S. Food and Drug Administration (FDA). The objectives of the roundtable workshops will be to (i) discuss findings from a commissioned landscape analysis report on regulatory harmonization for AMR innovation and research and development (Phase 1), (ii) facilitate collaboration amongst relevant stakeholders, and (iii) identify opportunities for regulatory alignment in select middle-income countries to improve innovation, clinical trials, registration and commercialization.
- Develop a series of country roadmaps highlighting good practices in innovation, registration and commercialization as well as opportunities for influencing market incentives, including the need for regulatory harmonization, in line with the work of the Tripartite Group (European Medicines Agency, Food and Drug Administration, and the Pharmaceuticals Medical Devices Agency).

Deliverables and timelines

In line with the objective of the consultancy, the main deliverables and corresponding timelines are outlined below.

- 29 October 2021: Roundtable workshop plan
- 1-30 November 2021: roundtable workshop(s)
- 14 January 2022: Draft roundtable workshop report and communication plan
- 31 January 2022: Final roundtable workshop report and communication plan
- 15 April 2022: Draft country roadmaps
- 30 April 2022: Final country roadmaps
- May 2022: Country roadmap launch

Estimated requirements, expertise and qualifications

The consultant should be a company, an international consulting group, or other type of organization or an individual with proven expertise in:

- Developing and managing inter-institutional partnerships/coalitions.
- Organizing meetings/roundtables, facilitating consultations and building consensus amongst diverse stakeholders, including private sector actors, global donors, multilateral and not-for-profit organizations.
- Understanding access to medicines / AMR challenges and the broader global health ecosystem, including key actors and funding mechanisms.
- AMR-focused work in both high- and middle-income countries / low-resource contexts.
- Clinical trials, randomized controlled trials and data harmonization.

Proposals will be assessed against these selection criteria.



Proposal content/structure

Proposals should include the sections and elements outlined below.

Section 1: Technical

- The methodology and work plan for addressing the functional requirements set out in the terms of reference. This should include a tentative schedule of the activities outlining the timelines for major action.
- Expertise of the bidder with respect to the objectives of the terms of reference.
- If applicable:
 - Staff dedicated to the project, with lead identified.
 - Expertise of staff involved.
 - CV of the staff.

Section 2: Profile of the bidder

- Location
- Status (individual, private company, etc.)
- Statement of relevant experience (incl. key clients)
- Previous experience with private sector and access to medicine / AMR
- Code of conduct
- Declaration of non-conflict of interest

Section 3: Financial / cost

The bidder is asked to provide a detailed budget to be evaluated in either CHF or USD, including categories related to staff (role, number of days and cost per day), supplies, and travel.

Responding to the Request for Proposal (RFP)

Proposals and requests for additional information regarding this RFP should be submitted by email to Melissa Gong Mitchell, AMR Industry Alliance Secretariat Lead at mmitchell@amrindustryalliance.org. The deadline for submission of proposals in response to this RFP is **Friday 30 July 2021**. Please note that the AMR Industry Alliance may decide to extend the period to receive proposals, if deemed necessary.