Global Antibiotic Research and Development Partnership (GARDP)

Environmental Aspects and Criteria to Help Counter AMR

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We are facing a global health crisis: antibiotic resistance
Superbugs are emerging everywhere and outsmart even the best of available antibiotics.

Currently we are losing this race. We need more innovation to keep up.
Superbugs know no borders

Spread of NDM-1 by 2015
Addressing antibiotic resistance is critical to achieving SDGs

Direct impact on SDG 3, through increased risk of disease spread, severe illness and death

Indirect impact on:

- **GOOD HEALTH AND WELL-BEING**: Direct impact on SDG 3, through increased risk of disease spread, severe illness and death

- **NO POVERTY**: High cost of treatment and chronic infections: 28.3 million people pushed into extreme poverty by 2050

- **ZERO HUNGER**: Negative impact on farmers’ livelihood and food security

- **DECENT WORK AND ECONOMIC GROWTH**: Decline in productivity: 3.4 trillion losses by 2030
A One Health approach to antibiotic resistance

Meaningful change can be achieved through a holistic One Health approach that embraces efforts to redress the inappropriate use of antimicrobials in humans, animals and the environment, all of which are inextricably linked.
Accelerating access to antibiotics for appropriate use around the world

Affordable in limited-resource settings

Available at the right time in the right place

Developed for use in children and adults

Used appropriately to minimize resistance
An agreement signed with Shionogi and the Clinton Health Access Initiative (CHAI) to improve access to cefiderocol in 135 countries, mostly low- and middle-income countries, is paving the way for sustained access to this and other antibiotics.

The cefiderocol access project: A comprehensive approach to access

Manufacturing
Affordable and quality-assured products from a licensed manufacturer

Registration
Support for commercialization in high-burden countries

Implementation
Partnerships to co-develop and introduce robust implementation plans

Guidelines
Evidence-based guidance to steward appropriate use
In Wave 1, we have shortlisted 14 countries with the biggest unmet needs and an enabling environment to ensure appropriate use and stewardship.
Environmental Aspects and Criteria for Suppliers
Number of pharmaceuticals detected in surface water, groundwater, tap water, and/or drinking water globally
Examples of evidence of high concentration of antibiotics

In Lahore, Pakistan, a study found 49 µg/L of sulfamethoxazole in waterways downstream of formulation facilities.

In Korea, concentrations of up to 44 mg/L of lincomycin were found in effluent from a pharmaceutical manufacturing facility in Hebei Province, China.

Croatia: concentrations up to 3.8 mg/L of azithromycin were found in effluent from a pharmaceutical manufacturing plant.

Concentrations of moxifloxacin, voriconazole, and fluconazole of 0.69, 2.5, and 240 mg/L, respectively, around a manufacturing site in India.

Ciprofloxacin concentrations of 914 mg per kg organic matter in sediment downstream of an industrial WWTP in India.

AMR in the environment is a cross-cutting issue

Source: Lydia Niemi (2020), One Health Breakthrough Partnership
What is GARDP doing?

- Working and developing its environmental strategy;
- Refining the environmental criteria to include in Requests for Proposals (RFP);
- Developing environmental conditions to include in its suppliers sublicenses;
- Looking at what is being done by important initiatives and stakeholders;
- Engaging and partnering with key stakeholders that have our shared goal of countering antimicrobial resistance worldwide;
- Due diligence audits to shortlisted manufacturers/suppliers;
Due Diligence – Doing the Right Thing from the Start

• Perform due diligence audits to ensure its suppliers have:
  o Environmental Management System (EMS) and Occupational Health and Safety Management System (OHSMS).
  o Standard Operating Procedures (SOPs) and manufacturing site factsheets for consistency with permits, orders and other regulatory requirements.
  o Wastewater Treatment Plant (WWTP):
    ▪ Technologies implemented (i.e., it is very important to understand how Zero Liquid Discharge (ZLD) is achieved)
    ▪ Sampling points, key process parameters that are monitored as well as the thresholds (targets for API) and the respective monitoring frequency.
    ▪ Look into breaches and/or non-compliances in the last 5 years.
    ▪ Actions carried out to improve the WWTP and make sure API is not released into the environment.
Due Diligence – Doing the Right Thing from the Start

• Ensuring its suppliers have:
  o Appropriate waste management, with special focus on the sludge from the WWTP and hazardous waste.
  o Certified Industrial Cooling Systems interventions and maintenance.
  o Chain of Responsibility (i.e., if they ensure that their own suppliers and contractors follow all applicable environmental, health and safety laws and regulations);
  o Environment and safety: if they have documented standard policies and/or codes of conduct?
  o Identified concrete risks, potential mitigation actions and areas of improvement.
AMR in the environment is a cross-cutting issue and it requires that multiple stakeholders and partners who have the same shared goal to work together in a One Health approach to counter antimicrobial resistance worldwide.
Thank you!