Environmental Antimicrobial Resistance Disclosures

Overview

We are committed to doing our part to counter the growing risk of drug-resistant bacteria. Abbott's antimicrobial resistance (AMR) provisions, which cover branded generic medicines, include template contracts requiring antimicrobial suppliers to implement adequate liquid and solid waste management practices, adhere to antimicrobial discharge limits, and provide discharge-level information to Abbott upon request. We offer suppliers support to help with compliance, including free wastewater analysis to suppliers associated with high AMR risk. Suppliers associated with a higher risk of AMR and medicines in the environment are identified using a desktop, questionnaire-based assessment protocol.

Management of water discharge-related impacts

Abbott's medicines business acts to reduce antimicrobial discharge to the environment, both from our own sites and those of our suppliers and to help minimize the spread of AMR. We regularly assess discharge levels at each of Abbott's antibiotic and antifungal manufacturing sites. We quantify antimicrobial discharge levels in the wastewater by conducting a high-level theoretical assessment of the potential discharge risk (mass balance) and we follow up with chemical analysis of water samples for a more precise assessment as needed. For sites where multiple active pharmaceutical ingredients are produced, we consider the lowest antimicrobial discharge limits available among all publicly available databases, including those set by the AMR Industry Alliance. If limits are not publicly available, our preclinical safety laboratory calculates them based on European Medicines Agency (EMA) guidelines.

When setting antimicrobial discharge limits, we consider the lowest predicted no-effect concentrations (PNECs) and those with the biggest batch size. Abbott's PNECs are risk based. For antimicrobials, Abbott has a default PNEC system based on an internal standard. In parallel, our preclinical safety laboratory evaluates PNECs' availability on publicly available databases, including PNECs established by the AMR Industry Alliance. If multiple values are available, the most stringent value is selected. If PNECs do not exist but ecotoxicological information is available publicly, our preclinical safety laboratory calculates PNECs based on the EMA guideline on the environmental risk assessment of medicinal products for human use.

Beyond the inclusion of AMR in our contracts with manufacturing suppliers, we work to enable our suppliers to monitor their performance as a first step to identifying potential issues and taking remedial measures as needed. To optimize our audit mechanisms, we offer free water testing at 100% of sites that exceed set limits from the mass balance exercise. By covering the cost and facilitating the testing of water, we encourage suppliers to swiftly proceed to water analysis and handle with them any logistical issues that they may experience in the process. Free testing also covers any follow-up tests needed during the actions taken to remedy any potential exceedances, supporting the successful execution of remediation plans.