Teva's Position on Pharmaceuticals in the Environment

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A healthy planet is fundamental to the well-being of individuals and communities worldwide. As a global pharmaceutical company championing the health of people and the planet through our Healthy Future strategy, we recognize and aim to address the unintended consequences that certain pharmaceutical residues may have upon their release to the environment.

Pharmaceuticals have played a significant role in enhancing modern life—increasing life expectancies, bringing treatments and relief for a myriad of ailments and diseases that would have previously been life-threatening or debilitating and ultimately, improving health and well-being for billions of people across the world.[1] One of the consequences of increased variety, production and usage of pharmaceuticals is that they can enter the environment through agriculture and veterinary use, overuse or inappropriate use, incomplete metabolism and excretion from the body or manufacturing wastewater discharges. Once in the environment, some types of pharmaceuticals may cause environmental impact, including to wildlife, and, in some cases, lead to public health issues

Pharmaceuticals in the Environment (PiE), of which one subset is antimicrobials, including antibiotic, antifungal and antiviral medicines, can contribute to antimicrobial resistance (AMR). AMR occurs when bacteria and other microbes become resistant to antibiotics and related medicines. Without effective antimicrobial medicines, infections caused by bacteria, parasites, viruses and fungi can become deadly, both in humans and in livestock, affecting public health and even the security of our global food supply. AMR is an urgent global health challenge, leading to more than 1.27 million deaths each year. By 2050, this figure is expected to rise to 10 million.[2] While the main drivers of AMR are misuse and overuse of antimicrobials in humans, animals and plants, pharmaceutical residues in wastewater effluents, of which pharmaceutical production facilities are one source, also contribute.[3]

Our Position on PiE is aligned with our purpose, values, Code of Conduct, position on Environmental Sustainability and Healthy Future strategy and commitments and considers key stakeholders' inputs. The scope of this position covers Teva's production operations and business facilities, research and development (R&D), products and services, distribution and logistics, direct suppliers, service providers and contractors and other key business partners. The PiE issues covered by this position statement represent actual and potential impacts of Teva. Teva Pharmaceutical Industries Ltd (hereinafter "Teva"), including its directors, executives, employees and subsidiary and affiliated companies, is committed to reducing the environmental impact of PiE from our products and operations, with an aim to do the same across our value chain, helping to protect and enhance the organization's long-term sustainability.

Pharmaceuticals in the Environment Aspirations, Approach and Commitments

Determination of Safe Discharge Levels

Teva's PiE program manages two key groups of APIs—antimicrobial APIs that can lead to AMR, and priority APIs, which are thought to have increased potential to cause environmental harm and are defined by Teva as APIs on the European Union Water Framework Watch List as well as hormones and cytotoxic APIs.

The scientific community recognizes predicted no-effect concentrations (PNECs) as a credible method for determining safe levels of wastewater discharge. When pharmaceutical manufacturers follow PNEC guidelines, they help protect ecological species such as algae, crustaceans and fish.[4] The antimicrobial PNECs used by Teva have been established by the AMR Industry Alliance (AMRIA) to protect against resistance in bacteria and fungi.

Teva also applies PNEC values for priority APIs, which are aligned with the industry or developed by a regulatory agency. For APIs that do not have a published PNEC, Teva determines an approach in collaboration with environmental toxicologists.

We also carefully assess the waterbodies that receive effluents and consider their profile to understand low-flow conditions and estimate the predicted environmental concentration (PEC) of the API based on the worst-case scenario. These assessments are based on the Responsible Manufacturing Effluent Management Technical Guidance from the European Federation of Pharmaceutical Industries and Associations (EFPIA), Association of the European Self-Care Industry (AESGP) and Medicines for Europe and the AMR Industry Alliance Antibiotic Manufacturing Standard, as relevant.

Teva determines safe discharge levels through an environmental risk assessment, in which PEC values of Teva's effluents are divided by PNEC values to determine the risk quotient (RQ). We aim for an RQ lower than 1, as an RQ greater than 1 indicates potential risk, suggesting the API concentration exceeds predicted safe levels. For entities with an RQ greater than 1, Teva implements actions to reduce APIs in wastewater.

Management of PiE in our Own Operations

Recognizing pharmaceutical-containing effluents from manufacturing facilities are one of the contributors to PiE, our Environmental, Health and Safety Management System (EHSMS) requires sites to comply with emission and effluent-related regulatory and permit requirements, conditions and limits, as well as our internal program requirements for safe discharges of antibiotics and priority active pharmaceutical ingredients (APIs). Our PiE-specific program expectations are detailed in our internal Emissions Management Standard and supporting documents. In addition, we developed and use PiE assessment tools to enable Teva sites to assess pharmaceutical discharge levels according to their product portfolio and new product introductions. The program is managed by Teva's corporate Environmental, Health, Safety and Sustainability (EHS&S) function, which is comprised of knowledgeable and technical specialists from across the globe.

We take a risk-based approach to prevent and control APIs in our facilities' wastewater, and our PiE program focuses on the assessment and mitigation of such risks. We address discharges of pharmaceutical residues that are above scientifically determined safe discharge levels, through engineering and/or administrative controls.

Most Teva sites discharge effluents to a publicly operated wastewater treatment facility. Off-site treatment is conducted by the operator of these facilities and would typically include pre-discharge monitoring at Teva sites to ensure conventional pre-treatment limits are met. Some Teva facilities also operate their own wastewater treatment facilities, as appropriate, to meet regulatory requirements.

Management of PiE in our Supply Chain

Teva's commitment to address antibiotics and priority APIs extends beyond our own operations, including upstream (in our extended manufacturing supply chain) through responsible production. To assess and monitor sustainable practices among our suppliers, we implement an API discharge questionnaire. The questionnaire is used to collect information about water and waste management systems and encourages suppliers to achieve relevant standards related to PiE management. As the program continues, we expect to offer further support to suppliers in creating action plans for managing water, waste and discharges.

AMR Stewardship

Downstream, Teva's antibiotic portfolio enables affordable access to basic antibiotic treatment for people around the world. Access to basic and high-quality antibiotics helps limit the spread of anti-microbial resistance, both globally and in low-resource settings, where product availability is limited and low quality substitutes are rampant. This is achieved by enabling use of antibiotics that have lower potential for resistance and helping to minimize use of counterfeit products and antibiotics with higher potential for resistance.[5]

In addition, we are committed to educating healthcare professionals and patients on appropriate antibiotic use through AMR stewardship campaigns and programs.

Partnerships to Address AMR

We believe in a global, collaborative approach and are committed to working with industry peers, regulators and global health organizations to identify solutions that protect people and reduce the impact of AMR. This includes board membership of the AMRIA, which provides multifaceted, sustainable solutions to reduce AMR, invest in R&D to meet public health needs and improve access to antibiotics, vaccines and diagnostics. We are an active member of the AMRIA Access Working Group and the Manufacturing Working Group. Through our participation in the Manufacturing Working Group, we helped establish the Antibiotic Manufacturing Standard and supported the British Standards Institution (BSI) in establishing its Minimized Risk of AMR certification program. Teva is committed to meeting the AMRIA Antibiotic Manufacturing Standard at all sites that manufacture antibiotics. In addition, we support open collaboration between industry and public researchers to overcome the scientific challenges of creating new antibiotics and diagnostics, such as through our ten-year, multi-million-dollar commitment to the AMR Action Fund.

Pharmaceuticals in the Environment Governance

At Teva, sustainability is everyone's responsibility.

Teva's Board of Directors provides strategic guidance and direction for Teva's Healthy Future strategy, including efforts to address environmental impacts and risks. Our CEO-led Sustainability Steering Committee drives and monitors performance and decision-making on key matters.

Our Corporate EHS&S Committee, comprised of senior executives from each business unit, ensures appropriate engagement and oversight of material environmental sustainability issues. Management of PiE, including AMR, is an operational responsibility of each business unit's line management.

Teva's Global Environmental Sustainability Task Force and Environment and Sustainability Technical Advisory Committee (ESTAC) have complementary oversight of our PiE program and performance.

Management of PiE activities in our manufacturing facilities is overseen by our Head of Environmental Sustainability, with the support of their team, and includes membership and active participation in the AMRIA Manufacturing Working Group. At our facilities, management is responsible for EHS&S compliance and performance, supported by Environment, Health and Safety (EHS) professionals who drive local implementation of the EHSMS, programs and initiatives.

Reporting

We periodically review our environmental sustainability performance with our Executive Management and Board of Directors. We report externally on our actions and progress against our targets in our annual Healthy Future Report and accompanying disclosures.

Application of this Position

This position is approved by the responsible Teva management members and endorsed by Teva's Executive Management. It is supported by our EHSMS, which includes policies, standards and procedures to ensure our commitments are upheld, including periodic audits. We communicate this position to our employees and on our website.

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[1] World Economic Forum. Available: https://www.weforum.org/agenda/2018/03/the-50-most-important-life-saving-breakthroughs-in-history/. Accessed 23 May 24.
[2] AMR Action Fund. Available: https://www.amractionfund.com/threat-of-amr. Accessed 29 May 24.
[3] World Health Organization. Available: https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance. Accessed 12 June 24.
[4] World Health Organization. Available: https://cdn.who.int/media/docs/default-source/wash-documents/burden-of-disease/waste-and-wastewater-management-in-pharma-manufacturing---pub-consult-231214.pdf?sfvrsn=5e5e3acc_3. Accessed 12 June 24.
[5] World Health Organization. Available: https://www.who.int/publications/i/item/2021-aware-classification. Accessed 12 June 24.