

Position on Antimicrobial Resistance

Background

Antimicrobial resistance (AMR) is one of the defining scientific, health and economic challenges of our time. Without urgent and meaningful action to address specific diseases and system-level issues, patients, families and communities around the world will face a monumental threat in the years ahead from untreatable infections. While AMR is primarily driven by the misuse and overuse of antimicrobials and the subsequent evolution of resistant strains of pathogens, its impact is amplified by factors that span economic, healthcare and agricultural domains. Furthermore, the increase in hospitalizations and antibiotic use in COVID-19 treatment has exacerbated AMR.¹

The complexity of AMR and its potential adverse impact on people worldwide requires that stakeholders across multiple sectors (e.g., government, industry, society and academia) work together with a shared agenda to fight AMR. While the goal is ambitious, successful global efforts around HIV, TB, polio eradication and other health issues show that progress is possible when we work in collaboration. Together, we must improve how we prevent infection, effectively deploy and deliver current tools across all countries, and spur the development of innovations.

We must address multiple systemic hurdles impacting the world's ability to innovate against AMR, including the challenges of early pharmaceutical research; the high costs and risks of developing new medications and diagnostics; the lack of sustainable markets for new antimicrobials; and the barriers to finding, diagnosing and treating patients across all geographies and economic backgrounds. Solving just one issue in isolation is not enough; the world needs both—incentives to develop new innovative medicines, as well as improved capacity to deliver them to the right patients and steward their use to protect effectiveness. Even the best health systems will not be able to help patients if government, industry, society and academia do not continue creating innovative tools.

Relevance

As the largest, most diversified healthcare products company, Johnson & Johnson is committed to changing the course of human health. To achieve this goal, it is critical that we address the global challenges of AMR. At Johnson & Johnson we work to outpace AMR through the development of new therapeutics and preventive vaccines, invest in collaborative solutions that will help advance much needed AMR innovation to tackle a range of bacterial infections, and support advocacy and educational efforts to bring needed global attention to AMR.

¹ <https://www.cdc.gov/drugresistance/pdf/covid19-impact-report-508.pdf>

From a health perspective, AMR is associated with an estimated 4.95 million deaths worldwide each year, including 1.27 million deaths directly attributable to AMR.² By 2050, those numbers could increase to 10 million globally—a greater global impact than we currently face from diseases like cancer and diabetes.³ As a nation's health and wealth are intertwined, AMR is expected to have a catastrophic economic impact as well, drawing parallels to the 2008 global financial crisis.⁴ It has been estimated that AMR could cost the global economy more than \$100 trillion by 2050.⁵ This makes AMR one of the most significant global health issues facing nations over the next several decades.⁶ These threats have been detailed in several reports, including the [Review on AMR](#), the World Health Organization (WHO) Global Antimicrobial Resistance and Use Surveillance System Report, the World Bank report on [Drug-Resistant Infections](#), the AMR Industry Alliance 2021 [Progress Report](#), and others.

Resistant pathogens can cause outbreaks of disease that are resistant to treatment with antimicrobials locally and that are carried within and across national borders. While the impact and threat of AMR are global, the main causes and consequences of AMR play out differently in high-income compared to low-income countries. Three response strategies have been identified by leading health organizations as critical to help reduce the potential adverse impacts of AMR globally.

- **Preventing individuals from acquiring resistant infections:** Broad awareness and education strategies are needed to advance infection prevention. Among prevention measures, vaccines in particular play a crucial role in minimizing a range of AMR-relevant infectious diseases around the world by reducing drug-sensitive and possibly resistant infections, antimicrobial use, and the evolution and transmission of resistant microbial genes. Other tailored prevention strategies are also needed, and can be implemented based on local contexts. In places like the United States and Europe, healthcare-associated infections (HAIs) are a major driver of AMR-related infections and can be prevented with appropriate tools.⁷
- **Treating existing AMR-related infections:** Giving patients with AMR-related infections the best chance at recovery requires preserving and extending the effectiveness of current therapies. To do so, therapeutics must be appropriately used in humans and animals. Surveillance to track prevalence of resistant pathogens and the effectiveness and utilization of existing therapies are crucial additional components of impactful strategies. Success requires that robust health systems be in place to diagnose at the point of care, track and effectively treat AMR-related infections.
- **Discovering, developing and stewarding new tools to reverse the trend of growing drug resistance:** Infectious pathogens will continue to evolve and develop resistance to new and existing therapies. The market for antibiotics is unique because product use must be carefully stewarded so that treatments reach the right patients at the appropriate dosages, preventing the development of further resistance. This drives the need for tailored incentives to reward innovation and spur further research and development (R&D) investment. New diagnostics are essential to ensure antimicrobial use is limited to patients with appropriate infections. Furthermore, stewardship efforts are crucial to ensure that antibiotics are used safely and correctly and, ultimately, to protect their long-term effectiveness.

² <https://www.thelancet.com/action/showPdf?pii=S0140-6736%2821%2902724-0>

³ <https://amr-review.org/>

⁴ <https://www.who.int/news/item/29-04-2019-new-report-calls-for-urgent-action-to-avert-antimicrobial-resistance-crisis>

⁵ <https://amr-review.org/>

⁶ <https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance>

⁷ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6296034/>

Guiding Principles

[Our Credo](#) states: “We believe our first responsibility is to the patients, doctors and nurses, to mothers and fathers and all others who use our products and services.”

Our Position

At Johnson & Johnson, we are taking action to be a part of the solution to AMR. We have focused efforts across our business to address many facets of the AMR challenge, and we are working with partners around the world to champion a sustainable ecosystem of innovation.

Timeline of Johnson & Johnson’s key contributions to combating AMR:

2012:

- Through our Janssen Pharmaceutical Companies, we received accelerated approval from the U.S. Food and Drug Administration (FDA) for SIRTURO (bedaquiline), our medicine for the treatment of multidrug-resistant tuberculosis (MDR-TB) in combination with other anti-TB drugs.⁸ It was the first TB drug with a novel mechanism of action to be approved in more than 40 years. Drug-resistant TB accounts for nearly one-third of all deaths attributable to AMR.⁹
- Johnson & Johnson committed to the development of vaccines that target pathogens of high AMR priority such as [extraintestinal pathogenic Escherichia coli \(ExPEC\)](#), which cause dangerous and even fatal infections, particularly in the elderly. Due to [rising AMR](#), the antibiotics used to fight dangerous infections caused by ExPEC, like bacteremia and sepsis, are becoming less effective.

2015:

- We committed to donating SIRTURO through a four-year donation program operated in partnership with the U.S. Agency for International Development (USAID) and JSC Pharmstandard. We ultimately donated 105,000 courses.

2017:

- We implemented our Drug Resistance Emergence Assessment in MDR-TB (DREAM), a five-year prospective study in partnership with National TB Programs, reference laboratories and research institutions in 11 countries, which aimed to assess the emergence of resistance to bedaquiline and other second-line anti-TB drugs. The results of this collaborative assessment indicate that the prevalence of resistance to bedaquiline has remained very low. By mid-2018, thousands of bacteria recovered from TB patients from 10 countries were tested, and preliminary results indicated that the prevalence of resistance to bedaquiline has remained very low. We have confirmed drug mutations and the impact on DR-TB treatment outcomes.

2018:

- Ahead of the first-ever United Nations (UN) High-Level Meeting on TB, we announced a comprehensive 10-year initiative in support of the UN Sustainable Development Goal target of ending the TB pandemic by 2030. Through the initiative, Johnson & Johnson is working with partners to

⁸ [Approval is through Subpart H--Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses.](#)

⁹ https://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf

support efforts to find the millions of people with undiagnosed TB, broaden access to bedaquiline for MDR-TB, and invest in R&D to discover next-generation TB treatments.

2019:

- Johnson & Johnson publicly committed to an investment of more than \$500 million over four years in discovery, development and delivery programs to advance the global effort to eliminate HIV and TB by 2030. With co-funding from Europe's Innovative Medicines Initiative (IMI), we also launched RespiTB, an international research consortium to discover and develop new TB antibiotics in collaboration with eight European academic and biotechnology partners and as part of the IMI AMR Accelerator.

2020:

- Together with a consortium of philanthropic, nonprofit and private-sector organizations, we helped launch the Project to Accelerate New Treatments for Tuberculosis (PAN-TB collaboration), which will focus on treatment regimens comprised of medicines to which there is limited or no drug resistance and that are ready for Phase 3 development. As of 2022, the collaboration is now advancing two investigational TB combination treatment regimens, each containing bedaquiline, into Phase 2 clinical development.
- Joining with more than 20 leading pharmaceutical companies, Johnson & Johnson committed \$100 million to the approximately \$1 billion [AMR Action Fund](#) with the goal of bringing two to four new antibiotics to patients by the end of the next decade.

2021:

- Johnson & Johnson launched our inaugural Satellite Center for Global Health Discovery, hosted at the London School of Hygiene & Tropical Medicine. The Center is focused on addressing the threat of AMR and TB.¹⁰
- Johnson & Johnson joined with private and public collaborators to launch UNITE4TB, a seven-year initiative on clinical TB drug development to accelerate and improve the clinical evaluation of combinations of existing and novel drugs. UNITE4TB is part of the IMI AMR Accelerator and aims to develop new and highly active TB regimens for drug-resistant and drug-sensitive TB.¹¹
- Johnson & Johnson published its [2025 Health for Humanity Goals](#), including those around TB R&D and Access to Treatments.
- Johnson & Johnson was recognized for the third time as a leader among our peers in the fight against AMR in the 2021 Antimicrobial Resistance Benchmark.¹²
- Johnson & Johnson advanced our ExPEC vaccine to Phase 3 clinical testing.

2022:

- Johnson & Johnson launched our Satellite Center for Global Health Discovery at the Holistic Drug Discovery and Development Centre, University of Cape Town, South Africa. The Center is working to

¹⁰ <https://www.jnj.com/johnson-johnson-launches-network-of-global-health-discovery-centers-that-aim-to-speed-up-science-and-tackle-pandemic-threats>

¹¹ <https://www.unite4tb.org/newsroom/unite4tb-fires-its-engine-race-develop-new-tb-treatment-regimens>

¹² <https://accessmedicinefoundation.org/publications/2021-antimicrobial-resistance-benchmark>

drive new solutions to address the present and rising threat of AMR with a specific focus on multidrug-resistant Gram-negative bacteria (MDR-GNB).

Read on for more details of our approach to combating AMR, including:

Advocating and partnering for action to combat AMR: We leverage our size and scale to promote shared accountability in addressing AMR. We are a proud signatory to the [AMR Roadmap](#) and the [Davos Declaration on Combating AMR](#), and remain committed to their One Health principles. We have been an active member of the [AMR Industry Alliance](#), including contributing to multiple position papers and presentations and serving on the board. We have also testified before the U.S. Congress on the topic, and have provided input and support to other international and domestic actions to address AMR, including the [U.S. National Action Plan for Combating Antibiotic-Resistant Bacteria](#), World Economic Forum AMR working groups, the [EU One Health Action Plan against AMR](#) and the [Global Health Security Agenda AMR Action Package](#).

To help drive standardized approaches to evaluating the environmental, health and safety performance of suppliers across the pharmaceutical industry, including antimicrobial suppliers, we are also active members of both the AMR Industry Alliance Manufacturing Work Group and the Pharmaceutical Supply Chain Initiative. We have reported transparently on our progress in this area through the [AMR Industry Alliance Progress Report](#).

See also an [Appendix](#) to this Position that provides further details on Johnson & Johnson's policy approach to combating AMR.

Delivering medicines, enhancing access and monitoring for tuberculosis: Globally, TB is one of the leading causes of death. Until the COVID-19 pandemic, TB was the leading cause of death from an infectious agent, ranking above HIV/AIDS. In 2021, approximately 450,000 people around the world developed DR-TB, which accounts for nearly one-third of all deaths attributable to AMR.¹³ Currently only one in three people with DR-TB is treated. In addition to delivering the most widely used treatment for MDR-TB, bedaquiline, our actions include:

- **Simplifying treatment regimens for MDR-TB:** Until recently, the standard of care for patients with MDR-TB—which does not respond to two of the most powerful TB medicines—required a complex regimen of approximately 14,000 pills taken over two years, with daily injections for six months, which had significant side effects and only moderate treatment success. Simpler, safer and more effective treatments are essential to decrease the overall burden of MDR-TB. Johnson & Johnson has invested in these R&D efforts for more than two decades. Today, bedaquiline is recommended by the WHO as a core component of shorter, all-oral treatment regimens for nearly all DR-TB patients. We have taken numerous steps to promote broad, equitable access to bedaquiline while ensuring appropriate use and stewardship in line with WHO guidelines to prevent the development of resistance.
- **Enhancing access to TB treatment:** Johnson & Johnson facilitates access to bedaquiline around the world, including through the Stop TB Partnership's Global Drug Facility. It is available to more than 150 countries, including the 30 highest TB-burden countries. Revenues generated are reinvested to support critical access-related activities, including global manufacturing and distribution, health systems strengthening and surveillance programs to safeguard the antibiotic's long-term effectiveness. We have carefully selected our manufacturing partners to ensure quality-assured supply continuity.

¹³ https://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf

- **Advancing stewardship through training, monitoring and research:** We work with a variety of local, national and global stakeholders to support healthcare provider training to ensure the appropriate use of our medicines. We additionally provide training in robust pharmacovigilance and drug surveillance activities to monitor resistance to bedaquiline and companion drugs within the same regimen.

Developing additional anti-infective vaccines and therapies: We have several ongoing research projects to develop new drugs, regimens, and vaccines for AMR-related diseases, in high-, middle- and low-income countries, through our own labs and in collaboration with leading global health organizations. These include projects targeting TB, ExPEC, Staphylococcus aureus, Clostridium difficile, and MDR-GNB. We are proud to have been advancing multiple programs across Europe's IMI AMR Accelerator since July 2018. The AMR Accelerator aims to expedite the development of tools and treatments to fight drug-resistant bacteria and strengthen the scientific basis of AMR and TB research that Johnson & Johnson contributes across all seven projects, spanning the entire R&D pipeline. The PAN-TB collaboration, which we helped launch, is advancing investigational TB combination treatment regimens. We also launched two Johnson & Johnson Satellite Centers for Global Health Discovery, which focus on MDR-GNB and TB, including MDR-TB.

Combating healthcare-associated infections (HAIs): One of the major drivers of AMR-related infections in high-income settings like the United States and Europe is HAIs. Many HAIs are preventable with appropriate strategies in place. Across Johnson & Johnson MedTech, we seek to reduce the risk of these infections through a variety of antimicrobial and sterilization tools and technologies. Examples include:

- DePuy Synthes' Expert Tibial Nail PROtect, which releases an antibiotic locally into the implant's surrounding tissues;¹⁴
- Certain DePuy Synthes' bone cements (e.g., SMARTSET GHV and SMARTSET GMV), which contain the antimicrobial gentamicin;
- ETHICON BIOPATCH, a protective disk with chlorhexidine gluconate, shown to reduce catheter-related bloodstream infection (CRBSI), local infections and skin colonization of microorganisms commonly related to CRBSI; and
- ETHICON Plus Antibacterial Sutures, coated with the antimicrobial agent, triclosan, which has been shown to inhibit colonization of the suture by microorganisms known to contribute to surgical site infection.

Supporting access to antibiotics and relevant vaccines: We use mechanisms such as tiered pricing, partnerships with public health organizations, donation programs and other mechanisms as appropriate on a country-by-country basis to help achieve broad and timely access to our medicines in a way that is locally affordable and sustainable.

We support the [WHO Action Framework for AMR Vaccines](#) to contribute fully, sustainably, and equitably to the [prevention and control of AMR](#) by preventing infections and reducing antimicrobial use. We are engaged in multilateral partnerships to help achieve broader use of existing vaccines and development of new vaccines to tackle AMR.

Supporting work to ensure antibiotics are being used only in patients who need them: Our education efforts for healthcare professionals include topics such as appropriate use, diagnosis, pharmacovigilance and adverse event reporting, and monitoring of side effects. For example, we supported USAID training on the

¹⁴ As of this publication, this device is not cleared or approved for use in the United States.

implementation of a pharmacovigilance program for TB drugs for staff from national TB programs and health authorities in several countries.

Minimizing environmental antibiotic exposure from our research and manufacturing: Across Johnson & Johnson, we take a proactive, comprehensive approach to minimizing environmental antibiotic exposure from our research and manufacturing. Our environmental risk management strategy includes establishing and applying science-based discharge limits, ensuring effective wastewater treatment and residual management, and auditing both our own sites and those of third-party manufacturers.

Application

This Position is relevant for the Johnson & Johnson Family of Companies, as detailed in our [governance materials](#). We provide updates relating to AMR in our annual [Health for Humanity Report](#) where relevant.

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APPENDIX to Johnson & Johnson's Position on Antimicrobial Resistance

Anti-infective drugs, vaccines and diagnostic technologies have been some of the most effective health innovations in the history of modern medicine, responsible for dramatic gains in life expectancy globally. They are the backbone of modern medicine. And yet, without meaningful, collective action we risk squandering these gains and returning to an era where infection outpaces innovation and patients are left without treatment options. Working together, we can address this threat and change the trajectory of health for humanity.

We advocate for the following approaches to combating AMR, representing a holistic system of policies, mechanisms and actions across sectors:

Access mechanisms and R&D incentives to address AMR challenges: The global pipeline for new products targeting resistant infections is not sufficient, given the size and scale of the challenge posed by AMR. When it comes to therapeutics, a number of scientific, regulatory, and market challenges contribute to the paucity of antimicrobials in development, which is evidenced by companies that develop antimicrobials exiting the space.

We welcome various mechanisms, such as the AMR Action Fund, of which we are a founding member, and the Biomedical Advanced Research and Development Authority's CARB-X, which have been set up to encourage innovation in AMR. We see opportunity for further use of market-based incentives, such as:

- **Subscription Models and Market Entry Rewards:** New products targeting resistant infections should be used judiciously, which poses a challenge to market entry in the current landscape. Providing a reward for companies that reach a defined milestone (e.g., bringing a product to market) can overcome this barrier. Implementing these effective solutions necessitates that governments or other sources secure adequate funding for these mechanisms.
- **Transferable Exclusivity Vouchers:** These vouchers could be a powerful motivator for companies to invest in research and revitalize the AMR pipeline. These incentives would allow companies that develop specific medicines for neglected areas to extend the exclusivity period—for instance by extending regulatory data protection, existing patents or any extensions—of a separate product in a defined therapeutic category for a defined time. Like Priority Review Vouchers, they have the advantage of not requiring any appropriated funding from governments. We support further exploration of this model.
- **Special reimbursement / Health Technology Assessment (HTA):** We support creation of special reimbursement mechanisms or HTAs that address the complexity and unique nature of the AMR marketplace. These mechanisms should follow a holistic approach, capturing the full value of innovative antimicrobials and being based first and foremost on the meaningful clinical benefits and health outcomes delivered to patients. Assessments should be evidence-based and include all relevant evidence and outcomes, incorporate multiple stakeholder views and preferences, and recognize the benefits to the health systems and to society at the local level. Acknowledging this broader value will help better predict demand and encourage investment in future research.
- **Priority Review Vouchers:** Building on our experience with SIRTURO, we are a strong proponent of the U.S. Priority Review Voucher (PRV) system, which grants companies that successfully develop a drug for certain under-resourced diseases or populations a voucher for expedited review of another therapeutic candidate. While the market value of a PRV is highly variable and does not in itself

provide recompense for a full-scale drug development program, we believe this system should be maintained in the United States and explored elsewhere as an incentive for AMR research.

Regardless of the additional incentive models that may be pursued, it is important to maintain existing regulatory exclusivities and intellectual property protections for companies that bring innovations to the market. As we have experienced with SIRTURO, these protections are a key element of any comprehensive strategy to stimulate innovation and access to new treatments.

Specific incentive methods to address the gap in fit-for-purpose diagnostic tools and technologies are also needed. Finally, we support initiatives like those of the [Coalition for Epidemic Preparedness Innovations](#) and others that seek to incentivize the development and access to new vaccines that can limit the spread of resistant infections.

Promoting appropriate use and access: Ensuring that new and existing anti-infective tools, AMR-relevant vaccines, and diagnostics are used appropriately is paramount to addressing the AMR issue globally. This requires concerted action on several fronts:

- **Health infrastructure and delivery:** A critical factor to addressing the threat of AMR is the existence of a robust health system that can effectively find and treat AMR-related infections and work to prevent their spread. We have been proud to work with the government of South Africa and others in their accelerated case finding, training and treatment programs. We aim to ensure they have the appropriate technology to promote sufficient access to SIRTURO, and we encourage donors and governments to make the necessary investments to deal with this critical challenge. This includes training healthcare workers and providing them with appropriate infrastructure, ensuring patients have access to essential care and services, tracking and reporting resistant infections, and more. Globally, we are proud to champion the Universal Health Coverage (UHC) movement and believe that actions to address AMR will be most sustainable when taken as part of country-level efforts to achieve UHC.
- **Diagnostics:** As noted by the U.S. Centers for Disease Control and Prevention (CDC), overprescribing of antibiotics is a significant problem that contributes to drug resistance: In the United States, 28% of all antibiotics prescribed in doctors' offices and emergency departments are not necessary.¹⁵ We support the CDC's recommendations¹⁵ for prescribers and patients to promote appropriate use of antibiotics. Additionally, we believe there is an important need for diagnostics that can help ensure the right treatments are used for the right patients. Beyond the R&D incentives mentioned previously, reimbursement reforms are also needed to encourage doctors and providers to use these diagnostic tools.
- **Medical technologies:** We support the creation and adoption of guidelines that favor use of technologies designed to reduce the risk of HAIs in hospitals, and policies that encourage health workers and hospitals to adopt systematic checklists regarding the use of these technologies.
- **One Health framework and animal use:** One Health is a collaborative, multisectoral approach that recognizes the significant connection between the health of humans and that of animals and the impact that they both have on the environment.¹⁶ While Johnson & Johnson does not have an animal health business, we do recognize the importance of good antibiotic stewardship in animal populations and support global and local efforts that limit the inappropriate use of antibiotics in these settings. We support ending the use of prophylactic dosing of antibiotics for infection prevention and growth promotion, as well as limiting use in animals of antibiotics that are critical for human use. Vaccines

¹⁵ <https://www.cdc.gov/antibiotic-use/antibiotic-resistance.html>

¹⁶ https://www.who.int/health-topics/one-health#tab=tab_1

have a key role to play within the One Health framework since they can control cross-species disease transmission. We support science-based evidence to improve awareness, knowledge and understanding of the interdependencies of the health of humans and animals, and the benefits that come with improving vaccination rates in animals and humans to counter emerging infectious diseases.

Harmonizing regulatory approvals: The approval of therapies targeting resistant infections poses unique challenges in clinical design and evaluation. We commend guideline changes and legislative efforts to streamline regulatory pathways, e.g., the Antibiotic Development to Advance Patient Treatment Act in the United States and the FDA / European Medicines Agency / Pharmaceuticals and Medical Devices Agency Tripartite Meeting. Building on this progress, we believe further gains can be made by continuing to harmonize regulatory data requirements across countries. Where appropriate, mutual recognition of approvals and regulatory reliance can expedite access worldwide.

Environmental considerations: We support the environmental management and transparency principles captured in the AMR Roadmap document and in the [AMRIA Antibiotic Manufacturing Standard](#). We encourage other manufacturers of antimicrobials to endorse, embrace and enact these principles as well, and to report on their progress in meeting these principles.

Systems approach: While we see implementing the policy solutions mentioned above as critical to ensuring additional industry engagement in AMR, they will not be sufficient in isolation. As we have learned from our experience, working collaboratively with all stakeholders is what ultimately creates rapid improvements and drives patient outcomes. Solving for AMR will require a new way of thinking, where stakeholders work transparently in mission-oriented consortia designed to enforce better collaboration and create mutual accountability for results. The incentives of all stakeholders—industry, government, society and academia—must be aligned toward reducing further development of resistant infections and the delivery of better health outcomes for patients and caregivers.

We therefore believe we need focused and collaborative action to deliver against AMR. Success will require committed leadership across sectors, ambitious yet measurable priorities and targets, detailed execution plans, regular performance management, and public accountability.

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