# Leading Pharmaceutical Companies Present Industry Roadmap to Combat Antimicrobial Resistance

- Comprehensive roadmap lays out key commitments the pharmaceutical companies pledge to deliver by 2020 to reduce antimicrobial resistance
- Represents major milestone following the Industry Declaration signed in January 2016 at the World Economic Forum by more than 100 companies and trade associations

NEW YORK, N.Y., September 20, 2016 – Ahead of the United Nations General Assembly (UNGA) High-Level Meeting on Antimicrobial Resistance (AMR), 13 leading pharmaceutical companies today presented a new roadmap that lays out four key commitments they will deliver by 2020 to reduce AMR. The commitments follow the principles identified and agreed upon in the Industry Declaration made at the 2016 World Economic Forum in Davos earlier this year, and reflect the companies' intent to continue to proactively contribute to the global efforts to address AMR. This unprecedented collaboration between the pharmaceutical companies marks a major milestone in the fight against AMR.

In presenting this roadmap, the signatory companies firmly demonstrate their shared ambition to overcome the staggering threat AMR represents for our society, economies, and citizens. We are committed to working to reduce the development of antimicrobial resistance, improve access to high-quality antibiotics, vaccines, and diagnostics, invest in R&D, and collaborate with governments and stakeholders to sustain those investments.

Specifically, this group of diversified companies commit to:

- 1. Reduce the environmental impact from the production of antibiotics, including a review of the companies' manufacturing and supply chains, and work with stakeholders to establish a common framework for assessing and managing antibiotic discharge;
- 2. Help ensure antibiotics are used only by patients who need them, recognizing this requires concerted efforts from many stakeholders, through continued provider and patient education, an examination of the companies' promotional activities, sharing of surveillance data with public health bodies and healthcare professionals, and collaboration with stakeholders to reduce uncontrolled antibiotic purchase;
- 3. Improve access to current and future antibiotics, vaccines, and diagnostics, including working with stakeholders to strengthen global health systems and address access bottlenecks; establishing new business models that balance access needs, appropriate antibiotic use, expanded vaccine coverage and adequate return to companies; and working to reduce the prevalence of substandard/counterfeit antibiotics in high-risk markets; and
- 4. Explore new opportunities for open collaborations between industry and the public sector to address challenges in the research and development of new antibiotics, vaccines, and diagnostics, recognizing the value these bring to society.

The companies also reiterate our support for a comprehensive multi-sectoral approach to address the other factors contributing to AMR as defined by the World Health Organization Global Action Plan, the AMR Review, the US National Strategy and Action Plan, and the just released United Nations AMR High Level Meeting declaration.

Progress will not be achieved without concerted efforts from all stakeholders, and we call on governments to support the reduction of inappropriate antibiotic use in humans and animals, the improvement of surveillance and infection control measures, the ongoing research and development into novel antibiotics through financial and regulatory incentives, and finally, to deepen commitments to develop and adopt advanced diagnostics to address over-prescription in patients.

The companies support the establishment of a high-level coordinating mechanism to provide global leadership, mobilize resources, set goals, and measure progress towards them. We also welcome similar commitments from other stakeholders involved in combating AMR.

To view the full Industry Roadmap, click here.

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#### SIGNATORY COMPANIES

Allergan (NYSE: AGN)

AstraZeneca (NYSE: AZN)

Cipla (NSE: CIPLA)

DSM Sinochem Pharmaceuticals (Euronext: DSM)

F. Hoffman-La Roche Ltd., Switzerland (VTX: ROG)

GSK (NYSE: GSK)

Johnson & Johnson (NYSE: JNJ)

Merck & Co., Inc., Kenilworth, New Jersey, U.S.A. (NYSE: MRK)

Novartis (NYSE: NVS)

Pfizer (NYSE: PFE)

Sanofi (EURONEXT:SAN, NYSE: SNY)

Shionogi & Co., Ltd. (TYO: 4507)

Wockhardt (NSE: WOCKPHARMA)

#### QUOTES ABOUT THE INDUSTRY ROADMAP

Dr. Marc Sprenger, Director of the World Health Organization Antimicrobial Resistance Secretariat, said:

"I welcome these commitments from the pharmaceutical companies and commend their support of the global action plan on antimicrobial resistance. In particular, the measures to reduce the environmental impact of the production of antibiotics, advance stewardship and minimise over-the-counter and non-prescription internet sales of antibiotics will be of great benefit. I strongly encourage the collaboration between industry and governments, as it is only together that we can tackle antimicrobial resistance."

H.E. Ambassador Juan José Gómez Camacho, Permanent Representative to the United Nations Organization, appointed facilitator for the organization and outcome document of the High Level Meeting on Antimicrobial Resistance by the President of the General Assembly, said:

"Tomorrow we are recognizing at the United Nations General Assembly that AMR is a global risk that needs to be addressed worldwide and that all the States need to work together. We are also recognizing that AMR is a complex multisectorial threat that requires the joint efforts, not only of governments but also of different stakeholders. In this frame, it is with great pleasure that I welcome this new phase where the biopharmaceutical industry is assuming bold commitments to tackle microbial resistance."

# Carlos Moedas, European Commissioner for Research, Science and Innovation, said:

"I welcome the continued commitments from major pharmaceutical companies to contribute to the global fight against drug-resistant infections. The European Commission and the European Federation of Pharmaceutical Industries and Associations created in 2012 the world's largest public-private partnership "New Drugs for Bad Bugs" under the Innovative Medicines Initiative, which is now started to deliver on the challenge. We are committed to strengthen our partnership with pharmaceutical companies both large and small."

#### Lord Jim O'Neill, Chairman of the Review on Antimicrobial Resistance, said:

"I am very excited by these latest commitments from major pharmaceutical companies to do their bit in the world's response to drug-resistant infections. We will only overcome this challenge through effective collaboration between governments, NGOs and the private sector. The roadmap launched in New York this week shows that a growing number of pharmaceutical companies are taking this seriously – I commend this display of leadership, and now is the time for an even wider range of companies in this industry and beyond to follow suit."

# Mark Pearson, Deputy Director, Directorate of Employment, Labour and Social Affairs, OECD said:

"This is an excellent initiative to tackle an urgent problem. Pharmaceutical companies are right in wanting to prevent unnecessary use of antibiotics, while ensuring access for all who need them. I look forward to discussing with the companies how to advance these goals."

#### **Jeremy Farrar, Director of the Wellcome Trust, said:**

"The emergence of infections that are resistant to drugs is the most pressing health issue of our time. The UN General Assembly meeting must be a turning point - creating the awareness, political momentum and the swift and cohesive action required to bring drug resistant infections under control.

"More prudent use of antimicrobial drugs is an important first step in stemming the rise of drug resistant infections. As developers and distributers of these drugs, pharmaceutical companies have a pivotal role to play in tackling this issue. I welcome these pledges and hope they will help the industry tackle overuse of antimicrobial dugs, while ensuring they are available to those who need them."

# Professor Ramanan Laxminarayan, Director and Senior Fellow, Center for Disease Dynamics, Economics & Policy (CDDEP), said:

"These commitments by pharma are essential pieces of the global response to antibiotic resistance, and actions that only industry can take. It means that stakeholders in civil society and government can play their parts with the assurance that we are all pulling in the same direction. We look forward to collaborating with industry partners in all aspects of antibiotic conservation and access."

# Johan S. Bakken MD, PhD, FIDSA, President, Infectious Diseases Society of America, said:

"Infectious diseases (ID) physicians see firsthand the devastating impact of antimicrobial resistance on our patients and public health. We are out of treatment options for increasing numbers of patients. IDSA welcomes the commitment of industry to address AMR and invest in the research and development of urgently needed new antimicrobial drugs, diagnostics and vaccines. Robust public private collaboration is essential for effective solutions to AMR."

#### Allan Coukell, Senior Director for health programs at The Pew Charitable Trusts, said:

"We applaud the series of commitments announced today for recognizing that progress against antibiotic resistance requires a focus on stewardship, environmental use, and innovation. Open collaborations to tackle key research questions and a commitment from industry partners for access to medicines and wise use are crucial."

#### ABOUT ANTIMICROBIAL RESISTANCE

- 1. Antimicrobial resistance (AMR) is the natural process by which bacteria and other microbes develop resistance to the drugs commonly used to treat infections. Antimicrobials include antibiotics (which act only on bacteria), antivirals, antiparasitics and antifungals. The independent Review on AMR, chaired by the economist Lord Jim O'Neill, estimated in 2014 that without effective global action, the rise of AMR could claim 10 million lives globally each year by 2050 and result in a cumulative loss in global output of USD 100 trillion.
- 2. The growth of resistance to antibiotics represents a particularly serious threat to modern healthcare. We rely on effective antibiotics to treat common infections and to ensure that

other medical procedures (such a surgery or cancer chemotherapy) remain safe and routine, but a combination of scientific, regulatory and commercial challenges has meant that the discovery of new antibiotics in recent decades has failed to keep pace with the rise of antibiotic-resistant infections. Meanwhile, we face the problem of inappropriate use of antibiotics and other antimicrobials in animals and humans in most parts of the world – something that exacerbates the development of drug resistance – and a lack of affordable access to antimicrobials in others.

#### **ABOUT THE DAVOS DECLARATION**

- 1. On January 21, 2016, the *Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance* was launched at an event at the World Economic Forum in Dayos. Switzerland.
- 2. When published in January 2016, the Declaration had been drafted, agreed and signed by 85 companies and nine industry associations from across the global pharmaceutical, diagnostics and biotechnology industries. As of April 1st, 2016, a total of 98 companies and 11 industry associations in 21 countries have signed the Declaration.
- 3. In the Declaration, signatory companies call on governments to work with them to develop new and alternative market structures that provide more dependable and sustainable market models for antibiotics, and to commit the funds needed to implement them. These mechanisms are needed to provide appropriate incentives (coupled with safeguards to support antibiotic conservation) for companies to invest in R&D to overcome the formidable technical and scientific challenges of antibiotic discovery and development. These include mechanisms to ensure that, where appropriate, the pricing of antibiotics more adequately reflects the benefits they bring; and novel payment models that reduce the link between the profitability of an antibiotic and the volume sold. An integral part of these models is a reduced need for promotional activity by companies.

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