Pharma industry launches call for coalition of countries to pilot new incentives for antibiotic R&D

16 November, Geneva – The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) draws attention on the urgent need for governments across the world to put in place a suite of incentives to reinvigorate the antimicrobial pipeline. Adoption by governments of sustainable and substantial measures to fund or reward research inputs and outputs incentives must be achieved if the R&D-based biopharmaceutical industry is to continue to invest and take on the risk in research, development, and commercialization for new medicines and vaccines to address AMR.

IFPMA recommends three action areas: continue to support incentives that help “de-risk” early stage R&D (“push incentives”), increased support novel mechanisms that help companies ensure a predictable return for new medicines (“pull incentives”), and adapt reimbursement procedures to better capture the value novel antibiotics bring to patients, healthcare systems and society.

Over the past two decades, there has been a significant decline in the number of companies conducting antibiotic R&D due to the significant scientific, regulatory, and economic challenges specific to this therapeutic area. As published in the AMR Industry Alliance’s progress report, in 2016 companies invested at least $2 billion in R&D to counter AMR. While, this figure is significant all experts agree that it is nowhere near sufficient to address the urgent need for new antibiotics.

“Antibiotic R&D is not for the faint-hearted. It is one of the toughest innovation environments, with only a fraction of pre-clinical targets ultimately being proven safe and effective enough to make it to the market”, said Thomas Cueni, IFPMA Director-General. “Current market conditions make it very difficult for companies to sustain their investments. Without changes to reimbursement, valuation mechanisms and ultimately commercial models, nearly one-third of all responding companies, including half of all large R&D biopharmaceutical companies, report that they will likely decrease their investments in antimicrobial R&D. We therefore urge governments to form a ‘coalition of the willing’ that will pilot novel economic models that will influence the development and availability of tools to tackle antimicrobial resistance”.

If governments can create market conditions where there is a sustainable return on investment, the pharmaceutical industry and private investors have demonstrated their willingness to take on the risk and uncertainty that comes with the development and commercialization of a new medicine or a vaccine. These incentives should be able to stimulate R&D across the full R&D cycle, from discovery through development, to see an impactful long-term change on the pipeline of new products. Companies participating in the AMR Industry Alliance survey have acknowledged the role that upfront funding and financing streams, as well as facilitated regulatory requirements have played in maintaining current early-stage efforts. However, these efforts alone will not be sufficient to address AMR.

Three top-line recommendations for action outlined by IFPMA on the occasion of World Antibiotic Awareness Week include:

1  AMR Industry Alliance first Progress Report.
• **Continue to support push incentives** that primarily target pre-clinical and early stage clinical research by helping “de-risk” companies’ initial investments by pooling funds and expertise. While these mechanisms help reduce the upfront R&D spend, they need to be accompanied by sustainable pull mechanisms that have an impact on the potential returns on investment.

• **Support novel pull mechanisms** which reward successful delivery of innovative products to the market, and ensure a predictable return on investment. Transferable exclusivity extensions and market entry rewards are two such mechanisms that can preserve competition between companies, and can be designed to focus on only the highest-priority antimicrobials to treat or prevent urgent or serious health threats.

• **Reform reimbursement and HTA processes** so that they better capture the value novel antibiotics bring to patients, healthcare systems and society in reimbursement decision making. Current guidelines for hospital reimbursement systems used in the US, most of Europe and Japan impose a strict budget constraint to treat patients in hospital settings which can impede or delay the prescription of higher priced novel antibiotics—even if they may be the most appropriate treatment. Reimbursing certain antibiotics outside bundled payments for patients treated in the hospital would facilitate better stewardship, especially if coupled with mechanisms to ensure appropriate use.

**About IFPMA**

**IFPMA** represents the research-based pharmaceutical companies and associations across the globe. The research-based pharmaceutical industry’s 2 million employees discover, develop, and deliver medicines and vaccines that improve the life of patients worldwide. Based in Geneva, IFPMA has official relations with the United Nations and contributes industry expertise to help the global health community find solutions that improve global health.

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