Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance

January 2016

Antimicrobials, and specifically antibiotics, play a crucial role in modern medicine. These precious medicines are often taken for granted and are not only necessary to treat life-threatening infections, but are also vital to underpin most common surgical procedures and many chronic treatments such as chemotherapy and HIV and transplant medicines. They also play a crucial role in the health of animals.

The increase in bacterial resistance to antibiotics has been dramatic, and combating this growth is a top priority for global policy and public health. There is a particular concern that antibiotics are losing effectiveness faster than they are being replaced by new, innovative drugs, including both antibiotics and alternative non-antibiotic approaches to treating and preventing infections.

This innovation gap has been examined extensively and is widely acknowledged to be the result of a combination of scientific as well as commercial barriers that have impeded antibiotic development over a number of years. The scientific difficulties are formidable and traditional R&D approaches have largely failed: companies, private and public funders have invested billions of dollars over the last 20 years to discover new antibacterials, yet no new class of antibiotic for Gram-negative infections has reached approval in over 40 years.

This situation poses a unique set of challenges. We will always need a supply of innovative new antibiotics; all antibiotics need to be used cautiously to conserve their effects; and, in many countries, we still need to improve access to existing antibiotics.

We welcome the economic analysis of Jim O’Neill’s Review on Antimicrobial Resistance (AMR), which quantifies both the costs and investments needed. The challenges are clearly substantial and call for transformational changes from many stakeholders. The pharmaceutical, biotechnology, and diagnostics industries have an important role to play, and we are committed to doing our part. Leadership from other sectors is also required, and we welcome the initiative of the Review on AMR, as well as the attention of governments and politicians world-wide (including the recent G7 Berlin declaration), and the leadership of key international organisations (WHO, OIE, FAO, ECDC, US CDC), public funding bodies (NIH, BARDA, the European Commission, and IMI), and charitable foundations (Wellcome Trust, BMGF, and Pew Charitable Trusts)\(^1\), amongst others.

We similarly welcome those steps already taken by key regulatory authorities around the world, such as the US Food and Drug Administration (FDA) and European Medicines Agency (EMA), to enable antibiotic development in advance of widespread resistance, and we support a continuation of these efforts to ensure greater harmonisation of regulatory processes internationally.

**Taking collective action**

We support the increasing recognition that the value assigned to antibiotics and diagnostics often does not reflect the benefits they bring to society, nor the investment required for their creation. Therefore, we call on governments to commit to allocating the funds needed to create a sustainable

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and predictable market for these technologies while also implementing the measures needed to safeguard the effectiveness of antibiotics. Specifically:

- **Creating a sustainable and predictable market.** We call for governments to commit funding and support the development and implementation of transformational commercial models that (a) enhance conservation of new and existing antibiotics, while (b) improving financial and access-related predictability for both industry and health systems.

  - **Enhancing conservation.** We support measures for the prevention of infection along with conservation and appropriate use of all antibiotics, including:

    - Implementation of the WHO’s Global Action Plan calling for comprehensive stewardship programmes and activities that enhance health system capability to use antibiotics appropriately.

    - Enhanced integration of fast and accurate point-of-care and laboratory diagnostics with antibiotics to ensure appropriate use of antibiotics for the patients who need them. To enable this, we call for improved reimbursement and use of advanced diagnostics.

    - Furthermore, we call for governments, insurers, healthcare providers and other health system stewards to remove financial incentives for individuals (such as doctors, veterinarians and pharmacists) or institutions that reward the prescribing of antibiotics in greater volumes.

  - **Improving financial and access-related predictability** for both Industry and health systems is required to ensure sustainable investment in new antibiotics and diagnostics. To this end, we welcome appropriate incentives, coupled with safeguards to sustain the effectiveness of new and existing antibiotics. We believe two fundamental approaches are needed to accomplish these goals:

    - We welcome proposals that (a) support reduction in the link between financial revenues for new antibiotics and the amount they get used while (b) mitigating the financial risk for both developers and health systems. As different jurisdictions may require different solutions, a range of approaches to creating such delinkage will likely need to be utilised. Possible approaches include the system of lump sum Market Entry Rewards proposed by the Review on AMR, insurance-like purchase models, and novel intellectual property-based approaches with appropriate safeguards. An integral part of these models is a reduced need for promotional activity from companies.

    - We also support the principle that in developed markets, prompt reimbursement decisions at prices that reflect value should be provided for new drugs and diagnostics to reflect the benefits they bring (with measures for stewardship to prevent misuse) – as also acknowledged in the work of the Review on AMR. This calls for funding to be allocated and for payers to appropriately assess and value innovative antibiotics and diagnostics, in line with the good progress that has been made by regulatory authorities.

  - **Global coordination, local action.** We call for a global commitment to coordinated action on stewardship, conservation, hygiene, and the creation and use of new commercial models for antibiotics and diagnostics. As noted above, we recognise different models may be appropriate for different countries, health systems, and
products. All parties should commit to allocating funding and finding paths that work for their situation. We are ready to work stepwise with countries to implement such models.

**Commitments by signatory companies**

The under-signed companies are already actively engaged in combating AMR as appropriate to their business. We stand ready to work in partnership with leading countries to deliver sustainable solutions to meet this global challenge. We invite other companies to join this Declaration and comments from all other stakeholders are welcome. We will review and update the Declaration every 2 years, to reflect progress and changing priorities.

We commit to:

**Work to reduce the development of antimicrobial resistance**

- We are committed to antibiotics only being used in patients who need them, we support continued education for clinical professionals on appropriate use, and we welcome the WHO Global Action Plan’s focus on improved stewardship.

- We encourage infection control via improved hygiene, vaccination, and preventive treatments to help reduce the number of infections needing antibiotic treatment.

- We support measures to reduce environmental pollution from antibiotics, along with a 'one health' approach towards prudent and responsible use, including a global reduction of unnecessary antibiotic use in livestock, and we applaud moves from major food groups to work towards this goal.

**Invest in R&D to meet public health needs with new innovative diagnostics & treatments**

- We are investing in a range of innovative antibiotics, vaccines, alternative technologies, and diagnostics for resistant infections. We are advancing our pipelines, but more work and investment into multiple approaches is needed to overcome the significant scientific difficulties of antibiotic discovery.

- We will continue to support research in academia and SMEs on new and re-purposed antibiotics. We welcome proposals to increase investment via coordinated global routes in efforts to develop useful diagnostics, antibiotics, vaccines, and alternative technologies.

- We support new ways of working such as open collaborations between industry and public researchers to overcome the scientific challenges of creating new antibiotics and diagnostics. Collaborative public-private projects already demonstrate what we can achieve together, but more can be done: several companies co-established the New Drugs for Bad Bugs (ND4BB) programme as part of IMI with the European Commission and others are actively engaging in collaborations funded in the US by BARDA and the NIH.

- As acknowledged, the value assigned to antibiotics and diagnostics often does not reflect the investment required for their creation or the benefits they bring to society, and we stand ready to work with payers and policymakers on new valuation mechanisms and commercial models that specifically address the unique challenges of this market.
Improve access to high-quality antibiotics and ensuring that new ones are available to all

- As part of the WHO Global Action Plan’s proposal for a comprehensive program of sanitation, hygiene, vaccination, infection control, education, and stewardship, we support mechanisms to ensure affordable access to new and existing antibiotics to the patients who need them, in all parts of the world and at all levels of income.

- We recognise the success of programmes to improve global access to drugs in HIV, TB, and malaria and call for a similar collaborative effort to address issues of access to antibiotics.
Signatories – as at April 29, 2016

Pharmaceutical and biotechnology companies

- ABAC Therapeutics, Spain
- Abgentis Ltd., United Kingdom
- Absynth Biologics Limited, United Kingdom
- Achaogen Inc., United States
- Actelion Ltd., Switzerland
- Aequor Inc., United States
- AiCuris Anti-infective Cures GmbH, Germany
- Alaxia Pharma, France
- Allegra Therapeutics, Germany
- Antabio, France
- AntibioTx ApS, Denmark
- Arsanis, Austria
- AstraZeneca plc, United Kingdom
- Auspherix Limited, United Kingdom
- BioFilm Control, France
- BioVersys AG, Switzerland
- Biovertis AG, Austria
- Blueberry Therapeutics Ltd., United Kingdom
- Cantab Anti-infectives Ltd., United Kingdom
- Cardeas Pharma, United States
- Cempra Inc., United States
- Chemical Biology Ventures Ltd., United Kingdom
- Cipla Ltd., India
- Contrafect, United States
- Da Volterra, France
- Deinobiotics, France
- Destiny Pharma Ltd., United Kingdom
- Dipexium Pharmaceuticals, United States
- Discuva Ltd., United Kingdom
- DSM Sinochem Pharmaceuticals, Netherlands
- Eigo Bioscience, France
- Entasis Therapeutics, United States
- Evotec, Germany
- F. Hoffmann-La Roche AG., Switzerland
- Fedora Pharmaceuticals Inc., Canada
- GlaxoSmithKline plc, United Kingdom
- Helperby Therapeutics plc, United Kingdom
- IMMT, Slovenia
- iNTRON Biotechnology, Inc., Korea
- Johnson & Johnson, United States
- Laboratorios Cifna, Spain
- Lamellar Biomedical Ltd., United Kingdom
- MaaT Pharma, France
- Macrolide Pharmaceuticals Inc., United States
- Meiji Seika Pharma Co., Ltd., Japan
- Melinta Therapeutics, Inc., United States
- Merck & Co., Inc., Kenilworth, New Jersey, U.S.A
- Merck, Germany
- MGB Biopharma Ltd., United Kingdom
- Microbion Corporation, United States
- MicuRx Pharmaceuticals Inc., China and United States
- Motif Bio, United States
- Mutabilis, France
- Nabriva Therapeutics AG, Austria
- NAICONS, Italy
- Nexgen Bio, United States
- Northern Antibiotics Ltd., Finland
- Nosopharm, France
- NovaBiotics, United Kingdom
- NovaDigm Therapeutics, Inc., United States
- Novartis AG, Switzerland
- OJBio Ltd., United Kingdom
- OLMIX Group, France
- Otsuka, Japan
- Peptilogics Inc., United States
- Pfizer Inc., United States
- PHARMA VAM Ltd., Russia
- Pherecydes Pharma, France
- Phico Therapeutics Ltd., United Kingdom
- Polyphor AG, Switzerland
- Redx Pharma plc, United Kingdom
- Sanofi S.A., France
- SetLance, Italy
- SETUBIO S.A., France
- Shionogi & Co. Ltd., Japan
- Spero Therapeutics, LLC, United States
- Synamp Pharmaceuticals B.V., The Netherlands
- Synthetic Genomics, United States
- TechnoPhage, Portugal
- Tetraphase Pharmaceuticals, United States
- The Medicines Company, United States
- VenatoRx Pharmaceuticals Inc., United States
- VibioSphen, France
- Vitas Pharma Ltd., India
- Wockhardt Ltd., India
**Diagnostic companies**

Alere Inc., United States  
bioMérieux SA, France  
BD, United States  
Cepheid, United States  
Curetis AG, Germany  
F. Hoffmann-La Roche Ltd., Switzerland  
HemoCue AB, Sweden  
Hyrax Biosciences (Pty) Ltd., South Africa  
LabCorp, US  
Luminex B.V., The Netherlands  
Mobidiag Oy Ltd., Finland  
Momentum Bioscience Ltd., United Kingdom  
QuantuMDx Ltd., United Kingdom  
Spectromics, United Kingdom  
Thermo Fisher Scientific, United States

**Industry Associations**

*We support the aims of the Declaration signed by our Member companies and look to work with all stakeholders to help deliver its objectives.*

Alliance of Biopharmaceutical companies from Europe innovating in Anti-Microbial resistance research (BEAM Alliance)  
Association of the British Pharmaceutical Industry (ABPI)  
Antimicrobial Innovation Alliance (AIA)  
Biotechnology Innovation Organization (BIO)  
British Generic Manufacturers Association (BGMA)  
The British In Vitro Diagnostics Association (BIVDA)  
European Federation of Pharmaceutical Industries and Associations (EFPIA)  
European Generic and Biosimilar Medicines Association (EGA)  
International Federation of Pharmaceutical Manufacturers Association (IFPMA)  
The German Association of Research-Based Pharmaceutical Companies (VFA)  
Japan Pharmaceutical Manufacturers Association (JPMA)  
Nefarma, the association for innovative medicines in The Netherlands  
The UK BioIndustry Association (BIA)