Industry Roadmap for Progress on Combating Antimicrobial Resistance – September 2016

The Davos Declaration[*] signed by >100 companies and trade associations in January 2016, called for collective action to create a sustainable and predictable market for antibiotics[†], vaccines and diagnostics, that enhances conservation for new and existing treatments. It also called for coordinated action to improve prevention of infections, hygiene, stewardship and conservation measures.

As a group of leading companies supporting the Davos Declaration, we welcome the continued high level political focus on Antimicrobial Resistance (AMR), including discussions at the UN, WHO, G7, G20, the AMR Review team's Final Report as well as regional and national debate. This work has established an ambitious, comprehensive agenda for the world and challenges each key stakeholder group to act and contribute to managing the threat of resistance.

The pharmaceutical industry recognises our responsibility and remains committed to playing a significant part in this long-term effort. Given the unique scientific, economic, public health and environmental challenges presented by AMR, collaboration between stakeholders is essential to maximise progress. We will continue to engage and partner with governments, global institutions, academia, prescribers and patients at global, regional and national levels. Resolving the complex economic challenges for the development, access and appropriate use of new antibiotics, vaccines and diagnostics remains of critical importance for us. It is necessary to attract sustained investment in developing new technologies to combat AMR.

As signatory companies of the Davos Declaration, we are committed to working to reduce the development of antimicrobial resistance, to invest in R&D and to improve access to high quality antibiotics and vaccines. These are ambitious goals, requiring new ways of working and investments of time, money and skilled people. This paper lays out a Roadmap for four key commitments on which the undersigning companies of this document will deliver, as applicable according to their different businesses and capabilities. Although work is underway on most aspects of the Roadmap, the precise end-points are not yet defined in all cases. These commitments therefore reflect our intent to proactively contribute to the fight against AMR, by developing and implementing solutions that will make a difference. We would welcome similar commitments from, and working collaborations with, other companies involved in combating AMR.

1) We support measures to reduce environmental impact from production of antibiotics, and will:
    i. Review our own manufacturing and supply chains to assess good practice in controlling releases of antibiotics into the environment.
    ii. Establish a common framework for managing antibiotic discharge, building on existing work such as PSCI[‡], and start to apply it across our own manufacturing and supply chain by 2018.
    iii. Work with stakeholders to develop a practical mechanism to transparently demonstrate that our supply chains meet the standards in the framework.
    iv. Work with independent technical experts to establish science-driven, risk-based targets for discharge concentrations for antibiotics and good practice methods to reduce environmental impact of manufacturing discharges, by 2020.

2) We are committed to antibiotics only being used in patients who need them. We recognise this requires concerted efforts from many stakeholders, and, to help achieve this, we will:

[*] http://amr-review.org/industry-declaration

[†] We use the term antibiotics, recognising that antibacterials represent the top priority for all stakeholders. These principles could subsequently be applied to other types of antimicrobial over time.

[‡] Pharmaceutical Supply Chain Initiative https://pscinitiative.org/home

i. Support governments and public health work to educate healthcare professionals and patients on the value and importance of appropriately using antibiotics, and the value of vaccination as a cost-effective intervention that complements antibiotic stewardship.
ii. By the end of 2017, examine our promotional activities to ensure they align with the goal of advancing stewardship and eliminate those that do not, to protect the utility of antibiotics by encouraging their correct use.
iii. Continue to share the surveillance data we generate with public health bodies and healthcare professionals, and work with them to improve understanding of resistance trends, inform appropriate antibiotic and vaccine use and, over time, thereby help increase surveillance capabilities globally.
iv. Collaborate with governments, their agencies and other stakeholders to reduce uncontrolled antibiotic purchase, such as via over-the-counter and non-prescription internet sales.

3) For existing and future antibiotics, diagnostics and vaccines, improved access is essential, and must be balanced with health system measures to ensure appropriate use. We support mechanisms to facilitate affordable access to high quality new and existing antibiotics, diagnostics and vaccines to the patients who need them, in all parts of the world and at all levels of income. We recognise the success of programs to improve global access to vaccines and drugs in HIV, TB, and malaria. We will:
   i. Work with international bodies, governments and other stakeholders to identify and address specific access, market sustainability and supply bottlenecks for existing antibiotics, diagnostics and vaccines, and develop innovative financing and procurement mechanisms to resolve them.
   ii. Work with stakeholders to establish new business models which will improve access to new antibiotics, diagnostics and vaccines globally, while supporting appropriate use and delivering an adequate return to companies. We are willing to explore all options to achieve this and believe that receipt of an adequate Market Entry Reward will greatly facilitate global access and stewardship for that product.
   iii. Seek to accelerate the introduction of processes, technologies, and regulations required to reduce the prevalence of substandard/counterfeit antibiotics in high risk markets.

4) We support new ways of working such as open collaborations between industry and public researchers to overcome the scientific challenges of creating new antibiotics, vaccines and diagnostics. Collaborative public-private projects already demonstrate what we can achieve together, but more can be done and we commit to:
   i. Progress incentives, such as lump-sum payments, insurance models and novel IP mechanisms, that reflect the societal value of new antibiotics and vaccines and will attract further investment in R&D.
   ii. Explore opportunities to address key scientific challenges via further pre-competitive collaboration, building on experience with the TB Accelerator, IMI and GHIT[§].
   iii. Support the creation of open and sustainable clinical trial networks globally, with our expertise and experience. As proposed by the AMR Review, this would build on work started in Europe and US with the goal of improving the speed and efficiency of conducting clinical trials.
   iv. Engage with stakeholders, including the new GARDP[**] initiative, to facilitate data exchange on old antibiotics to try and fill specific gaps in the global pipeline.

Finally, we reiterate our support for a comprehensive multi-sectoral approach to addressing the other factors contributing to, and impacted by AMR, as defined by the WHO Global Action Plan, the AMR

[§] For these and other examples of partnership, see http://partnerships.ifpma.org/partnerships/by-letter/all
[**] Global Antibiotic Research and Development Partnership http://www.dndi.org/2016/media-centre/press-releases/gard-garners-key-support-for-launch/

Review and the UN AMR High Level Meeting declaration, including reducing inappropriate antibiotic use in humans and animals, improving surveillance and infection control measures and commitments to develop and adopt advanced diagnostics. We support calls for the establishment of a high-level coordinating mechanism to provide global leadership, mobilise resources, set goals and measure progress towards them.

Signatory Companies

Allergan, U.S.A.

AstraZeneca, U.K.

Cipla, India

DSM Sinochem Pharmaceuticals, Netherlands

F. Hoffman-La Roche Ltd., Switzerland

GSK, U.K.

J&J, U.S.A.

Merck & Co., Inc., Kenilworth, New Jersey, U.S.A.

Mylan, U.S.A.

Novartis, Switzerland

Pfizer, U.S.A.

Roche, Switzerland

Sanofi, France

Shionogi , Japan

Wockhardt, India