28 June 2019

Department of Health
GPO Box 9848
Canberra ACT 2601, Australia
amr@health.gov.au

Dear Department of Health

Re: AusBiotech’s response to the public consultation on “Australia’s Next Antimicrobial Resistance Strategy: 2020 and Beyond”

AusBiotech is pleased to provide comments to the Department of Health on its consultation paper to inform the development of Australia’s next Antimicrobial Resistance (AMR) Strategy.

Antimicrobials are a critical weapon in our fight against human and animal disease. We all have a stake in the integrity and ongoing efficacy of these products and in the development of new treatments that will continue to help protect us from microbial disease.

AusBiotech is a well-connected network of over 3,000 members in the life sciences industry, which includes the bio-therapeutics, medical technology (devices and diagnostics), food technology, and agricultural biotechnology sectors.

We have not attempted to provide a detailed response to each of the 34 questions in the Submission Template. We have instead focused on the role of the biotechnology industry in AMR, as this is of most relevance to our members.

Response to proposal

AusBiotech is supportive of efforts to enhance the global response to AMR, and supports the comprehensive refresh of Australia’s First National Antimicrobial Resistance (AMR) Strategy 2015-2019 leading to a new AMR Strategy for 2020 and beyond (‘the Strategy’) being led by the Department of Health (DoH) and the Department of Agriculture (DoA).

The UN has labelled AMR ‘a global crisis.’ Approximately 700,000 people die every year from drug-resistant infections, which could increase to 10 million by 2050 unless action is taken. The response necessitates including all stakeholders and international collaboration.

We agree in principle with the future direction of the Strategy. The ‘One Health’ approach reflects interdependencies in combating AMR across different sectors (e.g. animal and health) and across government, research facilities and industry. This reflects key findings from the April 2019 UN report to the UN Secretary-General, including:

3 No Time To Wait: Securing The Future From Drug-Resistant Infections - Report To The Secretary-General Of The United Nations, April 2019
Because the drivers of antimicrobial resistance lie in humans, animals, plants, food and the environment, a sustained One Health response is essential to engage and unite all stakeholders around a shared vision and goals.

However, we believe that the consultation paper – which will inform the next Strategy – underplays the role of the life sciences industry in addressing AMR. Industry involvement is essential to implementation of the Strategy and achieving the 35 priority action areas currently identified, and needs to be better reflected in the revised Strategy.

**The life sciences industry is a key stakeholder in AMR**

The commercial life sciences industry is pivotal to addressing AMR. Industry plays a crucial role in the research, development and subsequent availability of new treatments for patients. Without industry involvement, it will be impossible to meet the goal of the Strategy: ‘Minimise the development and spread of antimicrobial resistance and ensure the continued availability of effective antimicrobials.’

Yet this critical role is not reflected in the Strategy consultation document, or wider AMR discourse. For example, the number one priority for the MRFF is:

- “Support stronger partnerships between researchers, healthcare professionals, governments and the community. This will help position Australia as a leader in significant global research, such as tackling antimicrobial resistance.”

Industry needs to be included in an entire ‘eco-system’ approach to AMR. The UN Interagency Coordination Group (IACG) on Antimicrobial Resistance highlighted the importance of engaging with industry:

- ‘The IACG calls for the systematic and meaningful engagement of and enhanced action by the private sector as key stakeholders in the One Health response to antimicrobial resistance at global, regional, national and local levels.’

We all have a stake in addressing AMR and if we are to collectively address what the 68th World Health Assembly described as the ‘pressing need for new antimicrobial medicines,’ industry needs to be part of these discussions and response.

The Strategy therefore needs to more explicitly acknowledge industry as a key stakeholder. Opportunities to do so include explicitly mentioning of industry’s role when addressing priority areas such as ‘7.1: Identify, establish and maintain linkages between implementation partners across all sectors,’ and ‘7.2: Work with stakeholders to develop an Implementation Plan for the Strategy.’ This then needs to be reflected in its actual implementation.

The consultation paper notes that the Australian Strategic and Technical Advisory Group membership will be reviewed to ensure it includes adequate representation from all sectors, and we encourage the consideration of additional industry representatives to be included.

**Ongoing involvement with industry to progress the research agenda is critical**

Objective Five – the national research agenda – in particular is relevant to industry, but the Strategy consultation document does not adequately reference industry’s R&D role.

This sentiment is reflected in the 2017 review of progress of the National AMR Strategy – *Australia’s First National Antimicrobial Resistance Strategy 2015-2019: Progress Report*. Virtually no industry initiatives have been identified in its analysis of ‘what we have achieved,’ and the first of the next steps identified in the document states: ‘Australia will continue to encourage research institutes, centres of research excellence and national research funding bodies such as the NHMRC, MRFF and Australian Research Council to work collaboratively to establish agreed national AMR research priorities.’
We acknowledge Priority Action 5.3: ‘Explore opportunities to increase support for research and development, including incentives for greater private sector investment’, and AusBiotech extends an invitation to DoH and DoA to discuss this further.

When considering options to support industry-led R&D and incentives, the unique challenges in developing new treatments must be considered. These include the need for careful, phased human clinical trials, long lead times for products to reach the market (often 10-15 years), and significant costs incurred often before revenue is achieved. These costs can exceed $1 billion. It is also research intensive, with average spending on R&D representing the industry’s largest operational cost, at about 21 per cent of total expenditure (McKell 2017).

These significant challenges and risks are compounded by the low returns available to industry for AMR, which further disincentivises AMR research and product development.

![Table 1: Antibiotics with similar financial risk but without the financial upside of other drugs](image)

To address these challenges, greater incentivisation for industry is required, and this needs to be reflected in the Strategy. Incentives should support the development of treatments across the developmental cycle. Organisations such as International Federation of Pharmaceutical Manufacturers and Associations and the World Economic Forum have identified that these could include: research and development tax credits; addressing market economics barriers (reimbursement and HTA reform); and other pull mechanisms to incentivise private-sector investment. 4,5 In this context, access for the life sciences industry to Australia’s R&D Tax Incentive is critical, and a commitment to keep it in place for an extended period of time would be attractive to industry.

**AMR is a global problem**

AusBiotech strongly agrees with the paper’s recognition that ‘AMR is a global issue that requires a global response’ and again emphasises the importance of industry to this response. Objective Six – ‘Strengthen international partnerships and collaboration on regional and global efforts to respond to antimicrobial resistance’ – will in particular require greater involvement and engagement with industry.

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5 International Federation of Pharmaceutical Manufacturers & Associations, *Supporting sustainable investments in antimicrobial R&D*
Co-ordination with international strategies and greater engagement with global and regional initiatives to combat AMR (e.g. the Biotech companies in Europe combating AntiMicrobial Resistance (BEAM) Alliance) should also be undertaken.

AusBiotech is well-placed to help DoH and DoA act on the issues raised in this paper and to help facilitate industry engagement as the Strategy is finalised. Our members include small start-ups trying to bring new technologies and treatments to patients, larger more established companies, research institutes, and the health, Medtech and agricultural biotechnology sectors. We would welcome the opportunity to engage directly with DoH and DoA and discuss in more detail how our industry’s role can be better reflected in the next Strategy and subsequent implementation.

When relevant, we would appreciate advance notice of implementation of the changes and the opportunity to comment on any subsequent amendments proposed.

We also look forward to receiving further information about the proposed approach to resourcing the implementation of the Strategy.

All Australians have a vested interest in addressing AMR. Industry is integral to the Australian and global response, and we look forward to working with the entire sector on behalf of our members in relation to finalising the next AMR Strategy.

AusBiotech Ltd
ABN 87 006 509 726
Level 3, 15 Queen Street
Melbourne VIC 3000 Australia