

Declaration by the *In Vitro* Diagnostics Industry on Tackling Antimicrobial Resistance

November 2017

The importance of *in vitro* diagnostics (IVDs) in tackling the antimicrobial resistance (AMR) challenge cannot be overstated.

While the widespread use of broad-spectrum antibiotics has helped to create multi-drug resistant strains of bacteria, greater adoption of IVDs would lead to a reduction in cases of unnecessary antibiotic prescribing by:

- Reducing time to appropriate treatment decision
- Allowing for a more targeted use of therapy against infection

Urgent action is required to halt AMR and we strongly urge healthcare professionals in the UK to make use of the quick, accurate and effective IVDs already available to them. Until IVDs are more widely adopted, we will not be able to combat AMR effectively.

Much of the focus of the AMR debate has been on the development of new antimicrobials. While this is important, it must be remembered that this is **only one, temporary solution**. Unless we change our approach to their use, new antimicrobials will also become ineffective over time, reinforcing the status quo.

Therefore, we welcomed the acknowledgement of the O'Neill Review on AMR that, "*rapid diagnostics are essential for the transition from broad to targeted antibiotics*". BIVDA and its members were also pleased that the Government highlighted the importance of increasing the uptake of rapid diagnostics in their response to the O'Neill Review.

The IVD industry is committed to playing its part in tackling AMR but we understand that it is a global problem requiring global collaboration. The 2016 UN General Assembly Meeting on AMR was a great opportunity to put AMR at the front of the global health agenda and built on the earlier discussions held at the G20.

With attention on AMR now at its highest, it vital that we continue to build on this momentum. The UK is widely credited for being at the forefront of the AMR debate. Now we must lead the way on demonstrating the value of IVDs in tackling the threat of AMR to human health.

Collaborative Action

While the value of IVDs is often recognised by policymakers and clinicians, the variable adoption of IVDs across the NHS makes it difficult for diagnostics to fulfil their role. Therefore, we call on the Government to support the IVD sector to play its part in tackling AMR by:

Identifying best practice on AMR in the NHS and replicating it across the system

- There are examples of best practice across the NHS where IVDs have been used to tackle AMR.
- The Academic Health Science Networks (AHSNs) should be tasked with spreading this best practice throughout the healthcare system.

Developing clear and concise guidance on the evidence required for IVDs to be more widely adopted across NHS England

- IVDs struggle to be adopted due to a perceived lack of supporting evidence.
- However, it is not always clear to companies what evidence they need to produce in order for their product to be adopted.
- We would welcome the opportunity to work with the Department of Health and NICE on establishing clear and concise guidance for the NHS on the data and evidence they require from companies.
- Industry is also happy to work with the Government, NHS and AHSNs to make best use of the evidence that is already available. AMR is a global threat and there is a wealth of existing global data available, which supports the importance of IVDs in tackling AMR.
- However, while evidence gathering is valuable, it is also important to remember that globally, approximately 700,000 deaths may be caused each year by AMR¹. Therefore, it is vital that we take action now to fast-track the adoption of IVDs to ensure that real world evidence is collected.

Educating the public about the role of diagnostics in tackling AMR and ensuring prudent use of antimicrobials

Surveys have found that patients put their GPs under pressure to prescribe antibiotics, even if it may not be the correct course of treatment².

- To help diminish this pressure and reduce instances of inappropriate prescribing, it is vital that the public are educated about the vital role of diagnostics in antimicrobial stewardship.
- The Government has run many effective health campaigns in the past; for example, the message that we should eat five portions of fruit and vegetables a day is well known among the public.
- Industry urges the Government to look at the success of its previous health campaigns and work with Public Health England to devise a strategy that looks to educate all age groups about the relationship between IVDs and overcoming AMR.
- We want to empower the public so that they feel knowledgeable enough to request a diagnostic test before automatically accepting a prescription for an antibiotic.

Focusing on delivering the outcomes of the O'Neill Review and providing clarity on who is responsible for delivering on the recommendations

- The IVD industry has been actively involved in the O'Neill Review and welcomes the final report of the Review and the subsequent Government response.
- It is vital that now the Review is concluded, the recommendations are fully implemented at the earliest opportunity.
- We strongly support Recommendation 5 of report which calls for the promotion of "rapid diagnostics to cut unnecessary use of antibiotics" and that stronger economies "should

¹ <https://www.oecd.org/health/health-systems/AMR-Policy-Insights-November2016.pdf>

² <http://www.bmj.com/content/349/bmj.g5238>

make it mandatory that by 2020 the prescription of antibiotics will need to be informed by data and testing technology wherever available”.

- BIVDA needs confirmation from the Government on who will have ownership for implementing and delivering this recommendation, how updates on progress will be communicated and how AHSNs will be engaged to disseminate examples of best practice throughout the NHS.

Designating funding for the implementation of rapid diagnostics

- BIVDA and its members note the funding the Government has focused on combatting AMR through the development of new diagnostics.
- While this commitment is welcome, the development of new diagnostics will be undermined unless funding is put in place to support the *implementation* of existing IVDs.
- BIVDA and its members call on the Government to designate funding for the adoption and implementation of rapid diagnostics at the point of impact.

Commitments by Signatory Companies

The IVD industry takes its commitment to AMR seriously. BIVDA has established an AMR Working Party, which brings industry together to drive forward collaborative action.

BIVDA and the under-signed companies are keen to demonstrate their dedication and have committed to:

Promoting the appropriate use of diagnostics

- BIVDA and its members always seek to promote the role of diagnostics in the diagnosis, treatment and management of patients.
- However, we will only encourage the use of diagnostic tests in situations where it is appropriate to do so.
- We support continued education for clinicians and the wider public on the availability and appropriate use of IVDs to enable better stewardship.

Investing in innovative new diagnostics

- There are a number of quick, accurate and effective IVDs already available to clinicians, particularly in the area of AMR, that have not yet been adopted widely across the NHS.
- However, we acknowledge the emphasis on the development of further rapid and value-based diagnostic tests in the Government’s response to the O’Neill Review.
- Therefore, industry will continue to invest in the research and development of new rapid diagnostics to assist the stewardship of antimicrobials.
- BIVDA will also continue to provide support to the Longitude Prize, a “£10m prize fund that will reward a competitor that can develop a point-of-care diagnostic test that will conserve antibiotics for future generations and revolutionise the delivery of global healthcare”.

Making better use of the tools already available to us to accelerate adoption

- The IVD sector appreciates that a number of initiatives have been established to help industry accelerate the adoption of IVDs including the Diagnostic Evidence Co-operatives (DECs) and AHSNs.
- While BIVDA and its members already work with a number of these organisations, we will look at how we can engage more effectively with them and make better use of their services to further the adoption of IVDs.

List of BIVDA member signatories, correct as of 15 November 2017

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EME and Chairman of BIVDA



Steve Holland,
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Jan Rogers, Chief Scientific Officer



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Because every result matters™

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About BIVDA

The British In Vitro Diagnostics Association (BIVDA) is the trade association for manufacturers and suppliers of *in vitro* diagnostics (IVD) companies.

It has been leading the industry for 25 years since its establishment in 1992 and represents over 150 members. Our industry plays a critical role in the NHS and health care pathway; 70% of clinical decisions are made using some form of IVD test.