UK Manufacturing Capability

Industry View

British In Vitro Diagnostics Association (BIVDA)

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Contents

1. Foreword

BIVDA (British In Vitro Diagnostics Association) is the national industry association for the manufacturers and distributors of in vitro (IVD) products in the UK, representing almost 200 organisations including multi-nationals and SME's.

There is a highly active and competitive UK IVD sector with products, equipment, and tests available within robust, highly regulated supply chains with capacity to supply in the volumes required to support the Government in combatting Covid-19 – and with the capacity to lend this assistance in any future pandemic.

Our members are continuing work to provide quality tests with differing methodologies, such as PCR, Rapid, Lateral Flow, Point of Care and Antibody. We are also developing non-invasive tests such as saliva and molecular multiplexing for identification of Covid-19, alongside the seasonal respiratory infections.

As we see the pandemic beginning to ease, we hope permanently, is a need to build on the lessons learned during the last year to build a UK diagnostic industry of critical mass. Covid-19 has highlighted challenges the UK faces in terms of the limited diagnostic manufacturing capacity, as well as issues caused by a stretched international supply chain, which has become an acute issue in the face of a global pandemic. Building a larger UK diagnostic industry from our strong base should be a matter of national importance for the UK and should be seen as a strategic asset, worthy of specific attention as the Government considers reforms to the NHS and its associated bodies. This is not to say that there is not an important place in the UK for multi-national suppliers, as the international supply chain is massively aware of the touch points and with the necessary environment which consists of surety, use cases and adoption of technology as well as the international R&D and innovation opportunities.
There must continue to be a level playing field and fair procurement. The Green paper for NHS procurement transformation goes some way to change the procurement environment. It appears to attempt to rebalance the emphasis on simple open market principles and move towards a more considered holistic approach more in line with national procurement strategy and objectives. The definition of "Discrimination" seems only to be in the context of domestic suppliers and is therefore unclear as to how the principle would be applied to international proposals.

This paper is provided to policy makers to ensure that the breakthroughs, experience, collaboration and infrastructural changes brought about by the pandemic are capitalised upon to access innovation and manufacturing capacity to support the on-going efforts to control this, and future pandemics.

2. Background

It has led to extraordinary scientific breakthroughs and created collaborations between academics, universities and organisations to a level that has not been seen before. It forced the development of necessary infrastructure and behavioural change that would have taken a decade to achieve at any other time, introducing the concepts of self-testing and remote use of diagnostics to an engaged public.

The pandemic led to a revolution of the national capacity for lateral flow manufacture. It also led to the creation of a validation framework for a wide range of point-of-care and self-test systems. We have

disintermediated clinicians and created logistics chains to deliver mail-order diagnostics, and report data via smartphones. We have in short 'democratised' diagnostics.

There is no Holy Grail solution but the availability of high street, mail-order and digitally-enabled diagnostics coupled with a disrupted post-pandemic establishment, lab capacity, skills and a flow of venture capital into the sector give the UK momentum and purpose to create new market, muscle and meaning for the industry over the next 20 years.

Addressing National Need

In the early period of the pandemic, shortfalls in the UK's manufacturing capacity to meet the growing testing needs slowed our ability to manage the spread of infection. During the pandemic a number of new capacities have been created including lateral flow device production capacity.

As we move forward, vaccination is expected to reduce the pandemic to an epidemic. We will have to learn to live with Covid-19 as we do with influenza. To strengthen our ability to better manage future pandemics, different public and private entities will require different things from the UK IVD sector:

- Government needs a robust domestic industry that it can call on.
- Individual members of the public need to have the capability to test themselves cheaply and regularly to ensure that they can use passporting, facilitate foreign travel, and can seek medical help early in an infection before symptoms worsen.

Lateral Flow Tests (LFDs) are being used in the latter two categories, but are not the long term solution.

The solution is a cheap and more accurate device that will give instant results anywhere, is readily portable, and can report results electronically. BIVDA members are working on such devices, a process that could be accelerated with targeted government support.

There is a need to incentivise companies to be sited in the UK to increase a vibrant industry, without incentives, manufacturers are often forced to move manufacturing to other global sites which affects not just the manufacturing skills, but also expertise. Need to create an environment to improve the talent pool and knowledge as this will also affect ancillary industries. University courses, specialised degrees, more vocational training to qualification "on the job".

IT – why pay a graduate in UK when it can be done remotely. IT enables globalisation. What is the link to digital technologies and UK manufacturing.

IP.

How can industries adapt (IF/WHEN) Covid-19 is a manageable disease (Pharma)

Tooling and adaptation for other tests – what is the pipeline to secure investment.

Is it lab tests, it is POC patient tests or is it community testing or is it consumer testing. It is all, but how to determine investment – needs government long term use guarantee.

3. Summary of recommendations

A clear roadmap for additional public investment in research – this will help to encourage private investment and aim to close the gap between the UK and comparable countries such as Germany, who already invest almost 3% of GDP.

Maintain the balance of funding across research and innovation in the dual support system and allocate public resources to diverse streams, from the Charity Research Support fund, to the network of Catapults that drive innovation.

Align tax regimes, access to long term patient capital, and support for medicines manufacturing and uptake to create and internationally competitive environment for private research.

Policy enablers – a smoother regulatory landscape and greater cooperation from the NHS – are needed for swifter commercial access to samples to develop not just Covid-19 tests but all novel and innovative tests to diagnose conditions. Patient material is truly essential and it is imperative that this is available – a system similar to the UK Biobank to access samples could be considered.

**The expectation from Government is that it would take 6m to double the UK made capacity, but Industry need to know how much is needed to scale up to capacity rather than scaling up with no guarantee. It is not the guarantee to procure by government that needs to be set, but the policy, long term strategy for testing in terms of Covid-19 and the use cases that will allow the market place to be fair and accessible to suppliers to invest in manufacturing capacity.

Government needs to set a long term Covid-19 testing strategy that will include NHS, central Government, private and public testing so suppliers will know what to support and the policy makers to share and commit to a stable environment.**

4. Testing, Passporting and Personal Health

Better, quicker tests are being developed, in line with the general developments towards personal diagnosis for health monitoring with, for example, electronic devices and smart phones. It would be beneficial to the UK to be in the forefront of this effort, to develop a domestic industry – logistical and financial support would help.

Beneficial features of these tests will be:

- essentially instant results;
- accuracy similar to PCR;
- cheap enough for daily testing;
- compatible for logging with electronic devices;
- usable by anyone anywhere without training;
- no use for reagents;
- capable of testing more than one virus at a time e.g. multiple variants of one virus or two or more respiratory viruses, and;
- have long shelf lives under broad storage conditions (one could purchase them in a pharmacy).

These tests should be based on saliva as research has shown this to be a better indicator of lung disease than mucus. Such tests are in development today and their development should be encouraged – cost efficiency would be high when compared with Government spend to date on diagnostics. Fast track approvals for new devices should also continue to give the UK strong systems for dealing with SARS – Cov-2 when it is long term endemic and with current, e.g. influenza, and future challenges[1].

[1] Hurdle performance requirements should match US FDA requirements to enable an export industry to be built – viz: The FDA expectation is that PPA (sensitivity) should be >95% (lower bound of the two-sided 95% confidence interval >76%) and NPA (specificity) should be ≥98% (with a lower bound of the two-sided 95% confidence interval >95%).

5. Innovation

Research funding and allocation

The pandemic has demonstrated that the United Kingdom is a world leader in medical research, and this expertise can and should be utilised to help to achieve the Government's aim of making the UK a science superpower. Efforts can also have an economic benefit if Ministers were to allocate greater resources towards translating science into commercial products. This can be achieved by better co-ordination of diagnostic funding activity across the various UK Government organizations (the new UK Health Security Agency, Innovate UK etc.) and a focus on innovation in manufacturing and investment in manufacturing capability. The critical difference to make post-pandemic will be to ensure that funding does not just develop the ideas here but translates them into products which are made in the UK to boost our manufacturing capability in IVDs, including capacity for testing products for future pandemics. When developing this capacity, the focus should be on automated manufacturing to enable the UK to compete with low labour-cost countries.

There needs to be more funding opportunities linked to use cases for manufacturers to meet the need rather than create innovative products that the government (for whatever reason) fails to validate or determine a use case. Consideration of innovation. Manufacturers need to consider product improvement and next generation vs genuine innovation.

More use of regional bodies for funding and access to scientific advisory panels feeding into a centralized testing strategy, but not just for Covid-19.
The Industry has become insular – crick, bank of biomedical scientists, access to national panels.

Adopt the principles of silicon valley with a more robust linkage between academics and experience and the producers. Clustering is important, with an industry rise in certain areas, with an equivalent academic set up, considering local workforce, funding opportunities, training and regionalization.

What is the skill set required for building manufacturing, systems engineer, BMS's – identify this and invest in those skills. Current education does not recruit into these skills. IT and engineering is low intake. Small number of people required for high value jobs. How to make the rest of the jobs attractive.

How does the UK industrial strategy support this does anything need to change?

Not an easy route for innovative products that have a use but are not required in large mass numbers, doesn't seem to be the same fast track for products (niche). This needs to change to foster innovation and adoption.

Reluctance to go through validation process (central) for 1 product.
Once validation is undertaken at supplier expense – the procurement often falls to cheaper (less good??) products as the specification for UK validation is higher than the specification for procurement?

No margin for UK company to reach the end point at the same cost. The real cost in the UK would exceed the actual cost from overseas. Will government pay a premium for UK based goods to reach economies of scale for a long term investment

Investment in UK manufacturing will require an investment is the budget of users of the manufactured goods. What is the industrial and health economic benefit.

Make to order for use cases/ contract manufacturing. Need to push for countries to adopt UK CA.

Novel use cases, not novel products.
Need regulatory, approval and external systems in place to be consistent.
Pay for quality.
Test more at cheaper cost and lower quality or less at higher cost and better quality – what are the health economics.

Capacity needs to be filled with money, not tests.

The Government should also ensure that tax and funding policies related to innovation should be properly targeted. Specific policies should include;

- A clear roadmap for additional public investment – this will help to encourage private investment and aim to close the gap between the UK and comparable countries such as Germany, who already invest almost 3% of GDP.
- Maintain the balance of funding across research and innovation in the dual support system and allocate public resources to diverse streams, from the Charity Research Support fund, to the network of Catapults that drive innovation.
- Align tax regimes, access to long term patient capital, and support for medicines manufacturing and uptake to create and internationally competitive environment for private research.

Advanced manufacturing

Scalable advanced manufacture provides the UK with huge export potential in a truly global market. It also provides significant of manufacturing onshoring opportunities, a trend we are likely to see across all manufacturing in the next decade as lessons learned from the pandemic demonstrate the need for a domestic diagnostic and research capability. The capacity put in place during the pandemic gives us a strong base to build on. How big is the UK market now in terms of ££ and capacity? How big can it be in the future? It can be as big as the need, so identify the need and it can be matched with the enablers outlined.

Building the UK critical mass in diagnostics by supporting investment in manufacturing in the UK will be vital in ensuring that we have the capacity to rapidly scale up our testing ability in the face of future pandemics. This can be done on a macro-level, providing projects like the Northern Powerhouse with financial support to invest in manufacturing-focused diagnostic business, or at company-level, provision of asset-backed support to allow SMEs to grow and scale-up, or greater R&D funding for automated manufacture and innovation in manufacturing processes.

The collaborative approach taken during the last twelve months between private business, academia, the Government and the health service should continue – not only does this allow for efficient sharing of data, it also means that the communication channels will already be open in the event of a future pandemic. The ability to rapidly re-scale up our testing capacity will depend on shared learning not being forgotten.

Quicker Adoption of new products

The unprecedented change in process in the rapid adoption of new methods of working, as well as the rapid validation of new products and technologies in the health service during the last twelve months should be acknowledged and celebrated. We cannot go back to the old ways of working and assessing devices, with the old ten-year lag between approval of innovative IVDs and their adoption by the NHS.

In order to scale up the capacity in the UK for large scale manufacturing, it will be necessary to fast track the use of not only innovative, but UK manufactured products into the diagnostic field. Whilst there needs to be a centralized drive, this does not mean to say that the government needs to finance

the procurement of UK products, but the enablers in terms of processes, R&D funding and use cases need to be addressed, as many UK manufacturers are able to export their products far easier than deliver into the domestic markets. (WHY?)

Whilst the Pandemic has highlighted an ability to put diagnostics into the hands of the users in terms of lateral flow .

Regulation could be seen as a barrier. Regulatory affairs teams need 5 years' experience so this prevents upskilling in pace in SME's. Interpretation of the regulations buy the user is more of a barrier than the regulations themselves.

New origin rules come in to play – are uk manufacturers disadvantaged compared to china – costs to comply higher?

Could get over the challenge and go through process and get investment only to lose to a kit made by a Chinese company.

Consideration should be given to continuing the ease of access to samples for testing and research purposes. In ordinary circumstances and even during the pandemic, neither UK companies nor global organisations have been able to easily access Covid samples from UK for commercialisation of R&D. This is largely due to excessive process and paperwork, and a restrictive regulatory landscape – there is also a lack of incentive for the NHS to facilitate the access. This pattern is not consistent across the country, with companies having issue with some Trusts more than others.

It is illogical in terms of the direction that the UK government wishes to travel for a strong domicile manufacturing industry for UK companies to rely on imported patient samples at a significant cost requiring a return on investment.

Policy enablers – a smoother regulatory landscape and greater cooperation from the NHS – are needed for swifter commercial access to samples to develop not just Covid-19 tests but all novel and innovative tests to diagnose conditions. Patient material is truly essential and it is imperative that this is available for research and diagnostic purposes – a system similar to the UK Biobank to access samples could be considered.

6. Analytical and Ancillary Equipment

Ensure that companies who did not receive contracts for Test and Trace or DHSC testing requirements are not excluded from their commercial pipeline due to gifted, or in situ equipment, as this will have a long term impact of the UK being an attractive country for investment.