

# Involvement of BIVDA and its members in the UK's COVID-19 testing strategy.

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# BIVDA, IVD suppliers and DHSC

- There is a highly active and competitive UK IVD Sector. With consultation and collaboration with Government, we are confident that our members can work together to increase capacity to further increase supply in the volumes required to support the Government in combatting COVID-19.
- Our members are ready to supply technically acceptable and available diagnostic tests and are continuing work to provide quality tests with differing methodologies, such as PCR, Rapid, Lateral Flow, Point of Care, Antibody and now non-invasive tests such as Saliva and molecular multiplexing for identification of COVID-19 alongside the seasonal respiratory infections, and other respiratory conditions.
- By involving BIVDA, DHSC gains immediate access to world leading R&D and diagnostic products through the extensive membership who are keen to support all efforts to combat COVID-19. Our members continue to be ready and able to design, manufacture and supply high quality products to be deployed within the COVID-19 testing strategy.

# Supporting the Strategy

- Working with BIVDA and its members will enable you to;
  - Ensure effective procurement processes using established frameworks and supply chains which can be utilised.
  - Access quality products and ensure laboratory and technical support is available to your centres.
  - Address capacity, ensuring sustainable testing levels can be maintained, manufacturing redundancy is incorporated across the supply network, minimising the impact of diverted testing components away from NHS pathology laboratories.
  - Ensure transparency within the UK market.
  
- The Industry recognises that the Pandemic required urgent and decisive action when COVID-19 reached the UK as early as February 2020, and the use of emergency regulations and direct awards to suppliers was perceived to be the most appropriate course of action to secure the necessary stock of health supplies and testing. However, BIVDA as the industry trade association was not utilised to best effect at the outset. Issues relating to multiple departments and individuals being involved probably contributed to this, particularly at the time between PHE, NHS England and Deloitte. This has improved significantly, but must be consistent moving forwards.

- BIVDA's subsequent involvement in the wider scope was after many decisions and actions had been taken.
- Therefore an opportunity for an overall faster response, and one of quality was unfortunately missed under the assumption that there was no UK Diagnostics industry. BIVDA understands that the DHSC was inundated by suppliers with products to offer, many were likely unsuitable, but also unlikely to have been from BIVDA members.
- Even today there is the belief that

*“one of the things that is a constraint of the nation is that there are no domicile UK companies there is no ability to scale up and manufacture and the holistic piece cannot be achieved without this”*

Sir John Bell. 28.09.2020.

- This is something we seek to re-dress and where required improve by working closely and collaboratively to respond to demand.

# Evaluation and Use

- The process to acquire testing for both supplies and capacity was unclear from the start, and embedded and existing procurements were not utilised.
- Whilst PHE states publically that products do not have to be approved and they do not mandate the use of particular products, this was (and still is) the message that laboratories have been given.
- The evaluation of tests particularly the well-publicized antibody test evaluations were disjointed and there was no apparent process with some suppliers having the same kits returned with materially different evaluation reports, and many suppliers receiving no response at all.
- This means that supplies are available but there is no way to provide them due to laboratories not realizing they are free to procure as they choose.
- Following a very informative discussion between BIVDA and the Deputy Chief Scientific Officer at DHSC and the Technical Manager at PHE in August we were able to derive the correct process and notify our members collectively. Centrally procured kits and instrumentation are provided to the NHS with no cost to the Trust, where Trusts procure directly which they are able to; they will be reimbursed a cost per test price.

- Quality has been at the forefront of the fight against the pandemic, with much being reported in the media about low quality and unapproved methods, the BIVDA membership are all highly reputable companies who sell high quality, regulated products and who work in an arena where reputation, quality and safety is what drives success. The reputation and quality of the organisations would have ensured that the quality and performance of the products available would have been more reliable.

- The insistence that there is no capacity in the UK is not fully understood, since capacity in terms of supply chain and ability to supply from our members seems to be at odds with the view of government. It would be useful to understand if there is another criteria included in the government view that is not considered by Industry.
- **Finished Goods** –UK suppliers had access to stock of test kits and materials required for the demand, and whilst the demand was significant and there may have been some issues they would have been reduced and stocks could have been secured with a much lower risk of failure to supply.
- **Analytic Platforms** – Within the NHS laboratories and several other private laboratories which support the NHS there was spare capacity to undertake testing. This was largely due to the routine and non-COVID-19 testing reducing by as much as 60-70% for suppliers and laboratories where analytic platforms were idle due to the core laboratory business reducing so much. BIVDA supports the calls from RCPATH, ACB and IBMS to be more involved in the next steps of the testing strategy, and the need for laboratory capacity properly scoped.
- **Manufacturing** – similarly, manufacturing lines and scheduled orders were no longer required for many manufacturers and contract manufacturers who BIVDA are proud to have within the membership. Partnerships between R&D and Contract manufacturers already exist in the UK and these were not utilised.
- Many suppliers would have been able to scale up UK manufacturing to re-purpose existing manufacturing capability and there would be less reliance on overseas imports and the supply chain risks associated.

- Communication both formally and informally across NHS Trusts, Industry Webinars and direct communications was often inconsistent. There has been an improvement seen by members, and this is largely to do with procurement teams ensuring that contacts are updated and introductions made when internal personnel changes occur on these projects and we are confident that this will continue.
- The UK usually enjoys a fair and transparent competitive IVD market in the NHS and in the private sectors, and there was no change in law to suggest anything other should have been expected. The use of Regulation 32 (2) (C) was understandable in some circumstances, but the transparency and call for competition could have been handled differently.
- The general perception within the membership was that only certain suppliers with direct influence were being awarded contracts and there were so many different people involved and all giving conflicting factual information.
- Routes to market and communication channels are already in place and ready to be utilised regardless of capacity needs. Utilizing these established routes, would not only enable procurement compliance and transparency, but also ensure cost control.
- BIVDA members still do not feel that procurement is as transparent as it could be and BIVDA would like to see more communication with members within commercial limitations in the months ahead. There is significant improvement over recent weeks for the sharing of requirements and we are keen to see this continue.



- **Transparency and Confidence in quality and procurement**

Working with BIVDA will enable DHSC to conduct transparent interaction, fairness and equal treatment with suppliers and ensure that risk and uncertainty is managed through clear communication channels and requests for information. This alongside a clear and understandable evaluation process is critical when determining access to market for suppliers, and quality and continuity of supply for the DHSC. NHS Trusts need to be independent and understand that they should be able to make local decisions based on clinical needs. BIVDA can also support the cascade of information to suppliers when the Government or DHSC requires alignment with information and messaging which will help ensure clarity at trust level as well as with Industry.

- **Shared procurement oversight across all Pillars**

NHS England runs the risk of undermining efforts in each Pillar if procurement teams do not inform each other of the continued needs of each Pillar, and thus the needs required of that Supplier. Working through BIVDA will help to drive a consolidated message across all suppliers to ensure clarity on supply across all Pillars/ programmes where testing volumes is weakened and behind target. To be effective discussions would need to be centralized at the NHS level as well.

- **Technical Understanding**

Many BIVDA members are already conducting discussions with the relevant allocations team with NHS England on the Pillar(s) they support. However, these discussions are often led by non-scientific personnel. Inclusion of scientific understanding within these procurement discussions would support speed and clarity on decisions from both entities as well as effective onward management of information where new or alternative options on constrained supply routes or alternative Pillar needs can be managed effectively.

- **Strategic Store**

Whilst NHS England is considering this through their central allocation's teams, this appears to be mainly reserved for those Companies with centrally organized supply contracts. Opening dialogue on this with BIVDA members may lend support ensuring sustainable supply levels where and when appropriate to enable the swift action of DHSC to address further infection spikes and the impact this has on all testing Pillar needs.

- **New test review and adoption**

All BIVDA members are familiar with regulatory compliance and, indeed BIVDA has a Regulatory Working Group, to address needs required to meet market changes. Working with BIVDA gives you direct access to members who are already well-versed in this area. BIVDA would welcome the opportunity to create a channel where call for actions are shared with its members enabling high calibre companies to be able to respond providing accurate information on relevant products and/or services.