

## ABHI & BIVDA JOINT LETTER ON THE IMPLEMENTATION OF THE CTDA PROCESS

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Dr Jenny Harries OBE  
Chief Executive Officer  
UK Health Security Agency

4<sup>th</sup> November 2021

**Dear Dr Harries,**

The Association of British HealthTech Industries (ABHI) and the British In Vitro Diagnostics Association (BIVDA) acknowledge concerns over the existing validation process for, and the quality of, some COVID-19 tests that are currently being supplied, and support action to remove poor quality tests from the market.

However, implementation of the Coronavirus Test Device Approvals (CTDA) process has disproportionately and unfairly damaged the UK diagnostics industry. It has led to the needless withdrawal of COVID-19 tests with no identified deficiency, which, as we face a critical time in the evolution of the pandemic, has weakened supply resilience in our country and threatens to disrupt testing capacity and capability.

A recent survey of ABHI and BIVDA members has underlined the impact on UK industry of the recent list of products that were approved or temporarily listed as exempt from the requirements of the process. Three quarters of large companies appear on one or both lists (approved or exempt) but fewer than half of smaller companies appear on either. Only one in ten large companies have no products listed compared with two thirds of smaller ones.

Without a full and open rationale as to why their products have not been listed, manufacturers have been left confused and unsure about what they are able to do with their tests. This has been compounded by delays in communications to applicants detailing precisely what is required for approval.

The confused and confusing implementation of the legislation has restricted the UK supply of COVID-19 tests to a few larger companies at the expense of smaller ones. Loss of smaller companies has an impact on the industry as a whole in the UK, and broader implications for innovation. Smaller companies now feel restricted in their ability to quickly bring new products and ideas to the market. By disproportionately affecting smaller businesses, this legislation has undermined confidence in the aim of the Life Science Vision to build a robust UK diagnostics industry.

The supply chain has almost immediately become more fragile and less resilient. This is evidenced by [news that two companies have voluntarily pulled COVID tests from the UK market](#) and any remedial action by UKHSA to correct this is already too late. Furthermore, NHS and private laboratories must now spend time and effort transitioning to new tests in an attempt not to disrupt the NHS Winter Plan. The capability to detect and respond to the emergence of new variants is also diminished.

We would respectfully suggest that you remove the confusion that threatens the diagnostics industry in the UK, make all decisions transparent, extend the transition period for all products, adopt a more flexible approach to ensure supply security and resilience, and allow sufficient time to properly and fairly implement this legislation in line with the needs of the NHS.

Yours Sincerely,

**Nishan Sunthares**



Managing Director, Diagnostics, ABHI

**Doris-Ann Williams MBE**



CEO, BIVDA

CC:

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