ABHI & BIVDA JOINT POSITION ON DEPARTMENT OF HEALTH AND SOCIAL CARE (DHSC) CONSULTATION ON COVID TEST LABORATORY VALIDATION

https://www.gov.uk/government/consultations/validation-of-covid-19-tests-laboratory-validation

ABHI and BIVDA members strongly disagree with the DHSC's new proposal for the mandatory laboratory validation of COVID-19 tests, and request it be rescinded. What is proposed is costly and undermines the existing UK regulatory framework, adding further cost and time to the existing process of manufacturer validation and laboratory verification.

UK industry resoundingly rejected the original proposal, with ABHI's response to the consultation on an additional mandatory desktop validation of COVID-19 tests stating that the proposed legislation felt punitive and reactionary, whilst BIVDA argued that the proposed legislation was not consistent with existing regulatory arrangements. Our members' experiences of the new desktop review process have been poor, with many problems in making payments and navigating an overly complex process. The proposal for a laboratory review has confirmed our original opinion.

Nishan Sunthares, Managing Director, Diagnostics at ABHI said:

"In our view this proposal creates an additional regulatory hurdle with significant time, cost and administrative burden and sits outside the existing regulatory system. The proposal is not a suitable template for future regulation and is punitive and reactive. This proposal could act as disincentive for innovation, particularly by smaller companies."

Doris-Ann Williams, CEO at BIVDA said:

"Setting up a separate validation process sets both an unwarranted precedent for the industry and undermines the regulatory system. Our position is that changes to the existing regulatory regime could achieve what the validation policy is trying to do, more effectively and without creating a two-layer system – a view in which we are aligned with the ABHI."

Notes to Editors

The current regulatory framework for laboratory tests was first published in 1998 and formed the basis of the UK 2002 medical devices regulation. Test manufacturers are responsible for validating the performance of the test, laboratories are responsible for verifying that the test performs as expected, and MHRA is responsible for ensuring the system works.

MHRA is now consulting on a new regulatory framework that will reinforce their oversight of the system and build on the last two decades of experience. Industry is considering what will be the biggest changes to regulation in a generation. Laboratories can continue to verify performance of tests and MHRA can look to create a new regulatory framework fit for the UK.

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