ABHI POSITION ON DHSC OPEN CONSULTATION ON PRIVATE CORONAVIRUS (COVID-19) TESTING VALIDATION

Department of Health and Social Care Open Consultation. Private Coronavirus (COVID-19) Testing Validation: https://www.gov.uk/government/consultations/private-coronavirus-covid-19-testing-validation

ABHI acknowledges concerns over the existing validation process and the quality of some COVID-19 tests that are currently being supplied, and supports action to remove poor quality tests from the UK market. ABHI has been working on a new regulatory framework with MHRA and other stakeholders to ensure the UK has access to tests that meet minimum performance specifications and have good quality supporting evidence.

Our feedback on the proposal

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 feels punitive and reactive. It may be viewed as a disincentive for innovation, particularly by smaller companies.

The proposal does not address batch-to-batch variation or improvements in safety and performance. Nor does it include standards for design and manufacturing quality, or include any requirements for post-market surveillance in line with proposed new standards.

Rather than adding to existing regulations, it is possible to make some changes now. The existing regulations will then be further strengthened as part of the new UK sovereign regulatory framework.

We are confident that new arrangements will address many current concerns and provide a platform for any that arise in the future, but we do recognise that this will take time to implement, and a more timely solution is needed to support private and workplace COVID-19 testing.

Our recommendation

ABHI suggests that the existing regulatory framework can be made to resolve all of the concerns surrounding quality. COVID-19 tests without existing good quality supportive evidence can be added to the highest risk category for in vitro diagnostic medical devices within MDR 2002. This will ensure tests meet minimum performance specifications as set out by UK Government, with independent assessment by a UK Approved Body who will ensure test performance has been properly validated. Approved Bodies will also verify performance of every batch and every significant change. This system also assures the quality of design and manufacturing process. Test safety and performance to the agreed specification can be included in the existing vigilance and post-market surveillance system operated by MHRA. Our recommendation allows independent validation and batch verification to be carried out by approved UK laboratories with relevant expertise and experience on COVID-19 test validation.

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