ABHI POSITION PAPER: HIGH-RISK DIAGNOSTIC TESTS

High-risk diagnostic tests in the UK and EU (such as those used in organ transplants, national blood screening and future pandemics) must have a new regulatory certificate issued before an EU deadline of May 2025. Without a new certificate, tests may need to be removed from use on both the UK and EU markets. Without access to these tests there may be risks to blood supply, pandemic preparedness and patient safety. A recent European survey[1] showed that new certificates can take up to 18 months to be issued. However, with less than 18 months now remaining before the May 2025 deadline, the survey also showed that only 62 certificates from 231 applications had been issued for these tests. Although we cannot be sure how many certificates will be needed, it could be in the order of 1,500 (the number of certificates issued under an older EU framework).

Progress towards new registrations of high-risk diagnostic tests in the EU has been slow, and there is now a real risk that these tests will be permanently or temporarily removed from the UK and EU markets. There is also a further deadline approaching in May 2026 for certification of medium-risk diagnostics tests (such as those for cancer, genetic diseases and infections). EU progress to full certification here has also been slow and it is not yet clear whether all the diagnostic tests that are needed for UK citizens will remain available for use.

We cannot say with any certainty what the underlying causes are for the lack of new registrations, but the EU can consider further actions that are essential to protect blood supply, pandemic preparedness and patient safety. To fully address the potential causes of delay, the EU should now consider:

1. A further deadline extension to give the system more time, such as that suggested in the recent EU discussion on 30th November[2].
2. Regulatory reform in the EU recently proposed by MedTech Europe[3].

While the EU considers whether a further deadline extension will resolve the problem or simply delay its resolution, additional options for the UK could include:

1. Automatic recognition of diagnostic tests cleared in other jurisdictions (USA, Australia etc).
2. Exceptional authorisation of diagnostic tests that are essential for the nations' blood supply, pandemic preparedness and patient safety.

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[1] Notified Bodies Survey on certifications and applications (MDR/IVDR). Survey results with data status 30 June 2023 (medium and small dataset) 25 October 2023 (accessed 4th December).
[2] Employment, Social Policy, Health and Consumer Affairs Council (Health), 30 November 2023 AOB item. Implementation of the Medical Device Regulation (MDR) and the In Vitro Diagnostic Medical Device Regulation (IVDR) *(accessed 4th December)*.
[3] The Future of Europe's Medical Technology Regulations. *(accessed 6th December)*