Following a satisfactory review, MHRA extends authorisation of NHS Test and Trace lateral flow devices

Government response

Information for the public about lateral flow devices (LFDs) provided by NHS Test and Trace

The MHRA has extended the Exceptional Use Authorisation (EUA) for NHS Test and Trace lateral flow devices (LFDs) used as part of the Government's asymptomatic testing programme to 28 August 2021.

This follows a satisfactory outcome of the review undertaken as a result of recent action in USA. The US Food and Drug Administration (FDA) recently issued a warning about LFDs manufactured by Innova Medical Group Inc in the United States. Innova are the supplier of NHS Test and Trace LFDs, although the Department of Health and Social Care (DHSC) take on the responsibilities of the legal manufacturer for the products used in the UK.

Graeme Tunbridge, MHRA Director of Devices, said:

> Our priority is to ensure patients and the public have access to safe and effective medical devices and tests. Following our normal process to investigate any product concern, the MHRA immediately began reviewing all available information. A full risk assessment was undertaken by DHSC as legal manufacturer of the LFDs in the UK and the MHRA has undertaken a thorough review to ensure that we were satisfied with the assessment and any action proposed.
>
> We have now concluded our review of the risk assessment and are satisfied that no further action is necessary or advisable at this time. This has allowed us to extend the EUA to allow ongoing supply of these LFDs over the coming months. People can be assured of the

> MHRA’s work to continuously monitor the tests in use; as is our standard process.

These LFDs are authorised for use in detecting positive cases of COVID-19 in asymptomatic people. This means they can be used for one-off testing prior to an activity to reduce risks as well as for outbreak testing.

In exceptional circumstances the MHRA can issue EUAs allowing medical devices to be used that have not followed the standard approval process. The EUA process has been used during the pandemic to ensure that the health system has access to critical products. Once an EUA is issued following an assessment by the MHRA, the products given approval through this process are closely monitored by the MHRA.

Notes to editors

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