NHS Test and Trace

Incident and corrective and preventative action report
MHRA incident reference: 2021/006/011/601/004
[redacted]
June 2021

1 Background

On Thursday, June 10, the FDA released a safety notice which warned US citizens to stop using the Innova SARS-CoV-2 Antigen Rapid Qualitative Test (hereafter referred to as the "Innova LFD Antigen Test" for diagnostic use due to a range of "significant concerns" around the product. They also sent a warning letter to Innova which set out the findings the FDA obtained from an inspection of Innova's medical device operations hub in Pasadena, California. Between the date of the inspection (across the end of March and early April) and now, the FDA has not received an adequate response to the non-conformities raised. The non-conformities raised can be summarised as follows.

1. Firstly, the inspection revealed that Innova had been distributing the product in the US without approval from the FDA (thereby breaching US law).

2. Secondly, the labelling of the product for the Innova 25s included a clinical performance section which claimed a level of sensitivity and specificity that was not matched by the evidence that the FDA had seen at the time of the inspection.

3. Thirdly that there were significant failures in the quality management system in the US company.

A fourth item, outside of the FDA letter, has been added by DHSC as Innova did not make DHSC aware of the audit and findings

Innova in the US did not provide an adequate response to the FDA audit findings which led to the FDA issuing a safety notice and Innova in the US issuing a recall of the:

- Innova COVID-19 Self-Test Kit (3T Configuration)
- Innova SARS-CoV-2-Antigen Rapid Qualitative Test (7T Configuration)
- Innova SARS-CoV-2-Antigen Rapid Qualitative Test (25T Configuration)

DHSC are both the legal manufacturer of Innova 3's and 7's which is made available in the UK under the NHS test and Trace brand name and is also distributor of Innova 25s. DHSC is a service provider/ commissioner with a clinical governance structure and operates clinical testing services via NHS Test and Trace, which use both the DHSC-manufactured Self-Test and the Innova 25s.

Upon becoming aware of the FDA enforcement action, DHSC initiated a formal review (both in its role as manufacturer of the DHSC Self-Test, distributor of Innova 25s and its role as clinical service provider) to determine if the FDA's claims represent a risk to patient safety and public health in the UK market. DHSC notified the MHRA through the Manufacturer's On-line Reporting Environment (MORE) of a potential safety incident (reporting reference 2021/006/011/601/004)

2 DHSC Investigations

This report examines the FDA findings to determine whether they impacted on the use of the Innova tests in the UK and sets out our response against each of these claims

2.1 FDA Claim 1: Not authorised to be made available in the US

The FDA inspection revealed that the SARS-CoV-2 Antigen Rapid Qualitative Test had been distributed in the United States without marketing approval, clearance, or authorization from FDA

DHSC Response: Innova was initially lawfully introduced into the UK marketed as a general class CE marked IVD test for use by professionals. Subsequently the Department for Health and Social Care (DHSC) obtained an Exceptional Use Authorisation in December 2020 from the Medicines and Healthcare products Regulatory Agency (MHRA) for the use of Innova SARS-CoV-2-Antigen Tests in a self-test capacity for asymptomatic users.

DHSC became the legal manufacturer for packs of 3s and 7s and went through the correct regulatory procedures including usability testing, analytical performance testing at Porton Down and service evaluations to ensure the device performed as expected. No CAPA was raised for this claim as the CE marking of the professional use device and EUA for the self test devices is a statement of fact.

Conclusion: The Innova product met and obtained the regulatory approvals to be made available on the United Kingdom (UK)

2.2 FDA Claim 2: Performance claims not supported

The performance of the Innova SARS-CoV-2 Antigen Rapid Qualitative Test device (25T) as detailed in the IFU has not been adequately established, presenting a risk of false results. The FDA noted that to date that they have not received reports of injuries or death associated with use of the Innova SARS-CoV-2 Antigen Rapid Qualitative Test. The FDA where specifically concerned by;

- **False-negative results** which may lead to delayed diagnosis or inappropriate treatment of SARS-CoV-2
- **False-positive results** could lead to a delay in both the correct diagnosis and the initiation of an appropriate treatment for the actual cause of patient illness