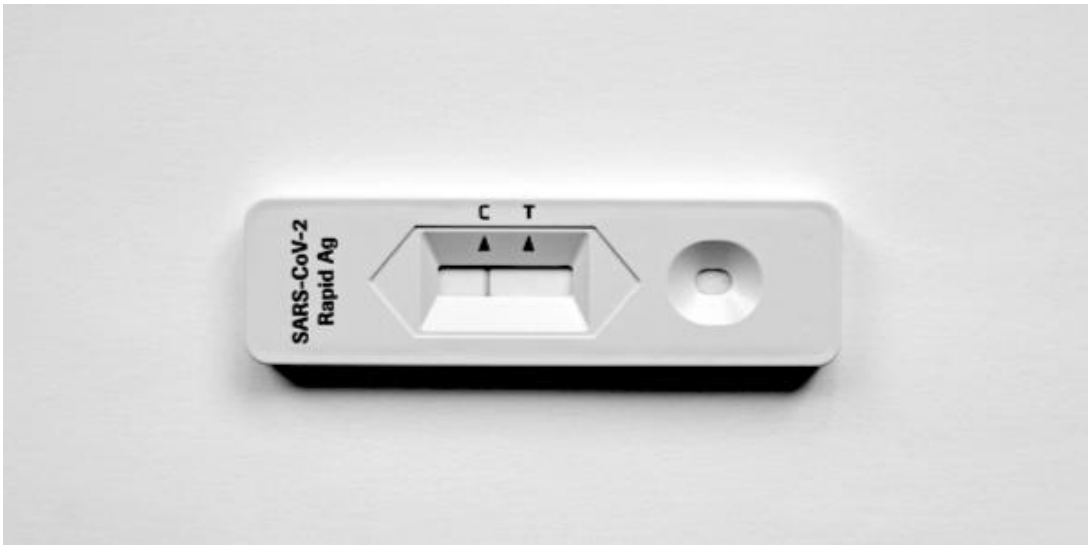
Innova's iniquity, Part 2: Protected by the UK regulator

By **Sonia Elijah** September 17, 2021



MY original investigative report on Innova Medical Group's Lateral Flow Test (LFT) last June was timely. The four parts were published in June, before and after the United States Food and Drug Administration (FDA) told the public to stop using the tests 'by placing them in the trash'. It was a dramatic announcement, not just highlighting serious concerns about the performance of the lateral flow test, but warning that it presented 'a risk to health'.

Shockingly, the UK government decided to take no notice. Instead they doubled down on their £4billion investment in the product.

In response to the FDA warning, the Medicines and Healthcare products Regulatory Agency (MHRA) released a statement which announced that 'following a satisfactory review', MHRA was extending authorisation of NHS Test and Trace lateral flow devices: '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'.

While Americans were busy throwing them in the trash, the UK extended the exceptional use authorisation (EUA) of the Innova LFT until August 28.

It is now well past that August 28deadline and there has been no further official extension of the EUA by the MHRA. Yet schools, colleges and universities are once again strongly encouraging students to use these unauthorised lateral flow tests. As well as risking health, the test will continue to inflate case numbers as a result of its proven unreliability and inaccuracy and will be a 'tool' in the Prime Minister's box of tricks to 'justify' yet another lockdown this autumn/winter.

The MHRA's intransigence is matched by its inattention to accuracy. Its classification of the *Department of Health and Social Care* (*DHSC*) as the 'legal manufacturer' of the Innova test in the UK is simply incorrect. Xiamen

Biotime Biotechnology in China is the manufacturer, with Innova Medical Group acting as exclusive global supplier.

But the MHRA and the Innova lateral flow test scandal does not end there. A reply to Freedom of Information requests made to the MHRA by a TCW reader, Duncan Carmichael, for the data and rationale behind their decision to extend LFT emergency authorisation reveals both a lack of transparency and discreditable abuses of loopholes. The email he received from the MHRA Customer Services which he gives us permission to publish is set out in full below and my critique follows.

Thank you for your information request, dated 2nd July. You requested:

- to be given "the data and rationale in this decision"

We have determined the decision to which you are referring is related to the extension of the Department of Health and Social Care/NHS Test and Trace exceptional use authorisation which was reported on gov.uk: Following a satisfactory review, MHRA extends authorisation of NHS Test and Trace lateral flow devices - GOV.UK (www.gov.uk)

We have also received a further information request dated 30th July in which you requested:

- I wish to know the basis of the extended authorisation of the Innova LFT antigen test.
- What led to the satisfactory review?
- What is the regulator doing?
- I am requesting the information which led to this outcome.

The Department of Health and Social Care (DHSC) / NHS Test and Trace have published data on 7th July 2021 on lateral flow test performance: https://www.gov.uk/government/publications/lateral-flow-device-performance-data . We recommend that you contact the legal manufacturer (DHSC) directly who may be able to offer you more information.

Unfortunately, the information requested with regards to be given the data presented to MHRA is exempt from release under Section 44:

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Section 44 – Prohibitions on disclosure: the release of information is exempt as its disclosure is prohibited by other legislation. In this case, section 237 of the Enterprise Act 2002 prohibits a public authority from releasing information which came to it in connection with the exercise of its functions,

and which relates to the affairs of an individual or business.

The MHRA is satisfied that the information you have requested:

- constitutes information which came to us in connection with the exercise of the Agency's functions. The MHRA has a duty of consumer protection under the Consumer Protection Act 1987 which is listed as a specified function under Schedule 14 of the Enterprise Act 2002, and receives information while exercising consumer protection functions in its role as the regulator of medicines and healthcare products.

- relates to the affairs of DHSC, a business which continues to exist.

On that basis we are satisfied that section 44 of FOI Act apply, and the information is exempt from release.

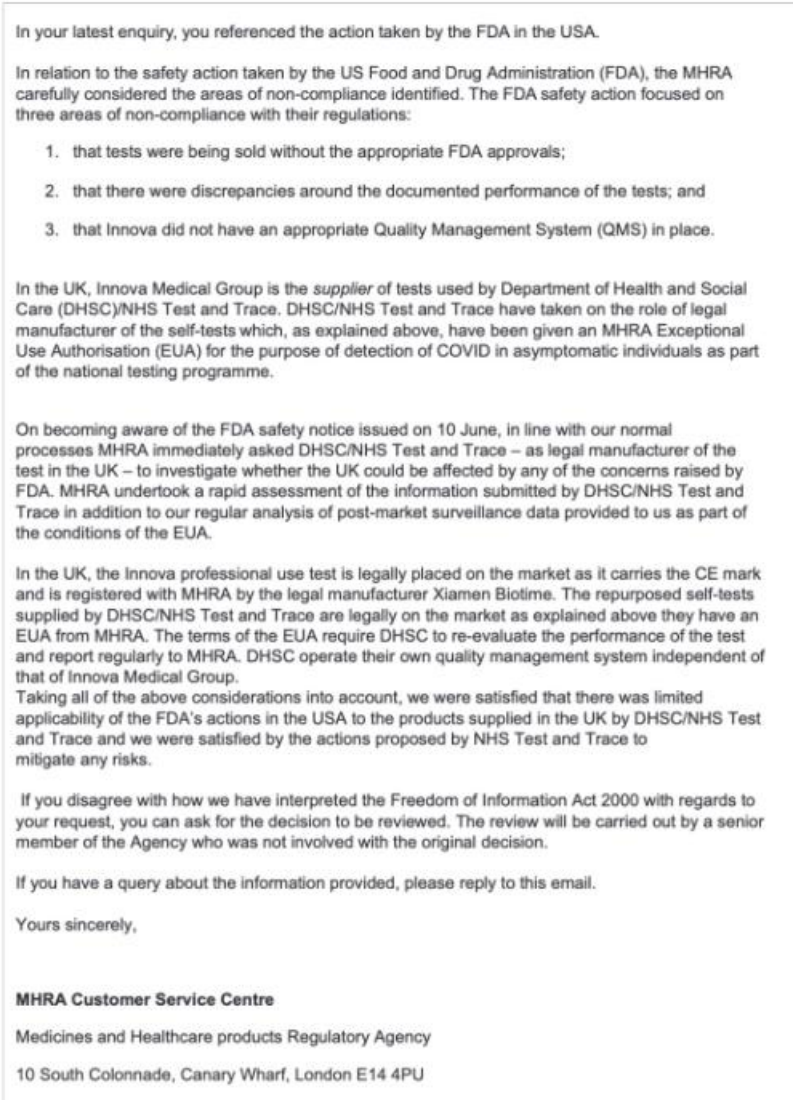
In December 2020, MHRA provided DHSC with an Exceptional Use Authorisation. Please see the list of medical devices given exceptional use authorisations here: https://www.gov.uk/government/publications/medical-devices-given-exceptional-use-authorisations-during-the-covid-19-pandemic/list-of-medical-devices-given-exceptional-use-authorisations

This permitted DHSC/NHS Test and Trace to deploy a repurposed professional use test (i.e. Innova COVID-19 lateral flow test kit) as a self-test throughout the UK as a test to detect infection in asymptomatic individuals. In exceptional circumstances the MHRA can issue Exceptional Use Authorisations (EUAs) allowing medical devices to be used that have not followed the standard regulatory 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 are closely monitored by the MHRA.

The EUA extension was granted subject to a number of conditions including a requirement to re-evaluate the performance of the test. You may request a copy of the Exceptional Use Authorisation conditions from the legal manufacturer (DHSC/NHS Test and Trace). The burden of proof is on the legal manufacturer to provide sufficiently robust data as to be able to demonstrate that their test performs as intended. Should there be an application for a further extension, we will follow our usual processes which involves requirements for further data, a robust internal review and input from external experts where required. As part of our safety and surveillance activities MHRA reviews a range of data sources to triangulate information sent to us by legal manufacturers.
Information on the EUA process can be found here: Exemptions from Devices regulations during the coronavirus (COVID-19) outbreak - GOV.UK (www.gov.uk)

Based upon the evidence we have reviewed to date we believe that there is a satisfactory likelihood that when used in combination with other measures the DHSC rapid lateral flow self-tests have the potential to moderately reduce the number of infected individuals entering events or conducting activities through the identification of some positive cases. However, this is heavily reliant on the compliance and behaviour of participants and evidence of impact is yet to be demonstrated. We will continue to press DHSC/NHS Test and Trace to generate and demonstrate this evidence and to make it publicly available.

It is the role of DHSC and NHS Test and Trace to determine how the tests are deployed in the UK and to ensure that they are fit for purpose.



In your latest enquiry, you referenced the action taken by the FDA in the USA.

In relation to the safety action taken by the US Food and Drug Administration (FDA), the MHRA carefully considered the areas of non-compliance identified. The FDA safety action focused on three areas of non-compliance with their regulations:

1. that tests were being sold without the appropriate FDA approvals;
2. that there were discrepancies around the documented performance of the tests; and
3. that Innova did not have an appropriate Quality Management System (QMS) in place.

In the UK, Innova Medical Group is the *supplier* of tests used by Department of Health and Social Care (DHSC)/NHS Test and Trace. DHSC/NHS Test and Trace have taken on the role of legal manufacturer of the self-tests which, as explained above, have been given an MHRA Exceptional Use Authorisation (EUA) for the purpose of detection of COVID in asymptomatic individuals as part of the national testing programme.

On becoming aware of the FDA safety notice issued on 10 June, in line with our normal processes MHRA immediately asked DHSC/NHS Test and Trace – as legal manufacturer of the test in the UK – to investigate whether the UK could be affected by any of the concerns raised by FDA. MHRA undertook a rapid assessment of the information submitted by DHSC/NHS Test and Trace in addition to our regular analysis of post-market surveillance data provided to us as part of the conditions of the EUA.

In the UK, the Innova professional use test is legally placed on the market as it carries the CE mark and is registered with MHRA by the legal manufacturer Xiamen Biotime. The repurposed self-tests supplied by DHSC/NHS Test and Trace are legally on the market as explained above they have an EUA from MHRA. The terms of the EUA require DHSC to re-evaluate the performance of the test and report regularly to MHRA. DHSC operate their own quality management system independent of that of Innova Medical Group.
Taking all of the above considerations into account, we were satisfied that there was limited applicability of the FDA's actions in the USA to the products supplied in the UK by DHSC/NHS Test and Trace and we were satisfied by the actions proposed by NHS Test and Trace to mitigate any risks.

If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review will be carried out by a senior member of the Agency who was not involved with the original decision.

If you have a query about the information provided, please reply to this email.

Yours sincerely,

MHRA Customer Service Centre

Medicines and Healthcare products Regulatory Agency

10 South Colonnade, Canary Wharf, London E14 4PU

The MHRA response raises many questions. Firstly, it identifies the DHSC, a ministerial department of the government funded by the UK taxpayer, as a private business. The irony is that a credible argument can be made that the DHSC, headed by Matthew Hancock at that time, behaved as if it was a private business in which 'friends and family' were rewarded handsomely, the scandalous 'VIP lane' for lucrative PPE contracts being a prime example of this.

But classifying the DHSC as the 'legal manufacturer' of the Innova LFT and by doing so, a business, the MHRA egregiously abuses the loophole of section 44 under the Freedom of Information Act making it exempt from releasing the information requested under the Act. The fact that 'other legislation' exists prohibits their disclosure of it. In this case, it is section 237 of the Enterprise Act 2002 which 'prevents the disclosure of "specified information" that relates to the affairs of an individual or business which a public authority has obtained in connection with the performance of certain functions'.

In this extraordinary case, the MHRA is stating that it is exercising its 'consumer protection' function in its role as a regulator of medicines and healthcare products, included as a specified function under schedule 14 of the Enterprise Act 2002. In short, the MHRA, a regulatory agency which is supposed to protect the interests of the public, is instead protecting the DHSC, which it has remarkably classified as a business shielded by the Consumer Protection Act.

The MHRA email written by the customer service department, conveniently copies and pastes the paragraph below, the same paragraph used in its earlier response to the FDA warning, published on the Government's website in June.

'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.'

Again, the mention of not following 'the standard approval process' is made alarmingly clear. How is this admission from the MHRA supposed to garner public confidence in the Innova LFT? It simply fails to.

The MHRA states that 'the burden of proof is on the legal manufacturer [in this case DHSC not Innova/Xiamen Biotime Technology] to provide sufficiently robust data as to be able to demonstrate that their test performs as intended.'

This provides a convenient way for the MHRA to shirk responsibility and transfer it to the DHSC. How can the public trust the data coming out of the DHSC will be 'sufficiently robust' when it's doing its own self-evaluation, having procured close to £4billion worth of these tests?

To exacerbate the matter, the MHRA states the legal manufacturer of the Innova professional use test is Xiamen Biotime but the DHSC is the legal manufacturer of the 'repurposed self-tests'. It is questionable why the MHRA have chosen to separate the test into two versions with two different 'legal manufacturers' when it is the same test made by the same manufacturer, Xiamen Biotime, in China.

If there's any credibility left in the MHRA, it vanishes under their rubber stamp approval of the evidence supplied by the DHSC, where they conclude 'there is a satisfactory likelihood that when used in combination with other measures the DHSC rapid lateral flow self-tests have the potential to moderately reduce the number of infected individuals.' In other words, they're satisfied with just how inferior these tests are, enough to extend their EUA of it.

Whilst the MHRA believes it is 'the role of the DHSC and NHS Test and Trace to determine how the tests are deployed in the UK and to ensure they are fit for purpose', there are experts, such as Jon Deeks, professor of Biostatistics from Birmingham University, who has concluded they are certainly 'not fit for purpose' and has heavily questioned how they've been deployed, as self-testing kits for anyone above the age of 12 without symptoms.

In January 2021, he wrote in the *BMJ*: 'In the face of so much potential for harm and so little evidence of benefit, why is the government pushing the rollout? It seems at least plausible that this is because hundreds of millions of Innova testing kits were purchased before it was known how they would perform in people without symptoms and when administered by less than expert hands.' There is ample evidence in my investigative reports on Innova to support his statement.

Following the FDA's warning, Deeks said: 'There have been many problems with transparency in the evidence to support the government's policies for use of this lateral flow test, which negatively impacts on uptake. Given the more serious concerns identified by the FDA, it is essential that full explanations and

data are provided to explain decisions made about its continued use, if that is the decision made.'

In short, this government and its agencies have failed to be transparent by not providing the data/evidence to support the argument for the exorbitant cost of the DHSC/NHS Test and Trace scheme or even to show that it has been an effective endeavour. They have also failed to show any substantial evidence to support their decision to extend the EUA of the Innova LFT. The MHRA's email to Mr Carmichael and their statement published on the government's website exemplifies this.

In Part 3 of my follow-up report, I shine light on the overreaching tentacles of Innova Medical Group.