Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]
Department of Health and Social Care (DHSC)
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MHRA
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28th May 2021

Our Ref: DEU/012/2020/003

Dear [redacted]

MEDICAL DEVICES REGULATIONS 2002 / MEDICAL DEVICE REGULATIONS (EU) 2017/745
AUTHORISATION OF SPECIAL USE OF DHSC COVID-19 Self-Test Kit

I refer to your letter dated 30/04/2021 in which you requested an extension to the special authorisation for the above non-UKCA/CE marked medical devices, which was originally granted on the 22nd December 2021.The reasons for the extension cited:

"We believe it remains in the interests of the protection of public health to extend the grant of this authorisation and will ensure security of supply to meet the ongoing clinical need caused by the COVID-19 pandemic. […] The objective of the DHSC testing strategy remains the detection and quarantine of cases with transmissible virus infection to reduce R and control the pandemic and protect the vulnerable, allowing return to work and restoring the economy and society to near normal. This requires a test to identify people with transmissible virus for quarantine and, thereby, interrupt viral transmission. This objective requires the continued distribution of lateral flow devices which is currently the only simple, self-test approach that will deliver at scale and pace and at a low unit cost. Reflecting on our use cases we intend to streamline these and will provide a further update over the next several weeks."

Based on this confirmation, the Secretary of State acting as the MHRA is satisfied that the request is duly justified, and that it is in the interests of the protection of public health to authorise the supply of the device to Great Britain under regulation 39(2) IVD of the Medical Devices Regulations 2002 and Northern Ireland under Article 59(1) of the Medical Device Regulations (EU) 2017/745, subject to the conditions set out below:

This authorisation commences on 28/05/2021 and ends on whichever of the following dates occurs soonest:

a. 28/08/2021;

b. the date when the device is UKCA/CE marked; or

c. the date when sufficient quantities of UKCA/CE marked alternative product is available on the market.

If this authorisation ends on 28/08/2021, and there continues to be a need for a further authorisation, the position will be reviewed by the MHRA and a decision taken on whether it remains in the interests of the protection of health for a further authorisation or an amendment to this authorisation to be made.

2. That DHSC will satisfactorily address all non-conformities raised as a result of MHRA's audit of 25th - 26 h May 2021. This includes the provision of evidence of all the corrective and preventive actions as well as associated actions taken following receipt of MHRA's post audit documentation dated 27 h May 2021.

3. That DHSC satisfactorily address the recommendations raised as a result of MHRA's audit of 25th - 26th May 2021 as detailed in the post audit documentation dated 27th May 2021.

4. That this authorisation is solely for the use for repeat testing to detect positive cases amongst asymptomatic people, one-off testing prior to an activity to reduce risks, outbreak testing and asymptomatic testing. Daily testing of contacts is not covered by this authorisation.

5. This authorisation is solely for the use of the repurposed Innova tests as reviewed by MHRA. DHSC must inform MHRA prior changing any of the components of the devices.

6. That the devices are fit for the purpose intended, will work as intended in line with stated performance and have been assessed as such.

7. That the plan for distribution and roll-out continues to be shared with MHRA on a monthly basis, clearly highlighting any amendments since the last update.

8. That MHRA are consulted before any modifications are made to the Instructions for Use, ensuring DHSC await MHRA's feedback before the proposed changes to the Instructions for Use are implemented and released.

9. That the recipients of the devices in question are supplied with the necessary instructions for use.

10. That you implement a robust Quality Management System ensuring full control in the adopted system.

11. That you implement a robust Risk Management System appropriate for the self-test kit under this authorisation.

12. That you agree to the details of the authorisation being listed on MHRA's website to confirm the manufacturer & products authorised under this exemption including the issue date and duration.

13. That you submit to the MHRA a detailed time plan for UKCA/CE marking of the device (progress with PCBC should be submitted as part of the routine reports as documented below).

14. That once every three weeks you submit to the MHRA a report detailing, a summary of adverse incidents whilst under this authorisation, the number of devices supplied and to whom; the manufacturer must keep track of every device down to the end user through their distribution network. This must be included in the report to MHRA.

15. That at the end of the above period or when UKCA/CE marked alternative supplies of the device become available DHSC will cease the supply of any devices under the authority of this authorisation.

16. That supply of the devices is only permitted by the Department of Health and Social Care as part of their planned deployment of COVID-19 tests in the UK.

17. That DHSC continue to conduct suitable verification prior to deployment of the tests. This should include regular use of controls including a blinded sample panel for the verification of product prior to product release.

18. That you fulfil MHRA requirements to conduct fortnightly monitoring for variants against the available information on GISAID and that both favourable and unfavourable data should be reported to the MHRA as assurance of either positive or negative performance. This is in line with MHRA expectations that manufacturers should submit a monthly update (on the second week of each month) for *in silico* assurance of assay performance. MHRA regards variants as a serious public health threat and any potential concerns should be reported to MHRA within 48 hours.

19. That you have in place mechanisms for monitoring the performance of the devices supplied under these conditions, including Post Market Performance Follow-up studies.

20. That you submit the outcome of the ongoing Post Market Performance Follow-up studies to collect further evidence of clinical and analytical performance of the device.

21. That you continue to develop a Post Market Surveillance plan and a robust Quality Management System to collect and evaluate any complaint received in relation to compromised safety, quality or performance of the device and undertake the necessary corrective and preventive actions such initiating and undertaking recall of products if a safety action is identified.

22. That within three weeks, you submit an updated Post Market Surveillance plan for monthly reports to MHRA to include the following:

- **a.** Results and conclusions of the analyses of the post market surveillance data gathered as a result of the post market surveillance plan (e.g. report of ALL complaints plus report of those considered to be reportable as vigilance);
- **b.** A rationale and description of any preventive and corrective actions taken;
- **c.** The conclusions of the benefit-risk determination;
- **d.** The main findings of the post market performance study;
- **e.** The volume of the devices and an estimate of the size and other characteristics of the population using the device and the usage frequency of the device;
- **f.** A report from EQA/PT scheme, when available, for the kit's performance overall.

23. That DHSC as a legal manufacturer consider issuing Field Safety Corrective Action when the need arises.

24. That DHSC continue to gather evidence through a Proactive Post Market Surveillance plan to survey user experience to monitor events such as:

- **a.** Material break (if something breaks during use);
- **b.** Detachment of device component (for example, if the swab head of the swab falls off);
- **c.** Component missing (if something in the kit is missing);
- **d.** Packaging problem;
- **e.** Unable to obtain readings (e.g. failure of control line or if the user is unsure of the result);
- **f.** Failure to obtain sample;
- **g.** Inadequate instructions;
- **h.** Device handling problem, i.e. the opening and emptying of the of the buffer solution container;
- **i.** Negative clinical effect associated to the test, e.g. cuts, nose bleeds etc;
- **j.** Including Details of the test kit (e.g. brand name/model, Lot/batch, barcode number) to help with traceability when investigating incidents.

25. That, in addition to the summative reporting detailed in Condition 14, you agree to provide full details of any serious adverse incidents that occur in relation to the device or the use of the device in addition to the normal procedures (as detailed in the vigilance reporting guidelines) for reporting such incidents to the MHRA.

26. That DHSC agrees to provide details to the users that any adverse incidents that occur in relation to the device or the use of the device are reported via the Yellow Card Scheme in addition to meeting your obligations for reporting as legal manufacturer (see Condition 23).

27. That DHSC understand that failure to adhere to any of the conditions stipulated will result in this authorisation being removed.

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Please take this letter as formal approval. Please contact Devices.ExceptionalUse@mhra.gov.uk if you require any clarification in relation to this process.

Yours sincerely

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