Department of Health & Social Care

Freedom of Information Team
Department of Health and Social Care
39 Victoria Street
London SW1H 0EU

www.gov.uk/dhsc

Mr Wynne Jones
By email to: cj-editor@biggeesblog.cymru

23rd December 2021

Dear Mr Jones,

Freedom of Information Request Reference FOI-1376108

Thank you for your request dated 28th November, in which you asked the Department of Health and Social Care (DHSC):

"I refer to the Regulatory Impact Assessment [RIA] undertaken to support the "Medical Devices [Coronavirus Test Device Approvals] [Amendment] Regulations 2021". A copy is attached hereto. I note from paragraph 78 - highlighted for your convenience - that new strains [variants] of SARS-CoV-2 virus will require new test kits to be developed by the private sector and re-validated to ensure public confidence in the quality of the testing process. As the validation process is under the control of the Department for Health and Social Care [DHSC] I would be grateful if you could arrange to provide me with the following information.

I would be pleased to receive a copy of the guidance issued by DHSC to test kit manufacturers regarding the re-validation process when new SARS-CoV-2 variants - for example " Delta variant" and "Omicron variant" - are detected in the UK."

Your request has been handled under the Freedom of Information Act 2000 (FOIA).

DHSC holds the information you have requested.

When new SARS-CoV-2 variants are detected in the UK, this is managed by a pathway which is highlighted here: SARS-CoV-2 variant of concern diagnostic assurance - GOV.UK (www.gov.uk). This explains the process for variants of concern (VOCs) and variants under investigation (VUIs) which are being monitored and tracked by the Variants of Concern Assurance Group, including SARS-CoV-2 variants.

Members of the group include expert scientists and clinicians from all 4 UK administrations and representatives from the Medicines and Healthcare products Regulatory Agency (MHRA). MHRA regularly engages with suppliers and manufacturers of test products in the UK to review their post-market assurance processes for the most recently published VOCs and VUIs in circulation in the UK.

When a test product is impacted by a VOC or VUI, MHRA works with manufacturers to take mitigative actions and inform testing service providers.

If you are not satisfied with the handling of your request, you have the right to appeal by asking for an internal review. This should be sent to freedomofinformation@dhsc.gov.uk or

to the address at the top of this letter and be submitted within two months of the date of this letter.

Please remember to quote the reference number above in any future communication.

If you are not content with the outcome of your internal review, you may complain directly to the Information Commissioner's Office (ICO). Generally, the ICO cannot make a decision unless you have already appealed our original response and received our internal review decision. You should raise your concerns with the ICO within three months of your last meaningful contact with us.

The ICO can be contacted at:

The Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow SK9 5AF

Website: https://ico.org.uk/concerns

Yours sincerely,

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