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### **Open Correspondence**

30<sup>th</sup> June 2021

Mr G. Kinrade – Chief Executive Officer  
Department of Education, Sport & Culture  
Corporate Services Division  
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By Post & By Email: [graham.kinrade@gov.im](mailto:graham.kinrade@gov.im)

Dear Mr Kinrade

#### **RE: Lateral Flow Testing of Isle of Man Secondary School Children**

We have recently been contacted by a number of parents seriously concerned about the introduction of lateral flow testing for Covid-19 in Manx Secondary Schools as from Monday 21<sup>st</sup> June 2021.

As you are aware, the lateral flow test is self-administered at home by children using a swab in the nostrils and/or on the tonsils, with test results available within 30 minutes.

If the lateral flow test is negative, the child can obviously continue to attend school.

If the lateral flow test is positive, we understand that the child should isolate and book a confirmation follow-up PCR test (with the child's household also having to isolate pending the child's PCR results).

If the child's PCR test is negative that will override the lateral flow test and the pupil can return to school.

However, if the PCR test is positive the child must self-isolate for a period of days as directed by the 111 team (together with any unvaccinated members of his or her household).

We are aware that such lateral flow testing will be on a voluntary basis for those children invited to be tested and also require parental consent.

However, we have received a number of respectful queries regarding the specific issues as set out below.

## **Role**

In the United Kingdom, lateral flow tests manufactured by the US Company Innova, have formed the cornerstone for what has been referred to by the UK Prime Minister Boris Johnson as "*Operation Moonshot*", with hundreds of millions of test kits offered to adults and school children at a cost of over £2 billion to date.

In fact, on 25<sup>th</sup> June 2021, the National Audit Office announced that 691 million lateral flow tests were sent out between October 2020 and May 2021, although only 14% had subsequently been registered with NHS Test and Trace, suggesting an astonishing 600 million lateral flow tests may have gone unused.

We understand that the reasoning (whether correct or a fallacy) behind the lateral flow testing of secondary school pupils on the Island is that of providing a rapid way of finding Covid-19 cases in young people who may not have any symptoms but may still be infectious and pass the virus on to adults. In other words, children are being subjected to testing not for their own benefit but for the supposed benefit of elderly and vulnerable people.

However, one proper concern which has been expressed to us is in relation to the accuracy of such lateral flow tests.

## **False Positives**

Research carried out by Public Health England for the period 8<sup>th</sup> March 2021 to 4<sup>th</sup> April 2021 showed that from 26,144,449 lateral flow results, 39,904 positive cases were identified.

However, follow up PCR tests revealed that an alarming 18% came back negative, meaning that thousands of individuals and their households had been self-isolating for no reason. This obviously caused needless inconvenience, stress and upset to many households, often deprived of any financial support during the period of self-isolation.

## **False Negatives**

Research was carried out by scientists at the University of Liverpool in relation to the Liverpool Covid-19 Community Testing Pilot. This was a pilot mass Covid testing scheme in Liverpool City which commenced on 6<sup>th</sup> November 2020.

The British Medical Journal reported on 15<sup>th</sup> December 2020 that the lateral flow test was only 49% effective at picking up infections in asymptomatic people in the Liverpool pilot scheme. This meant that 51% of positive Covid cases were missed by the lateral flow test.

Jon Deeks, Professor of Biostatistics at the University of Birmingham, commenting on the Liverpool research and also a small University of Birmingham study, stated, *"Clearly, there is a risk of giving false reassurance to people who get a negative result (from a lateral flow test). You also have to question whether mass screening using a test that performs so poorly is the best use of our limited resources"*.

Professor Deeks continued by stating, *"I personally find it quite shocking that the government thinks this is an adequate evidence base on which to base such a large, expensive, and quite invasive policy"*.

It is also worth adding that a University of Oxford assessment last November found that the sensitivity of the lateral flow test dropped by 21% when used by untrained members of the public as opposed to trained laboratory scientists.

## **Director of Public Health**

We refer to previous Open correspondence we have had with Dr H. Ewart, Director of Public Health on the Isle of Man, in which she rejected the idea of mass testing of asymptomatic individuals on the Island by stating on 16<sup>th</sup> April 2021, *"The evidence from LFD use in Liverpool is not robust and is insufficient to guide policy in the very different context here. As above, further evidence is awaited. The possible utility of mass testing is highly dependent on background rates of infection. In a context of no or very low community transmission the pre-test probability that anyone screened for Covid-19 actually will have it is extremely low. This means that false positives become a significant problem and the disbenefits of managing these are likely to outweigh any benefits"*.

We are obviously aware that the Manx Government has stated that the Island has recently moved from the elimination phase of Covid to the mitigation stage in relation to living with Covid for the foreseeable future.

- Q.1 However, given such clear clinical opinion, why does the Department of Education now intend to progress a policy which appears contrary to such recent scientific advice from Dr Ewart?
- Q.2 In view of the evident potential for a significant proportion of false positives and false negatives as referred to above, this is a far from satisfactory situation. On one side of the coin, false positives will result in unnecessary stop-start disruption to the child's schooling and parents' employment during the period of isolation. Whilst on the other side of the coin, false negatives may result in schoolchildren unwittingly spreading the virus.

In such circumstances, would you agree that the mass lateral flow testing of all secondary school children on the Isle of Man is potentially damaging and counterproductive?

## **Manufacturer**

We are aware that there are several different lateral flow devices in use around the world, made by various manufacturers.

One of the most popular lateral flow kits is the device manufactured by **Innova** in California, United States. However, on 10<sup>th</sup> June 2021 the US Food and Drug Agency (FDA) raised significant concerns about the Innova device, stating in a blunt letter to the manufacturer, *"The data, reliability and accuracy problems noted herein raise significant concerns that the performance of the SARS-Cov-2 antigen rapid qualitative test has not been adequately established, and that the products distributed by Innova without FDA approval, clearance, or authorisation could present a serious risk to the public health"*.

Remarkably, the agency warned the US public to immediately stop using the Innova lateral flow test and suggested that the kits should be binned or returned to the manufacturer.

Clearly, this is extremely significant because not only was the Innova lateral flow test used in the Liverpool community testing pilot scheme but in fact remains the lynchpin of the UK mass testing regime.

In light of the FDA's stark warning, the UK Medicines & Healthcare Products Regulatory Agency (MHRA) issued an urgent response stating *"The MHRA are reviewing all available information and are working closely with NHS Test and Trace to ensure that a full risk assessment is undertaken, as is our normal process, to understand any implications for*

*products being used in the UK. Patient safety is our main priority and we will issue safety information as and when necessary”.*

Q.3 Were you aware of the FDA’s dramatic intervention on 10<sup>th</sup> June 2021 to in effect ban the use of the Innova lateral flow test in the US?

Q.4 Is the lateral flow test which is used on Isle of Man secondary school pupils in fact the Innova test device?

Q.5 We are aware that the UK’s Government’s first contract with Innova was agreed on 17<sup>th</sup> September 2020, before evaluation of the tests had been completed. In such circumstances, the MHRA issued a special authorisation for the Innova test and such authorisation was due for review on 22<sup>nd</sup> June 2021.

Are you are aware as to the outcome of such official review of the Innova test by the MHRA?

Q.6 We note that the lateral flow device manufactured by Innova is in fact repackaged for deployment in the NHS but nevertheless is essentially the same device as used in the United States. Will there be any repackaging of the Innova test device if such test kit is used in the Isle of Man?

Q.7 If such lateral flow test device as manufactured by Innova is to be used in Isle of Man schools, what is the sensible justification for this in light of the FDA’s drastic decision to ban such test device in the US?

Q.8 If the Innova lateral flow test instrument is not to be used on the Island, please can you confirm which specific manufacturer brand is to be used in Manx schools and how this differs from the Innova device?

## **Mental Health of Students**

Q.9 Some parents have expressed understandable concern to us that their teenagers will be at risk of psychological harm through participating in a long-term Covid testing programme.

Firstly, this is on the basis that by frequent testing, children may worry that they are at risk of personal harm themselves from the virus. Clearly, this would be ill founded given that Government scientific advice is that the risk of physical harm to schoolchildren from Covid-19 is miniscule.

Secondly, some pupils may be anxious that by testing they run the continual risk of testing positive and thereby will have to stay away from school (as has recently

happened with a student at St. Ninian's High School, Douglas on Monday 28<sup>th</sup> June 2021).

Moreover, there is genuine concern that children could become overly fearful with the constant reminders that they may be guilty or culpable transmitters of a serious disease to the elderly. Such apprehension would seem to be entirely unwarranted given the rather important fact that the vast majority of vulnerable groups in the community have already been fully vaccinated for Covid-19.

One parent has reasonably remarked that a teenager's life is stressful enough without the added burden and anxiety of twice weekly Covid testing. Do you accept any of these concerns?

### **Cost**

We are aware that lateral flow device kits cost in the range £5.00 to £15.00 each.

Q.10 Although the lateral flow test kits will be issued free of charge to parents of secondary school children on the Isle of Man, how much will each test kit cost the Isle of Man Government to purchase at wholesale prices?

Q.11 We understand that there are at least 5000 secondary school pupils on the Island. Please can you confirm the exact current head count of pupils across the Island's five secondary schools?

Q.12 How many test kits are expected to be distributed each week?

Q.13 If every secondary school child aged 11 -18 were to test twice a week (as intended by the Government), this would suggest a cost of a minimum of £50,000.00 per week or £2.5 million for the next calendar year (conservatively based on the lowest price of £5.00 per test x 5000 pupils = £25,000.00 x twice weekly).

Do you consider that this eye-watering expenditure on such a patently dubious scheme is appropriate and proportionate or would such monies be much better spent on different educational priorities such as a proper pay rise for teachers or funding The Family Library on Westmoreland Road, Douglas and the Mobile Library both of which are currently under serious threat of closure due to the withdrawal of government grant assistance?

Q.14 In light of all the considerations raised above, including the critical issue of false positives and false negatives, do you not regard the rollout of mass testing of asymptomatic secondary school pupils on the Isle of Man as a scandalous waste of Manx taxpayers' money?

## School Policy

- Q.15 Will all teachers in secondary schools on the Isle of Man be encouraged to participate in the lateral flow testing programme?
- Q.16 Will teaching assistants and school auxiliary staff (such as catering and cleaning personnel) be similarly encouraged to participate in the programme?
- Q.17 Are all secondary school years 7 to 13 (i.e. ages 12–18) to be included in the programme or only certain selected years?
- Q.18 Will vaccinated persons (whether teachers or pupils) still be encouraged to participate in the lateral flow testing programme?
- Q.19 We are aware of an alarming separation policy apparently introduced at Hornchurch High School in Greater London during March 2021.

The Romford Recorder newspaper dated 8<sup>th</sup> March 2021 reported that the Head Teacher of such school, Ms Val Masson told a Year 9 female pupil (14 year old) whose parents did not consent to the school's Covid-19 rapid testing, that she would be prevented from joining her usual classes, meaning that the girl would instead be taught in a "*separate bubble*" on school premises. Accordingly, will there be any repercussions (including segregation or suspension) for Manx pupils refusing to participate in the testing programme?

- Q.20 Will parental consent be required from both parents?
- Q.21 Will the lateral flow testing of schoolchildren continue throughout any/all school holidays?

## Test Results

- Q.22 Will the Isle of Man Government publish statistics on a weekly basis in relation to the following:-
- i) The total number of lateral flow tests undertaken in Isle of Man secondary schools?
  - ii) The number of positive results from such lateral flow tests?
  - iii) The number of persons (pupils and their households) having to self-isolate after such pupils' positive lateral flow test?
  - iv) The percentage of subsequent PCR tests revealing false positives i.e. the false positive rate?

- v) The number of secondary school teachers participating in the lateral flow testing programme?
- vi) The accumulating total financial cost of the lateral flow test kits?

Please may we receive a substantive response from you in relation to the above matters no later than Friday 9<sup>th</sup> July 2021.

Thank you for your assistance.

Yours sincerely

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