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Open Correspondence

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By Post & By Email: publichealth@gov.im

Dear Dr Ewart

RE: Covid-19 – Testing and Vaccine Issues

We have recently been contacted by a number of persons in respect of the current Covid-19 testing regime and also in relation to the Covid vaccines presently being used on the Isle of Man.

The persons who have contacted us are a mixture of ages and some have children. We make the point at the outset that these persons have been vaccinated themselves for the usual childhood illnesses such as tetanus, polio and mumps. The matters raised below do not therefore relate to vaccination in principle but are focused on safety concerns and issues specific to Covid-19.

We have also considered the Isle of Man Government's Coronavirus podcast on vaccines which was aired on Saturday 20th March 2021, which was very helpful. However, those persons who have been in touch with us have carried out their own research and have a number of outstanding queries which they respectfully seek your expert opinion on.

Clearly, the present context of concern is the recent suspension of the use of the AstraZeneca vaccine in a number of European countries such as Germany, Italy, Spain and France. Although this proved to be only a temporary measure for some countries, other nations such as Finland have maintained the suspension pending the outcome of further investigations. In addition, France is currently recommending that the AstraZeneca vaccine should not be given to those under 55 years old.

A. Covid-19 Testing

Lateral Flow Test

We are aware that you have consistently resisted calls for random mass testing for Covid on the Isle of Man and have referred for example to the trial in Liverpool last autumn. Lateral flow testing produced on the spot results from swabs/saliva samples but in that pilot programme over 30% of Covid positive cases were missed by the lateral flow testing used.

This raises a number of queries as follows:-

1. Are there any plans to use the same lateral flow test on the Isle of Man, for example in schools this autumn after the adult population on the Island has first been vaccinated?
2. If the lateral flow test was deemed inaccurate in the Liverpool programme, why in your clinical opinion would such test be considered appropriate for use on the Isle of Man?

PCR Test

As you will be aware, on Monday 8th March 2021, most secondary schools in England re-opened and pupils returned to classes. All pupils were eligible for testing with the lateral flow device twice in the first week and once in the second week, with all three tests being conducted in the school under supervision. After that, lateral flow device kits are to be given to pupils to take home.

If the lateral flow test reveals a positive result and was taken under supervision at school there is apparently no need for further testing. The pupil and his or her whole family will need to self-isolate. However, if the test was taken *at home* and returns a positive result, the pupil should take another test namely the PCR test. In the event that the PCR test is negative, this overrides the lateral flow test and the pupil can return to school.

In such context a number of technical queries have been raised as follows (continuing with our sequential question numbers):-

3. Are you aware that the inventor of the PCR Test, Dr Kary Mullis, who was awarded the Nobel prize for chemistry in 1993 for such discovery, regarded such test as wholly unsuitable for detecting a viral infection (such as is Covid-19)?
4. Are you also aware that this point was recently highlighted in the significant Lisbon Court of Appeal case number 1783/20, citing Jaafar et al 28 September 2020, where it was held that a German national ordered to quarantine on the

Portuguese Azores Islands after testing positive with the PCR test, had been unlawfully ordered to self-isolate, with the Court holding that, "*Given how much scientific doubt exists about the reliability of the PCR tests ... there is no way this Court would ever be able to determine whether C was indeed a carrier of the SARS-Cov-2 virus*"?

5. Moreover, Dr Anthony Fauci, the US President's Chief Medical Advisor, stated on 16th July 2020 on the TV programme "*This week in virology*", that the PCR Test was inaccurate over 35 cycles. He said that, "*The chances of it being replication competent (over 35 cycles) are miniscule*". As you will be aware, the greater the number of cycles, the bigger the net is cast and therefore the greater the chance of false positives.

Notwithstanding this, we understand from a recent Freedom of Information request that the Isle of Man Public Health Directorate is currently carrying out PCR Tests on the basis of 45 cycles, with a threshold of 40 for a positive result. The obvious concern is that the use of such questionable PCR testing regime may result in a substantial number of *false* positives which will or has already caused needless consequential self-isolation, disruption to schooling and closures of businesses.

In light of Dr Fauci's comments, why is the Isle of Man Public Health Directorate still carrying out PCR tests on the basis of 45 cycles?

6. Do you agree that the Covid-19 virus has not yet been scientifically isolated i.e. is not a virus isolate, and therefore this renders testing for Covid-19 with the PCR test somewhat problematic?
7. In turn, can the PCR test truly be regarded as the "Gold Standard" for Covid testing or simply the least inaccurate?
8. Does the government propose to adopt a similar policy in Isle of Man secondary schools as that in England i.e. initial lateral flow testing in school, followed by home testing and then potentially a PCR test?

B. Covid -19 Vaccines

We understand that Public Health on the Island is currently administering both the Pfizer vaccine and the AstraZeneca vaccine.

Those persons who have contacted us have raised a number of specific medical and safety concerns as follows:-

9. Do you agree that a person has a right, if they choose to enquire, to know in full what is in a vaccine before agreeing to have that vaccination?
10. Do you accept that in relation to professional medical ethics, such right to know is relevant and necessary to the issue of true informed patient consent?

11. It appears from the AstraZeneca website that their Covid-19 vaccine has as its active ingredient, a version of a common cold virus from **chimpanzees**. It also appears that the vaccine uses cloned cells taken from the kidney of an aborted **human foetus**.

The excipient ingredients (i.e. the other substances alongside the active ingredient) are stated as being L-histidine, L-histidine hydrochloride monohydrate, magnesium chloride hexahydrate, polysorbate 80, ethanol, sucrose, sodium chloride, disodium edatate dehydrate and water.

Please can you confirm that the AstraZeneca vaccine does in fact contain a version of a common cold virus from chimpanzees?

12. Has such virus (otherwise known as adenovirus) been genetically modified?
13. Does such virus enter the recipients cells following vaccination?
14. We understand that the AstraZeneca vaccine uses a host cell line called HEK-293 to produce this modified virus. It has been stated that such HEK-293 cells are clones of cells taken from the kidney of a legally aborted human foetus in 1973. Please can you confirm that this is in fact correct?
15. Please can you confirm whether the ingredients listed at paragraph 10 above represent the full and *complete* content list of the AstraZeneca vaccine?
16. It appears from the literature provided to those called for vaccination e.g. the Invitation letter and the Information leaflet, that there is no specific mention of the active ingredient being a version of a common cold virus in chimpanzees nor any mention of it containing genetically modified organisms (GMOs) nor any mention of it containing the cloned cells from a human foetus. These startling facts appear to be hidden. Do you not consider it appropriate for any proposed recipient to be clearly and explicitly informed about such potentially controversial and ethical facts, either **prominently** in writing or verbally on the day of vaccination?
17. Was the common cold virus from chimpanzees obtained from living and captive chimpanzees and if so, from how many apes, where and how long ago?
18. We understand that the AstraZeneca vaccine is recommended by the manufacturer only for persons over the age of 18. In contrast, the Pfizer vaccination is recommended by its manufacturer for persons over the age of 16. Please can you explain the scientific basis as to why the Pfizer vaccine can be given to a 17 year old but not the AstraZeneca?
19. Given that neither of the Covid vaccines provide complete immunity from the virus nor stop the recipient spreading the virus, should both vaccines not be

more correctly described as *experimental biological treatments* rather than vaccinations?

20. Given the active ingredient referred to above, is the AstraZeneca vaccine suitable for vegans and why does Government literature state that it, “does **not** contain animal products”?
21. We understand that the AstraZeneca vaccine contains ethanol. Given the presence of ethanol, commonly referred to as alcohol, is the AstraZeneca vaccine appropriate for recovering alcoholics? This is particularly pertinent bearing in mind that the vaccine is injected directly into the muscle, in contrast for example to traces of alcohol in bread which are by-products of yeast fermentation and which will pass through various stages of digestion through the body.
22. We are aware that the AstraZeneca vaccine is not generally recommended for breastfeeding women. Is this the case because of the risk of the vaccine entering the baby through the mother’s breast milk and can you confirm whether any breastfeeding women have in fact been given the AstraZeneca vaccine on the Island?
23. Similarly, we understand that the AstraZeneca vaccine is not currently recommended for pregnant women. Is this because of the risk of the vaccine reaching the unborn child and can you confirm whether any pregnant women have in fact been given the AstraZeneca vaccine on the Island?
24. Are statistics being collated in relation to breastfeeding and pregnant women who have been vaccinated for Covid on the Island and if not, why not?
25. With regard to the specific risk of blood clots after vaccination, we understand that Dominique Le Guludec, Head of the French Health Regulator, has recently stated that 9 persons aged under 55, most of them women, had died in Europe as at 16th March 2021, of a particular brain blood clot disorder known as “cerebral venous sinus thrombosis” (CVST), after receiving the AstraZeneca vaccine. Have there been any reported cases of CVST following vaccination on the Island?
26. As stated above, the French Health Regulator has recently advised that the AstraZeneca vaccine not be given to anyone under the age of 55. Ironically, this comes just a few weeks after the same Regulator previously advised that the AstraZeneca vaccine should not be given to anyone over the age of 65. Given the present uncertainty, would it be prudent for Isle of Man Public Health to reserve judgment and either suspend use of the AstraZeneca vaccine (as in Finland, Sweden and Norway) or at least not recommend it for anyone under 55?

27. With regard to those persons currently taking medication, are there any specific medications (such as chemotherapy) that are contra-indicated for either vaccine?
28. Do you concur with Professor Chris Whitty's recent assessment that for a person who has had Covid, the antibodies probably last around 6 months and that the vaccine may give protection for only about the same period?
29. Given the number of Covid-19 variants that have arisen over the last 11 months, what is the predicted overall protection provided by the Pfizer and AstraZeneca vaccines respectively (e.g. 90%)?
30. We understand from your vaccine podcast that it anticipated that all persons vaccinated for Covid-19 will likely require to be re-vaccinated or receive a "booster" jab which, based on Professor Whitty's comments above, may need to be as early as this July for those vaccinated in January. Will this take account of research on the cumulative effect of multiple doses of the vaccines and on any long-term side effects from having the initial vaccination becoming apparent?
31. Do you regard either of the current vaccines as being harmful to gut microbiome, given that microbiological research clearly shows how important the gut ecosystem is for immune health and overall wellbeing?
32. We are aware that the Health Minister, Mr Ashford, has recently stated that the government is unable to collate and/or share the vaccination status of people who are in hospital with or who have died from Covid-19. However, the question of *hospitalisations* and *deaths* after vaccination is clearly a very important issue which is currently being considered by health authorities in a number of European countries. We understand that the health authorities in Norway, Austria and elsewhere are already collecting data on this significant issue of public interest. Particularly in view of the likely need for re-vaccination, do you agree that the Public Health Directorate should, as a priority, be carefully monitoring and transparently *publishing* statistics in relation to hospitalisations and deaths following Covid vaccination with either vaccine?
33. We are aware that the UK Medicines and Health Care products Regulatory Agency (MHRA) operates a **Yellow Card** safety scheme for the reporting of suspected adverse reactions (ADRs) such as anaphylaxis, Bell's palsy and thrombo-embolic events following vaccination. For example, up to 7th March 2021 the MDHA received 61,304 UK reports of suspected ADRs to the *AstraZeneca* vaccine and 35,325 UK reports of suspected ADRs to the *Pfizer* vaccine. For both vaccines, the overall reporting rate is 3-6 Yellow Cards per 1000 doses of vaccine administered.

We understand that the IOM is operating a similar Yellow Card reporting scheme. Please can you confirm how many ADRs have been reported using

the Yellow Card scheme on the Isle of Man (given that as at 22nd March 2021 28,499 Manx persons have received their first vaccine dose and therefore based on the UK Yellow Card scheme may have been expected to have yielded approximately 100 ADRs)?

34. One of the persons who has contacted us raises the sensible suggestion of whether a printed hard copy Yellow Card could be given to persons at the time of vaccination (or with the invitation letter), in order to make the safety reporting system more accessible for those without internet capacity and allow for easier feedback?
35. Would it not also be an appropriate and reasonable measure for Public Health to provide statistics on the number of persons who have received a first vaccine but have subsequently tested *positive* for Covid-19?
36. Equally, would it not be helpful for statistics to be provided on the number of persons who have received their second vaccination but have subsequently tested positive for Covid-19?
37. Is the Isle of Man Government intending and planning to vaccinate all children of school age (4-16) for Covid-19 later this year?

We would be very grateful for your answers to the above questions, asked in good faith by those who have contacted us, and thank you in advance for your professional assistance.

Yours sincerely

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