16 February 2023

Dear

ATISN 17068 – COVID-19 VACCINATIONS

Thank you for your request to the Welsh Government for information under the Freedom of Information Act (2000) received on 19 January 2023. We interpreted your request as:

1. Provide evidence including all documents, clinical trial data, peer reviewed papers and studies, held by the Chief Medical Officer (CMO) and the Department for Health and Social Services (DHSS) - that prove the public claim “We now have a lot of worldwide experience to know that the vaccine is safe and effective at all stages of pregnancy”.

2. Provide evidence including all documents, clinical trial data, peer reviewed papers and studies, held by the CMO and the DHSS that prove these “excess deaths” in “Britain” are not the result and or linked to COVID-19 “vaccines” / gene therapies / jabs / boosters deaths also called adverse reaction(s) and/or effects regarding the claim that “Britain will face a 'prolonged period' of excess deaths due to the pandemic, but not from coronavirus itself on 10 January 2023.

3. Provide a copy of any quantitative risk assessment data and report held by the CMO and the DHSS which demonstrates that the excess deaths and MHRA Yellow Card Vaccine Adverse Reaction reports are not the results of vaccine adverse reaction(s) and /or effects.

4. Provide any information available on the working definition of the word “effective” regarding COVID-19 “vaccines” / gene therapies / jabs / boosters that was used / deployed by the CMO and DHSS in relation to vaccine deployment including, but not limited to the public advertising campaigns from 01 March 2020 – 31 December 2022.

5. *As the Supreme Court of the United States decided that vaccine manufacturers would be exempt from strict liability as vaccines are "unavoidably unsafe products” in Bruesewitz versus Wyeth 2010**
   Provide any information available on the working definition of the word “safe” regarding COVID-19 “vaccines” / gene therapies / jabs / boosters that was used / deployed by the CMO and DHSS in relation to vaccine deployment including, but not limited to the public advertising campaigns from 01 March 2020 – 31 December 2022.

Response: Please be aware that in responding to the questions raised we are providing information held by the Chief Medical Officer for Wales and the Health and Social Services Group (HSSG) within Welsh Government. The Department of Health and Social Services is part of the UK Government and you would need to contact them directly for information held by them.

Question 1

The Medicines and Healthcare Regulatory Authority (MHRA) is responsible for regulating all medicines in the UK. All work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks. The MHRA continually reviews evidence on all medicine products, including vaccines, to advise the 4 UK nations. Information specific to the COVID-19 vaccine and pregnancy can be found here:

COVID-19 vaccination in pregnancy surveillance - GOV.UK (www.gov.uk)

All governments of the UK, including the Welsh Government, have relied upon the advice of the Joint Committee on Vaccination and Immunisation (JCVI) during the pandemic. The Committee's role is to advise all UK health departments on immunisations for the prevention of infections and/or disease following due consideration of the evidence on the burden of disease, on vaccine safety and efficacy and on the impact of immunisation strategies. For all vaccination programmes, including the COVID-19 programme, the JCVI continually reviews evidence on behalf of all 4 UK nations to make their recommendations. Their statement and guidance on COVID-19 vaccinations for pregnant women, which includes reference to real-world data from the United States regarding the vaccination of pregnant women, can be found using the following links:

JCVI issues new advice on COVID-19 vaccination for pregnant women - GOV.UK (www.gov.uk)

COVID-19 vaccination: a guide on pregnancy and breastfeeding - GOV.UK (www.gov.uk)

The CMO for Wales and HSSG also has relied on advice and guidance from UKHSA and PHW.

The safety of COVID-19 vaccines when given in pregnancy - GOV.UK (www.gov.uk)

COVID-19: the green book, chapter 14a - GOV.UK (www.gov.uk)

Questions 2 and 3

On behalf of the 4 UK nations, the MHRA continually monitors safety during the widespread use of any vaccine to ensure these are performing as expected, to identify any new side effects that may arise, and to ensure the benefits continue to outweigh the risks.

Data on any adverse drug reactions (ADR) – including deaths - reported to the Medicine and Healthcare products Regulation Authority (MHRA) regarding the COVID-19 vaccines is routinely published and can be found here: Coronavirus vaccine - weekly summary of Yellow Card reporting - GOV.UK (www.gov.uk). It should be noted that a report of a suspected adverse drug reaction (including death) to the MHRA Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines. All reports are kept under continual review in order to identify possible new risks.

Questions 4 and 5

The MHRA is responsible for regulating all medicines in the UK. It is this organisation's definition of 'safe' and 'effective' which is relied upon. For more information on this definition and how they make decisions to make sure that all medicines and healthcare products available in the UK are **safe** and **effective**, please see the attached link:

About us - Medicines and Healthcare products Regulatory Agency - GOV.UK (www.gov.uk)

If you are dissatisfied with the Welsh Government's handling of your request, you can ask for an internal review within 40 working days of the date of this response. Requests for an internal review should be addressed to the Welsh Government's Freedom of Information Officer at:

Information Rights Unit,
Welsh Government,
Cathays Park,
Cardiff,
CF10 3NQ

or email: FreedomOfInformationOfficer@wales.gsi.gov.uk

Please remember to quote the ATISN reference number above.

You also have the right to complain to the Information Commissioner. The Information Commissioner can be contacted at: Information Commissioner's Office,
Wycliffe House,
Water Lane,
Wilmslow,
Cheshire,
SK9 5AF.

However, please note that the Commissioner will not normally investigate a complaint until it has been through our own internal review process.

Yours sincerely,