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Briefing for the Citizen Participation and Public Petitions Committee on petition: PE2086: Recognise the vaccine injured and offer appropriate treatment lodged by William Queen

Overview of issues raised by the petition

The petitioner is calling on the Scottish Parliament to urge the Scottish Government to properly acknowledge those injured by Covid-19 vaccines and to have the NHS offer appropriate treatment to those who are injured by the vaccines.

The petitioner believes that his wife was injured by one of the vaccines developed to combat COVID-19. The <u>Scottish Vaccine Injury Group</u> comprises people who developed new symptoms following vaccination. The website provides links to information, sources of support, research and other relevant sites.

The petitioner does not define or detail what is meant by recognition of vaccine damage – or, for instance whether they are asking for some sort of redress or legal recognition. This aspect has not been covered in this briefing. However, according to this study, led by the Faculty of Law, University of Oxford, there have been a number of no-fault compensation schemes in a number of countries, set up to provide redress.

The focus of the petition is on recognition that the vaccines caused injury and ensuring access to appropriate medical treatment. The current evidence, as outlined below, has identified a number of conditions that have been linked to the vaccines. However, in respect of access to medical treatment, a petition should not be required because if someone presents to a GP with a set of symptoms which may or may not be caused by the same underlying issue (or to having had a vaccination), then they should be treated and supported regardless. Treatment isn't necessarily based on, or connected to the cause of the symptoms, but on alleviating the symptoms and, if possible, treating the underlying cause if this can be identified. Of course, in the case of vaccine harm, the vaccine itself is the underlying cause. Further research is required to link any additional suspected symptoms to the vaccine, and for appropriate treatments to be identified.

Background

Vaccinations are a slightly peculiar form of medicine in that they are given to healthy people with the aim of preventing a specific disease. Their benefit is at a population level, but, as with all medicines, some individuals will suffer side effects which are sometimes serious and disabling.

It is not in the interests of population level public health, if, overall, the vaccines prevent more harm than they cause, to emphasise harms done or possible harms of vaccination. Governments and health authorities have to balance risks and harms according to the available evidence. As with all medicines, not all side effects of vaccines are known as a result of the clinical trials conducted, and can only be observed once its use is widespread.

It was clear from the start of the pandemic, that the virus itself was experienced very differently by different people – from being asymptomatic to requiring long-term ventilation, and, for some, death. People also respond differently to medicines, including vaccinations. In information leaflets this is expressed in frequency of different known side effects as a proportion. For example, if a side-effect is common, the information might say that 1 in 10 people experience this side effect, or, 1 in 10,000, if the side effect has not been so commonly experienced.

Because the aim of vaccination is to promote an effective immune response against future infection, there is no fixed, treatable underlying cause requiring medical treatment, and the ingredients of vaccinations cannot be removed from the body. There are warnings on information leaflets about allergies to the constituents of the vaccines, but there have been concerns expressed about the potential effects of the new technologies used in the COVID-19 vaccines and the speed of their introduction.

Vaccine Damage Payment Scheme

In recognition of potential vaccine harm, there is a UK-wide Vaccine Damage Payment Scheme (VDPS) that has operated for many years, covering most of the commonly administered vaccinations. The COVID-19 vaccine was added to the scheme in December 2020. It is not a compensation scheme and the payment is a one-off payment of £120,000. However, there is a high eligibility bar, both in terms of level of disability, which must be 'severe', (at least 60% disabled), and in terms of proof of causality. Two legal tests have to be met to qualify:

- "1. establishing, on the balance of probabilities, that the disablement was caused by vaccination covered by the Vaccine Damage Payment Scheme (VDPS);
- 2. the resulting disablement is severe disablement (60% or more)"

Of the 2347 claims made between 1 January 2000 to June 2021, only 41 resulted in an award.

<u>Up until 14 March 2024 10,655 claims involving COVID-19 vaccine have been received by the VDPS. Just under 170 people have been notified of an award, and the process takes approximately a year.</u>

Evidence of vaccine harm and surveillance and reporting system

Vaccines are classed and licenced as medicines on a UK wide basis by the Medicines and Healthcare products Regulatory Agency (MHRA), and, like all medicines, their accompanying information has to provide details and likelihood of any side effects. The challenge with COVID-19 vaccines was that the technology was relatively novel for some of the vaccines and a faster testing route was used to ensure that vaccines were available while the risk from COVID-19 was still high. The Wellcome Foundation published a blog on the difference between the usual process for testing and assessing vaccines and the process followed for the COVID-19 vaccine process. Once a medicine is licensed and available, then sometimes side-effects might emerge that did not appear during the clinical trials. While the process was faster, none of the steps to assure safety were missed out.

The Medicines and Healthcare Products Regulatory Agency (MHRA) collated all its guidance and information on coronavirus in one place, although this has not necessarily been comprehensively updated. This includes information on vaccines and vaccine safety. Additionally, the Agency received a very large volume of yellow card reports throughout the pandemic relating to the vaccines

The timing of reporting any symptoms following vaccination can also be problematic. The longer the interval, the harder it becomes to attribute any harms to the vaccination, rather than any other cause. But not all effects of medicines will be observed in the first 48 – 72 hours for example. The National Institute for Health and Care Excellence provides information on adverse reactions to drugs, including newer drugs and vaccines, describing the process of reporting and how reporting is handled.

The safety information on the Covid-19 vaccines in use has been updated over time as reports of side-effects have been verified. The <a href="mailto:

It is very difficult to find comprehensive and reliable evidence and research that details and defines COVID-19 vaccine injury, particularly in relation to ongoing issues (rather than immediate effects). In research terms, the

introduction of the vaccines is still relatively recent, and a search of the internet, and the plethora of articles, some conflicting, some hypothesising, indicates that it is still a very 'live' area of research.

Yellow Card reporting on Coronavirus vaccines

Not all potential side-effects can be identified before any vaccine or medicine is licenced for use. Clinical trials tend to be carried out on cohorts of healthy people, so it is inevitable that some effects emerge after licencing. The UK licencing body, the Medicines and Healthcare Products Regulatory Agency (MHRA) has a system – the Yellow Card Scheme which acknowledges this, and allows clinicians and members of the public to register suspected side effects of any medicines or medical products and devices. The MHRA website explains what happens after someone has reported an issue:

"The Medicines and Healthcare products Regulatory Agency, the manufacturer or a medical specialist may investigate the problem depending on how serious it is. It'll be recorded to help prevent similar incidents in future, even if it's not investigated."

Vaccines are also slightly unusual medicines in that they are given to healthy people in an effort to prevent disease and infection, rather than to treat a condition, so some may assume that cannot cause harm.

The MHRA published <u>summary reports of yellow card reporting following the introduction of the vaccines, and published its final one on 8 March 2023, following the Autumn 2022 booster programme.</u>

The MHRA's view on side effects is that:

"All vaccines and medicines have some side effects. These side effects need to be continuously balanced against the expected benefits in preventing illness."

The argument is that side effects are rare when compared with the effects of the disease itself. One compounding factor is potentially the rise in natural immunity over time once a novel disease is present, so it is difficult to fully ascertain the effects of the vaccine in an already partially immune population.

The MHRA have <u>compiled detailed reports on all of the vaccinations in use</u>, and there were many thousands of yellow card submissions. They can be filtered via the individual vaccines, as well as by the symptoms or organs affected. <u>These can be viewed by going to the 'Report profile' tab</u> for each vaccine. The MHRA make it clear that a report of an effect does not necessarily equate to an association with the vaccine.

In <u>March 2023 the UK Government updated its summary of yellow card</u> reporting on the Coronavirus vaccines.

In the case of all medicines, including vaccinations, symptoms which might be experienced shortly after administering the dose might or might not be linked to the medicine, and might be coincidence. The yellow reporting system allows for all symptoms to be recorded, and allows the MHRA to monitor any trends. Researchers also have access to these reports and data.

It is only over time, and with reporting of symptoms and subsequent research, that a full range of any side effects become known, eventually allowing individuals to weigh up the balance of risk and benefit of any medicine for themselves.

Coronavirus vaccinations and prevention of harm and lives saved

Research and modelling have shown the impact vaccinations, along with other public health measures such as mask wearing and lock downs, had on slowing down the spread of COVID-19 and reducing hospitalisations and deaths. Public Health Scotland published a news briefing stating that a World Health Organisation study estimates that 22,138 lives in Scotland were saved by the COVID-19 vaccination programme.

Potential for symptoms linked to either Long COVID and/or vaccination

Another confounding factor in assessing harm and symptoms with a novel disease (or a novel vaccine) are the effects of the disease itself. A wide range of symptoms emerged when people caught COVID-19, affecting people for different lengths of time and to varying degrees, which have been labelled long COVID. Most of these people will have also had the vaccines. Long term studies are still to be carried out, but one study published in Nature in January 2024 that some long COVID symptoms could persist regardless of vaccination status. Another cohort study published in the Lancet found that vaccination reduced the risk of long COVID symptoms, and the cohort was significantly larger.

UK Parliament – Private Members' Bill

A bill was introduced in 2022 – the <u>Covid-19 Vaccine Damage Payments Bill</u> to improve the support and financial assistance to people who suffer disablement from vaccines. It would set up a compensation scheme rather than a fixed payment scheme. It reached its second stage, so <u>was debated</u>, but because the 2022-23 session of Parliament prorogued the Bill will make no further progress.

Anne Jepson Senior Researcher, SPICe 18 April 2024

The purpose of this briefing is to provide a brief overview of issues raised by the petition. SPICe research specialists are not able to discuss the content of petition briefings with petitioners or other members of the public. However, if you have any comments on any petition briefing you can email us at spice@parliament.scot

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