# PE2086/G: Recognise the vaccine injured and offer appropriate treatment

### Scottish Government written submission, 1 April 2025

A lack of adequate treatment for conditions, resulting in some individuals seeking private care.

The Scottish Government recognises the importance of people receiving appropriate care.

In many cases it may be difficult for a clinician to explicitly determine if an illness or condition is linked to vaccination. The Scottish Government understands how this lack of acknowledgement may be deeply frustrating for citizens.

If a patient has been vaccine injured and is experiencing a particular condition or symptom as a result, then the NHS should treat them for that condition, as they would with any other patient who displayed those symptoms, regardless of the cause.

A clinician's inability to attribute symptoms or conditions to COVID-19 vaccine injury does not prevent them from effectively treating the patient.

There are certain conditions, like MCAS and PoTS, the examples quoted by the petitioner, where a patients' clinical presentation can vary substantially, not only from person to person, but even within a patient from one point in time to another. Diagnosis may take time, as clinicians rule out a series of possible causes, which can be a lengthy process, no doubt leading to frustrations in some cases.

### A lack of recognition of postural orthostatic tachycardia syndrome (PoTS) in the NHS, leaving individuals without diagnosis or treatment

While the Scottish Government provides core funding and is responsible for setting the strategic policy for the NHS in Scotland, responsibility for the delivery of care rests locally with NHS boards who configure services taking into account local circumstances and the reasonable needs of their patient populations.

The Scottish Government expects NHS boards to provide high quality, personcentred care and support for everyone, including people with PoTS. Support is often provided via primary care, with referral to secondary care if necessary to rule out other causes of symptoms or provide management advice.

NHS Education for Scotland's learning platform 'Turas' contains the learning resources listed below on PoTS and autonomic nervous system dysfunction. These resources are accessible to a multidisciplinary audience.

• 14 June 2022 – PoTs UK webinar 'Long Covid and the autonomic nervous system - a top - down and bottom - up approach'.

• 17 July 2023 – NHS Education for Scotland slide pack learning bite 'The autonomic nervous system and Long Covid'.

We have commissioned and funded NHS National Services Scotland to establish a national Long Covid Strategic Network. A pathway for the diagnosis and management of PoTs in Long Covid was developed by the network in 2023. This has since been withdrawn pending a review of evidence to support an updated pathway, with Healthcare Improvement Scotland having been asked to carry out a rapid evidence review to support this work.

## Reports of individuals being described as over-anxious, leading to hesitancy in seeking further support, and resulting in some individuals seeking private care

The Scottish Government would encourage anyone who is suffering from any symptom or condition to seek medical intervention in order to access suitable healthcare support. For those patients who feel like they have had their concerns dismissed, or badged as anxiety, Health Boards have set complaints procedures that patients can follow. The Government is committed to improving public health and alleviating pressures on the NHS to allow for better treatments for patients.

#### Challenge in diagnosing vaccine-induced myocarditis

The Scottish Government has great sympathy for anyone who has been injured as a result of receiving the COVID-19 vaccines and acknowledges the difficulties some citizens have experienced in receiving appropriate treatment as a result of these injuries.

In many cases it may be difficult for a clinician to explicitly determine if an illness or condition, such as myocarditis, is explicitly linked to vaccination, as it can be caused by multiple factors.

If a patient has been vaccine injured and is experiencing a particular condition or symptom as a result, then the NHS should treat them for that condition, as they would with any other patient who displayed those symptoms, regardless of the cause.

The UK Health Security Agency (UKHSA), in partnership with the Royal College of General Practitioners (RCGP) and the Royal College of Emergency Medicine (RCEM), produced clinical guidance to support the detection and management of clinical cases of myocarditis and pericarditis associated with coronavirus (COVID-19) vaccination. This clinical guidance was endorsed by the British Congenital Cardiac Association (BCCA) and is available here; Myocarditis and pericarditis after COVID-19 vaccination: clinical management guidance for healthcare professionals - GOV.UK

Clinicians can also obtain further information on side effects of the COVID-19 vaccines via the COVID-19: the green book, chapter 14a - GOV.UK.

Ongoing concerns about whether people are being provided with accurate information to support them to give fully informed consent

The Scottish Government in partnership with Public Health Scotland (PHS) gave, and continues to give, recipients of the COVID-19 vaccines as much information on the potential benefits and risks of the vaccines as possible.

Information on the side effects stated on these materials is based on the expert advice of the Joint Committee on Vaccination and Immunisation (JCVI) and the UK Medicines and Healthcare products Regulatory Agency (MHRA).

There is a formal mechanism by which new side effects are recognised and included in official materials such as Patient Information Leaflets, Summary of Product Characteristics, and the Green Book Chapter. When this occurs, we update our materials.

This is managed by the MHRA, when signals are such that something becomes a formally recognised side effect, due to its prevalence in those receiving the vaccine.

High level information on potential side effects is provided with the information leaflet that accompanies each appointment letter. That leaflet has web links directing people to the patient information leaflets, via NHS Inform, should they require more information prior to their appointment.

Patients are given further materials at their appointments, including the manufacturer's 'Patient Information Leaflets' and our NHS 'What to expect after your Covid-19 vaccine' leaflet, which contains more information on side effects. The Scottish Government is aware that some people were given the Patient Information Leaflet (PIL) after receiving vaccination. Best practice would be for clinics to provide these to patients whilst they wait for vaccination. The leaflets sent with appointment letters gave patients the chance to read the PILs online prior to attending their appointment.

Staff training materials are updated regularly, so that staff at clinics can answer any questions about side effects during consent conversations at the point of vaccination.

The informed consent materials developed by PHS are available in a range of accessible formats, including multiple languages, Easy Read, Braille and British Sign Language (BSL).

#### **Monitoring the side-effects of Covid-19 vaccination**

The UK Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for medicine licences and it only grants approval to COVID-19 vaccines following rigorous reviews of the safety, quality and effectiveness of such vaccines. All mRNA vaccines currently in use in the UK and Scottish programmes have been subject to this process. As with all vaccines and medicines, the safety of COVID-19 vaccines is being continuously monitored.

The MHRA monitors the safety of all medicines throughout their marketed life, in what is known as pharmacovigilance. Information is derived from multiple national and international sources including:

- spontaneous adverse drug reaction reporting schemes, such as the Yellow Card Scheme
- clinical and epidemiological studies
- worldwide published medical literature
- pharmaceutical companies
- worldwide regulatory authorities
- morbidity and mortality databases

Public Health Scotland is a participant in the multinational Global Vaccine Data Network (GVDN) cohort study, looking at COVID-19 vaccines and adverse events in over 99 million vaccinated individuals. The UK National Institute for Health and Care Research also commissions research and studies into COVID-19 vaccines.

Further information on Pharmacovigilance can be found here:

<u>Pharmacovigilance how the MHRA monitors the safety of medicines.pdf</u>
(publishing.service.gov.uk)

**Population Health Directorate**