Citizen Participation and Public Petitions Committee

15th Meeting, 2022 (Session 6), Wednesday 9 November 2022

PE1950: Ensure immunosuppressed people in Scotland can access the Evusheld antibody treatment

Note by the Clerk

Petitioner	Alex Marshall
Petition summary	Calling on the Scottish Parliament to urge the Scottish Government to enable access, via the NHS, to Evusheld prophylactic treatment for people who have zero or weak response to the COVID-19 vaccines.
Webpage	https://petitions.parliament.scot/petitions/PE1950

Introduction

1. This is a new petition that was lodged on 9 August 2022.

2. A full summary of this petition and its aims can be found at **Annexe A**.

3. A SPICe briefing has been prepared to inform the Committee's consideration of the petition and can be found at **Annexe B.**

4. While not a formal requirement, petitioners have the option to collect signatures on their petition. On this occasion, the petitioner elected to collect this information. 214 signatures have been received.

5. The Committee seeks views from the Scottish Government on all new petitions before they are formally considered. A response has been received from the Scottish Government and is included at **Annexe C** of this paper.

6. The Committee has also received a submission from Blanche Hampton. This is included at **Annexe D**.

Action

The Committee is invited to consider what action it wishes to take on this petition.

Clerk to the Committee

Annexe A

PE1950: Ensure immunosuppressed people in Scotland can access the Evusheld antibody treatment

Petitioner
Alex Marshall

Date lodged
12 July 2022

Petition summary
Calling on the Scottish Parliament to urge the Scottish Government to enable access, via the NHS, to Evusheld prophylactic treatment for people who have zero or weak response to the COVID-19 vaccines.

Previous action
Written to MSP and MP.

Background information
Immunosuppressed people are at high risk of serious illness or death.

In a similar **petition to the UK Parliament**, the petitioner notes:

- Lockdown and shielding has not ended for many people with blood cancer, organ transplants, and other forms of immune compromise
- Treatments like Evusheld may offer protection for immunosuppressed people, similar to the way COVID-19 vaccines protect much of the wider population.

The clinical trials for Evusheld, showed positive results and was found to reduce the risk of developing symptomatic COVID-19 by 77%. As a result Evusheld has been **authorised by the Medicines and Healthcare products Regulatory Agency (MHRA)**.

This treatment has also been recommended for authorisation by the **European Medicines Agency**, with further information on the clinical trial and decision to approve Evusheld in the UK available in **the BMJ**.

Annexe B

Briefing for the Citizen Participation and Public Petitions Committee on petition PE1950: Ensure immunosuppressed people in Scotland can access Evusheld antibody treatment, lodged by Alex Marshall

Brief overview of issues raised by the petition

The petition calls on the Scottish Parliament to urge the Scottish Government to enable access, via the NHS, to Evusheld® prophylactic treatment for people who have a zero or weak response to the COVID-19 vaccines.

Evusheld®

Evusheld® is a long-acting antibody treatment made up of two antibodies – tixagevimab and cilgavimab. The treatment has a conditional marketing authorisation from the UK Medicines and Healthcare products Regulatory Agency (MHRA) for use in adults who are unlikely to mount an immune response from COVID-19 vaccination, or for whom vaccination is not recommended. Recipients should not be currently infected with or had recent known exposure to a person infected with the COVID-19 virus.

The medicine is administered by intramuscular injection by a healthcare professional before exposure to the virus. This is known as pre-exposure prophylaxis (PrEP).

Patient need

Evusheld® is seen as a promising treatment for those who cannot benefit from the COVID-19 vaccines.

Research to date indicates that certain people do not mount a strong immune response to the vaccines, for example, people with blood cancer and those who have had transplants and take immunosuppressant drugs.

It is believed there are around 500,000 immunocompromised people in the UK.

In July 2022, 18 charities and patient groups wrote to the UK Health Secretary asking for antibody therapies such as Evusheld® to be procured and provided to people who remain vulnerable to COVID-19 after vaccination.

Access within the UK

Normally, when a medicine receives a marketing authorisation from the MHRA (also known as a licence), the agency responsible for Health Technology Assessments (HTA) in each UK country (e.g. the Scottish Medicines Consortium (SMC) in Scotland or National Institute for Health and Care Excellence (NICE) in England) then decides whether it should be made routinely available on the NHS.

These are two distinct parts of the process and just because a medicine has a licence does not necessarily mean it will be made available on the NHS.

The licence indicates that a medicine is safe and effective. The HTA process is to consider its wider value, such as clinical and cost-effectiveness. Affordability is not considered in the HTA process.

In the case of Evusheld®, the MHRA granted a conditional marketing authorisation in March 2022. Conditional marketing authorisations are given on the basis that a medicine addresses an unmet need in patients but has less available data and research evidence than is required for a full marketing authorisation.

The available data must indicate that the medicine's benefits outweigh its risks but the manufacturer should provide the comprehensive clinical data in the future.

Evusheld® was developed before the emergence of the Omicron variant and therefore, at the time when it was being considered by the MHRA, there was limited understanding of its efficacy against Omicron, or the duration of any protection it may afford.

Subsequently, the UK Health Security Agency (UKHSA) was tasked with carrying out further testing on the treatment's effectiveness against Omicron.

However, in their letter to the UK Health Secretary, the patient groups and charities claim there is strong clinical support for Evusheld® and express their concerns that the medicine is 'being held to an impossible standard of evolving evidence'. The letter goes on to say that it is unclear what information and concerns the Government hold in relation to Evusheld's effectiveness, and that there has been a lack of transparency in relation to Government testing.

In August 2022, the UK Government confirmed that it would not procure Evusheld® until the conclusion of an appraisal by NICE.

"Following a robust review of the available data, our clinical experts advise there is currently insufficient data on the duration of protection offered by Evusheld in relation to the Omicron variant and the government will not be procuring any doses at this time."

The NICE appraisal is expected to conclude by April 2023 at the earliest.

The UK Government's clinical advisors have also recommended that, in order to gain further evidence, a trial would be a suitable route to answer outstanding questions on the clinical outcomes for current and future variants, together with evaluating the effectiveness and safety of using a higher dose of Evusheld®. This was not tested in the company's randomised controlled trials.

The UK Department of Health and Social Care (DHSC) has offered to explore with Astrazeneca (AZ) the possibility of a clinical trial and to that end have offered to include Evusheld® in the PROTECT-V study.

Scottish Government Action

The Scottish Government and the NHS in Scotland can independently procure and prescribe licensed medicines. However, throughout the pandemic, a UK-wide approach to the procurement of therapeutics has been pursued to allow the UK to have the buying power to secure significant numbers of therapeutics in a competitive global market. In

addition, NHS Scotland follows clinical advice issued by the UK RAPID C-19 group, which continues to consider the evidence as it emerges for Evusheld®.

The SMC (Scotland's equivalent to NICE) is a partner in a UK-wide multi-agency RAPID C-19 initiative, a collaborative partnership facilitated by NICE. Building on this work, the SMC is exploring the potential for collaboration with NICE on a single technology assessment of Evusheld® for the prevention (pre-exposure prophylaxis) of COVID-19[1].

UK Government Action

The UK Government issued a response to a petition which was seeking to have Evusheld funded by the NHS for immunocompromised patients.

The response explains that Evusheld® needs to be tested further against the Omicron variant before a decision is made on roll-out.

It also details that the new Therapeutics Clinical Review Panel is providing advice on the most appropriate patient cohorts for new COVID-19 therapeutics, including Evusheld®. This is with a view to determining who will benefit the most from any new treatments.

Other relevant petitions and reports

There have been no previous petitions or reports considered by the Scottish Parliament on this topic.

Kathleen Robson
SPICe Researcher
[08/09/2022]

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[1] Personal communication with the Scottish Government – 8 September 2022.

Annexe C

Chief Pharmaceutical Officer submission of 9 August 2022

PE1950/A – Ensure immunosuppressed people in Scotland can access the Evusheld antibody treatment

Thank you for the Committee's email of 12 July regarding petition PE1950 which calls on the Scottish Parliament to urge the Scottish Government to enable access, via the NHS, to Evusheld® prophylactic treatment for people who have zero or weak response to the COVID-19 vaccines.

In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) is the UK agency responsible for the approval of clinical trials and marketing authorisations (licences) for new medicinal products. The MHRA, together with independent advisory groups, continues to review the emerging body of evidence regarding potential medicines and vaccines for the treatment and prevention of COVID-19.

The MHRA recently granted a conditional marketing authorisation for Evusheld® (tixagevimab/cilgavimab). A conditional marketing authorisation is the approval of a medicine that addresses the unmet medical needs of patients on the basis of less available comprehensive data than is normally required. The available data must indicate that the medicine's benefits outweigh its risks and that the manufacturer should be in a position to provide the comprehensive clinical data in the future. Evusheld® has been authorised to be used before an individual is exposed to the risk of COVID-19 infection in order to prevent disease (known as 'pre-exposure prophylaxis'). For most people, the best way to prevent infection is vaccination. However, Evusheld® can be used in adults who are unlikely to develop an immune response from COVID-19 vaccination or for whom vaccination is not recommended.

Evusheld® was developed and tested before the emergence of the Omicron variant, and the MHRA's authorisation outlined some remaining questions, including how effective Evusheld® is against Omicron and the

duration of its effect against current circulating variants. As a result, there is currently no established UK supply arrangement for Evusheld®. The UK Health Security Agency (UKHSA) is carrying out further testing on the effectiveness of Evusheld® against the Omicron variants which involve "live virus" tests taking place in the lab ("in vitro"). These tests are important because they provide certainty of the effectiveness of Evusheld® against circulating variants and avoid the risk of introducing new variants through viral mutations.

The Scottish Government will continue to closely monitor the outcome of further research to ensure that any decisions to make Evusheld® available to patients in Scotland in the future are based on the best available evidence. The UKHSA is also completing in vitro testing against variants for other drugs, details of which can be found here: COVID-19 therapeutic agents: technical briefings - GOV.UK (www.gov.uk). These tests will give experts information about the likelihood that the treatment remains or does not remain effective.

Throughout the pandemic, a UK-wide approach to the procurement of therapeutics has been vital to allow the UK to have the buying power to secure significant numbers of therapeutics in a competitive global market. This approach has ensured patients across the UK have had equal access to safe and effective medicines.

It may be helpful to highlight that there are also a number of new COVID-19 treatments for selected groups of people with COVID-19 already in use in Scotland, including new novel oral antivirals (molnupirovir and Paxlovid®) and the monoclonal antibody treatment, sotrovimab. General information on the arrangements for direct access to COVID-19 treatments in Scotland can be found on NHS Inform. The decision on whether to prescribe a medicine for a patient, and which medicine to prescribe, is entirely one for the clinician in charge of a patient's care to make, having taken into account the patient's clinical condition and their safety.

COVID-19 oral antiviral treatments are also being evaluated through a study called PANORAMIC, run by the University of Oxford. The study is testing whether these antivirals treatments may benefit a wider group of patients than the current eligibility criteria. The results from the first part of the study are due to be published later this year.

I do hope this information is helpful to you and the Committee. I will write to update the Committee in the event that, based on the evidence from the UKHSA, there is a decision to make Evusheld® available to patients in Scotland.

Thank you again for your correspondence.

Annexe D

Blanche Hampton submission of 14 October

PE1950/B – Ensure immunosuppressed people in Scotland can access the Evusheld antibody treatment

My name is Blanche Hampton, I am 66 and immunocompromised due to the immunosuppressant drugs I take to control Systemic Lupus Erythematosus. After 5 vaccines I had zero response on antibody testing. I had my sixth vaccine on 9 October. I completely support the petition.

Having shielded throughout the pandemic, I caught COVID-19 in early August. I immediately contacted the number on my NHS letter to get the antivirals I knew I would need. I was then caught in a bizarre NHS health board border dispute which delayed the delivery until it was too late for the one I really needed and nearly too late for the one that finally arrived. I had improvement while on the course, but within 24 hours of finishing it, had a rebound COVID-19 infection that was worse than the first and has left me with scarred lungs. Nobody told me that antiviral rebound might happen or what to do. The same antivirals number was unable to help and my GP wasn't available. I was very ill with a high fever for 10 days, cared for by my neighbours. The GP did come, but diagnosed a post-covid chest infection that didn't respond to two+ courses of antibiotics, and the sputum showed no bacterial infection. Any opportunity to protect my lungs was lost.

As an immunocompromised person, for nearly 20 years I have avoided crowds and sick people. Irrational as it may seem, I was worried that if I went to hospital, I might be treated for COVID-19, but would pick up some other infection that would kill me. My decision was based on my assessment of risk v benefits of hospital care when the NHS is under such pressure.

With no vaccine immunity and the patchy nature of the antivirals delivery, I have no protection from COVID-19 and until something better comes along, Evusheld is the only hope I have at being able to live anything like a normal life. I suffered severely with the COVID-19

infection in August and now look to be slipping into Long Covid with scarred lungs, which will make me even more vulnerable to a bad outcome. I have just had my 6th vaccine, but going on past performance and with the numbers going up, I can't risk getting COVID-19 again. It's like sitting on a railway track waiting for the next train to hit me. I have gone back to full shielding and will see no-one until the numbers come down in spring.

When new medicines are introduced, they are evaluated and the Medicines and Healthcare products Regulatory Agency (MHRA) approved Evusheld in March 2022. More than 30 other countries are using Evusheld without complaint, including US, Europe, Australia, Singapore etc. The National Institute for Health and Care Excellence (NICE) process to approve a medicine can take up to a year, but COVID-19 treatments were and continue to be fast-tracked for approval. I was shocked to read that having approved Evusheld for use, the UK Government then announced in August, just as I went down with COVID-19, that it would not buy any doses.

As I understand it, the reason given was that as the Omicron variants weren't in circulation at the time Evusheld was being trialled, it couldn't be proven to be effective for them. This has been addressed by AstraZeneca in July 2022. It was also suggested that while Evusheld has been proven to reduce hospitalisation and death, it hasn't been proven to prevent symptomatic COVID-19. As no other coronavirus drugs had been required to meet this particular threshold, including the vaccines, I find this to be a very strange response. Now, instead of being fast-tracked, it has become subject to a cumbersome NICE process that won't report till 31 May 2023. The Scottish Medicines Consortium (SMC) usually follow NICE, and in this instance have said they will do that.

I strongly support this petition and I would ask the Committee to consider:

- Cost/benefit approx. £800 per year for two six-monthly doses v A&E attendances and hospitalisations
- Scotland's immunocompromised have nothing to protect them and it can feel like we are an abandoned underclass.
- More than 30 countries use Evusheld as part of their covid strategy, with no negative comment.
- While it might not cover every variant, Evusheld is best used now, before it becomes redundant. As with the early vaccines, it is

better than nothing. With winter coming, we need it now, by late May it may be too late.

- Delivered by 2 injections on the same occasion, I understand that rollout could be fast enough to protect us during winter, when the risks are highest and the pressures on the NHS are greatest.

I am asking the Scottish Parliament to ask that the SMC revise their decision to wait for the NICE report and protect Scotland's immunocompromised now, before more of us die knowing there is a treatment that could have saved us.