Citizen Participation and Public Petitions Committee

6th Meeting, 2023 (Session 6), Wednesday 19 April 2023

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

Lodged on	9 August 2022
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. The Committee last considered this petition at its meeting on 8 February 2023, where it heard evidence from Mark Oakley and Nikola Brigden, members of the Evusheld for the UK campaign group. At that meeting, the Committee agreed to consider the evidence it heard at a future meeting.

2. Members will be aware that the petitioner declined to participate in the evidence session on 8 February 2023 on the basis that the emergence of new COVID-19 variants has (in the petitioner's view) rendered the Evusheld treatment ineffective.

3. The petition summary is included in **Annexe A** and the Official Report of the Committee's last consideration of this petition is at **Annexe B**.

4. Written submissions received prior to the Committee's last consideration can be found on the petition's webpage.

5. Further background information about this petition can be found in the SPICe briefing for this petition.

6. The Scottish Government's initial position on this petition can be found on the petition's webpage.

7. Members may also wish to note that, on 16 February 2023, the National Institute for Health and Care Excellence (NICE) issued draft guidance which does not recommend Evusheld for preventing COVID-19 in adults who are unlikely to have an adequeate immune response to COVID-19 vaccination, or who can't be vaccinated. Further details are available on the NICE website.

Action

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

Clerk to the Committee

Annexe A

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

Petitioner

Alex Marshall

Date lodged

9 August 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

Extract from Official Report of last consideration of PE1950 on 8 February 2023

The Convener: Our second petition, for which we will be joined by witnesses remotely, is PE1950, on ensuring that immunosuppressed people in Scotland can access the Evusheld antibody treatment. The petition, which was lodged by Alex Marshall, calls on the Scottish Parliament to urge the Scottish Government to enable access, via the national health service, to the Evusheld prophylactic treatment for people who have a zero or weak response to the Covid-19 vaccines.

We previously considered the petition at our meeting on 9 November, when we agreed to write to various organisations and to invite the petitioner and representatives from the patient campaign group, Evusheld for the UK, to provide evidence to the committee. Members will have noted in our papers for today's meeting that the petitioner, Alex Marshall, has declined the opportunity to provide evidence or pursue the petition further, as he feels that the emergence of new Covid-19 variants has rendered the Evusheld treatment ineffective.

I note that the committee has now received responses from the Scottish Medicines Consortium, Immunodeficiency UK, Blood Cancer UK and Kidney Research UK.

Despite the unusual circumstances in which we find ourselves and the fact that the pandemic has moved on, there are issues that the committee wishes to explore. I am pleased to welcome Mark Oakley and Nikola Brigden, who are from Evusheld for the UK. Good morning to you both.

We move straight to questions. Please raise a hand or put an R in the chat function—that is the usual way. The clerks are monitoring that and will ensure that we know when you would like to come in and contribute. I move straight to my colleague David Torrance.

David Torrance: Good morning. How do the witnesses respond to the assertion that Evusheld is not so effective against the omicron variant of the virus?

The Convener: Perhaps you can decide who will answer first.

David Torrance: I will ask Mark Oakley first.

Mark Oakley (Evusheld for the UK): We are certainly in an ever-changing position with the virus. At the moment in the United Kingdom, Evusheld is still effective—it is not effective against all variants, but it is still giving some level of protection. We are in the situation in which some—[Inaudible.]—immunocompromised have not had any protection. I am one of those people. If you told me that I could take something that would give me 10 per cent protection, I would take that hand over fist.

At the moment, the United States has temporarily suspended Evusheld because of the variant mix there, but it is looking to bring it back once the variant mix changes again. It is still in use in all the European countries and the other 32 countries that are using it, although they are using it with the caveat that it is not a magic bullet and that people still need to take other precautions. Having had to shield for nigh on three years, I think that anybody who is immunocompromised is not stupid enough to take unnecessary risks.

David Torrance: Perhaps Nikola Brigden has something to add.

Nikola Brigden (Evusheld for the UK): Most of the studies that have been carried out on how Evusheld works against the new variants are in vitro—in test tubes—but we know from feedback from immunologists and people who we are in contact with abroad that Evusheld works a lot differently in the human body in the real world. It seems to be a lot more effective in that situation. We hear that the number of hospital admissions is down in other countries due to its use.

David Torrance: Thank you for that. Is there any real-world research being undertaken on Evusheld that could be considered by the National Institute for Health and Care Excellence to help to promote its use?

Mark Oakley: The honest answer is that I am not sure what studies are being undertaken abroad. Obviously, there have been a lot of studies. Globally, there is the veteran study in America, the one that was done in France by the Louis Pasteur institute and the Kertes study in Israel. They have all shown very good results against various variants.

David Torrance: Nikola Brigden, do you have anything to add?

Nikola Brigden: No—it is pretty much as Mark Oakley has said. There are new studies coming out all the time. As quickly as we can get hold of them, we submit them to the Government to give it the additional information.

The Convener: Given your experience—I now have some direct experience, as well—in what way did you find that the inability to access this particular treatment resulted in a different pathway through and out of the pandemic to that of other people? Clearly, bigger concerns still rested with people who are immunosuppressed, even as they saw everybody else acting more normally.

Mark Oakley: Picking up on the issue of moving out of the pandemic, which was one of the phrases that you just used, I note that people in this situation are still very much in the pandemic. People who have not been fortunate enough to fund the drug themselves, which is the vast majority of people, are still living the pandemic every day.

I was fortunate enough to be able to pay for the drug. I had it on 1 November. Up until that point, I was shielding—I was doing so for close to 1,000 days. It affects

your family, and it affects your work. There are people who are still stuck in that situation—it is on-going. They are fearful, and they have no financial support. It is having a long-term mental effect on people. It is not a good situation, and they are still stuck in it, yet here we are trying to use a drug evaluation system outside of the pandemic instead of the one that we used for the vaccines and so on in order to get them approved quickly.

Come March, some people will be entering their fourth year of shielding. More drugs are being developed by companies such as AstraZeneca, but, if we carry on down the route of using the NICE process—the same system that has been used for Evusheld—with the amount of time that it takes, there will be people in this situation who will be going into five years of shielding. Those people and their families will be left in that position for nearly half a decade.

The Convener: I understand the point that you are making. As I said, I have some direct experience.

You said that you received the treatment in November. This is the contradiction that I want to try to understand: given the reservations that have been expressed by some jurisdictions about the treatment's effectiveness, has it given you confidence to act in a more complete way? I think that you said, "Even if it gives me 10 per cent additional benefit, that is 10 per cent additional benefit that I did not have". Is it the case that, although it might not give the sense of full and complete security that vaccination might give to other people, it nonetheless advances confidence among people who cannot have the vaccines but who could take Evusheld? Is it essentially that? On the back of taking it, have you felt more confident about acting in a way that is consistent with how you operated before?

Mark Oakley: Yes. There is a big change when you step out of the door for the first time and start going into shops and so on. From talking to others, I think that most people experienced that when they came out of the nationwide lockdowns. It takes a while to get used to it.

No one—not me, certainly, nor other people to whom I have spoken—in this position is foolish enough to put themselves at risk. However, Evusheld has allowed me to have more choice—to choose whether to go into shops that are quieter, or to go at quieter times of day, and to choose whether to do more normal activities such as going to a restaurant when it is not too busy. I can pick and choose and be careful; I can choose at what time I travel on public transport if I need to do so. It is a balance, and I have to do things with other mitigations in mind in order to protect myself. At the moment, Evusheld will not give me 100 per cent protection, but neither would a vaccine provide that to anybody else.

Nikola Brigden: I will add to that by giving you a little background about my husband, Scott, who was diagnosed with mantle cell lymphoma at the age of 46 in 2021. It is quite a rare type of blood cancer. His prognosis is not great; they have

said that he possibly has five years. Over the past two years, he has had to fight through chemotherapy treatments and have a stem cell transplant—he has really fought to stay alive—but there has also been the impact of having to shield and not be able to spend time with his loved ones. There has been an impact on our daughter, who is studying away at university, because she has had to stay away from us. There is a mental impact on families. Scott has not been able to see his mum and give her a hug.

Everybody who is immunocompromised has a similar situation. To have a life-changing diagnosis is hard enough without the mental impact of having to deal with shielding. It is one of the things that has gone unspoken: the huge impact on not just the people who are immunocompromised but on their immediate and wider families.

We speak to people every day who have fought so hard to stay alive but who say that they are at the point of giving up. Everybody needs a purpose in life, but they cannot go out and mix or even give their family members a hug. My husband had Evusheld on 2 November—about the same time as Mark Oakley—but we have not gone out and gone mad. It has meant that Scott could have time with his family on Christmas day and he could hug our daughter. It is about all the simple things that most people take for granted but that mean so much. That is why we are here today: to speak on behalf of so many people who feel so forgotten in this situation.

The Convener: I am grateful for that. Implicit in what you are saying is a sense among the community of those who are affected in this way that the lighthouse of public attention has maybe swung away and people who are in this position are left to cope on their own, without the same attention that there was when this was a much more general and widespread affliction that was being felt by a much wider community across the country. I appreciate and understand that.

To move away from anything that is so personal to you, do you have any knowledge of whether immunosuppressed people have disproportionately experienced morbidity as a result of the pandemic, or does the exceptional care that they are having to take make it difficult to draw any statistical conclusion or evidence in that regard?

Mark Oakley: There is statistical evidence that has been gathered through the years of the pandemic that shows that the risk to people in this situation is that much higher. I say this off the top of my head, but I think that the higher risk of morbidity and a bad outcome is in the realms of the late 20s to early 30s, in percentage terms. That puts people in a difficult position, because it is a massive risk. Nobody wants to put themselves in that position. It is also having a knock-on effect on the health service.

We could be protecting, but we are not, the very people whom we do not want to be going into hospital, taking up beds and taking up the resources for an extended period of time, and that has a knock-on effect for every other appointment that has to

be cancelled for people with cancer and so on, because those resources are being taken up. We should be taking the opportunity and doing everything that we can to stop those people going into hospital, but we are not.

The Convener: Various members of the committee have at different times served on the Parliament's health committee, so we are familiar with the commissioning process and the way in which these things progress. From time to time, we have all lodged questions to ministers about the availability of product and, of course, they have always deferred to NICE, the Scottish Medicines Consortium and the processes that are at play in that regard.

I suppose that ministers' argument would be that, were they to act by exception, that would be at the cost of diverting resource away from treatments that have been through the commissioning process and been recommended to them. What would you say to them, as ministers who have to come to decisions in relation to the commissioning authorities, in the face of that conundrum?

Mark Oakley: As I said before, the people in this position are still living the pandemic. We used much quicker systems for assessing these drugs and getting them into place during the pandemic than we have for Evusheld. You need only look at the most recent vaccine to be approved by the Government. It went through the Medicines and Healthcare products Regulatory Agency and was put into use within two months, on very limited testing. That is exactly right. That is what should happen in that situation. It is needed, and it needs to be assessed quickly. To put a drug like Evusheld through a prolonged process when so many people are affected by that is just wrong. It is unfathomable, to be honest, and it is cruel.

The Convener: I understand. Essentially, you feel that Evusheld should be the subject of the same emergency provisions as applied at the height of the pandemic, in order to accelerate consideration.

Alexander Stewart: Thank you for your comments so far. NICE has already done some appraisals and some technological outlook work to see what has been happening with the product in question. Are you aware of any other countries that are using Evusheld that have carried out appraisals or technological processes that are similar to those that are being undertaken by NICE?

Mark Oakley: It is being used in every G7 country. It is being used in 32 countries around the world. The European Medicines Agency sanctioned it. I understand from people we have spoken to that even Japan, which, normally, is notorious as being one of the slowest countries to recommend and implement use of drugs, has assessed it and brought it into use, yet here we are lagging behind. Worldwide, it is being used by a lot of countries.

Alexander Stewart: There was a health authority in one country—was it Ontario Health?—that had some issues with Evusheld. I think that Ontario Health would not

recommend its being used routinely. Are you aware of any other countries that have withdrawn it or are having difficulty with it?

Mark Oakley: As I said earlier, the Food and Drug Administration in America has temporarily suspended its use. That is because of the make-up of the Covid variants there at present. However, the FDA has made it clear that the intention is, once the variant mix changes, to bring the drug back into use. It has told medical facilities not to get rid of their stocks of the drug so that it can be used again and rolled out.

The Convener: I acknowledge that many other countries moved very quickly at a point when the drug could have been introduced and we did not. I understand that NICE and the SMC were participants in a meeting that took place a fortnight ago, and that they are now talking about final guidance being produced in April. I suspect that there is not a lot that the committee will be able to do that will accelerate the process, but I understand everything that you are saying as to why the petition is there and why you think it should succeed.

The petition also brings home lessons that could be learned, because who knows what situation we might face again? It seems that, at one point, there was a process. That process has been normalised back to existing practice and, therefore, people are struggling. This session has been very helpful to us in understanding the issues.

Fergus Ewing: Good morning. The information that has been provided to us suggests that around 650,000 people in the UK and around 80,000 in Scotland are immunosuppressed. We are advised that all those people are at high risk of serious illness or death. Obviously, we accept that this is an extremely serious matter that affects a great number of people.

Mark Oakley has mentioned a couple of times that people in this situation, who lack access to Evusheld, have been shielding. Do you have any hard evidence about how many or what proportion of the 80,000 or the 650,000 are actually shielding? As you have said, to have to shield for such a long time imposes an enormous strain—an unimaginable strain—on the individuals concerned. Nikola Brigden remarked upon that earlier. I might have missed this, but what I do not see is any evidence—if there is any; it might not be possible to obtain any—about how many of this group of people are still shielding and have been shielding for several years.

Mark Oakley: That is difficult to quantify. Even the figures on the number of people who are affected are from the NHS, and it is not entirely clear on its figures. Certainly, from our group’s experience, the vast majority of our 3,000 members are either shielding or living a very restricted life, which involves being very careful about where they go and what they do, and not taking part in normal activities that members of the committee and the vast majority of the population do not think about any more—activities such as going to a pub and taking a train or a bus.

Judging by our group, it is still a high number of people. It must be remembered that, for every person who is immunocompromised and who is having to deal with this, in most cases there is at least one other family member who is also having to put their life on hold to some extent. We have had members who have lived separately from their family at various times. I lived away from my family for nearly nine months, on and off; at times, I lived in a summer house in the garden when the risks were difficult.

There are people who are not able to go to work. At a time when, nationally, the workforce is missing people, we have lots of examples of people who are having to make a choice between working and not working. We were contacted by a school teacher whose school had removed the mitigations to protect her. She was left with a stark choice of whether to carry on working and put herself at risk or whether to go back and shield. She has done the latter with no financial support.

It is an ever-changing picture and it is very difficult to quantify, but certainly a high number of people are having to live their lives in a really restricted way, which is extremely difficult, mentally, for them and their family.

Fergus Ewing: I appreciate everything that you have said. It is an extremely serious matter. Nikola, do you have anything to add?

Nikola Brigden: To pick up on what Mark said, there are lots of articles in the newspapers about the lost workforce. Where have all those skilled people gone? The immunocompromised represent so many people. My husband is a remotely operated vehicle pilot. The issue affects the whole spectrum of professions. People who could go back to work cannot because they are not safe.

The other important issue that we need to mention is that it is not just Evusheld that we are talking about. There is a lack of protections in place for the immunocompromised. If they catch Covid, access to treatment is very limited, with some types of drugs potentially being withdrawn, which is another worry. We know from the reports on the group that whether people can access treatment if they catch Covid is hit and miss. That adds another layer of worry for the people whom we represent. The whole system needs to be looked at.

The Convener: I thank both of you for being with us this morning. The committee very much appreciates the personal circumstance of both of you individually, which, unfortunately, is a variation on a theme that is extraordinarily difficult.

What you have told us has been very helpful. We will give urgent consideration to what, if anything, we can do that might be useful and will act accordingly, but thank you very much for giving evidence to us to allow us to consider the petition further.

Colleagues, are we content to consider the evidence that we have heard later in private? *Members indicated agreement.*