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.

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

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[08/09/2022]

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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