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.