Dr Thérèse Coffey MP,
Secretary of State for Health and Social Care,
House of Commons,
London
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26th September 2022

Open letter to the Right Honourable Dr Thérèse Coffey MP, Secretary of State for Health and Social Care

Proposal to facilitate the use of Evusheld as a pre-exposure prophylactic treatment against COVID-19 disease in clinically extremely vulnerable individuals in the UK

Dear Dr Coffey

Congratulations on your appointment as Secretary of State for Health and Social Care.

We trust that you are aware of the drug Evusheld (cilgavimab and tixagevimab), a combination of two long-acting antibodies developed by AstraZeneca and approved by the Medicines and Healthcare products Regulatory Agency (MHRA) on 17 March 2022.

Evusheld is intended to be used as a pre-exposure prophylactic for the prevention of COVID-19 disease in persons who are clinically extremely vulnerable, for whom the infection remains extremely dangerous. For many of these individuals, immunosuppression leads to inadequate protection from COVID-19 vaccines. Furthermore, there are people for whom the COVID-19 vaccines are not clinically recommended, thus have no protection against COVID-19 disease. For these people, Evusheld was a promising development with the possibility of effective protection against COVID-19 disease, and perhaps their return to a more normal lifestyle.

A thorough and careful review of the safety and effectiveness of Evusheld by the Commission on Human Medicines provided favourable results. Nonetheless, Evusheld has not been endorsed by the UK government, and the drug is therefore not available for people at increased risk of severe COVID-19 disease. A recent publication in The BMJ¹ suggested the reason for this is the lack of efficacy data against currently circulating Omicron variants of SARS-CoV-2.

It has been proposed that AstraZeneca will determine whether any real-world evidence has emerged from other countries. Meanwhile, Evusheld will be submitted for full NICE approval, which may take up to 20 months. However, with the winter months approaching it is becoming increasingly important to provide immunocompromised and vulnerable individuals with protection against COVID-19; for these people, providing additional vaccine doses is not sufficient.

COVID-19 vaccines were adopted into the immunisation programme with data from the clinical trials on their safety and efficacy. Rapid and efficient understanding of the benefits and risks of the vaccines was enabled by post-authorisation monitoring of spontaneous reports of adverse reactions by the UK’s excellent Yellow Card Scheme and with observational studies. Products used for treatment of COVID-19 were handled in the same way (initial results from clinical trials were augmented by subsequent observational studies). A similar approach could be used for Evusheld.

Using observational studies to monitor the safety and effectiveness of medicines with frequent early interim reports is an internationally accepted approach supported by the MHRA. It enables early access to medicines that meet patients’ unmet needs with close monitoring of their effectiveness and safety. Early actions can be taken where necessary.

An observational study (a product registry) could be conducted in the UK to collect safety and effectiveness information from users of Evusheld in real-world clinical use. Data could be collected on the occurrence of breakthrough SARS-CoV-2 infections, results of regular antigen and antibody testing, and safety outcomes. This study with its high external validity will add to the information available from the clinical trials and the findings of post-authorisation studies in countries where Evusheld is being used.

There is already much discussion in patient groups, the British press, social media and in the medical profession about how clinically extremely vulnerable members of our society have been let down by the UK government during the COVID-19 pandemic. Indeed, there have been COVID-19 deaths amongst this patient subgroup since Evusheld was approved by the MRHA, which perhaps could have been prevented with use of this drug. There will be numerous COVID-19 related hospitalisations amongst clinically extremely vulnerable people if they remain unprotected. We are happy to discuss our proposed approach with you and colleagues at DoH and JCVI. Our approach is supported by good quality science and aims to significantly reduce or prevent serious morbidity and mortality. We implore you to prioritise this as one of your first tasks in your new position as Secretary of State for Health and Social Care.

Yours Sincerely,

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