



Dr Susan Walsh
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By Email: susan.walsh@immunodeficiencyuk.org

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**Medicines & Healthcare products
Regulatory Agency**

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Dear Dr Walsh,

Access to passive immunity therapies for the immunodeficiency community

Thank you for your email of May 20th detailing the concerns from patients with immunodeficiencies.

The MHRA is fully aware of the particular difficulties faced by patients with primary and secondary immunodeficiencies and that COVID-19 vaccines may not be of direct benefit to them. We recognise the opportunity these patients have to be treated with monoclonal antibodies as passive immunity against the SARS-CoV-2 virus and COVID-19 disease. We fully appreciate the concern these patients have about the limitations of vaccines and they are at the forefront of our efforts to find the most appropriate treatments for them working with our healthcare partners including the public health bodies.

We have been in regular contact with all the companies developing COVID-19 monoclonal antibody therapies and we have been receiving regular updates on their progress in acquiring the necessary quality, safety and efficacy data for these products. We in turn, have engaged in discussions with the MHRA's Expert Advisory Groups keeping them informed of the developments and seeking advice on the most effective and safe treatments in these special clinical circumstances. Once complete data on the quality, safety and efficacy of these products are submitted to the MHRA, we will review the submission expeditiously and seek advice from the Commission on Human Medicines regarding grant of a Marketing Authorisation in the UK.

Please note that we are unable to discuss specific company details and data submissions until the independent review process is complete.

We would also like to reassure you that at the MHRA we are committed to providing safe and timely access to treatments for UK patients; we give priority to products intended to treat COVID-19 disease.

Yours sincerely,



Dr June M Raine
CEO, MHRA