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Evusheld for the UK
By email

The Rt. Hon. Therese Coffey MP
Secretary of State for Health and Social Care
Department of Health and Social Care
39 Victoria Street
London SW1H 0EU

16th September 2022

Dear Secretary of State,

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

We are an independent patient campaigning group writing on a serious matter left unaddressed by your predecessor, which Lord Lansley of your party called a "failure of government" on national radio. Along with 18 national charities and with the support of 125 practicing clinicians from across 16 disciplines, coordinated by Dr Lennard Lee of Oxford University, we wrote to Mr Barclay to urge the government urgently to procure the prophylactic monoclonal antibody therapy, Evusheld. This drug protects the clinically vulnerable who do not respond to Covid vaccines. It is in use by 32 other countries and the UK is at odds with worldwide consensus in not protecting its vulnerable population by using Evusheld. Real-world studies have shown a 92% reduction in hospitalisation when using the drug.

As I am sure you are aware, Mr Barclay responded the day before he left his post, answering some of the points raised in our letter and partially explaining the decision by the government not to roll out this essential preventative drug for the Autumn/Winter protection plan for this year.

We are therefore writing to you as a matter of urgency to deal with the points contained within this letter and to make you aware further of the situation regarding those affected by this decision, as well as the effects on the NHS. There are fundamental problems with the DHSC response.

Data and Testing

With respect to testing and the claimed lack of data, the MHRA itself noted that there was no reason to doubt the long-term effectiveness of the drug against the omicron variant. There have been numerous studies worldwide and the drug is in widespread use in many countries already benefiting from its use. In Israel it is a key component in their protection plan, and the CDC in the United States have made it a priority to use in its protection plan for the immunocompromised and are seeing very good results with the higher recommended dosage. There is, in short, an abundance of real-world data that show this drug works. We would also point out that the Japanese Ministry of Health, Labour and Welfare, one of the most notoriously careful and protracted health departments in the world to take on new drugs, has now purchased the drug.

Laboratory studies do confirm some decreased neutralisation of this drug against certain Omicron variants, and this has been reflected by the adoption of the change in dose. It therefore seems that the DHSC's Antiviral and Therapeutics Taskforce is isolated in its opinion as to the degraded

effectiveness of Evusheld. In other words: 32 other countries looked at the same data and concluded the opposite of the UK's panel.

I am sure you can appreciate it is essential that all scientific studies are evaluated correctly and represented as such by the DHSC. The papers cited in the letter have shown the drug to be effective in 9 out of 10 patients in preventing hospitalisation and the authors of the papers assert ongoing effectiveness of the drug. The clear consensus is about whether the in-vitro data is robust enough to mean anything at all in terms of the latest and widespread real human data.

Testing virus assays in the laboratory can only tell us so much and they must come second to the evidence from real-world observational studies. Therefore, the assertion regarding testing and results referred to in the letter would not appear to be accurate.

Lack of Transparency and Due Process

We also have grave concerns about the process to which Evusheld has been subjected. There is a lack of clarity as to the remit of the RAPID-C19 Oversight committee and indeed the decision seems to lie outside their published remit/terms of reference. There is no transparency as to the makeup of the group or their expertise in this field. Despite asking for this since the decision was made no information has been forthcoming as to how and why the decision was made and upon what data it was based. No minutes, agendas or membership have been published. Nor has any data to back up the assertion of "11 reviews in 18 months". We asked NICE, via FOI, for details of RAPID-C19's meetings in July and August and were told that none had taken place, which seems to contradict the DHSC's claim that this committee was consulted.

No doubt you can appreciate that an issue of this import requires full transparency and the data looked at for these reviews must be made public. We are aware that members of the Expert Policy Working group, who were looking at this issue, feel that their views have been misinterpreted and they had not been consulted on the decision to not go ahead with the use of the drug in the Winter plan.

Antibody Testing, Rollout Process, and Further Trials

Mr Barclay's letter also raises doubt with respect to identifying who would receive Evusheld. This is clearly incorrect. This issue has already been resolved with the publication of the Definition of the Highest Clinical Subgroups paper for the use of the drug on 30th May 2022, which is currently published on the NHS website.

The letter also mentions the use of antibody testing to identify patients. This is extremely problematic. There has already been a study carried out (MELODY) to improve understanding of responses to COVID 19 vaccinations in individuals who are receiving immunosuppression. This provided valuable information on vaccine efficacy in clinically vulnerable patients. However, as we are sure you are aware, the use of antibody testing is still in its infancy in terms of the interpretation of results and would quite simply add another layer of complexity and cost to this issue. Indeed the CDC in the United States have stated that such tests are *not* to be used in the rollout as they will slow it down and the results cannot accurately be interpreted and they are administering the drug based on cohort eligibility, in the same way as are other countries.

I note the letter also refers to a possible trial, however full trials, such as the PROVENT trial, have already been successfully carried out and any further trials would simply prolong the time taken before this effective drug could be implemented. The PROVENT trial involved 5000 people and

showed there was a 77% reduction in the risk of developing symptomatic covid. It seems totally unclear why this urgently needed drug is now having to undergo such a full appraisal compared to other Covid-19 treatments, which have undergone fast-track assessment and introduction. Indeed the latest Moderna vaccine has been quite rightly rolled out just two months after authorisation with testing on just 437 trialists, and was not required to be placed under such stringent examination by NICE. There is a total inequality to how this live saving and life changing drug is being treated.

Impact on Patient Cohort and Strain on NHS ICUs from Immunocompromised Patients

There are in the region of 500,000 immunocompromised patients in the UK, covering a wide range of conditions. At present a large number of those affected are still not able to live full and unrestricted lives. The NHS guidelines for those at high risk dated 23rd May, are still in place detailing what protective measures they should take and many are still undertaking some form of shielding. Many now face their third winter under such conditions and they have been living under these precautions for 2 ½ years. Those affected cover all ages and abilities and in many cases education and working lives have had to be put on hold or stopped completely. There is no support for those affected and many are simply living off of their savings. As the cost-of-living crisis starts to hit, we are already seeing patients struggling to survive and this is only set to get worse. For many they already face higher living costs, with having to get shopping delivered, to avoid going to shops, increased costs for power as they have to run medical machinery, in addition to normal household costs. Others who are less fortunate are having to choose between their safety and putting themselves at risk by returning to work. At a time when employers are struggling to fill vacancies, the situation has also taken a large number of people involuntarily out of the workforce. It has also taken a large number of people out of the country's economic model, as those shielding are hardly full economic citizens.

It should be made clear that the situation does not just affect those that are immunosuppressed, but families that live within the household. Extra precautions for family members limit those who could otherwise carry on life as normal, again affecting education and work as well as social life. The continued toll of living under these conditions has mental health consequences for those involved, with many suffering from anxiety and feelings of isolation and depression.

The reality of the situation for those that are immunocompromised is stark. Despite the continued message that the government is providing additional vaccines and Covid treatments, the reality is different for those affected. Vaccines offer little or no protection for those in this position. For Covid treatments to be effective there is a small window of opportunity to administer the drugs in order for them to be effective. The most recent QCovid data figures show that of those eligible only 13.2% were able to access them. It should also be pointed out that Sotrovimab has been viewed as ineffective and has now been withdrawn by the CDC in The United States (also on the advice of the WHO). This leaves an immunocompromised person with the option of trying to carry on a normal life and live with Covid, or shield themselves away from the risks. Considering that 33% of patients in intensive care are immunocompromised and that 1 in 5 covid cases are contracted in health care settings, it is no surprise that many are choosing to shield themselves away. This surely cannot be the way for patients, many of whom have gone through expensive and life changing challenges such as transplants in order to live a normal life, to be treated and left in this limbo.

NHS leaders have recognised that this winter will be exceptionally difficult, with Covid waves predicted to be at a level of 1 in 15, alongside seasonal flu and the increased demand from the existing patient backlog. Even now the majority of those in ICU beds are immunocompromised. To leave those at the highest risk without protection will have a significant knock-on effect for the rest of the NHS. Previous waves have shown how quickly resources are stretched across all departments with routine appointments cancelled and Accident and Emergency depts becoming swamped due to

resources being deployed elsewhere. At a time when the A,B,C,D plan seeks to remove those that don't clinically need to be in hospital, it seems counterintuitive to ignore this issue and place a further strain on the resources by increasing the risk of them being there. Indeed when DHSC announced its decision on Radio 4 on August 12th, the following day they conducted interviews with former Health Ministers Lord Lansley and Rt Hon Jeremy Hunt. Both stated that they felt the decision not to deploy Evusheld was a mistake and any steps that could be taken to reduce impact and remove the most vulnerable patients from needing hospital resources should be taken.

Finally, we are very concerned by the assertion in Mr Barclay's letter that "the risks of proceeding to patient access are considered to outweigh the risks of not providing this treatment in the current pandemic context". The assumption seems to be, here, that because the protection is not perfect, patients will misjudge the benefits and place themselves at additional risk. This is incredibly patronising. The general population also does not have complete protection from vaccines, but they have been given the courtesy of being able to appraise this for themselves, rather than the decision being imposed from above. The patients we represent merely want the additional protection conferred by Evusheld, even if not perfect.

Conclusion and Next Steps

The letter we received states that it was doubted whether the drug could be rolled out in time to all those on the cohorts for the winter plan. This seems to be giving up before even trying. Any protection Evusheld gives now is far superior to what is in place at the moment. The NHS has shown how quickly they can work with rolling out vaccines across the entire population. Even if only 50% could effectively be given the drug during the program, it would have a large impact in reducing immediate strain and prevention of further necessary costly treatments. The Swiss SSI has concluded that costs of providing Evusheld are far outweighed by the obvious savings in both short and long term by one person being admitted to ICU. It should also be borne in mind that the greatest risk of the escape of new variants is through the immunocompromised and by doing nothing to prevent this, it is magnifying this risk to the general population and economy massively.

We fully recognise that no drug is ever perfect, and this is proved by the efficacy of many of the vaccines, however we wish to be clear that this is an ongoing situation that simply cannot be allowed to continue. The effects on people's health, the inequality of the way they are being treated and the impending effect this will have on the NHS and knock-on effect for other patients not affected by this issue, means it is a problem that needs addressing now, not in a years' time when the NICE review has been completed. From every angle the decision not to roll out Evusheld in order to give some protection to the immunocompromised seems to defy any form of logic and we strongly question how this fits in with good patient care. People in this position are not there by choice and cannot be expected to carry the burden of living with covid.

We are aware of an ever-increasing call for this situation to be reversed from many MPs and Peers, evidenced by over 100 questions being asked in the House. The issue has received considerable traction across all forms of media across the political spectrum, as well as many in the clinical world, both at home and abroad, and all are keen to continue to follow this important issue.

As a group we are more than happy to work to find a solution to this issue and we would ask the courtesy of a meeting to discuss the matter from both a patient and practical clinical perspective. We do not see this as a political issue, simply a humanitarian one that is about to get worse, unless you take the brave decision to review and overturn the matter. We and the charities we work alongside would welcome and publicly support such a move.

We wholly appreciate your time in reading what is a lengthy but necessary letter and look forward to your reply

Yours Sincerely

Mark Oakley
Nikola Brigden
Prof Martin Eve

For and on behalf of Evusheld for the UK