Department of Health & Social Care

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The Rt Hon Sir George Howarth MP
By email to: george.howarth.mp@parliament.uk

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Dear George,

Thank you for your correspondence of 15 September to Matt Hancock, on behalf of a number of your constituents, about the discontinuation of Priadel (lithium carbonate) 200mg and 400mg tablets and the price of Camcolit. I have been asked to reply and I apologise for the delay in doing so, which has been caused by an unprecedented volume of correspondence in recent months.

I am aware of this very serious issue and of the concerns not only from the Royal Colleges but from patients and their families. Pleased be assured that, like you, I want to do all I can to help mitigate the risks associated with this matter.

The Department has well-established procedures to deal with medicine shortages arising in the community and in hospitals, whatever the cause. We can take a range of actions to help mitigate and manage any issues. This includes working with the Medicines and Healthcare products Regulatory Agency to expedite regulatory procedures and with manufacturers to manage remaining supply and expedite the delivery of further stock. We will also work with alternative suppliers to meet demand, commissioning clinical advice on alternative options from specialist groups and, in some cases, working with specialist importer companies to obtain unlicensed products from abroad.

Since January 2019, it has been a mandatory requirement that pharmaceutical companies report information to the Department regarding any supply issues in a timely manner. The new requirement aims to highlight potential medicine supply issues, and to ensure that we have relevant information at the earliest point possible to help manage supply shortages and mitigate any potential impact on patients. Furthermore, we have implemented restrictions on the export of certain medicines that are in short supply to help ensure people can continue to access the medicines they need.

Essential Pharma, the sole supplier of Priadel tablets in the UK, notified the Department in April of its decision to discontinue this product from October. The reason provided was that the product was uneconomic to maintain on the market. Departmental officials had several conversations with the company, with the aim of reversing its decision to discontinue the product.

As part of ongoing discussions, it was made clear to the company that the Department has well-established and flexible mechanisms in place under the 2019 Voluntary Scheme for Branded Medicines Pricing and Access for the consideration and award of price increases where required, which include the evaluation of clinical need to maintain supplies of a product.

The company was reluctant to apply for a price increase, but was eventually persuaded to provide the required financial information to assess the merits for this. Unfortunately, the price increase requested by Essential Pharma was not allowable under the Scheme's rules. We were willing to discuss this request further, but the company declined. However, the company agreed to extend the discontinuation to April 2021.

By way of background, in 2015 another company within the Essential group of companies applied for a price increase to Camcolit (lithium carbonate) 400mg controlled release tablets. The price increase was agreed, based on the financial information provided at the time, and largely because of a very small patient population, to allow the company to make a reasonable return.

Given that the patient population for Camcolit will increase considerably with the discontinuation of Priadel, the Department explored several options to mitigate the increased costs and impact on patients, including bringing the issue to the attention of the Competition and Markets Authority (CMA), which has opened an investigation into possible abuse by Essential Pharma of a dominant position in the supply of lithium-based medicines. We have been working closely with the CMA and, due to the detrimental impact on patients, requested that it take urgent interim measures to require Essential Pharma to continue to supply Priadel whilst a full and thorough investigation is carried out. Following the opening of the CMA's investigation, Essential Pharma informed the Department on 6 October that, with immediate effect, it has withdrawn its Discontinuation Notice for Priadel and will continue to supply the medicine in the UK to facilitate discussions on pricing.

I am pleased to say that this has removed the immediate risk to supply for patients. We are working urgently with Essential Pharma to understand stock availability to reassure patients and clinicians that this product will remain available in the immediate future. We will soon issue updated guidance to the NHS regarding management of patients, and will be working with Essential Pharma to explore the long-term viability of this medicine.

The Department is aware of difficulties reported by pharmacies in obtaining Camcolit and Priadel tablets and is in regular contact with Essential Pharma. As part of the management plan for the expected discontinuation, Essential Pharma placed quotas with wholesalers based on historic ordering patterns for both products. Although quotas are in place to prevent stockpiling, purchasers can contact Movianto if additional stocks are required. These arrangements remain in place.

We continue to engage with manufacturers of all lithium carbonate preparations (Liskonum 450mg tablets, Priadel 200mg and 400mg tablets, Camcolit 400mg tablets and lithium carbonate Essential Pharma 250mg) to ensure adequate supplies remain available.

With regard to importing unlicensed Priadel tablets from abroad, we have proactively engaged with Essential Pharma to establish all alternative supply options. The company has indicated that Priadel tablets will be available across Europe; however, certain countries have quotas in place to safeguard supplies to local markets and therefore availability of imports cannot be guaranteed. In order to safeguard our supplies, we have added lithium carbonate tablets to the parallel export restriction list that came into effect on 8 September.

We understand the importance of careful management of any changes to a patient's lithium treatment, which is why the Department is working closely with NHS England and NHS Improvement and with senior representatives from mental health, pharmacy and primary care to support all affected healthcare professions, patients and their carers across primary and secondary care. A supply disruption alert was shared on 21 August.

I hope this reply is helpful.

LORD BETHELL