



Department
of Health &
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From the Baroness Blackwood
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Stephen Doughty MP
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Dear Stephen

Thank you for your correspondence of 18 March to Matt Hancock about the supply of HIV medicines after the UK leaves the EU.

I appreciate your concerns. We understand the importance of this issue to those patients with complex conditions, and I am grateful to you for taking the time to raise this matter.

I would like to reassure you that patients can be confident in the Government's contingency plans. These include sensible mitigations for medicines, such as precautionary stockpiling by suppliers, to ensure that the supply of essential medicines to patients are not disrupted.

Separately, the Department has introduced a new regulation into the Human Medicines Regulation 2012 to allow ministers to issue serious shortage protocols. This is not part of the Department's contingency planning for if the UK leaves the EU without a deal. It is an additional tool to manage supply shortages of medicines and to mitigate the impact on patients. In the event of a serious shortage of a prescription-only medicine, a protocol that helps manage a specific shortage can be issued. A protocol can specify that a community pharmacist can, if appropriate, supply an alternative quantity, an alternative pharmaceutical form, an alternative strength, a therapeutic equivalent or a generic equivalent, without going back to the prescriber.

Serious shortage protocols can help patients get timely access to medicines, easing pressure on GPs and therefore increasing their availability to see more patients with complex health needs, including where any medication changes are required.

Any protocol would be developed with input from clinicians, ensuring that strong safeguards are in place. Community pharmacists can only supply something different to what is set out on the prescription if the protocol allows it. Each protocol would clearly set out what action can be taken by the community pharmacy, under what circumstances, for which patients and during which period. Pharmacists will still have to use their professional discretion as to whether supplying in line with the protocol is appropriate, or whether the patient needs to be referred back to their prescriber.

Protocols would only be issued in exceptional circumstances. Protocols for a different quantity, strength or pharmaceutical form are likely to be more common than protocols for a therapeutic or generic equivalent, which would only be used in very exceptional circumstances.

Protocols for therapeutic or generic equivalents will not be suitable for all medicines. For example, such protocols would not be suitable for treatments that must be prescribed by brand for clinical reasons, which includes anti-epilepsy medicines and lithium. In line with guidance from the Medicines and Healthcare products Regulatory Agency (MHRA), in these cases, patients would always be referred to their prescriber for any decision about their treatment before any therapeutic or generic alternative is supplied.

The Department always works with the industry, the NHS and the MHRA to mitigate the impact of supply issues on patients. A protocol would only be introduced in case of a serious shortage, if it would help manage the supply situation, if clinicians think it is appropriate, and after discussions with the manufacturer and/or marketing authorisation holder. The operation of the serious shortage protocol legislation will be reviewed one year after the first protocol has been issued.

I want to assure you that our commitment to ensuring that patients have safe and timely access to medicines remains unchanged. We know that maintaining continuity of supply of all medical products, including medicines, medical radioisotopes, vaccines, blood products, devices and consumables, after the UK leaves the EU is essential.

Leaving the EU with a deal remains the Government's top priority. We are considering the impact of the EU exit date being extended until 31 October on our preparations, and are working closely with our stakeholders to review our position. We know that HIV medications are vitally important and we have a multi-layered

approach to minimise any supply disruption, whatever the outcome of the UK's exit from the EU.

Under the conditions of the Withdrawal Agreement, there will be a two-year Implementation Period, within which we will negotiate the UK's future relationship with the EU. During the Implementation Period, there will be no change to the current trading arrangements with the EU and European Economic Area, meaning the supply of medicines and medical products will continue unhindered.

However, as a responsible Government, we are planning for all potential outcomes, including 'no deal'. The Department is working closely with trade bodies, product suppliers, the health and care system in England, the Devolved Administrations and Crown Dependencies to ensure continuation of the supply of medicines and medical products to the whole UK in the event of a no-deal EU exit.

I hope this reply is helpful.

Best wish

Nicola

NICOLA BLACKWOOD

