Department of Health & Social Care

From Edward Argar MP
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Lord Teverson
By email to: EUCLORDS@parliament.uk

22 January 2021

Dear Robin,

Thank for your letter of 25 November 2020 on the supply of pharmaceuticals to Northern Ireland. I apologize for the delay in replying. I'm conscious that events have moved on since but let me address your points.

As you noted in your letter, the Department and Cabinet Office have been working hard with the EU to find a mutually acceptable approach to full implementation of the Northern Ireland Protocol with respect to medicines. Recognising the challenges, not least with the ongoing COVID-19 response, in adapting to the requirements of the Protocol, the parties recognised the need to provide further time for the industry to be ready to comply in full. The parties therefore agreed a pragmatic approach to implementation, including the one-year time-limited approach to the application of the regulatory requirements for imports and the 'safety feature' elements of the Falsified Medicines Directive (FMD) that you referred to. #On 10 December 2020, the EU published a unilateral declaration, noted by the UK, which sets out the principles of this agreement.

In respect to your two questions, you asked us when guidance will be published that sets out how the one-year phased implementation period will work in practice. On 11 December 2020, the Medicines and Healthcare products Regulatory Agency (MHRA) published guidance setting out that companies will have 12 months from 1 January 2021 during which they can continue to supply medicines to Northern Ireland in much the same way as they have previously done, and after which they will need to be compliant with regulatory importation and Falsified Medicines Directive safety features requirements when supplying medicines from Great Britain to Northern Ireland. This guidance has subsequently been updated, most recently on 31 December 2020. Guidance on supplying medicines to Northern Ireland can be found here: https://www.gov.uk/guidance/supplying-authorised-medicines-to-northern-ireland. Guidance on supplying investigational medicinal products (IMPs) to Northern Ireland is available here: https://www.gov.uk/guidance/supplying-investigational-medicinal-products-to-northern-ireland.

To your second point, the 12-month phased implementation provides the time and flexibility industry needs to plan and implement long-term solutions to supply Northern Ireland under the Protocol. This may include using the Common Transit Convention (CTC) or rerouting supply directly to Northern Ireland. We are currently working internally and with industry partners to agree a new approach to 2022 readiness and aim to communicate this as soon as possible, and I look forward to discussing this with your Committee.

Our strong relationship with the pharmaceutical industry has been pivotal for our approach to the end of the Transition Period and we continue constant engagement with industry partners – this will be vital to help ensure readiness for 1 January 2022. Officials from my Department, the MHRA and Northern Ireland's Department of Health are working closely with industry to support them to take the action needed over the next 12 months to help ensure readiness for the full implementation of regulations from 2022.

More Broadly, on 10 December 2020, the Government announced £400m of new money guaranteed in a 'New Deal for Northern Ireland' to help boost economic growth, increase Northern Ireland's competitiveness and invest in infrastructure. As noted in the Command Paper published on the same day, we will support the pharmaceutical industry to make the long-term changes it needs to supply under the terms of the Protocol, such as support for the delivery of additional warehousing capacity in Northern Ireland, if appropriate. The Command Paper can be found here: https://www.gov.uk/government/publications/the-uks-approach-to-the-northern-ireland-protocol.

I hope this information helps provides reassurance in respect of the questions you raised. I am sure you will understand it would be premature for me to include further detail of our plan for 2022 readiness at this point, as further engagement with industry, which is already underway, is required to confirm the details of the approach before finalisation. However, you have my commitment to work openly and collaboratively with your Committee as this work progresses, and I will be happy to answer any further questions you may have now or once the 2022 plan is communicated.

EDWARD ARGAR MP