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The Lord Jay of Ewelme GCMG
Chair of the Protocol on Ireland/Northern Ireland Sub-Committee
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4th May 2022

Dear Michael,

Thank you for your letter of 18 March regarding the European Union (EU) proposals for the supply of medicines to Northern Ireland (NI). My officials have confirmed that a response was sent out on 28 March by Minister Cleverley in response to your previous two letters; I would like to apologise for the delay.

I note that the Minister Cleverley's letter provided an overview of the UK Government's analysis of the EU proposal and a summary of industry feedback. I would be happy to respond to the additional questions from your most recent letter that were not addressed in the response that was shared with you.

UK Government engagement with the Commission

It is worth starting by noting that the EU proposals were published in the Official Journal of the European Union on 20 April 2022, concluding the legislative process and brining the proposals into force retroactively from January 2022.

In your letter, you asked about some of the follow up engagement the UK government has been doing with the Commission and whether we plan to re-enter talks. There are two main risks that we are continuing to monitor: the application of EU law for centrally authorised products (CAPs) and the three-year deadline on the falsified medicines directive (FMD). We raised these risks with the EU at the Ireland / Northern Ireland Specialised Committee (INISC) meeting on 8 March 2022, and we requested ongoing technical discussions while the EU legislation progressed through Parliament.

Whilst we have not continued intensified talks on medicines, officials continue to meet with EU counterparts for negotiations on other sectors, as the UK is urgently seeking to address the issues of the Protocol. This means that channels are open and if there

is a clear risk to patient safety that we cannot address through domestic measures, we will raise this with the Commission. Our priority is patient safety and ensuring that patients in NI get the medicines that they need.

You also asked whether the UK government would continue to ask for the removal of medicines from the scope of the protocol entirely. The UK government proposed in July 2021 that the simplest way to ensure all citizens across the UK could have access to the same medicines at the same time was to remove medicines from the scope of the Protocol. We still consider removing medicines from the scope of the protocol to be the best option; however, we believe the EU legislation does address some of the immediate and urgent supply issues. We will continue to monitor the practical impact of the legislation now that it has been approved by the EU Council.

In your letter, you mentioned how the Commission may be treating medicines as a separate issue from that of the wider negotiations occurring across the protocol. We welcome the EU's recognition that there are serious problems which cannot be solved simply through ongoing implementation of the existing Protocol. We will continue to press for discussions on other areas, for example, we still need permanent solutions that address the supply issues facing veterinary medicines.

Impact of EU unilateral legislation

You mentioned that the Commission is progressing legislation unilaterally and you asked how the EU proposals concern Cyprus and Malta. Cyprus and Malta, historically, are reliant on medicine supply from the UK. The EU included these countries in the proposal as they recognised there would be a serious risk to the supply of medicines. A consultation on the EU proposal was conducted recently; the consensus from the responses gathered was that the proposal addresses the key issues raised concerning the supply of medicines to Cyprus, Ireland, and Malta. The EU proposal for medicines successfully passed a European Parliament vote on 7 April; this was a further opportunity for Cyprus and Malta to voice any concerns regarding medicine supply.

You also asked about what changes the UK will need to make to allow the EU proposals to function. Under the rules of the Protocol, the EU legislation will have direct effect in Northern Ireland; the UK does not need to make any legislative changes for the EU proposals to function. The MHRA has issued industry guidance on the interpretation of the grace period and will continue to issue more as the EU proposals become law. We are not aware of any plans to add annexes to the Protocol.

Discontinuations

I note that in your recent evidence session on 6 April you enquired about the most recent state of medicines discontinuations. DHSC does not publish lists of these products due to commercial sensitivity but there are a number of contingency

measures in place to help ensure supply of these medicines to patients.

First, we have a team of pharmacists who review discontinuation notifications and check whether there is a clinical alternative which can be supplemented. Second, if there is no licensed alternative medicine available, we can use the Northern Ireland MHRA Approved Route (NIMAR). NIMAR allows prescription medicines, which are unavailable in NI, to be supplied into NI if there is clinical need. This is compliant with UK and EU rules and can include medicines that are unlicensed in NI, but which are licensed and approved in GB. These medicines need to meet UK Government criteria and can only be supplied on a public health basis. These mitigations mean that there are no direct supply shortages for NI patients.

I trust this response is helpful and please do not hesitate to contact us should you have any further questions.

EDWARD ARGAR MP