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The Lord Jay of Ewelme GCMG
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Dear Michael,

Thank you for your letters of 18 November 2021 and 28 January regarding the Northern Ireland (NI) Protocol and medicines supply. I am responding as the Minister for Europe and North America.

Lord Frost was delayed in responding to your letter of November because of the ongoing discussions between the UK and the EU. It has since been important to take the time to scrutinise the EU's proposals before responding to both letters. I will start by setting out our current appraisal of the EU proposals, before turning to your questions which are not addressed via the Government's assessment about Provision of medicines- Northern Ireland Protocol.

Are you now able to share with us the Government's full assessment of the EU's proposals? To what extent do they resolve the issues around provision of medicines to Northern Ireland? What issues remain outstanding? What update can you give us on the UK-EU discussions on medicines? When do you expect these discussions to conclude?

As you know, the United Kingdom (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.

The EU, on 17 December 2021, published a unilateral package of measures intended to address the barriers to supplying medicines into NI. The package is made up of two parts: an extension to the existing grace period, and new legislative proposals which seek to resolve supply issues permanently.

The grace period, which provides flexibilities for supplying medicines in Northern Ireland,

has been extended until 31 December 2022, or until the legislative proposals come into force. This means that companies can continue to supply medicines to NI as they are now able to do, which avoids any risk of immediate supply issues.

The legislative proposals remove a requirement for batches of medicines to be re-tested when moved into NI; allow a single UK pack to be authorised for medicines sold in retail shops and for generic (non-branded) medicines; permit a temporary authorisation for novel medicines in NI, such as new cancer drugs, for up to six months when there are delays in the EU making a decision; and provide a temporary three-year derogation on certain EU Falsified Medicines Directive (FMD) requirements when medicines are transported from the EU and through Great Britain (GB) into NI.

Close engagement has taken place with stakeholders and industry have been broadly positive about the EU proposal. Webinars, hosted by DHSC and the MHRA, on the practical implications of the EU's proposals have taken place for industry stakeholders on 19th January, 2nd and 3rd February 2022. DHSC have also supported the Department of Health NI in engaging healthcare stakeholders on the proposals. Industry guidance has been published on the EU proposals in December with further guidance due to be published shortly.

The EU's package is not comprehensive however and there are two supply risks related to EU rules which we will need to keep under close review.

Firstly, EU authorised packs of novel medicines are still required for NI. Most novel medicines are widely available across the EU and are therefore eligible for supply to NI. As part of a temporary UK easement for industry until January 2024, suppliers can use EU packs for existing products in GB. We know that industry would have preferred a UK-wide route for these products, to ensure companies wouldn't need to supply NI and GB with two separate packs. During talks, my officials clearly set out that without a UK wide route, companies would need to supply NI with two separate licences; this may lead to some companies discontinuing novel medicines in NI or not launch them at all. The EU decided not to address this and so we will need to monitor how suppliers can adapt to supplying separate packs to GB and NI over time.

Secondly, we know that some industry stakeholders have raised concerns over the continual application of the EU FMD in NI. Our view is that FMD should not apply in NI. Despite this, the Commission decided they would be open to discussing this with us in the future.

To mitigate against these two risks, the NI MHRA Authorised Route (NIMAR) is being used to support the continuity of supply in NI. This route is fully compliant with UK law, with the NI Protocol, and with EU legislation. It makes sure patients in NI can access prescription only medicines at the same time as patients in GB. Discontinued products will now be substituted with the NIMAR alternative, which should maintain a constant supply of medicines. NIMAR can also be used for products that will be launched in GB but not in NI in the future. All medicinal products using NIMAR will have met the MHRA's stringent requirements for safety, quality, and efficacy. Doctors, pharmacists, and patients in Northern Ireland do not need to do anything different to prescribe or access

medicines through this route once medicines are included on the NIMAR list.

We note the EU proposal states that UK packs (excluding novel medicines) can be sold in NI on condition that UK rules on quality, safety and efficacy are 'essentially equivalent' to the international standards the EU follows. The UK Government is committed to following international standards in any future changes to its regulations.

We are closely monitoring supply and gathering evidence on the risks not dealt with in the EU's proposals. Our priority is patient safety and ensuring that patients in NI get the medicines that they need. If a clear risk emerges which we cannot address, we will raise this with the Commission. We must ensure that any solutions work in the long term. We remain committed to ensuring that citizens across the whole of the UK, including in NI, have access to the same medicines at the same time.

What update can you give on the scale of potential or confirmed medicine product withdrawals from Northern Ireland? Do you recognise the range of products and treatments that are likely to be affected as depicted by our witnesses? What impact has the standstill period announced in September had on the rate of notification of discontinuations? Have there been any reversals of such notifications?

The UK Government does not publish individual figures on discontinuations due to commercial sensitivities but has a robust management process in place. We would be happy to discuss this important risk with you further at your convenience.

What is your response to our witnesses' view that the different nature of medicine provisions in Ireland and Northern Ireland limits the scope for development of cross-border supply chains on the island of Ireland, and that the risk of leakage of medicines into the EU Single Market is consequently minimal?

Businesses are more likely to supply medicinal products to the bigger market in the UK, compared to the relatively smaller market such as in Ireland. This can be seen in the wider provision of low-profit generic medicines and early access to more expensive novel medicines in the UK, which has been cemented in clinical and consumer practice. As your witnesses commented, this means there is limited crossover in the availability and demand for medicines between Ireland and the UK, limiting the potential for developing cross-border supply chains on the island of Ireland.

We have also been very clear about the theoretical, and in any case very low, risk of leakage of medicines from NI into the Single Market. This is because of the strong regulatory controls on which products can be marketed in a territory. For example, a product with a national marketing authorisation (MA) for GB granted by the MHRA cannot be marketed in any other territory, just as a medicine with a national MA from the French regulator could not be marketed in Germany. The existing regulatory controls would prohibit such a UK product from being marketed in Ireland or any other Member State. Furthermore, as one of your witnesses pointed out, an absence of FMD unique identifiers on UK medicine packs would mean Irish pharmacists could not dispense these and nor could pharmacists in any other Member State. Under the EU proposal, FMD unique identifiers on UK packs supplied to NI will generate an alert if scanned in

EU Member States.

Do you share [the witnesses] view that there are no benefits deriving from the Protocol for the provision of medicines to Northern Ireland? If so, what is your response to those arguing that the recent announcement of the creation of 1,000 new pharmaceutical jobs in Northern Ireland over the next three years is evidence of the benefits to Northern Ireland of dual access to the UK and EU markets?

Almac Group's announcement in November 2021 of the creation of 1,800 new pharmaceutical jobs globally over the next three years, including 1,000 in NI and some in GB, is welcome news. Almac is a success story with a unique ownership arrangement that requires constant reinvestment of profits in its NI roots, so it is welcome and no surprise to see the creation of the new jobs in NI, especially given Almac's strong growth over the last 15 years and the increase in demand for its manufacturing and clinical trial services during the COVID-19 pandemic. However, this does not take away from the very real issues that have arisen from the Protocol for the supply chains on which patients in NI rely.

What is your detailed response to each of the outstanding issues highlighted by industry stakeholders and as set above, including concerning UK-based qualifying persons, Wholesale Dealers Authorisation, MR/DCP and combining UK and GB licences, and the need to retain equivalent standards between the UK and the EU?

The use of a UK based qualified person for pharmacovigilance (QPPV) allows some flexibility for licence holders although we note that this is only in instances when a licence holder does not have an EU based QPPV who can be used. A Wholesaler Dealer Authorisation (WDA) which is registered for a site in GB or NI and issued by the MHRA is indeed acceptable to import from GB or NI.

On the suggestion for industry guidance on changing GB to UK licences, in December the MHRA published guidance to reflect the EU proposals. The MHRA will shortly be publishing further guidance to assist companies who want to update GB or NI authorisations so that a single authorisation covers the whole of the UK.

In regard to the points raised on the UK's retaining its standards for medicine regulations, the MHRA is reviewing licensing procedures to optimise processes: improving overall efficiency and timing of approvals. The UK Government is also undertaking a review of medicine batch testing policies.

What is your response to continuing industry fears over the long-term impact of the requirement for compliance with EU Single Market rules for the ability of smaller UK wholesalers and distributors to supply Northern Ireland?

As you will know, the UK Government is continuing to discuss a range of issues with the European Commission on the Protocol, which need to be addressed urgently. The trade technicalities are important and need a long-term sustainable solution, especially for smaller UK wholesalers and distributors, but the talks also need to address issues of

identity, peace and stability.

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

Yours ever,

The Rt Hon. James Cleverly MP
Minister of State for Europe and North America