HOUSE OF LORDS
European Affairs Sub-Committee on the Protocol on Ireland/Northern Ireland

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Edward Argar MP
Minister of State (Minister for Health)
Department of Health and Social Care
39 Victoria Street
London SW1H 0EU

18 March 2022

Dear Minister,

C(21) 9668: COMMUNICATION TO THE COMMISSION Approval of the content of a draft Commission Notice on the application of the Union's pharmaceutical acquis in markets historically dependent on medicines supply from or through parts of the United Kingdom other than Northern Ireland

EM 15188/21: Proposal for a Directive of the European Parliament and of the Council amending Directives 2001/20/EC and 2001/83/EC as regards derogations from certain obligations concerning certain medicinal products for human use made available in the United Kingdom in respect of Northern Ireland, as well as in Cyprus, Ireland and Malta

EM 15189/21: Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) No 536/2014 as regards a derogation from certain obligations concerning investigational medicinal products made available in the United Kingdom with respect to Northern Ireland as well as in Cyprus, Ireland and Malta

EM 15291/21: COMMISSION DELEGATED REGULATION (EU) …/... of 17.12.2021 amending Delegated Regulation (EU) 2016/161 as regards the derogation from the obligation of wholesalers to decommission the unique identifier of medicinal products exported to the United Kingdom

Thank you for your Explanatory Memorandum, dated 24 February 2022, on the above documents relevant to Northern Ireland in the context of the Protocol on Ireland/Northern Ireland. The House of Lords Sub-Committee on the Protocol on Ireland/Northern Ireland considered these documents at its meeting on 16 March 2022.

As the EM notes, the Committee has already undertaken detailed scrutiny of the issues relating to provision of medicines to Northern Ireland, including through oral evidence from pharmaceutical industry representatives in October 2021, a detailed letter of 18 November summarising their concerns to Lord Frost (in view of his then ministerial responsibility for the Protocol), and a follow-up letter to the Foreign Secretary dated 28 January 2022, taking account of follow-up evidence from pharmaceutical industry representatives on the Commission proposals published in December and summarised in this EM. We regret that we have yet to receive a response to our two letters, and urge you, working with FCDO colleagues, to ensure that a reply to the specific points raised in these letters is received as swiftly as possible.

In view of this, and given the central importance of the provision of medicines for the people of Northern Ireland, we welcome your positive response to the request by Committee officials that these documents should be deposited in Parliament for scrutiny. However, we regret that this EM was not received until over two months after the publication of the proposals. In view of their importance for Northern Ireland, we stress the importance of prompt provision of documentation to the Committee to enable it to fulfil its scrutiny function.

We welcome the Government's analysis, as far as it goes, of the proposals as set out in the EM, although we note that the Government is still working to scrutinise fully "the legislative proposals to determine the extent to which they address the concerns that industry stakeholders have raised". Given that the proposals were published over two months ago, when will the Government complete this process of review and set out in full its analysis of the Commission's proposals?

We welcome the Government's engagement with the Northern Ireland Executive and industry stakeholders. Are you able to summarise the views and concerns that they have put to you? Have these been communicated to the Commission, and if so, what was its response?

In their feedback to us as set out in our letter of 28 January and subsequently, pharmaceutical industry representatives and other stakeholders told us that the Commission proposals were a significant step forward, but drew attention to a number of outstanding issues, including concerning:

- UK-based qualifying persons;
- Wholesale Dealers Authorisation;
- MR/DCP (Mutually Recognised Product/Decentralised Procedure);
- combining UK and GB licences;
- the continued application of the Falsified Medicines Directive to Northern Ireland (raising issues concerning the viability of FMD-compliant medicines packs for Northern Ireland only);
- how divergence between the European Medicines Authority and MHRA will be handled if the EMA refuse to issue a Marketing Authorisation for a product licensed by the MHRA for use in the UK;
- how variations to licencing conditions for Centrally Authorised Products will be managed;
- whether citizens in Northern Ireland (as well as citizens resident in Ireland but receiving treatment or prescription medicines in Northern Ireland, or using pharmacies there) will be able to take medicines out of Northern Ireland for personal use;
- the fact that Centralised Procedure licences are not covered by the EU proposals;
- the need to retain equivalent standards between the UK and the EU; and
- the proportionality of the criteria, monitoring and inspection to be used by the Commission in assessing whether the level of protection of public health provided in the UK is equivalent to that within the EU, and the consequences for Northern Ireland if the Commission judges that this is not the case.

Have each of these issues been highlighted in your own engagement with stakeholders? Have they drawn any other concerns to your attention? How is the Government seeking to take these issues forward, including in engagement with the Commission?

In view of these concerns, and given your statement that "the draft EU legislation was not jointly agreed with the UK Government and is being progressed unilaterally by the European

Commission" and that "the Government's preferred approach to medicines supply issues is to remove medicines entirely from the Protocol so that UK rules only apply", what is the Government's overall position in relation to agreement and implementation of these proposals? In particular, is the Government inviting the Commission to consider amendments to the proposals to meet industry concerns, or does it take the view that the proposals are as far as the Commission is willing to go? Alternatively, is the Government continuing to press for the removal of medicines from the Protocol?

Can you also clarify the political, legal and political implications of the legislation being progressed unilaterally by the Commission without agreement by the UK Government? In particular, what are the implications in terms of provision of legal certainty for industry and citizens? How will the legislative proposals have legal effect in Northern Ireland in the absence of UK agreement? Does the Commission wish to add them to the Annexes to the Protocol? If so, what is the Government's response?

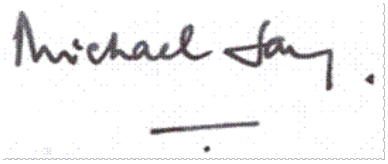
In that context, can you provide an update on and explain how this issue is being taken forward in the context of the continuing UK-EU discussions on the future of the Protocol? By bringing forward these proposals unilaterally, is the Commission seeking to treat the provision of medicines separately from the other issues under discussion? If so, what is the Government's response? What is the status of these proposals in the absence of progress on the other issues under discussion?

Finally, we note that aspects of the draft legislation also apply to Cyprus, Ireland and Malta in view of their historical reliance on medicine supply from Great Britain. Do you support this application? Do the Governments of Cyprus, Ireland and Malta support these measures insofar as they apply directly to them? What is the view of industry stakeholders either based in these countries or supplying them from Great Britain? Do the proposals go far enough to meet their concerns?

We would be grateful for a response to our questions before the House rises for the Easter recess, and therefore by 7 April 2022 at the latest. In the meantime we retain an active interest in these documents.

I am copying this letter to Rt Hon Elizabeth Truss MP, Secretary of State for Foreign, Commonwealth and Development Affairs, Rt Hon James Cleverly MP, Minister of State for Europe and North America, FCDO, Sir William Cash MP, Chair of the Commons European Scrutiny Committee, George Wilson, Clerk of the Commons European Scrutiny Committee, Simon Hoare MP, Chair of the Commons Northern Ireland Affairs Committee, Les Saunders and Donald Harris, Cabinet Office, Harry Flannery, Scrutiny Coordinator, Department of Health and Social Care, Robin Swann MLA, Minister of Health in the Northern Ireland Executive, and Colm Gildernew MLA, Chair of the Northern Ireland Assembly Committee for Health.

Yours sincerely,



Lord Jay of Ewelme
Chair of the Protocol on Ireland/Northern Ireland Sub-Committee