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European Affairs Sub-Committee on the Protocol on Ireland/Northern Ireland

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Rt Hon Elizabeth Truss MP
Secretary of State for Foreign,
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Foreign, Commonwealth and Development Office
King Charles Street
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28 January 2022

Dear Foreign Secretary,

PROVISION OF MEDICINES TO NORTHERN IRELAND UNDER THE PROTOCOL ON IRELAND/NORTHERN IRELAND

Summary

1. I am writing to you today in relation to the provision of medicines to Northern Ireland under the Protocol on Ireland/Northern Ireland:
    - Inviting you to respond to the Committee's detailed letter on this topic sent to Lord Frost on 18 November;
    - Asking for the Government's detailed analysis of the EU's proposals on provision of medicines published on 17 December, and the extent to which they will resolve the problems that have arisen;
    - Inviting your response to feedback provided to the Committee by pharmaceutical industry stakeholders, welcoming the progress that has been made towards a resolution of the issues;
    - Seeking your views on the various outstanding issues requiring resolution flagged up by industry stakeholders, and how the Government is seeking to address them;
    - Asking for an update on the current state of discussions between the UK and the EU on the provision of medicines to Northern Ireland.

Background

2. In our introductory report published in July 2021, we drew attention to the concerns of the pharmaceutical industry about the potential impact on the provision of medicines to Northern Ireland under the Protocol.

3. Following the publication of the Government's Command Paper, also in July, its unilateral announcement in September of a 'standstill period' for the various grace periods (including that on medicines), and the publication in October of the Commission's 'non-paper' on medicines (updating its previous paper published in July), the Committee held an evidence session on 20 October with representatives of the pharmaceuticals industry, to explore these issues further. The Committee also received supplementary written evidence from these organisations and other industry representatives who had previously submitted evidence to our introductory inquiry.

4. On 18 November, we wrote a detailed letter to Lord Frost, summarising the evidence we had received, and asking a series of questions, under the following headings:
    - The cost and operational impact of Brexit and the Protocol
    - The scale and risk of product withdrawal
    - The scope for cross-border provision on the island of Ireland and the risk to the EU Single Market
    - The impact of the extension of the grace periods for medicines
    - The EU's 13 October 'non-paper' on medicines
    - The Government's 21 July Command Paper
    - The new for a mutually agreed solution
    - Industry engagement

5. We were informed that Lord Frost was not able to respond to our questions by our deadline of 6 December due to the ongoing discussions between the UK and the EU. We understand that responsibility for a response to our letter now falls to you following your assumption of ministerial responsibility for the operation of the Protocol. Following the publication of the EU's proposals on provision of medicines on 17 December, we would be grateful for a prompt and detailed response to our 18 November letter.

The EU's December 2021 proposals

6. On 22 December, Edward Argar MP, Minister for Health, wrote to us following publication of the EU's proposal. He stated that the Government's initial reading was that the proposal "resolves some of the key problems", but that "the UK Government has been cautious about welcoming this proposal because we have not had sufficient time to review and scrutinise the legal text. We will begin this process now and will continue to work with the European Commission in January." **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?**

7. Given the significant implications of the EU proposals for the provision of medicines to the people of Northern Ireland, and to enable us to scrutinise it effectively, we stress the importance of deposit in Parliament of the EU Regulation and related documents published on 17 December , and the submission of a Government Explanatory Memorandum to this Committee, in the usual manner for EU legislation applying to Northern Ireland under the Protocol. We are grateful to have received confirmation from Government officials that these documents will be deposited, and look forward to timely receipt of the EM.

Stakeholder feedback

8. We sought the views on the EU's proposals of the pharmaceutical industry representatives that previously gave evidence to us.

9. PAGB welcomed the proposals, and expressed confidence that they would allow for the continued supply, distribution, and sale of OTC [over-the-counter] medicines in Northern Ireland. They also stated that the extension of the grace period to the end of December 2022 (or sooner if the legislation is in place) will ensure continuity of supply

of OTC medicines to Northern Ireland from 1 January 2022. They noted in particular that the EU proposals have addressed the following issues:

- "OTC/generic medicines (such as paracetamol) will be able to choose to authorise under national UK procedures, in compliance with EU rules on medicines. People in Northern Ireland will have access to these medicines at the same time as people in the rest of the UK.
- All regulatory functions can remain in the UK for national licences.
- For medicines brought into Northern Ireland from the rest of the UK, batch testing does not need to be repeated if it has already been carried out in Great Britain or the EU.
- No manufacturing authorisation or import licenses are needed for medicines supplied from Great Britain to Northern Ireland, subject to certain conditions.
- National authorisation by the UK regulator allows companies located in Great Britain to use a single pack and leaflet when supplying markets in Great Britain and Northern Ireland. There will be no need for separate packaging.
- The proposal provides for packaging requirements to ensure that UK-authorised medicines do not enter the Single EU Market.
- The UK assumes sole responsibility for authorising medicines for Northern Ireland. This is contingent on the UK complying substantively with EU law on quality, safety and efficacy of human medicines when issuing market authorisations for Northern Ireland. This reduces risks for the EU Single Market."

10. The Healthcare Distribution Association welcomed the provision in the EU proposals allowing for medicines tested and released in Great Britain to be distributed in Northern Ireland, and for medicines to be licensed UK-wide. They stated that "the responsibility is now with the MHRA and UK Government to make these positive proposals work in regulatory and operational terms."

11. Teva UK welcomed the "significant progress" and "constructive discussions" between the UK and the EU, which "mean that medicines supply from GB to NI remains in place and free from significant disruption".

12. **Do you share this positive stakeholder assessment of the EU proposals, in particular in terms of the provision of over-the-counter medicines to Northern Ireland, the extension of the grace period allowing for continuity of supply, the provision for medicines tested and released in Great Britain to be distributed in Northern Ireland, and allowance for medicines to be licensed UK-wide? How will you respond to industry stakeholders' calls on the MHRA and the Government to make these proposals work in regulatory and operational terms?**

Outstanding issues

13. Nevertheless, industry representatives each highlighted a number of outstanding issues.

14. PAGB stressed the importance of:

- Clarity on the circumstances in which a UK-based qualifying person (QP) may be used.

- Understanding of the implications of the proposal's (positive) reference that the QP for pharmacovigilance may be located in a part of the UK other than Northern Ireland.
- Confirmation that a Wholesaler Dealers Authorisation (WDA) which is registered for a site in Great Britain or Northern Ireland and issued by a UK competent authority is acceptable to import from Great Britain to Northern Ireland.
- The need for MHRA to put in place a simple and straightforward process to enable companies to unite a NI licence issued under a MR/DCP [Mutually Recognised Product/ Decentralised Procedure] with a GB licence.
- In order to ensure the continuity of supply to Northern Ireland, the importance of the UK regulator not imposing additional testing and release burdens on products entering the UK from Europe, while noting that, as the viability of the EU proposals "is predicated on the UK remaining aligned to the EU, with equivalent standards in all areas … the MHRA will need to ensure it publishes and meets timelines for licensing procedures related to UK national licences, which are consistent with those within the EU framework."
- The role of the joint Medicines Working Group, established under the TCA, in overseeing and monitoring the implementation of these proposals.

15. The Healthcare Distribution Association highlighted:
    - The need for early and rapid MHRA guidance allowing and recommending that medicines Marketing Authorisation Holders (MAHs) can change 'GB only' Product Licences (PLGB) to PLUK (UK-wide) licences. They stated that this "would seem to be under UK jurisdiction to enact given the recent EU announcement".
    - The implications of the continued application of the EU's Falsified Medicines Directive (FMD) requirements to Northern Ireland but not to Great Britain, given that there is no obligation for MAHs supplying Great Britain "to maintain FMD Safety Features on their products and upload the [Unique Identifier] (UI) data". MAHs can then only "supply GB if they choose … This may be further complicated if the UK decides to introduce its own version of the FMD in due course." This issue further complicates the agenda of promoting a UK-wide product licence, because the PLUK packs require the FMD safety features still to be applied.
    - The risk of a long-term reduction in the range of medicines and medical products available to patients in Northern Ireland because of the extra importation and regulatory requirements needed to enter the EU Single Market regime, leading to smaller UK wholesalers and distributors reviewing the viability of their own distribution routes to Northern Ireland. This will be compounded by the Sanitary and Phytosanitary (SPS) declarations and checks, due to come into force in July 2022, which will cover a range of critical patient medical feeds. They also highlighted the onerous requirements on importers under the EU Medical Device Regulations, notwithstanding a letter of comfort from the MHRA.
    - The urgent need for issuance of guidance, communication and clear signposting to supply chain stakeholders, to address uncertainty and confusion about the precise implications of the EU's proposals.

16. Teva UK noted one "outstanding and very significant issue", namely the treatment of CP (Centralised Procedure) product licences. Its understanding is that "the two licences for

one country problem has been addressed in all areas except for CP licences. This means that products that are licensed in the EU under the CP route are under threat, so far as supply to Northern Ireland is concerned. This covers most new patented medicines, i.e. those that create new treatments or address unmet clinical needs; and all biologic medicines including biosimilars." They cited as an example a branded (patented) respiratory medicine used to treat asthma, "whose continued supply to Northern Ireland cannot be assured for the long term unless the CP issue is addressed". Teva UK therefore stressed the need for the UK and EU negotiators to address the CP issue as a matter of urgency, and proposed that the UK national licence be regarded as sufficient to continue supplying Northern Ireland once the CP licence is granted, so long as it is aligned with the EU CP licence.

17. **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?**

18. **What clarity can you provide in response to industry concerns over changing 'GB only' Product licences to UK-wide licences, the continued application of the Falsified Medicines Directive to Northern Ireland, and the implications of both these issues for Market Authorisation Holders?**

19. **Can you also confirm that Centralised Procedure (CP) licences are not covered by the EU proposals? What are the implications for the provision of affected medicines to Northern Ireland? What is your response to the proposal that the UK national licence should be regarded as sufficient to continue supplying Northern Ireland once the CP licence is granted, so long as it is aligned with the EU CP licence?**

20. **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? What steps will the Government take to provide urgent guidance and communication to industry stakeholders about the implications of the EU's proposals?**

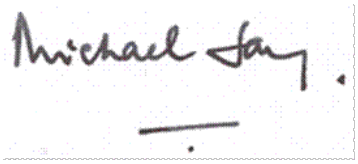
21. **How are each of these issues being addressed in practice? What is the respective responsibility of the UK and the EU in resolving them? What discussions have you had with the EU about them, and what are the prospects of these issues being resolved?**

Conclusion

22. We would be grateful for a response to this letter, and to our earlier letter of 18 November, by 21 February 2022 at the latest.

23. I have copied this letter to HE João Vale de Almeida, EU Ambassador to the UK; Chris Heaton-Harris MP, Minister of State for Europe; Edward Argar MP, Minister of State for Health; Robin Swann MLA, Northern Ireland Executive Minister for Health; Sir William Cash MP, Chair of the House of Commons European Scrutiny Committee; Simon Hoare MP, Chair of the House of Commons Northern Ireland Affairs Committee; 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