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18 November 2021

Dear David,

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

Introduction

1. Thank you for your letter dated 6 October 2021 on the impact of the Protocol on Ireland/Northern Ireland on medicines supply to Northern Ireland.

2. In our introductory report published in July, 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, in particular following the end of the 12-month grace period agreed between the UK and the EU in December 2020.

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 the following representatives of the pharmaceuticals industry, to explore these issues further: Michelle Riddalls, Chief Executive, PAGB; Martin Sawer, Executive Director, Healthcare Distribution Association (HDA); and Paul Williams, Senior Director Corporate Affairs, Teva UK. The Committee also received supplementary written evidence from these organisations and other industry representatives who had previously submitted evidence to our introductory inquiry.

4. This letter summarises the evidence given to us, and puts to you a number of questions, in the context of the ongoing dialogue between the UK and the EU about the future of the Protocol, under the following headings:

The cost and operational impact of Brexit and the Protocol

5. Our witnesses set out their assessment of the cost and operational impact first of Brexit, and then of the Protocol, on the provision of medicines to Northern Ireland. Michelle Riddalls drew attention to the requirements under EU law for importing medicines into the EU. These require a medicine to be retested in a certified laboratory when it enters the EU, and for a qualified person listed on a manufacturer's import licence to check that this has been done and re-release the product. These tests repeat processes in the country of the manufacturer, and require a valid manufacturer's import licence. As a result of

Brexit, and under the terms of the Protocol (if the standstill period ends without agreement of a permanent solution), these processes would be required on movement of all medicines between Great Britain and Northern Ireland. She said that this "has basically meant that we cannot distribute to Northern Ireland in the way we used to".

6. Ms Riddalls added that there were specific issues in relation to over-the-counter (OTC) medicines, which are sold in supermarkets and petrol stations as well as pharmacies. Such companies buy the product in Great Britain and distribute to Northern Ireland on demand. They do not own the manufacturer's licence, and so cannot retest or rerelease the product. Neither do they have storage capacity in Northern Ireland.

7. Martin Sawer said that application of the EU Falsified Medicines Directive, in particular, was "very costly for manufacturers but also impossible for us to administer". He said that 80% of medicines distributed by HDA members and destined for Northern Ireland are stored in Great Britain and shipped daily based on orders for hospitals and pharmacies. He added that the cost of HMRC declarations for HDA members moving medicines to Northern Ireland had amounted to £5 million in the first half of 2021.

8. Paul Williams said that the practical impact of the Protocol if the standstill period ends without agreement would be to require manufacturers to complete separate marketing authorisations for Great Britain and Northern Ireland. A licence for a prescription medicine with three strengths, of 20, 40 and 100 milligrams, would amount to £30,000 for the first year, and anywhere between £7,500 and £27,000 for subsequent years. He gave an example of a medicine for treating depression and migraines, of which 120,000 packs were sold in Northern Ireland in 2020, with a total gross margin of £4,700: "straightaway, you can imagine that that medicine is no longer viable in Northern Ireland". He said that there are large numbers of such products that give a marginal profit on the basis of volume savings across the UK which would become unviable on the basis of a separate market authorisation for Northern Ireland. On the other hand, the Falsified Medicines Directive was less burdensome for large companies such as Teva, as they were already applying it for their pan-European operations.

9. **What is your response to our witnesses' description of the practical difficulties around medicine provision to Northern Ireland under the Protocol? Do you share their analysis? Were these issues anticipated either by the UK or the EU at the time the Protocol was agreed? Have each of the practical issues outlined by our witnesses been raised in the context of the current dialogue with the EU?**

The scale and risk of product withdrawal

10. Michelle Riddalls said that a survey of PAGB members in February revealed that they anticipated between 75% and 98% of OTC medicine products could be discontinued at the end of the grace period. Following the announcement of the standstill period and as companies had adjusted their processes, they now estimated that 52% of products could be discontinued. Medicines for pain relief, cold and flu remedies, smoking cessation, indigestion and heartburn relief, dandruff/nits/headlice, eye care, oral care, hay fever/allergies and antiseptics were likely to be affected. The practical impact of this was that consumers may not be able to buy products to self-care and treat minor illnesses at home, but rather would visit GPs or A&E. Although entire categories of medicine would

not be discontinued, and companies would seek to ensure that at least one pack size of major brands would continue to be available, choice was likely to be limited: "there may be only one pack size of that left, you may only get it in certain shops".

11. Martin Sawer said that, before the standstill period was announced in September, there had been official notification that nearly 1,000 lines of medicines would have been discontinued from January 2022. There are still several hundred on the list in spite of the standstill, because "the uncertainty is creating its own costs. Companies, especially smaller ones, have to make decisions, and they may well have made irrevocable decisions, because notice periods for changing runs of medicines can run into months if not years." In addition, companies had already begun manufacturing medicines for GB only: "some medicines are already in Northern Ireland with GB licences on, and technically under EU law they are illegal, but we are making sure that patients still get those."

12. Paul Williams said that an assessment of the viability of Teva UK's portfolio of 610 products found that, having excluded exclusive products with little or no alternative, and those where there would be safety concerns around switching (for instance epilepsy medicine), there remained over 250 medicines where "it simply does not make economic sense to supply to Northern Ireland". Prior to the announcement of the standstill period, he had written "probably the hardest letter I ever had to write in my 15 years in the pharmaceutical industry" to the Secretary of State for Health "telling him that these medicines could be at risk. It was a very difficult letter for us to write because our mission is to provide medicine to patients. … We made a commitment to the Secretary of State that, come what may, if the patient has no alternative, we will supply them as long as we are physically able to do so. … We have a duty of care to those people." He added that a reduction of choice and supply would in all likelihood lead to increased costs.

13. Teva UK wrote that the medicines that could be impacted included those treating: antibiotic, travel sickness, depression and anxiety, skincare, COVID-19, anti-inflammatory, hayfever/allergy, cholesterol, migraine, cardio-vascular (heart conditions), blood pressure management, pain management, gastrointestinal, Alzheimer's disease, Parkinson's disease, Type 2 diabetes, diuretic, asthma and Chronic Obstructive Pulmonary Disease (COPD), gastric reflux, erectile dysfunction, rheumatoid arthritis and osteoporosis, sleep disorders, anti-nausea in chemotherapy, obesity, and prostate gland enlargement.

14. **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 scope for cross-border provision on the island of Ireland and the risk to the EU Single Market

15. Our witnesses told us that there were no obvious benefits of the Protocol from the point of view of medicines provision to Northern Ireland. However, we note that the pharmaceutical firm Almac, based in Craigavon, has recently announced the creation of 1,000 jobs in Northern Ireland over the next three years, which the deputy First Minister,

Michelle O'Neill MLA, has credited to the dual access for Northern Ireland to the UK and EU markets under the Protocol.

16. Our witnesses explained that the different models for medicines provision in Ireland and Northern Ireland constrained the development of cross-border supply chains on the island of Ireland. Paul Williams said that "the status quo evolved over many years, worked extraordinarily well and allowed pretty much seamless access to medicines for patients". On the other hand, the scope for supplying products to Northern Ireland from Ireland was limited. Teva supply 600 products in Northern Ireland and 300 in Ireland, but "for licensing reasons and even reasons of habit of doctors in Ireland, the overlap of licenses between the two is less than 100". All our witnesses agreed that, given the distinct nature of the pharmaceutical industry in Northern Ireland and Ireland, the risk of leakage to the EU Single Market was very low. Indeed, Mr Williams told us that the unique identifiers required under the Falsified Medicines Directive mean that, "if a pharmacist in Dublin tries to dispense a product with a UK marker, that Dublin pharmacist's system should say, 'No, this is a UK pack. You may not dispense it'." As a result, the volume of cross-border trade "is virtually nil".

17. Michelle Riddalls told us that licences for OTC medicines in Ireland and Northern Ireland are not compatible. Different licences are required, monitored by different regulatory authorities, and products may have different names, pack sizes or legal status. While a product such as ibuprofen can be purchased more widely in Northern Ireland (and the rest of the UK), including in supermarkets, in Ireland it can only be purchased from a pharmacy. The maximum size of paediatric paracetamol is 60 millilitres in Ireland, while in the UK it is 100 millilitres. The statutory warnings for products containing paracetamol also differ.

18. Martin Sawer said that, as a smaller market, Ireland has a smaller range of licensed medicines, "so we have not found many synergies in trying to distribute" from Ireland. Paul Williams added that the price of medicines tended to be higher in Ireland than in Northern Ireland.

19. **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? Do you share their 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?**

The impact of the extension of the grace period for medicines

20. In this context, Paul Williams told us that the Government's unilateral extension of the grace period had been "extremely helpful". However, he added that "it only kicks the can down the road. It is the uncertainty, because the pharmaceutical industry works on long-time horizons. Lots of things take years to do, so one year is not a long time for us."

21. Martin Sawer agreed that it was "good news for patients that medicines are continuing to be supplied as they were". However, continued uncertainty was "not particularly good news for business. … It probably means that there will eventually be less competition to supply Northern Ireland, because some of the smaller companies … will just not wait to see what happens."

22. Michelle Riddalls said that the extension had led suppliers to pause their plans to discontinue medicine supply to Northern Ireland. However, she was concerned that the unilateral nature of the extension could cause uncertainty, as "some of the things we were doing within the grace period require EU support". She stressed the need for clarity as to whether the standstill period would apply to new products introduced after January.

23. **We acknowledge our witnesses' evidence that the extension of the grace period for medicines was a necessary step in the short term. What is your response to their concerns about the negative impact for the pharmaceutical industry of continued uncertainty in the absence of a mutually agreed permanent solution? In that context, can you clarify how the standstill period will apply in the context of new products introduced after January?**

The EU's 13 October 'non-paper' on medicines

24. We sought views on the EU's proposed solutions, as set out in the Commission's 13 October 'non-paper' on medicines. Our witnesses all welcomed the EU's proposals as a positive step, although they stressed that further work was needed fully to resolve the issues.

25. Michelle Riddalls said that the non-paper went some way to addressing concerns for provision of OTC medicines. However, there remained uncertainty about whether products going into Northern Ireland would need to be rereleased. She added that the proposal that importers should obtain a wholesale dealer's licence would be impracticable, given that they included petrol stations and independent pharmacists. She said that confirmation was still needed that the UK competent authority is responsible for ensuring that products destined for Northern Ireland have the necessary code. While the non-paper dealt with national licences, she regretted that it did not propose a solution for centralised products, which could still be prevented from moving from Great Britain to Northern Ireland. She also stressed the need for further work on the proposals for a single medicine pack and a single leaflet for patient information.

26. Martin Sawer said that the non-paper had taken industry concerns into account compared to the previous paper issued by the Commission in July. He particularly welcomed the proposals in relation to batch release and batch control from Great Britain, and permitting the continued use of a single medicine pack for the whole of the UK. Yet there remained challenges in "trying to apply a legal and regulatory framework to an operational situation". In particular, applying the Falsified Medicines Directive remained a major hurdle for some companies supplying medicines to Northern Ireland. Likewise, the EU proposal in relation to a single medicine pack for the UK "implies that the [European Medicines Agency] would have authority over the MHRA to allow that to happen ... The MHRA would then become subservient in that licensing regime".

27. Norgine Pharmaceuticals acknowledged the EU's efforts to identify a sustainable solution, but expressed concern about the timelines and some of the conditions proposed in the non-paper, in particular the requirement for a specific authorisation code to be stamped on each medicine pack.

28. Paul Williams said that "the non-paper has a lot to commend it", and that the EU had "moved a long way". He highlighted the Commission's concession of one marketing authority for the whole of the UK, which meant that unviable solutions, such as moving qualified persons and batch release facilities *en masse* to Northern Ireland were no longer required, as a "big and worthwhile" concession which "exhibited a willingness to move on the part of the Commission".

29. However, Mr Williams added that there was "one huge hole in the non-paper" concerning Mutual Recognition and Decentralised Procedures (DCP/MRP). He explained that in the EU, one country, known as the reference state, goes through the process of assessing and licensing a new treatment or product. Once that country agrees and approves that product, it is approved in other countries via what is known as mutual recognition. Mr Williams pointed out that a single UK market authorisation for new treatments had not been conceded by the EU. Rather, there would be a GB licence, while Northern Ireland would continue to have new products licenced under the DCP/MRP rules. If product approvals were based on different conditions in Great Britain and Northern Ireland, "we are back at two authorisations for one country". Mr Williams said that while the EU non-paper acknowledged the issue, it had not been addressed fully. Teva UK warned that, unless the issue is resolved, there is a risk that new products will not be made available in Northern Ireland, limiting its access to new, more innovative products and treatments.

30. **Do you share our witnesses' assessment of the Commission non-paper as a constructive step that takes account of industry views, albeit that further work is required fully to meet their concerns? Do you agree that the EU's acceptance of the case for a single marketing authority for the whole of the UK is a positive step? Can this foundation be built on to reach a mutually agreed solution in relation to the provision of medicines?**

31. **Have you discussed with the Commission the specific issues identified by our witnesses as areas where further work is needed, including:**
    - **the viability of wholesale dealer's licenses for importers;**
    - **the requirement for a specific authorisation code to be stamped on each medicine pack destined for Northern Ireland, and the envisaged role of the UK competent authority in meeting this requirement;**
    - **the need for a solution for centralised products;**
    - **clarification in relation to a single medicine pack and single leaflet for patient information, and the respective roles of the European Medicines Agency and MHRA;**
    - **problems with the continued application of the Falsified Medicines Directive to Northern Ireland; and**
    - **the need for a solution concerning Mutual Recognition and Decentralised Procedures (DCP/MRP)?**

    What update can you provide on dialogue with the Commission on each of these issues?

The Government's 21 July Command Paper

32. We also sought views on the Government's July Command Paper as it related to medicines. Our witnesses were supportive of the Government's proposal in its Command Paper for the withdrawal of medicines from the Protocol entirely, but, as we explain below, on the condition that this was subject to mutual agreement between the UK and the EU. Martin Sawer explained that taking medicines out of the Protocol "would be sensible … in the interests of public health and security of supply for patients. … We have now had the best part of two years of discussion about the implications and it is so multifactorial and layered. It seems to me that, the more you go forward, as the EU non-papers have done, the less likely it is that we will finally agree on all the dots on the regulations."

33. However, our witnesses warned that the Government's alternative proposal for a dual regulatory regime in Northern Ireland would not work in the context of medicines provision. Paul Williams said that this could lead to "two different sets of safety advice for the same medicine, one from Ireland and one from the UK. Which leaflet does the patient see? … We do not see how a medicine could be subject to both sets of legal and regulatory frameworks at the same time." He gave examples where patient safety advice already varied between the UK and the EU, in relation to emollients, opioids and Viagra.

34. Martin Sawer agreed that, while allowing both a GB and EU medicines pack in Northern Ireland made sense on a piece of paper, "it is down to who regulates that and therefore what details are required to support a medicine. Our sector is very highly regulated, unlike other goods markets, so it would not really work on the regulatory side." Michelle Riddalls added that a dual regulatory regime would lead to confusion for the patient as regards safety information or dosing regimes: "there is a real risk to patient safety and understanding. There are enough issues with patient compliance and understanding of what is on the pack anyway without having two packs that could say two completely different things."

35. **We acknowledge the support of our witnesses for the Government's proposal that medicines should be withdrawn from the scope of the Protocol entirely, on the condition that this is subject to mutual agreement between the UK and the EU. How has the EU responded to the Government's proposal? Has it identified any practical problems with such a blanket approach?**

36. **On the other hand, we note our witnesses' view that the Government's alternative proposal for a dual regulatory regime in Northern Ireland would not be viable in the context of medicines provision. What is your response to their arguments that such a model could create regulatory uncertainty and confusion, and present a risk to patient safety? Were you aware of such industry objections before the Command Paper's proposals was published?**

The need for a mutually agreed solution

37. Our witnesses acknowledged the efforts of both the UK and the EU to identify a solution to these issues, and expressed confidence that they could be resolved. Paul Williams asserted that the issues at hand "are essentially technical rather than political issues … as long as both sides recognise that they are working on behalf of the patient, there is the room to reach an agreement here". PAGB argued that, in view of the minimal risk to the

EU Single Market, "an agreement that permits medicines licensed for use in Great Britain to be supplied to Northern Ireland only, without additional checks, would deliver on both sides' needs."

38. Furthermore, our witnesses underlined the need for a consensual, jointly-agreed solution. Teva UK informed us that they "have been asked on several occasions by Government interlocutors if we agree that medicines should be removed from the scope of the [Protocol]. Our view is that if the UK Government chose to do so unilaterally against the wishes of the EU Commission, this would be unhelpful in that the response from the Commission could be expected to be strong and potentially punitive, affecting our ability to operate effectively beyond the scope of supplying medicines to Northern Ireland. However if the effect of withdrawal of medicines from the Protocol was achieved by agreement between the UK and EU, it would … greatly simplify the process of supplying Northern Ireland".

39. Paul Williams explained that the unilateral removal of medicines from the Protocol would have undesirable knock-on consequences for the UK pharmaceuticals industry given its interdependencies with the EU, for instance in relation to safety alerts and interchange of data on products, which had already become more challenging post-Brexit. It might also imperil a UK-EU mutual recognition agreement on batch release, which he argued was urgently required.

40. The Ethical Medicines Industry Group likewise warned of the current "fragile situation being undermined following statements from the UK Government that the Protocol could be unilaterally suspended. The suspension of the Protocol, or the imposition of any unilateral or un-negotiated solution, threatens to undermine the delicate trading situation that currently exists between GB and Northern Ireland, and could provoke retaliative measures. … We are clear that the removal of the grace period, the unilateral suspension of the Protocol or the introduction of any measures that increases the burden placed on pharmaceutical companies, will result in products being discontinued from the Northern Ireland market. This will have a devastating impact on patients and patient care in Northern Ireland."

41. Martin Sawer said that UK distributors "could probably live with a unilateral declaration of the status quo where we are now", because "it is an upstream issue about the manufacturing and the interrelationship of businesses around the world". However, "the complications and the extra layers of cost of doing our own thing without an agreement would probably come home to roost after some time."

42. PAGB argued that "a negotiated settlement, agreed by both parties, is vastly preferable to unilateral action from either side. … While a unilateral solution from either side could resolve the current barriers in the short term, it carries a high level of risk of potential future divergent expectations or disagreements between the UK and EU regulators, which will not provide medicines manufacturers with the certainty or confidence to make long term business decisions."

43. Michelle Riddalls explained that "business needs certainty, and if there is no agreement between the two sides, there is always uncertainty as to how the other will react as a result of unilateral views being put forward." She noted that many PAGB members are part of European and global companies, "so just carving out something unilaterally for the

UK would make it very difficult for a company … Medicine and pharmaceutical companies are naturally compliant because we have such high regulatory levels to meet all the time and are inspected on those. It can be very difficult when, if you are in a European role, the EU is saying one thing and the UK is saying, 'It's all right here'."

44. Michelle Riddalls added that triggering Article 16 "would be very unsettling. The lack of certainty about what companies would do and how they would function could lead to more withdrawals, and more immediately, because … pharmaceutical companies are very compliant." Martin Sawer said that, while triggering Article 16 may work in the short term, it could have longer-term implications.

45. **What is your response to industry representatives' views that a mutually agreed solution is necessary in the context of provision of medicines to Northern Ireland? How would you respond to their arguments that a unilateral solution would have a damaging effect both on the provision of medicines to Northern Ireland, and on wider UK-EU cooperation on medicines? In that context, what update can you provide on the prospects for a UK-EU Mutual Recognition Agreement in relation to medicines?**

Industry engagement

46. Finally, we asked our witnesses for their reflections on the UK and EU engagement with them over their concerns. Martin Sawer described the Department of Health and Social Care's engagement with industry as "exemplary" and "second to none". However, he noted the structural challenge of having to filter through EU industry bodies when engaging with the Commission, rather than liaising with them directly.

47. Paul Williams agreed that engagement with the DHSC and the Cabinet Office had been "very constructive indeed". However, UK industry representatives "have found it difficult, particularly at an EU level, to be let into these discussions in confidence before they are published. We have already said that the big miss in the EU non-paper was the DCP/MRP issue. I am not excluding the UK Government from this point entirely, although the UK Government have engaged very constructively, but please get some subject matter experts in the room. Someone could have asked, before that non-paper was published, 'Can I have a chat about what this means for CP medicines, or DCP/MRP?', instead of playing your cards close to your chest so that the first the trade associations hear about it is the press release."

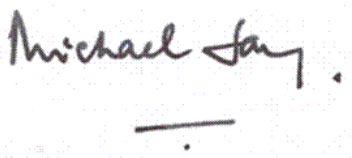
48. Michelle Riddalls proposed that, "as negotiations progress and solutions are put forward, there is a check step, perhaps on both sides, to come back to industry and the trade associations to double check what those implications might be and to ensure that they are on track, so that it provides the solutions that we all need."

49. **We welcome our witnesses' testimony of positive engagement with the UK Government in relation to the pharmaceutical industry's concerns. We urge you to maintain this dialogue in the context of the continuing discussions with the EU. What steps will you take to encourage the EU, together with the Government, to engage directly with UK pharmaceutical industry representatives to understand their concerns? Will you take forward our**

witnesses' proposals for a 'check step' by both sides with industry representatives before further proposals are brought forward?

50. We would be grateful for a response to this letter by 6 December 2021. I have copied this letter to HE João Vale de Almeida, EU Ambassador to the UK; Rt Hon Sajid Javid MP, Secretary of State for Health and Social Care; Robin Swann MLA, Northern Ireland Executive Minister for Health; 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