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

House of Lords
London
SW1A 0PW

Tel: 020 7219 5864
Fax: 020 7219 6715
hlprotocol@parliament.uk
www.parliament.uk/lords

Rt Hon James Cleverly MP
Secretary of State for Foreign,
Commonwealth and Development Affairs
Foreign, Commonwealth and Development Office
King Charles Street
London
SW1A 2AH

24 February 2023

Dear Foreign Secretary,

FOLLOW-UP SCRUTINY OF THE PROVISION OF MEDICINES TO NORTHERN IRELAND UNDER THE PROTOCOL

1. In the autumn of 2021, the House of Lords Sub-Committee on the Protocol on Ireland/Northern Ireland took evidence from representatives of the pharmaceutical industry on the impact of the Protocol on the provision of medicines to Northern Ireland. We wrote a detailed letter to Lord Frost on 18 November 2021 in his then ministerial responsibility for the operation of the Protocol. We wrote a follow-up letter to Rt Hon Liz Truss MP, the then Foreign Secretary, on 28 January 2022, following the publication of the Commission's legislative proposals on provision of medicines in December 2021. You replied to both these letters in your then capacity as Minister for Europe and North America on 28 March 2022.

2. In January and February 2023, we undertook a follow-up investigation to examine how, if at all, the situation regarding medicine provision to Northern Ireland had changed since our initial inquiry. We heard evidence from three witnesses who had contributed to our initial inquiry: Michelle Riddalls, Chief Executive, PAGB (the consumer healthcare association); Martin Sawer, Executive Director, Healthcare Distribution Association (HDA); and Paul Williams, Senior Director Corporate Affairs, Teva UK. We also heard from Dr Alan Stout, Deputy Chair of BMA NI Council, Chair of the NI GP Committee and Co-chair of the UK GPC at the British Medical Association; Kate Ling, European Policy Manager at the NHS Confederation; and Mark Dayan, Policy Analyst and Head of Public Affairs at Nuffield Trust. We also received written evidence from a number of industry representatives. We are grateful to all our witnesses for their assistance.

3. This letter summarises the findings of our follow-up work. We specifically draw these to your attention in the context of the discussions between the UK and the EU on the future of the Protocol.

The overall impact on the provision of medicines to Northern Ireland

4. It has been suggested that the EU legislation that came into force in April 2022 has resolved the problems with supply of medicines to Northern Ireland. However, the evidence we have received from industry stakeholders makes clear that this is far from the case. The provision of medicines to Northern Ireland (a significant majority of which are supplied from or via Great Britain) remains logistically complex, costly and inefficient. The impact has thus far fallen in particular on wholesale suppliers in terms of delivering product to Northern Ireland, and we were told that doctors and patients have largely been immune from the problems that have been encountered. Nevertheless, community pharmacists have reported increasing difficulty in sourcing medicines, and there is some evidence of delays in medicines reaching patients, as well as some products being replaced by generic medicines. Practitioners fear an interrupted supply of medicines if outstanding issues are not resolved.

5. Our witnesses pointed out that the problems with medicine supply to Northern Ireland are part of a wider set of issues affecting the sector, including the wider impact of Brexit on supply chains and product testing, issues with global supply chains, and shortages and rising costs of products since the COVID pandemic. This makes it difficult to disentangle the impact of the Protocol from other factors. Nevertheless, in the words of one of our witnesses, "there is a lot of extra pain and hassle involved in supplying products to Northern Ireland", not least because of the small size of the market. The question that arises is whether Brexit and/or the Protocol is the main factor, and we invite your comment on this.

6. Our witnesses told us that the Protocol offers no benefits compared to the situation before UK withdrawal from the EU. That said, they stressed that it was preferable to no agreement at all, in terms of providing some protection for the continued supply of medicines. Nevertheless, the Protocol has had no discernible impact on the cross-border supply of medicines on the island of Ireland, which remains at a very low level due to well-established supply chains to Northern Ireland from Great Britain, different licensing and regulatory regimes, and the small size of the market compared to Great Britain. However, we were told that the supply of medical devices was more reliant on cross-border provision.

7. Our witnesses acknowledged that the EU legislation designed to resolve the ongoing regulatory issues for medicines moving from Great Britain to Northern Ireland that came into force in April 2022 removed the immediate threat of a cliff-edge and large-scale withdrawal of medicines. This was particularly true for over-the-counter (OTC) medicines where, compared to original estimates of over three-quarters of products being discontinued, sector representatives were aware of only one product being discontinued. However, while issues with OTC medicines have been dealt with, the EU legislation did not

provide a comprehensive solution. Significant issues remain, creating the risk of further cliff-edges to come. In view of this, what lessons can be learned from the process leading to the EU's legislative proposals being brought forward, beginning with the Commission 'non-paper' on medicines published in October 2021, and the fact that the proposals that ultimately came into force only provided a partial solution to the problems that have arisen?

Principal outstanding issues

The Centralised Procedure/Centrally Authorised Procedure

8. Industry representatives expressed deep concern about the impact on Northern Ireland of the replacement of the EU Centralised Procedure/Centrally Authorised Procedure with Great Britain-only licences. We were told that the deadline for changing existing licences to GB licences by the end of 2023 was "astonishingly tight", and created the risk of a new cliff-edge in the supply of medicines to Northern Ireland at that time, as it will not be possible to provide the same pack to Great Britain and Northern Ireland after this point. This affected in particular prescription medicines, newer treatments, and those for more serious conditions: these include migraine, cancer pain and antipsychotic treatments. Our witnesses warned that "two licences and two packs for the same medicine in the UK is not viable", creating the risk that Northern Ireland patients will lose out.

9. What steps is the Government taking, in dialogue with the EU, to identify a sustainable solution to the licensing issue before the end of 2023? What will be the scale and impact of medicine withdrawals in Northern Ireland if this issue is not resolved? What is your response to industry claims that it is in the gift of the UK to use a CP licence across the whole of the UK? Are joint packs covering Great Britain and the EU a viable solution, and if so, what guidance will UK authorities provide to industry on how this would work? Are there any other viable means to provide for UK-wide MHRA authorisation for medicines? Short of this, will the Government consider extending the derogation for GB licences beyond the end of 2023?

The Falsified Medicines Directive

10. We were told that the single biggest factor causing difficulties under the Protocol is the continued application of the EU Falsified Medicines Directive (FMD) to Northern Ireland, but not to Great Britain. The application of the Directive places requirements on distributors moving products to Northern Ireland, including sample verifications of all medicine packs, and checking and decommissioning products before being passed to every healthcare institution in Northern Ireland that is not a hospital, pharmacy or doctor. For medicines moving from the EU to Northern Ireland via Great Britain, there is also the added administrative burden of deactivating security features as a product enters Great Britain and reactivating them as they enter Northern Ireland. Yet the scale of the problem is minuscule: we were informed that, according to EU figures for 2019, 0.005% of drugs were counterfeit in the UK, which would amount to one prescription per day in the UK as a

whole. Nor are there any reports of significant issues with counterfeit medication in Northern Ireland.

11. Do you share the view of our witnesses that the optimal solution is the disapplication of the FMD in Northern Ireland? Has this issue been discussed with the Commission during the UK-EU discussions on the future of the Protocol? Is the Commission willing to consider this, and if not, what is the basis of its objection? Have any other mitigations been discussed, for instance removing the need for checks on medicines moving from the EU to Northern Ireland via Great Britain? What other means is the Government proposing in dialogue with the Commission to ease the logistical burden of the application of FMD in Northern Ireland?

Medical devices

12. We have been informed of the burdensome impact of import requirements for medical devices moving from Great Britain to Northern Ireland, including the requirement for shops, petrol stations and pharmacies to provide information that they are the importer at the point of sale. Suppliers are currently reliant on a letter of comfort from the MHRA to enable that supply to continue.

13. What steps is the Government taking, in dialogue with the Commission, to identify a permanent solution to this issue that ensures the smooth and unhindered movement of medical devices to Northern Ireland both from Great Britain and the EU?

Regulatory divergence

14. We note the serious concern of industry representatives regarding the practical impact for Northern Ireland of regulatory divergence between Great Britain and the EU. We note in particular the impact of divergent approaches to licensing by the MHRA and the European Medicines Agency, and concerns that wholesalers may unwittingly be supplying unlicensed packs to Northern Ireland.

15. How do you respond to our witnesses' concerns that divergence between Great Britain and the EU represents a threat to the supply of medicines to Northern Ireland? In particular, what is the Government's assessment of the impact of divergent approaches to licensing by the MHRA and EMA? What steps is the Government taking, in dialogue with the Commission, to monitor and take account of the practical impact of regulatory divergence on the provision of medicines to Northern Ireland? In particular, what scope is there for intensified dialogue between UK and EU authorities, in particular the MHRA and EMA, to manage and minimise divergence on an ongoing basis?

Potential solutions

The Northern Ireland Protocol Bill and the dual regulatory regime

16. While some of our witnesses saw the potential in theory for a dual regulatory regime to resolve the above issues, they emphasised the lack of clarity as to how it would work in practice. Witnesses also argued that it could give rise to further difficulties or uncertainty in the case of a highly regulated sector such as medicines, in particular if the EMA and the MHRA gave conflicting guidance, or if imposed unilaterally.

17. Is the Government still pursuing the dual regulatory model? If so, how would it work in practice in relation to the supply of medicines to Northern Ireland? In particular, how would a dual regulatory regime account for conflicting guidance from the EMA and MHRA?

The Northern Ireland MHRA Authorised Route (NIMAR)

18. We acknowledge the crucial role that the Northern Ireland MHRA Authorised Route (NIMAR) has played in securing the continued supply of many prescription medicines to Northern Ireland, including treatments for diabetes, heart disease, leukaemia, respiratory disease and COVID. We also note that nearly 200 Stock-Keeping Units are subject to the NIMAR process. Nevertheless, we acknowledge industry concerns about the extra bureaucracy involved, the practical challenges of supplying such products, and uncertainty about whether products subject to NIMAR can be promoted in Northern Ireland.

19. Is NIMAR viable as a long-term mechanism for ensuring the supply of prescription medicines to Northern Ireland? If so, what practical steps will the Government, in dialogue with the Commission, take to reduce the bureaucracy and practical challenges involved in supplying products via the NIMAR route? Will the Government commit to providing more detailed guidance on the operation of NIMAR, including on whether products supplied via this route can be promoted in Northern Ireland? If NIMAR is not a long-term solution, what other means will be provided to ensure the continued supply of such medicines?

A mutual recognition agreement

20. We note the support of industry for a UK-EU Mutual Recognition Agreement as beneficial for the whole medicines industry. Is the Government pursuing this with the Commission? If not, why not? Short of this, what mechanisms can be created to provide for enhanced coordination between the MHRA and EMA, or for the mutual recognition of batch testing?

Continuation of existing mitigations and derogations

21. Short of permanent solutions to the issues identified above, what scope is there to continue with the derogations and mitigations currently in place in relation to medicine supply? What dialogue has the Government had with the Commission on this?

Removal of medicines entirely from the Protocol

22. We note the continued support of some witnesses for the removal of medicines in their entirety from the Protocol, as proposed by the Government in its July 2021 Command Paper, subject to mutual agreement with the EU. Does the Government continue to advocate the removal of medicines from the Protocol, and has this been proposed in dialogue with the Commission? If so, how has the Commission responded, and on what grounds has it been unwilling to agree this?

Enhanced engagement with industry

23. We welcome the Government's previously strong and intensive engagement with industry stakeholders. However, we are deeply concerned to hear that this engagement has diminished since the EU's legislation was brought forward, in particular given the clear evidence of significant outstanding issues that need to be resolved. We are also concerned to note the paucity of direct engagement between UK industry representatives and the EU, given the importance of a detailed technical understanding of the impact of the Protocol on medicine supply to Northern Ireland. Both the Government and the EU must take urgent steps to address this and to re-engage with pharmaceutical industry representatives.

24. How will the Government ensure that the concerns of industry are taken into account and addressed in its dialogue with the EU? In particular, what steps will the Government take to enhance its engagement with industry in order to identify solutions to the issues outlined in this letter, and to facilitate industry dialogue with the EU? What steps will you take, in dialogue with the Commission, to provide for such dialogue through the governance bodies established under the Trade and Cooperation Agreement, the Withdrawal Agreement and the Protocol itself?

A commitment to negotiate a sustainable solution

25. We share the concern of industry that the issues around the provision of medicines to Northern Ireland have fallen off the radar of the UK-EU discussions over the future of the Protocol, under a misapprehension that the issues regarding medicine supply have been resolved. The evidence we have heard makes clear that this is not the case.

26. In view of this, can you set out what, if any, consideration has been given to the issue of medicine supply to Northern Ireland in the UK-EU discussions on the future of the Protocol? What proposals will be brought forward to provide a long-term solution to the issues identified in this letter?

Conclusion

27. We conclude by endorsing the evidence put to us by medicine industry stakeholders:

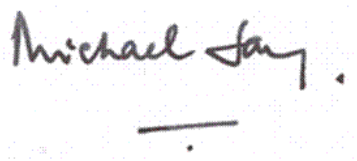
> "In the rush to get a deal done and to get something over the line, the issues about the supply of medicines will perhaps be forgotten about, side-lined or not dealt with properly.

We want to see a long-lasting, stable solution to this. … The impact of disruptions to medicine supply on the health of citizens in Northern Ireland must remain of paramount importance within these discussions. … It would be morally indefensible for patients to be caught in the crossfire like this, to be treated as chess pieces in a much larger political game."

28. We would be grateful for a response to this letter by 24 March 2023.

29. I have copied this letter to Maroš Šefčovič, Vice-President of the European Commission; HE Pedro Serrano, EU Ambassador to the UK; Leo Docherty MP, Minister for Europe, Foreign, Commonwealth and Development Office; Rt Hon Chris Heaton-Harris MP, Secretary of State for Northern Ireland; Rt Hon Steve Barclay MP, Secretary of State for Health and Social Care; Will Quince MP, Minister of State for Health and Secondary Care, Department for Health and Social Care; 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 the Secretariat of the Northern Ireland Assembly Committee for Health.

Yours sincerely,



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

APPENDIX TO THE LETTER FROM LORD JAY OF EWELME TO THE FOREIGN SECRETARY

FOLLOW-UP SCRUTINY BY THE HOUSE OF LORDS SUB-COMMITTEE ON THE PROTOCOL ON IRELAND/NORTHERN IRELAND ON THE PROVISION OF MEDICINES TO NORTHERN IRELAND UNDER THE PROTOCOL

1. The following summary cites oral evidence from Michelle Riddalls, Chief Executive, PAGB (the consumer healthcare association); Martin Sawer, Executive Director, Healthcare Distribution Association (HDA); and Paul Williams, Senior Director Corporate Affairs, Teva UK; Dr Alan Stout, Deputy Chair of BMA NI Council, Chair of the NI GP Committee and Co-chair of the UK GPC at the British Medical Association; Kate Ling, European Policy Manager at the NHS Confederation; and Mark Dayan, Policy Analyst and Head of Public Affairs at Nuffield Trust. It also cites written evidence from a number of industry representatives. We are grateful to all our witnesses for their assistance. All evidence is published online at https://committees.parliament.uk/work/7172/followup-scrutiny-of-the-provision-of-medicines-to-northern-ireland-under-the-protocol/publications/

The overall impact on provision of medicines to Northern Ireland

Overview

2. We asked our witnesses to summarise the current position in relation to provision of medicines to Northern Ireland under the Protocol. Martin Sawer said that "logistics loves simplicity. The Northern Ireland Protocol has driven complexity and uncertainty into the supply chain. … Distributing medicines to Northern Ireland is challenging, problematic, inefficient and a slow strangulation by 1,000 cuts."

3. Mark Dayan described an overall picture of "constant change in the obstacles to what can be legally marketed [in Northern Ireland] and to physically moving units from Great Britain to Northern Ireland."

4. Paul Williams said that, overall, "the complexity that the Protocol and Brexit in general has brought to us has led to a very large increase in cost and complexity for us. … There is no big, single 'Oh, my gosh, this is the thing that's really killing us'. It is suddenly there is a bit more regulatory difficulty, a bit more supply chain difficulty and a bit more licensing difficulty, and it all adds up."

5. The National Pharmacy Association stressed that, because of the various mitigations in place, the full impact of the Protocol had yet to be felt. Nevertheless, its members had found that the procurement of medicines has become more difficult and costly, and that "a just in time medicines supply function has now had a reduced choice of product leading to significant price rises."

A differential impact across the sector

6. We were told that there had been a differential impact across the sector.

7. Martin Sawer pointed to the burdensome impact on wholesalers. He noted that, because 80% of the different lines of medicines are sourced from bigger warehouses in Great Britain, the smaller warehouses in Northern Ireland cannot hold all those medicines, as there would previously have been no need to do so for a population of 1.8 million people. He said that the three biggest UK-wide wholesalers face the biggest challenges. Warehouses in Belfast "will be stuffed as full as they can be just because they want to be close to the patients and not have to worry about getting some medicines from GB, but they can by no means hold them all."

8. Mr Sawer added that some manufacturers had re-routed their supplies from the EU direct to Belfast, rather than via Great Britain. Wholesalers now had to deal with "an extra layer of complication" in smaller and more frequent deliveries destined for Northern Ireland. He also explained that "we are employing more people in Belfast, so the cost has gone up", due to the "much more manual approach for us in doing business in Belfast."

9. Paul Williams explained that the impact of moving products fell on wholesalers rather than manufacturers, for whom the main impact of the Protocol had been on the licensing and regulatory component of their work in the form of marketing authorisations.

10. The National Pharmacy Association noted that "community pharmacy teams in Northern Ireland now spend an increased amount of time sourcing medicines, exacerbated by the number of wholesalers and manufacturers who have withdrawn from the market." The community pharmacy sector reported that 74% of pharmacists were spending between one and three hours per day sourcing medicines.

11. Kate Ling also said that community pharmacists had pointed to increased transportation costs incurred by suppliers and distributors, which may eventually feed through into the costs of medicines. She also said that there had been some increased waiting times for medicines: "I am not talking about huge delays, but it might be an extra day if you have to get the medication from somewhere in Great Britain to Northern Ireland."

12. Ms Ling nevertheless reported that "patients are continuing to receive the medicines that they need, which is obviously the bottom line, the most important thing. However, I think that this is because of the easements that have been put in place by the EU and the UK. … A lot of work is being done behind the scenes to ensure that patients and providers are not seeing too much difference on the front line."

13. Dr Alan Stout agreed that doctors and patients had largely been immune from the work going on in the background to maintain medicine supply. However, he was fearful of interrupted supply of medicines if outstanding issues were not resolved.

14. Michelle Riddalls told us that, for over-the-counter (OTC) medicines, "there are no real barriers … in getting products over to Northern Ireland." She noted that only one PAGB member had changed its operating model since the EU brought forward its legislative proposals. Overall, "it is quite positive that there have been hardly any wholesale changes in our businesses on how we get products to Northern Ireland."

Distinguishing between the Protocol, Brexit and other factors

15. Witnesses noted the difficulty of distinguishing between the impact of the Protocol, Brexit more generally, and wider global supply chain issues, including in the context of the COVID pandemic. Paul Williams said that "Brexit overall has added a very large amount of cost and complexity to our services." For instance, prior to UK withdrawal from the EU, products destined for the market in Ireland would be made and tested in Cheshire, and then shipped from Liverpool to Dublin. However, "product for Ireland from that same factory is now taken to Dover, shipped to Rotterdam, driven to Germany where it is tested and released, driven back again, driven up the M1 and M6, and then it gets on a ferry to Ireland." This was because "product that goes from the UK to a European market must be tested in a European market." This applied to every new batch of medicine. Even products destined for the UK market, including Northern Ireland, were sent to the EU for testing "because logistically it is simply not worth duplicating that testing function. … Even product that is made in Cheshire and will be used in Cheshire is taken to the EU for release."

16. The National Pharmacy Association acknowledged that, following the pandemic, the cost of medicines has gone up across the UK as a whole. Kate Ling agreed that "it is very difficult to separate out the overall difficulties that everybody is having with the global supply chains, which affects everybody equally in the UK … [and] which have been particularly difficult in the last couple of years, from things that are specific to Northern Ireland." Nevertheless, it was clear that "there is a lot of extra pain and hassle involved in supplying products to Northern Ireland, particularly when they are small quantities for a small number of patients, when you have to supply different packaging. It is simply an absolute pain for them. Hence the problem … of some companies deciding that it is just not worth supplying the products into Northern Ireland."

Potential benefits

17. In our letter to Lord Frost in November 2021, we noted that "witnesses told us that there were no obvious benefits of the Protocol from the point of view of medicines provision to Northern Ireland." When we asked our witnesses if that was still the case, those who addressed this point were unanimous that, given the issues highlighted above, the Protocol offers no benefits compared to the position prior to the UK leaving the European Union. As Paul Williams told us: "does it offer any benefit that was not available before Brexit? No, it does not."

18. Martin Sawer said: "We do not believe that the current Protocol carries any benefits other than the fact that bringing it in was important for continuity." He gave the example of Trader Support Service (TSS) declarations in the Irish Sea: "For every consignment we send over, we have to declare what is on board by the fifth of the following month. In our sector, that amounts to about £2.5 million of extra costs in labour, IT and declarations per year at the moment. We have had two years, so that is £5 million already. We see no benefit in that at all."

19. However, witnesses also stressed that the Protocol (or any other negotiated agreement) was nevertheless preferable to no agreement at all. Mark Dayan said that the question of the Protocol must be put "in the context of what the alternative is. You could say that if we had left the single market but there was no Protocol, we would not have these problems but we would have lots of others. Most particularly, we would then have a hard border between Northern Ireland and the Republic."

20. Dr Alan Stout and Michelle Riddalls both said that the existence of the Protocol preserved the supply of medicines to Northern Ireland, although Ms Riddalls noted that this was largely due to the EU legislation brought in after the Protocol came into effect. She added that: "We would not want unilateral withdrawal from it, because we do not know what that would look like." Paul Williams agreed that in so far as the Protocol "is better than unilateral withdrawal from the Protocol, yes, it has benefit."

21. Kate Ling said that the Protocol itself may have created some potential benefits. For instance, "Northern Ireland's unique position in adhering to EU rules means that there are circumstances where patients in Northern Ireland could get earlier access to medicines that have been approved by one or the other regulator." However, she added, this must be balanced against the increased cost of the new arrangements. There is "the uncosted resource of people's time and effort, of course, not just actual cost of extra carriage charges or transportation. There is also the time spent filling in forms and doing the documentation and all the discussions that are going on."

The impact on cross-border supply of medicines on the island of Ireland

22. In our letter to Lord Frost in November 2021, we concluded 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." We asked our witnesses if this was still the case.

23. Paul Williams said that the cross-border supply of medicines between Ireland and Northern Ireland "remains at a very low level." Dr Alan Stout agreed and explained that this was due to "the well-established supply chains through GB and also because we will end up with different licensing and regulation with Northern Ireland."

24. Michelle Riddalls elaborated on this: "the medicine supply chain is one of the most tightly regulated in the world because of the regulatory actions behind it … The vast majority of OTC products are UK licences. In 2021, 98% of the licences for OTC medicines were national, which means that they have a unique UK product licence number on the packaging, and so are readily identifiable as UK products. Only 1% of products were joint with any other country, so if they were moved to Ireland they would be easily identifiable as illegal." She explained that some licensed medicines "have completely different names" and are sold differently. For example, "ibuprofen is a pharmacy product in Ireland, but it is available in general sales in Northern Ireland, so you can buy it off the shelf in a petrol station. There are completely different licensing regimes."

25. Dr Alan Stout said that "we have heard from the pharmaceutical companies that because of the size of the market in Northern Ireland … it was not really in their interests to change their major supply chains, certainly for some of the less frequently used medications. … The change to medications through the Republic was projected and it was thought could be a solution, but it has not happened." Martin Sawer agreed: "Ireland is quite a small market in terms of the number of people. Northern Ireland has always benefited from piggybacking on a GB market of such a huge, strong market force that nothing changed. The distribution routes did not change."

26. However, Mark Dayan said that a hard border on the island of Ireland would have created "big problems for the minority of medicines" that were supplied via that route, as well as "other problems for the majority of medical devices that come in like that" and "for service delivery across the border." Mr Dayan explained that medical devices "have a very different regulatory system. We have been consistently told, although precise data is quite hard to come by, that the Northern Ireland NHS gets most of its medical devices from the EU, unlike medicines that mostly come from Great Britain."

The impact of the EU's legislation

27. In December 2021, the Commission published a package of proposals to resolve the ongoing regulatory issues for medicines moving from Great Britain to Northern Ireland. The legislative proposals, which came into force in April 2022, included permitting the use of a UK-wide authorisation route for generic medicines and a bridging mechanism to ensure that a company's product is licensed for the whole of the UK if the MHRA issues a licence for a new product before the European Medicines Agency (EMA). We asked our witnesses to what extent this legislation had resolved the problems under the Protocol.

28. Witnesses agreed that the legislation had a positive impact in so far as it removed the immediate threat of a cliff-edge and large-scale withdrawal of medicines. As Paul Williams said: "It was helpful in that it allowed us to continue to supply the vast majority of our portfolio in Northern Ireland."

29. Michelle Riddalls agreed that the EU legislation avoided an imminent cliff-edge, especially with regard to OTC medicines. When the PAGB last gave evidence to the Committee in October 2021, it estimated that "between 75% and 98% of OTC medicines could be

discontinued." Due to the EU legislation, however, "we are aware of only one product being discontinued in Northern Ireland, which was linked to a centralised procedure licence. We estimated in 2021 that there were between 1,550 and 2,325 branded OTC medicines, and we are only aware of one that has been discontinued. It is fair to say from our side that the EU legislation has had a really positive impact, and if it was not there, there would be an issue." Michelle Riddalls also emphasised that the legislation was "the result of a very close working relationship between UK Government officials and the EU and the very detailed technical discussions that took place."

30. Martin Sawer stressed that the EU legislation "came just in time … the whole sector, supply chain manufacturers down to the pharmacy level, worked very closely with the MHRA and the Department of Health and Social Care to get to that UK position, which was only agreed at the last minute. The generics industry had to work hard to demonstrate—letters were sent in—that nearly [2,000] products were going to be discontinued before that legislation." Martin Sawer stressed that "it would have been a terribly difficult time if the legislation had not been passed. We maintain the distribution of those [nearly 2,000] products. Since then, there have been some discontinuations. In total, although there may be say, 90 products on the NIMAR list, that represents about 170 different presentations."

31. However, while the EU legislation may have provided a "long-term solution" for OTC medicines, the evidence we heard made clear that it was not a full solution to all the issues in relation to the supply of medicines to Northern Ireland. As Martin Sawer said: "It is not a long-term solution, in our view, because … the divergence of certain other types of products and the licensing issues are now approaching other deadlines. There are other issues to agree to. It was not a solution for everything." His deduction from the scale of products supplied via NIMAR (see below) was that "there are quite a lot of discontinuations, because there will be alternative generics that can be supplied to Northern Ireland."

32. We turn to the principal outstanding issues in turn below.

Conclusions

33. **It has been suggested that the EU legislation that came into force in April 2022 has resolved the problems with supply of medicines to Northern Ireland. However, the evidence we have received from industry stakeholders makes clear that this is far from the case. The provision of medicines to Northern Ireland (a significant majority of which are supplied from or via Great Britain) remains logistically complex, costly and inefficient. The impact has thus far fallen in particular on wholesale suppliers in terms of delivering product to Northern Ireland, and we were told that doctors and patients have largely been immune from the problems that have been encountered. Nevertheless, community pharmacists have reported increasing difficulty in sourcing medicines, and there is some evidence of delays in medicines reaching patients, as well as some products being replaced by generic medicines. Practitioners fear an interrupted supply of medicines if outstanding issues are not resolved.**

34. **Our witnesses pointed out that the problems with medicine supply to Northern Ireland are part of a wider set of issues affecting the sector, including the wider impact of Brexit on supply chains and product testing, issues with global supply chains, and shortages and rising costs of products since the COVID pandemic. This makes it difficult to disentangle the impact of the Protocol from other factors. Nevertheless, in the words of one of our witnesses, "there is a lot of extra pain and hassle involved in supplying products to Northern Ireland", not least because of the small size of the market. The question that arises is whether Brexit and/or the Protocol is the main factor, and we invite your comment on this.**

35. **Our witnesses told us that the Protocol offers no benefits compared to the situation before UK withdrawal from the EU. That said, they stressed that it was preferable to no agreement at all, in terms of providing some protection for the continued supply of medicines. Nevertheless, the Protocol has had no discernible impact on the cross-border supply of medicines on the island of Ireland, which remains at a very low level due to well-established supply chains to Northern Ireland from Great Britain, different licensing and regulatory regimes, and the small size of the market compared to Great Britain. However, we were told that the supply of medical devices was more reliant on cross-border provision.**

36. **Our witnesses acknowledged that the EU legislation designed to resolve the ongoing regulatory issues for medicines moving from Great Britain to Northern Ireland that came into force in April 2022 removed the immediate threat of a cliff-edge and large-scale withdrawal of medicines. This was particularly true for over-the-counter (OTC) medicines where, compared to original estimates of over three-quarters of products being discontinued, sector representatives were aware of only one product being discontinued. However, while issues with OTC medicines have been dealt with, the EU legislation did not provide a comprehensive solution. Significant issues remain, creating the risk of further cliff-edges to come. In view of this, what lessons can be learned from the process leading to the EU's legislative proposals being brought forward, beginning with the Commission 'non-paper' on medicines published in October 2021, and the fact that the proposals that ultimately came into force only provided a partial solution to the problems that have arisen?**

Principal outstanding issues

The Centralised Procedure/Centrally Authorised Procedure

37. Mark Dayan explained that the Centralised Procedure/Centrally Authorised Procedure (CP or CAP) is the mechanism for a single EU-level approval "for certain diseases, an innovative

substance, biological in nature, things like that. Many of the most cutting edge medicines get applied in this way." At the moment the UK is accepting a lot of the EU Centralised Procedure decisions "through what it calls the reliance route. It is not quite rubber-stamping, doing a bit of a check first but basically accepting a lot of what is decided in Amsterdam about which medicines should be approved. The intention is that they will stop doing that in a year. If that is the case, you have genuinely two different approval systems for Great Britain and for Northern Ireland and you could start seeing more of a drift apart with innovative medicines and which ones are allowed to be sold in Northern Ireland versus in England, Scotland and Wales."

38. Paul Williams said that the Centralised Procedure was the most urgent issue in need of resolution. Broadly speaking, the Centralised Procedure applied to prescription medicines, newer treatments, and those for more serious conditions. At present Teva had 40 stock-keeping units (SKUs) covered by CP licences in the UK, including an innovative migraine medicine, a breakthrough cancer pain treatment, and an antipsychotic. He explained that "we have until the end of 2023 to change all those licences to GB licences"—an "astonishingly" tight timetable:

> "As of today, we have moved seven of our own products to a GB licence. For the rest, we are continuing to supply the whole of the UK for now, because we can continue to supply CP licences across the UK until December. … From the end of this year we will not be able to supply the same pack to Great Britain and Northern Ireland, because in Great Britain we must have a GB licence and in Northern Ireland we must have a CP licence. It is the same product, the same patient, the same illness, the same medicine, but we must have a CP licence in Northern Ireland and a GB licence in GB. … two licences and two packs for the same medicine in the UK is not viable. There are simply not enough patients in Northern Ireland to make that worth while."

39. Mr Williams said that companies are already having to think about "whether they can afford, bluntly speaking, to have a Northern Ireland licence alongside a GB licence. … Companies are starting not to apply for a Northern Ireland licence alongside a GB licence … If there is a threat to a patient of not getting the medicine they need, it is the Centralised Procedure medicine. … It worries us greatly that this represents a cliff edge from the end of this year."

Possible solutions

40. Michelle Riddalls pointed out that it was the Government and the MHRA that had brought in the requirement that CP licences could not be used in the UK: "it is in the gift of UK to use a CP licence, and is something that could be theoretically changed back if needed to allow one SKU across the whole of the UK." She also said that there had been insufficient guidance on the feasibility of joint packs covering Great Britain and the EU/Northern Ireland, which would, in theory, be a potential solution.

41. Kate Ling said that the problem lay in "differences or divergence in the way in which the European Medicines Agency and the MHRA may authorise new treatments. For example, a new medicine could be licensed by the MHRA for different or broader indications than those that the EMA is prepared to authorise it for. You could end up with certain patients who could access that medication under one jurisdiction and not under the other." She agreed that UK-wide authorisation from the MHRA for medicines would solve the problem.

42. Martin Sawer stressed that manufacturers were already planning for the end-of-2023 cliff-edge, although "it might be kicked down the road. The derogation may be extended … but that does not solve the fundamental problem ... We would support a UK-wide licence." Dr Alan Stout likewise argued that "the simple solution" would be "to allow a GB licence to apply in Northern Ireland without us having to follow the different EU licences as well."

Conclusions

43. **Industry representatives expressed deep concern about the impact on Northern Ireland of the replacement of the EU Centralised Procedure/Centrally Authorised Procedure with Great Britain-only licences. We were told that the deadline for changing existing licences to GB licences by the end of 2023 was "astonishingly tight", and created the risk of a new cliff-edge in the supply of medicines to Northern Ireland at that time, as it will not be possible to provide the same pack to Great Britain and Northern Ireland after this point. This affected in particular prescription medicines, newer treatments, and those for more serious conditions: these include migraine, cancer pain and antipsychotic treatments. Our witnesses warned that "two licences and two packs for the same medicine in the UK is not viable", creating the risk that Northern Ireland patients will lose out.**

44. **What steps is the Government taking, in dialogue with the EU, to identify a sustainable solution to the licensing issue before the end of 2023? What will be the scale and impact of medicine withdrawals in Northern Ireland if this issue is not resolved? What is your response to industry claims that it is in the gift of the UK to use a CP licence across the whole of the UK? Are joint packs covering Great Britain and the EU a viable solution, and if so, what guidance will UK authorities provide to industry on how this would work? Are there any other viable means to provide for UK-wide MHRA authorisation for medicines? Short of this, will the Government consider extending the derogation for GB licences beyond the end of 2023?**

The Falsified Medicines Directive

45. Paul Williams explained that the EU Falsified Medicines Directive (FMD) introduced new measures to ensure that medicines in the EU are safe and that trade in medicines is properly controlled. Its core requirements are: a) measures to stop tampering with the pack so that medicines can't be interfered with, or substituted, before they are dispensed to

a patient; and b) the creation of a unique serial identifier for every pack, so that a medicine can be tracked and audited all the way from the point of manufacture to the point of dispensing.

46. While the FMD no longer applies in Great Britain, it continues to apply in Northern Ireland under the Protocol. Mr Williams explained that "having FMD measures for NI but not for GB would bring us back to the situation where a separate SKU would be required for Northern Ireland which … is untenable."

47. Dr Alan Stout said that "the single biggest factor that is causing the difficulties … is the requirement to follow the Falsified Medicines Directive. That is forcing the need for repackaging and everything else." Yet according to EU figures for 2019, "0.005% of drugs were counterfeit in the UK. That accounted to one prescription per day in the entire UK, so it is a tiny number and this is a completely disproportionate way to address it." He was not aware of any significant problems with counterfeit medication coming into Northern Ireland since then.

48. Martin Sawer said that "as distributors, we do not believe that [FMD] is working properly in Northern Ireland":

> "We understand that if FMD is to be in Northern Ireland, it needs to be proper and compliant, because our regulatory members are rather concerned about any liability issues and whether products are being handled legally or not. … Under the new [MHRA] guidance issued in December, for every batch or delivery received by the wholesalers in Northern Ireland, we now have to do a sample verification to make sure that it will be successfully decommissioned at the point of dispensing by the pharmacist, doctor or hospital doctor. We have to verify that the pack has been put on the European hub, has a tamper evident seal and is fully FMD-compliant. Our role is verification. We did not have to do that for every batch or delivery received prior to December last year under FMD. We were allowed to accept a manufacturer's product, without verification, that was delivered direct to an HDA company warehouse in Belfast or that arrived via a registered pre-wholesaler. We did not have to verify a sample of all packs. Now, we have to do that. … Secondly, we have to decommission, which means making sure that the pack is verified and then we have to decommission every pack off the European hub which is going to every healthcare institution in Northern Ireland that is not a hospital, pharmacy or doctor. The medicine might be going to a paramedic, a health clinic, a dentist, an optician, or other types of organisations that receive medicines. We have to fully check and decommission those before giving them to what are called Article 23 organisations in Northern Ireland. We do not have to do that now anywhere else in the UK. We are not convinced of the value of it, or that everybody in the supply chain is aware of what they are supposed to do or is compliant."

49. Mark Dayan said that, from the EU's point of view, "this is supposed to be a set of rules that eliminates the risk of fraudulent medicines. Essentially, if you have a part of its single

market—which Northern Ireland really is—that is allowed to just not do that, potentially that will raise concerns." He pointed to the "added complexity when a medicine is shipped from the EU to Northern Ireland through Great Britain, which is relatively common, of needing to essentially go through all the work of deactivating those security features as it goes into Great Britain and then reactivating them again as it crosses from … Stranraer or wherever it might do."

50. Paul Williams explained that, from the Commission's point of view, "FMD offers the cheapest and easiest safeguard against uncontrolled movement of medicines from the UK to the EU: it would be very simple for the EU's FMD serial identifier processes to flag a pack with a UK identifier and 'flag' it as not permitted for use in the EU." He understood that the Commission had expressed nervousness that, in the case of a single UK licence and pack, medicines could move from Northern Ireland to the rest of the EU without control. Yet, as we have seen, cross-border trade on the island of Ireland is at a very low level.

51. Martin Sawer acknowledged that the challenge for the EU negotiators is that UK packs valid in Northern Ireland can also go to Malta, Cyprus and Ireland. Yet he was concerned that "the FMD system is almost held up as a shining example … as part of the single market, and therefore Northern Ireland has to have the FMD."

Possible solutions

52. Martin Sawer advocated the disapplication of FMD in Northern Ireland, so that "we can go back to one licence for the UK." The National Pharmacy Association also argued in favour of "ceasing the application of this Directive within Northern Ireland, until further evidence is provided that ascertain that the Directive leads to patient safety."

53. Dr Alan Stout agreed that "if we were to look for one single solution or one fundamental solution it would be to remove Northern Ireland from the requirements of FMD. That would solve a huge number of the problems that are being faced at the moment."

54. Kate Ling agreed that "if moving medicines into Northern Ireland via Great Britain is not a problem at the moment … why would it be a problem in the future? In other words, is the Falsified Medicines Directive addressing a problem that does not really exist in the UK?"

55. However, Mark Dayan argued that it would be difficult to disapply FMD from Northern Ireland entirely "because Northern Ireland in regulatory terms is part of the European medicines market, which is using those features. That could be examined, but my suspicion is that it would be very challenging to negotiate apart from anything else." He thought it was more feasible to address the extra bureaucracy required for medicines moving from the EU to Northern Ireland via Great Britain.

Conclusions

56. **We were told that the single biggest factor causing difficulties under the Protocol is the continued application of the EU Falsified Medicines Directive (FMD) to Northern Ireland, but not to Great Britain. The application of the Directive places requirements on distributors moving products to Northern Ireland, including sample verifications of all medicine packs, and checking and decommissioning products before being passed to every healthcare institution in Northern Ireland that is not a hospital, pharmacy or doctor. For medicines moving from the EU to Northern Ireland via Great Britain, there is also the added administrative burden of deactivating security features as a product enters Great Britain and reactivating them as they enter Northern Ireland. Yet the scale of the problem is minuscule: we were informed that, according to EU figures for 2019, 0.005% of drugs were counterfeit in the UK, which would amount to one prescription per day in the UK as a whole. Nor are there any reports of significant issues with counterfeit medication in Northern Ireland.**

57. **Do you share the view of our witnesses that the optimal solution is the disapplication of the FMD in Northern Ireland? Has this issue been discussed with the Commission during the UK-EU discussions on the future of the Protocol? Is the Commission willing to consider this, and if not, what is the basis of its objection? Have any other mitigations been discussed, for instance removing the need for checks on medicines moving from the EU to Northern Ireland via Great Britain? What other means is the Government proposing in dialogue with the Commission to ease the logistical burden of the application of FMD in Northern Ireland?**

Medical devices

58. As we have seen, our witnesses told us that Northern Ireland was more reliant on supply from the EU (including from Ireland) for medical devices compared to medicines themselves. Michelle Riddalls drew attention to concerns about the burdensome impact of import requirements for medical devices moving from Great Britain to Northern Ireland:

> "The responsibility is put on those who are seen to import, and that is detailed as a shop, a petrol station or a pharmacy in Northern Ireland. There is a very wide-ranging, diverse population that could be seen as an importer. They are asked to provide information that they are the importer at the point of sale. If a corner shop was about to sell a customer a pack of plasters, which are medical devices, they would be obliged to give that customer the information that they are the importer of the product to Northern Ireland. That is a big issue of practicality. As well as that, there are regulatory obligations that they have to fulfil, understanding what happened in the supply chain and that the medical devices are appropriately certified."

Potential solutions

59. Ms Riddalls explained that, at present, suppliers were reliant on a letter of comfort from the MHRA to enable that supply to continue. However, she questioned whether this was sustainable in the long term. She stressed the need for a permanent solution, for instance through MHRA guidance taking account of EU guidance, or potentially through a dual regulatory regime.

Conclusion

60. **We have been informed of the burdensome impact of import requirements for medical devices moving from Great Britain to Northern Ireland, including the requirement for shops, petrol stations and pharmacies to provide information that they are the importer at the point of sale. Suppliers are currently reliant on a letter of comfort from the MHRA to enable that supply to continue.**

61. **What steps is the Government taking, in dialogue with the Commission, to identify a permanent solution to this issue that ensures the smooth and unhindered movement of medical devices to Northern Ireland both from Great Britain and the EU?**

Regulatory divergence

62. Witnesses expressed concern that increasing divergence between Great Britain and the EU would place medicine supply to Northern Ireland under threat. Martin Sawer said: "We have already seen signs of divergence in types of medicines not being supplied to Northern Ireland … The tectonic plates between GB and NI are slowly moving apart, and all the regulations are being stuck on top like sticking plasters, but the actual fundamental core of the problem, in our view, is the Northern Ireland Protocol because of Brexit. Medicines need to be available universally to all the citizens of the UK equally, and we believe that divergence will put that under threat."

63. On the practical consequences of divergence, Martin Sawer added: "It is making our members have to do a lot more manual regulatory work, which they do not always have confidence in because information is not always there in the supply chain, so they may unknowingly be supplying packs illegally to Northern Ireland that technically under the regulations are unlicensed. … The MHRA is catching up, but we do not know what to do when those medicines are found in the supply chain. We are not supposed to supply them to patients, but what does a doctor, pharmacist or hospital pharmacist do when they get one of those medicines in front of them?"

64. Michelle Riddalls agreed that divergent approaches to licensing by the MHRA and EMA was "extremely risky and concerning." For instance, the EMA may ask for a warning on a pack and "the MHRA might not agree and want a different warning on the pack, and your packs will split. What do you do and how can you manage that?" She also said that "divergence is

potentially in the gift of the MHRA. In the past "the MHRA said very strongly that it would not diverge from Europe for any reason; there would have to be a public health reason." However, "I have seen with my own eyes that there has been divergence in some of the products that we have been involved in at PAGB. … if more reassurance was given that there would not be divergence for the sake of divergence ... it might reassure companies more to do joint packs."

65. Mark Dayan explained that the Centralised Procedure issue highlighted above "creates not even a risk but a reality of divergence between what is available in the EU and what is available in the UK. … You have three divergent zones of the EU with its medicines centrally approved, Northern Ireland with the EU ones plus under NIMAR some of Great Britain's ones, and then Great Britain without the EU ones but with all of the ones that are done domestically." This could create problems in terms of divergence not only between Great Britain and Northern Ireland, and for cross-border service provision on the island of Ireland.

Potential solutions

66. In order to mitigate the negative impact of divergence, Mark Dayan called for "an expanded version of NIMAR for Northern Ireland and the mutual recognition of batch testing, so that you no longer have to worry about whether it is still legal to do it in the UK for Northern Ireland." However, he stressed that "this will need to be constantly worked on … because, as both the UK and the EU keep changing their regulatory systems, each side will generate more and more requirements that tend to clash with each other." He said that "some sort of resolution will have to be found … making it easier in Northern Ireland to basically fulfil single market requirements while fundamentally working alongside the UK regulatory system."

67. Kate Ling said that this required dialogue between the UK and EU: "there are governance arrangements that are set out in the agreements between the UK and the EU … A lot of these sub-groups and sub-committees and detailed technical arrangements have never been put into practice because of the political impasse." She stressed that this will become all the more important "as time goes on and the two sides diverge more and more … It is not one-way divergence … It is both ways. We need to have an ongoing, long-term way of managing that divergence sensibly, and I do not believe that it is beyond human wit to devise sensible solutions."

Conclusions

68. **We note the serious concern of industry representatives regarding the practical impact for Northern Ireland of regulatory divergence between Great Britain and the EU. We note in particular the impact of divergent approaches to licensing by the MHRA and the European Medicines Agency, and concerns that wholesalers may unwittingly be supplying unlicensed packs to Northern Ireland.**

69. **How do you respond to our witnesses' concerns that divergence between Great Britain and the EU represents a threat to the supply of medicines to Northern Ireland? In particular, what is the Government's assessment of the impact of divergent approaches to licensing by the MHRA and EMA? What steps is the Government taking, in dialogue with the Commission, to monitor and take account of the practical impact of regulatory divergence on the provision of medicines to Northern Ireland? In particular, what scope is there for intensified dialogue between UK and EU authorities, in particular the MHRA and EMA, to manage and minimise divergence on an ongoing basis?**

Potential solutions

70. In addition to the specific proposals outlined above, our witnesses discussed a number of other means for resolving outstanding difficulties.

The Northern Ireland Protocol Bill and the dual regulatory regime

71. We asked our witnesses for their assessment of the implications for medicines of the Northern Ireland Protocol Bill, and in particular the proposed dual regulatory regime. Overall, witnesses pointed to a lack of clarity on how dual regulation would work in practice. Michelle Riddalls said: "we do not know what that means in reality." Paul Williams said "there is a lack of clarity for us on what dual regulation might mean". Martin Sawer added: "I have no evidence from anywhere in the world of a dual regulatory system working … We have asked that question many times of the Department of Health and Social Care and the MHRA, but we have not yet had an answer from them … It sounds quite exciting, but we do not know how it would work, I am afraid."

72. Dr Alan Stout agreed: "I am yet to find somebody who properly understands not only what it means but how it would work in practice. It introduces an awful lot more risks, and it has the potential of introducing more bureaucracy. … I do not see dual regulation as a magic bullet. One of the biggest threats … is how the industry deals with it. It may pick and choose who it regulates with, who it licenses with and so on. That might expose us even more, with time."

73. Mark Dayan said that "on the face of it, the dual regulatory regime would resolve many of these problems." For example, it "would mean that a GB approval was good enough to use in Northern Ireland. It would take away the issues where there is a cliff edge around batch testing. It would mean that you did not have to do the Falsified Medicines Directive if you chose to use the GB rather than the EU regulatory system." However, he said that this could potentially give rise to further difficulties: "We have to be ready to interact with two different regulatory systems for essentially the same product. You would imagine that if that was the case some firms would get their products dual listed so that they could be signed off as either. Then there would be some working through as to whether that would work without having to be signed off as both." He added that the unilateral approach of the Northern Ireland Protocol Bill "just does not seem very acceptable to the EU, which is an important thing to take into account. … If this is imposed but not accepted by the EU, it

runs the risk of either some sort of wider breakdown in the protocol or of other EU retaliatory actions for breaching it."

74. Michelle Riddalls acknowledged that dual regulation could "help reduce unnecessary burdens", for instance around supply of Centrally Authorised Products and medical devices. However, "the fact that dual regulation is being proposed only for Northern Ireland seems strange to us. … If you are seriously looking at dual regulation, you need to have it across the whole country; otherwise, you have the complexity again—you have one part of the country doing something different from another." She added that "dual regulation is a unilateral action. There may be some merit" in such ideas, "but they have to be worked out and gone through, with technical discussions."

75. Kate Ling said that dual regulation "could work", as "manufacturers could choose to license their products for sale in Northern Ireland, either by the EU route or the UK route." The EU route would reach a bigger market initially, for example, while "the UK route could be attractive if medications were authorised more quickly if they were perhaps authorised for different or broader indications than the EMA authorisation." However, she stressed that there was a distinction to be made between the "practical impact of the proposed dual regulation system" and the "political impact", including any retaliatory action by the EU to the passage of the Northern Ireland Protocol Bill and enactment of its provisions.

76. Paul Williams asserted that "dual regulation only works in practice if there is no regulatory divergence." For example, if either the EMA or MHRA banned an ingredient and the other did not: "is the tablet now legal to supply in Northern Ireland or illegal? It is Schrödinger's tablet; it is both legal and illegal at the same time. In theory, I completely agree … In practice, we do not understand how it will work."

77. **While some of our witnesses saw the potential in theory for a dual regulatory regime to resolve the above issues, they emphasised the lack of clarity as to how it would work in practice. Witnesses also argued that it could give rise to further difficulties or uncertainty in the case of a highly regulated sector such as medicines, in particular if the EMA and the MHRA gave conflicting guidance, or if imposed unilaterally.**

78. **Is the Government still pursuing the dual regulatory model? If so, how would it work in practice in relation to the supply of medicines to Northern Ireland? In particular, how would a dual regulatory regime account for conflicting guidance from the EMA and MHRA?**

The Northern Ireland MHRA Authorised Route (NIMAR)

79. The Government stated that the Northern Ireland MHRA Authorised Route (NIMAR) "has been designed to ensure that people in Northern Ireland can continue to access prescription-only medicines (POMs) should clinical need be unable to be met through authorised products or any other existing regulatory routes. NIMAR provides a route for

the lawful supply of POMs in compliance with UK and EU rules, where there is a risk that clinical need in NI for that product cannot be met. This includes supply of medicines that are unlicensed in NI, but which are licensed and approved in GB."[1]

80. We asked our witnesses to assess how NIMAR was working in practice. The National Pharmacy Association welcomed NIMAR as a means to mitigate against the unavailability of prescription medicines. Michelle Riddalls said that, "if NIMAR did not exist, those products would not be going into Northern Ireland. … It is not a perfect solution by any means. There needs to be a better solution, but as a stopgap at least products are getting through in that way." Kate Ling and Mark Dayan agreed. Paul Williams described it as "a safety net" mechanism for supplying medicines in Northern Ireland where otherwise it would not be possible, including insulin and Metformin, which are both diabetes treatments; Clopidogrel, which is a heart disease product; Imatinib, which is for leukaemia; and Remdesivir, which is used in respiratory medicine and to treat COVID.

81. That said, our witnesses stressed that the NIMAR route was far from ideal. Paul Williams described it as "a temporary fix, not a long-term solution. It is bureaucratic and has grey areas. It is not something that anyone in the industry", including the Chief Pharmaceutical Officer of Northern Ireland, "thought was a long-term sustainable position. … [It] is a step outside the normal process; it represents an extra step that has to be undertaken, so there is extra complexity. In addition, there are rules around NIMAR, in particular that those products may not be promoted or detailed in Northern Ireland. Effectively, you are not allowed to speak to doctors about those products. That leaves some ambiguities."

82. Martin Sawer agreed that the NIMAR process was "very bureaucratic":

> "We have to chase the tail. We do not always know when things are going on the NIMAR list until they do. The list is growing every two weeks, roughly. It is incrementally increasing. It will get close to 200 SKUs shortly. Under the MHRA regulations, the trouble is that we have to record every NIMAR pack we supply. That means that when the NIMAR list is manually updated … we talk to the manufacturer, work out which product they are talking about, and then change our automation systems to try to identify that product. Often, if it is supplied from GB and not in Belfast warehouses to start with, it is difficult to disentangle from one column of medicines that is going to the rest of the UK from a big warehouse. We have no electronic system yet of identifying NIMAR products … because we have our own coding system in warehouses that covers all UK packs. If we identify separate types of packs, we will need double the space for the same medicine. … What happens when we are inspected and we have not recorded the information correctly?"

83. Michelle Riddalls explained that NIMAR did not affect OTCs, but nevertheless called for enhanced guidance on its operation. Kate Ling said that, while patients were getting

[1] The Northern Ireland MHRA Authorised Route (NIMAR) - GOV.UK (www.gov.uk)

medication, "as time goes on, the market is likely to get thinner and there is likely to be less choice and less diversity in the range of medications that will be available to patients in Northern Ireland if this trend continues."

84. Mark Dayan saw no particular reason why NIMAR would have to cease, but acknowledged the additional bureaucracy involved. He said that NIMAR could be a step in the direction of a comprehensive mechanism for GB authorisations applying in Northern Ireland. He also noted that through NIMAR, "it is now notionally possible that Northern Ireland could get some medicines before the EU if the UK approved them first."

85. **We acknowledge the crucial role that the Northern Ireland MHRA Authorised Route (NIMAR) has played in securing the continued supply of many prescription medicines to Northern Ireland, including treatments for diabetes, heart disease, leukaemia, respiratory disease and COVID. We also note that nearly 200 Stock-Keeping Units are subject to the NIMAR process. Nevertheless, we acknowledge industry concerns about the extra bureaucracy involved, the practical challenges of supplying such products, and uncertainty about whether products subject to NIMAR can be promoted in Northern Ireland.**

86. **Is NIMAR viable as a long-term mechanism for ensuring the supply of prescription medicines to Northern Ireland? If so, what practical steps will the Government, in dialogue with the Commission, take to reduce the bureaucracy and practical challenges involved in supplying products via the NIMAR route? Will the Government commit to providing more detailed guidance on the operation of NIMAR, including on whether products supplied via this route can be promoted in Northern Ireland? If NIMAR is not a long-term solution, what other means will be provided to ensure the continued supply of such medicines?**

A mutual recognition agreement

87. Paul Williams said that Teva and its trade association, the British Generic Manufacturers Association, had been arguing for several years for a UK-EU mutual recognition agreement "so that the EU and the UK would recognise each other's testing. … At this moment in time, we are unable to get any traction with that, but it would simplify the whole medicines chain for the UK considerably if it was possible."

88. Kate Ling said that the NHS Confederation had also been calling for a mutual recognition agreement for some time, "so that the two regulators would mutually recognise each other's decisions. … There are all sorts of possibilities where the UK and the EU could work together to agree some sort of joint marketing authorisation. The EMA and the MHRA could liaise about joint procedures, for example accepting the same evidence, sharing submissions and sharing assessment outcomes." However, she stressed that this was dependent on political will and trust on both sides.

89. Mark Dayan did not think it was feasible for UK approvals to apply automatically in the EU. However, as we have seen, he thought that "there could be an expanded version of NIMAR for Northern Ireland and the mutual recognition of batch testing."

90. **We note the support of industry for a UK-EU Mutual Recognition Agreement as beneficial for the whole medicines industry. Is the Government pursuing this with the Commission? If not, why not? Short of this, what mechanisms can be created to provide for enhanced coordination between the MHRA and EMA, or for the mutual recognition of batch testing?**

Continuation of existing mitigations and derogations

91. Dr Alan Stout was confident, based on the willingness hitherto of both sides to take action in relation to medicines, that the current mitigations and derogations in place would ultimately continue. Mark Dayan and Kate Ling also called for the current derogations to either be extended or made permanent. As we have seen, Martin Sawer suggested that the end-of-2023 cliff-edge for Centrally Authorised Products "might be kicked down the road", although this would not resolve the fundamental problem.

92. **Short of permanent solutions to the issues identified above, what scope is there to continue with the derogations and mitigations currently in place in relation to medicine supply? What dialogue has the Government had with the Commission on this?**

Removal of medicines entirely from the Protocol

93. Our witnesses noted that the Government had argued in its July 2021 Command Paper for medicines to be removed entirely from the Protocol. However, Kate Ling thought that this was unlikely to happen.

94. Martin Sawer said that, while he would still support removing medicines from the Protocol, "we do not want it to be done unilaterally. We would much prefer an agreement. It would seem to me that both sides could justify taking medicines out of the Northern Ireland Protocol on public health grounds and patient safety grounds, and not lose face."

95. The National Pharmacy Association likewise called for "a mutually satisfactory conclusion to the discussions between the UK and EU pertaining to the NI Protocol and … one of the best solutions would be to remove medicines from the scope of the Protocol."

96. Michelle Riddalls said that, while there may be some merit in this proposal, it could in turn lead to further uncertainty, especially if pursued unilaterally. She noted that many companies in the sector are global companies with "EU centres. … If you have arguments between the EMA and the UK as to what is allowed and what is not allowed, the easier solution for a

company within the EU is to refer to the EU 27 and pull out of the UK and Northern Ireland."

97. Mark Dayan acknowledged that removal of medicines entirely from the Protocol "would solve most of the problems" that had been identified. However, he warned that it could create issues, for instance with the (albeit limited) cross-border medicine supply on the island of Ireland and exports from Northern Ireland.

98. **We note the continued support of some witnesses for the removal of medicines in their entirety from the Protocol, as proposed by the Government in its July 2021 Command Paper, subject to mutual agreement with the EU. Does the Government continue to advocate the removal of medicines from the Protocol, and has this been proposed in dialogue with the Commission? If so, how has the Commission responded, and on what grounds has it been unwilling to agree this?**

Enhanced engagement with industry

99. Michelle Riddalls stressed that industry engagement with the UK and the EU had been crucial preparatory to the EU's legislative proposals being brought forward. She said that engagement had continued with the DHSC and MHRA. However, "over the last six months or so, there have probably been fewer interactions than we had previously on some of these topics." She called on the Government to "utilise the technical regulatory experts to say whether that is a solution, actually find the barrier to the problem, and then come up with a solution and an ask for the EU." Ms Riddalls added that "we have not been involved with anything with regard to the EU in recent times."

100. Martin Sawer said that engagement with UK authorities has been "exemplary", and he paid tribute to the hard work of officials. However, he shared concerns "that at this point in the negotiations, as we understand they are going on at the moment, we do not have access to the negotiating representatives as much as we did in 2021. I do not know whether that is significant or not, because obviously it is the whole Protocol and not just medicines." He said that the HDA had had no formal engagement with the EU, although its trade association in Brussels had brought concerns about Northern Ireland to the attention of the Commission.

101. Paul Williams likewise cited strongly positive relationships with the DHSC, the Northern Ireland Department of Health and the MHRA. Teva also sought to engage with the Commission through its office in Brussels, and therefore to speak to both sides of the debate. He also stressed the importance of engaging with industry on technical issues that required resolution. Yet he was concerned that "that is not the same as getting traction where the decisions are really made." He too noted that "the frequency of the interaction seems to have dropped off a bit."

102. Kate Ling said that one positive by-product of the Protocol was that it had "driven the health departments and industry and NHS to work together much more closely, and it has greatly improved the monitoring and management of the medicine supply chain. … For example, with the introduction of the NIMAR route they have had to work together very closely to ensure that medication that is available in England, which is licensed by MHRA, that whatever people are getting in Great Britain they are also able to access in Northern Ireland." She was disappointed that the medicinal products working group proposed under the UK-EU Trade and Cooperation Agreement had yet to meet, as this would be a forum where technical experts could discuss practical and workable solutions. It was her understanding that this was due to an unwillingness on the EU side. Nevertheless, she said that the NHS Confederation had strong links with EU counterparts, which were helpful in encouraging counterparts to make representations to the European Commission.

103. Kate Ling said that, whereas health sector representatives on both sides were "aligned in things that we would like to see", the obstacle was the "very legalistic … matter of principle" approach at the political level. Mark Dayan likewise suggested that, rather than a lack of understanding of the issues, "the points of tension as to why this is a different negotiation are probably more because the solutions offend the principles of one side or the other. At times, they are genuinely untested things that no developed country has tried to do before, even short of the full dual regulatory route, in terms of allowing two different regulatory systems to approve things into one place."

104. **We welcome the Government's previously strong and intensive engagement with industry stakeholders. However, we are deeply concerned to hear that this engagement has diminished since the EU's legislation was brought forward, in particular given the clear evidence of significant outstanding issues that need to be resolved. We are also concerned to note the paucity of direct engagement between UK industry representatives and the EU, given the importance of a detailed technical understanding of the impact of the Protocol on medicine supply to Northern Ireland. Both the Government and the EU must take urgent steps to address this and to re-engage with pharmaceutical industry representatives.**

105. **How will the Government ensure that the concerns of industry are taken into account and addressed in its dialogue with the EU? In particular, what steps will the Government take to enhance its engagement with industry in order to identify solutions to the issues outlined in this letter, and to facilitate industry dialogue with the EU? What steps will you take, in dialogue with the Commission, to provide for such dialogue through the governance bodies established under the Trade and Cooperation Agreement, the Withdrawal Agreement and the Protocol itself?**

A commitment to negotiate a sustainable solution

106. Linked to this was a fear that medicines had fallen off the radar of the UK-EU talks due to an erroneous assumption that the issue had been resolved. Paul Williams was concerned that "there is a perception, which has been talked about, that it is sort of fixed when it is clear that it is not. … Our fear at the moment is that at a top level there is a feeling that things have moved on, but, actually, they have not." The National Pharmacy Association stressed that "the impact of disruptions to medicine supply on the health of citizens in Northern Ireland must remain of paramount importance within these discussions."

107. Paul Williams said that the overriding priority was to secure "stability and certainty over the coming years." He stressed the need for a mutually agreed resolution, which would require compromise and pragmatism on both sides. Dr Alan Stout said that the Government was not doing enough: "there is no discussion and negotiation going on at the moment. That is why we are fearful of coming to yet another cliff edge." He called for "much more of a dynamic process than a crisis process. … We have clear evidence of what happens with a series of events as we hit various cliff edges."

108. Kate Ling warned that "in the rush to get a deal done and to get something over the line, the issues about the supply of medicines will perhaps be forgotten about, side-lined or not dealt with properly. We want to see a long-lasting, stable solution to this. We are worried that if something is rushed through there may be an agreement that ends up in another fudge, something half-baked, and that there will still be anomalies or unresolved issues to be sorted out later. We really do not want to see that. … It is all about trust and good will and getting down to those concrete discussions." She said that "it would be morally indefensible for patients to be caught in the crossfire like this, to be treated as chess pieces in a much larger political game."

109. **We share the concern of industry that the issues around the provision of medicines to Northern Ireland have fallen off the radar of the UK-EU discussions over the future of the Protocol, under a misapprehension that the issues regarding medicine supply have been resolved. The evidence we have heard makes clear that this is not the case.**

110. **In view of this, can you set out what, if any, consideration has been given to the issue of medicine supply to Northern Ireland in the UK-EU discussions on the future of the Protocol? What proposals will be brought forward to provide a long-term solution to the issues identified in this letter?**

Conclusion

111. **We conclude by endorsing the evidence put to us by medicine industry stakeholders:**

> **"In the rush to get a deal done and to get something over the line, the issues about the supply of medicines will perhaps be forgotten about, side-lined or not dealt with properly. We want to see a long-lasting, stable solution to this. … The impact of disruptions to medicine supply on the health of citizens in Northern Ireland must remain of paramount importance within these discussions. … It would be morally indefensible for patients to be caught in the crossfire like this, to be treated as chess pieces in a much larger political game."**