The Consumer Healthcare Association

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

The current situation in Northern Ireland as it relates to the Protocol

Submission from PAGB, the consumer healthcare association

11 June 2021

PAGB, the consumer healthcare association, welcomes the opportunity to provide evidence to this inquiry. We have restricted our comments to the areas where we feel we can most helpfully contribute to the Committee's discussions. We would be pleased to present further evidence to the Committee on the issues outlined in this submission.

PAGB is the UK trade association representing the manufacturers of branded over-the-counter (OTC) medicines, self care medical devices and food supplements. These products can be bought from a pharmacy or other retail outlets without a prescription and help people to stay healthy and self care for self-treatable conditions which do not require consultation with a medical professional.

Summary of key points

i. When the regulatory flexibilities for the supply of medicines to Northern Ireland cease on 1 January 2022, and if pragmatic solutions aren't agreed, between 75% and 98% of over-the-counter medicines currently available in Northern Ireland (measured in stock keeping units/SKUs) could be discontinued.

ii. This would mean people in Northern Ireland would not be able to access safe and effective medicines to enable them to self care for everyday health conditions and would place an increased burden on NHS services, as people would have no option but to visit their GP or A&E for treatment.

iii. As a result of the Northern Ireland Protocol, medicinal products for supply in Northern Ireland will need to meet the regulatory requirements of the EU. Medicines which are currently distributed from Great Britain to Northern Ireland will be considered imported products. This means that a number of importation and regulatory requirements will need to be fulfilled or repeated.

iv. The model of supply for over-the-counter medicines is based on product being sold to retailers such as Boots and Sainsbury's for the whole of the UK, and distributed through the country, including to Northern Ireland, by the retailers. It is impossible for a retailer or distributor to carry out the EU import requirements on a product that they do not manufacture or hold the licence for.

v. Different national licensing regimes in Ireland and the UK, mean it is not possible simply to supply medicines from Ireland to Northern Ireland.

vi. A long-term solution is needed for medicines, which avoids unnecessary regulatory complexity and duplication. We would like to see an agreement which permits medicines licensed for use in Great Britain to be supplied to Northern Ireland without additional checks.

1. What is your assessment of the overall socio-economic and political impact upon Northern Ireland of the Protocol on Ireland/Northern Ireland since it came into force on 1 January?

1.1 With regards the supply of over-the-counter medicines, the full impact remains to be felt in Northern Ireland. Under an agreement reached between the UK and the EU on 8 December 2020, a 'grace period' is in place until 31 December 2021. During this grace period:

- 'Quality Control (QC') testing in Great Britain continues to be valid in Northern Ireland
- 'Qualified Person (QP)' certification in Great Britain continues to be valid in Northern Ireland
- A pragmatic approach to EU importation requirements, and requirements to apply unique identifiers (FMD) to packs of medicines, is being applied

From 1 January 2022, these flexibilities cease and if pragmatic solutions aren't agreed, the impact will be that between 75% and 98% of over-the-counter medicines currently available in Northern Ireland (measured in stock keeping units/SKUs) could be discontinued.

1.2 This would mean people in Northern Ireland would not be able to access safe and effective medicines to enable them to self care for everyday health conditions such as headaches, sore throats, headlice, hay fever and earache.

1.3 This would place an increased burden on overstretched NHS services, as people experiencing these types of conditions would have no option but to visit their GP or A&E for treatment.

1.4 Medical Devices have continued to be supplied into Northern Ireland under the new rules since 1 January 2021. However since this time they are being supplied as imports into Northern Ireland from GB. This had been fairly smooth, however, the implementation of the EU Medical Device Regulation (MDR) on 26 May 2021 did cause potential concern because of the additional burdens that this placed on the importers of medical devices. Guidance on some of the nuances relating to importation and what this means in terms of both regulatory checks but also documentation accompanying the device had not been the subject of detailed guidance and there were outstanding concerns relating to how to implement these changes. Following sustained discussions by PAGB with DHSC and MHRA, MHRA did issue a "letter of comfort" to offer to help get products into compliance from this time. This ensured retailers and companies had the confidence to keep the product flowing into NI, however further meetings and discussions on agreeing what compliance looks like have yet to be followed up.

2. What would you identify as the main practical issues that have so far arisen in relation to the Protocol's operation, including both for GB and Northern Ireland-based businesses? How significant have these problems been, and what impact have they had on the ground?

2.1 As a result of the Northern Ireland Protocol, at the end of the grace period, medicinal products for supply in Northern Ireland will need to meet the regulatory requirements of the EU. Therefore, medicines which are currently distributed from Great Britain to Northern Ireland will be considered as imported products. This means that a number of importation and regulatory requirements will need to be fulfilled or repeated for medicines to be supplied to Northern Ireland from Great Britain.

2.2 Importation means that the product has to be:

- Re-tested in Northern Ireland or EU, to its product specification which is held by the manufacturer
- Re-released by a Qualified Person who is registered on an appropriate manufacturing licence for Northern Ireland and EU
- An appropriate Manufacturing Import Authorisation (MIA) needs to be held by the company importing the product
- The address of the site releasing the product in NI would need to be included on the Patient Information Leaflet which is provided with the medicinal product.

2.3 Because supply of medicines within the UK is managed as a whole, most OTC medicines are currently supplied to Northern Ireland from or through Great Britain. Supply is largely through retailer chains, such as Boots and Sainsbury's, and distribution sites. It is impossible for a retailer or distributor to carry out the import requirements listed above on a product that they do not manufacture or hold the licence for.

2.4 It is not possible to simply supply Northern Ireland with medicines from Ireland. Medicinal products for Ireland are approved for use by a different regulatory authority (HPRA) to the UK (MHRA) and therefore, the conditions of the licence may differ. Over 98% of OTC medicines available in Northern Ireland are registered under a national (UK) licence. This means that they can be, and often are, different to product placed on the market in other countries. Differences include:

- Availability – not all medicinal products which are currently available in Northern Ireland are registered in Ireland
- Legal status – for example ibuprofen can only be sold as a P or Pharmacy medicine in Ireland but is available on general sale (GSL) in supermarkets and other retail outlets in Northern Ireland
- Pack size – in Ireland the maximum GSL pack size for liquid paracetamol is 60ml and in Northern Ireland it is 100ml
- Statutory information – paracetamol has different legal statutory warnings that have to be on outer packaging and in the patient information leaflet in Ireland compared to the UK (including Northern Ireland)
- Manufacturing/product differences – because many OTC medicines are registered under a national licence, the registered details may be different to those on the product licence for Ireland. This means that although a nearly identical product may be available, the medicine may have to be made or tested differently in different countries to be compliant and legally sold. In some cases there may be slight variances in the ingredients contained in the product.

2.5 With regard to medical devices, there is still a lack of clarification regarding what is needed to fulfil the obligations under the EU MDR and this needs to be addressed. Further information needs to be provided to retailers to fully understand the requirements that are being placed upon them. Previously they had been distributing product to their own stores within the UK prior to EU exit, and now they are having to import to their own stores in NI. Many retailers are not fully aware of the obligations which this places on them. The outcome will be that they are either non-compliant, or they may reduce supply of products to Northern Ireland as they are unable to understand or fulfil the requirements and so opt to discontinue products instead.

3. What impact has the Protocol, and UK withdrawal more broadly, had on trade flows between Great Britain, Northern Ireland and Ireland, and the rest of the EU?

3.1 When the regulatory flexibilities for medicines cease on 1 January 2022, companies may not be able to supply from Great Britain to Northern Ireland because the

additional infrastructure and personnel to support the new regulatory requirements within Northern Ireland or the EU do not currently exist within their company or contract resources. It will, therefore, be economically unviable for them to supply Northern Ireland.

3.2 In respect of over-the-counter medicines specifically, the model of supply is often based on medicines being purchased from UK-wide retailers and pharmacies, and then distributed to Northern Ireland after having been stored in Great Britain – and this model of supply is impossible once existing flexibilities cease, since retailers will not be able to retest or release products they have not manufactured.

3.3 A recent survey of PAGB member companies helps quantify the risks to supply which exist:

- 50% of respondents reported that, although it was technically feasible for them to transit products from Great Britain to Northern Ireland once the new requirements were in place, just 10% said that it would be viable to do so
- 70% of respondents reported that, although it was technically feasible for them to transit products from the Republic of Ireland to Northern Ireland, just 30% said that it would be viable to do so
- As a result, and of the products currently supplied to Northern Ireland, between 75% and 98% are at risk of being discontinued once the new requirements take effect

4. Has the Protocol had any positive impact for Northern Ireland?

4.1 PAGB can only comment on the supply of medicines and other self care products, and in this regard, we have not seen any positive impact from the Protocol.

5. Is there a viable alternative to the Protocol?

5.1 PAGB does not have a view on this question.

6. How would you characterise the attitudes of the communities in Northern Ireland in relation to the Protocol? How significant, compared to other issues and concerns, has the Protocol been as a contributory factor to the recent community disturbances in Northern Ireland?

6.1 PAGB does not have a view on this question.

7. What action would you wish to see the Northern Ireland Executive take in relation to the Protocol, including in its engagement with the UK Government, the EU and the Irish Government?

7.1 PAGB does not have a view on this question.

8. What is your assessment of the UK Government's approach to the Protocol, and its engagement with Northern Ireland stakeholders, since it came into force?

8.1 Officials in the UK Department of Health and Social Care have engaged constructively with our industry to understand the issues and to identify solutions to

enable supply of medicines to continue to Northern Ireland. Using data and examples provided by trade associations such as PAGB, they negotiated the one-year grace period for medicines, which was incredibly helpful and positive. If the grace period had not existed, there would be very little supply of medicines to Northern Ireland at the current time. We have had the opportunity to attend meetings with Ministers to discuss the situation and raise our concerns. We have also co-chaired work with DHSC to try and find solutions to the issues for medicines and medical devices. Our view is that the UK Government is working hard to resolve the issues for medicines supply.

8.2 DHSC was also instrumental in facilitating the letter of comfort from MHRA to help allow continued supply of medical devices into Northern Ireland following the introduction of the EU MDR on 26 May 2021.

9. What is your assessment of the EU's approach to the Protocol, and its engagement with Northern Ireland stakeholders, since it came into force?

9.1 Officials at the European Commission have been prepared to meet with representatives of our European trade association and with some of our member companies. In recent weeks we have witnessed a greater willingness to engage in discussions about the supply of medicines to protect public health.

9.2 It has been clear that the EU has had a different interpretation to aspects of the Northern Ireland Protocol than the UK and this has caused difficulties for pharmaceutical companies. An example has been regarding whether a UK marketing authorisation holder can own a medicine's licence for Northern Ireland. The UK says yes and the EU says no, and the EU has sent letters to companies to tell them they are being non-compliant and held up procedures that are ongoing in the EU as a result. As such, the EU has appeared to be taking a "hard and inflexible" stance and one that will prevent supply of product to Northern Ireland, whereas a different interpretation e.g. the UK position, would allow supply to continue.

9.3 It is therefore positive that we are witnessing this change in engagement and reference to ensuring that medicines will be supplied to Northern Ireland because, as outlined above, at the moment there are legal and regulatory reasons they will not be able to as of 1 January 2021.

10. What practical steps can the UK and EU take through the Withdrawal Agreement Joint Committee and Ireland/Northern Ireland Specialised Committee to mitigate the Protocol's negative impact on the people and businesses of Northern Ireland?

10.1 We believe there needs to be a long-term solution for medicines which avoids unnecessary regulatory complexity and duplication. In our view, given the risks of medicines leaking onto the EU single market from Northern Ireland in an unregulated manner are very slim, we feel that 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.

10.2 A regulatory cooperation agreement (a Mutual Recognition Agreement or equivalent) for QC testing, would go some way in helping resolve the problems in supply to Northern Ireland, and would be a positive step in achieving a solution.

10.3 If more time is needed to arrive at a long-term solution for medicines, an extension to the grace period should be agreed as soon as possible.

11. What practical difference would a UK-EU veterinary/SPS agreement have on the operation of the Protocol?

11.1 The requirements to provide an export health certificate (EHC) when moving Products of Animal Origin (POAO) from GB to NI and from GB to the EU has been identified as one of the major factors in reducing and slowing the trade flow of these products between these markets since the UK left the EU. Both the costs involved in providing an EHC for each consignment of POAO and the availability of competent certifying officers, including vets and environmental health officers, have been cited as major barriers to export. Time delays due to the complexity of the system is also an issue and in particular for food products with a short shelf life that needs to reach the consumer quickly.

11.2 Since 1 January 2021, the British food industry has seen a dramatic increase in the number of EHCs required to meet demand for trade with the EU/NI. This increased demand has placed an overwhelming burden on businesses. As a result, many food companies have reported losing export business to the EU/NI as they no longer benefit from the agile supply lines that were previously available to them as members of the EU. Although the UK Government has eased the cost burden on trade with NI by reimbursing the costs of EHCs via the Movement Assistance Scheme (MAS), this is likely to be unsustainable long term and consideration needs to be given to a long-term solution.

11.3 The current GB export certification system relies on a small pool of official veterinarians and environmental health certifying officers (OVs) to inspect and sign off POAO leaving GB ports. Ahead of the full implementation of the Northern Ireland Protocol it is difficult to estimate what the exact increase in veterinary demands will be. However, companies remain concerned that there will not be enough OVs to process the volume of checks and paperwork needed to maintain current export volumes.

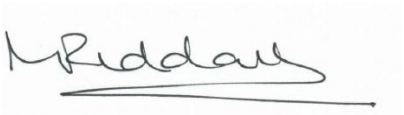
11.4 Prior to leaving the EU, UK companies moving POAO within the EU did so under a common set of rules. UK legislation is currently aligned with that of the EU. Since 1 January 2021, companies have continued to follow those rules but must now prove it by undergoing complex certifying and checking procedures. Reaching an UK-EU veterinary/SPS agreement would have a significant impact on reducing the need for veterinary measures and checks at borders. If equivalence of standards were recognised, it would support the flow of goods by reducing border checks but would not remove the need for EHCs. On the other hand, a Swiss style agreement where there was alignment on regulations would improve the flow of goods as well as reduce the need for OVs to sign EHCs.

12. How can concerns about the perceived democratic deficit at the heart of the Protocol, in view of the continued dynamic application of significant areas of EU law to Northern Ireland in the absence of UK participation in the EU institutions, be addressed?

12.1 PAGB does not have a view on this question.

13. What work would you like to see this Committee undertake in scrutinising the operation and impact of the Protocol?

13.1 PAGB would welcome the Committee's scrutiny of the supply of over-the-counter medicines to Northern Ireland under the Protocol. We would also welcome further analysis of wider impact on medical device supply via retailers and wholesalers into Northern Ireland, to ensure companies understand what compliance looks like and then assess whether it can be met. We would be happy to provide further written or oral evidence to the Committee on these issues.



Michelle Riddalls
Chief Executive

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For more information about PAGB, please see: https://www.pagb.co.uk/about-us/

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