Walgreens Boots Alliance – Written evidence (FUI0024)

Walgreens Boots Alliance's submission to the House of Lords Sub-Committee on the Protocol on Ireland/Northern Ireland's call for evidence on the impact of the Protocol on Ireland/Northern Ireland.

Boots is the UK's leading health and beauty retailer. With over 2,200 stores ranging from local community pharmacies to large destination health and beauty stores, our purpose is to help our customers look and feel better than they ever thought possible. Boots UK is part of the Retail Pharmacy International Division of Walgreens Boots Alliance, which is a global leader in health and wellbeing retail.

Boots in Northern Ireland (NI):

- Boots has 78 stores in NI - 66 of these hold NHS pharmacies.
- Our FY20 Revenue was £5.8bn for Boots UK, of which £147m is NI.
- We send roughly around 2-3 trailers daily which means around 10-15 weekly over to NI. Each trailer carries on average 6,000 SKUs.
- On average, we send 5,000 boots.com orders to Northern Ireland weekly.

Summary

- The implementation of the Northern Ireland Protocol (NIP) has entailed significant operational and practical challenges for our supply into Northern Ireland (NI). While derogations have been helpful, the lack of certainty over the future of the regulatory landscape in NI prevents businesses from preparing and investing the necessary resources to continue supplying goods into NI.
- The NIP has created specific requirements for NI which is considered as a small market for many of our business partners. It is not commercially viable to adapt and meet the new NI specific rules for many of them and some have already decided to stop supplying their products in NI or increase their prices.
- **Medicines** – the lack of clear guidance, ongoing confusion over the rules and upcoming market specific requirements have deterred some of our medicines suppliers from investing and supplying medicines into Northern Ireland. This has started impacting our customers and patients with fewer products available. We would like to see medicines removed from the Protocol so that Northern Irish patients can still have easily access to UK approved medicines.
- **Medical Devices** – as for medicines, the overall uncertainty regarding the regulatory landscape has hindered business planning. We have had to absorb significant additional costs due to the regulatory burden of re-registering Medical Devices above class 1. New importer requirements are also creating cost and practical challenges. Mutual recognition of EU and UK Medical Devices regulation would prevent the reduction of product availability in NI and avoid price increases.

- **Derogations** – the end of the derogations over customs requirements for SPS checks and parcels will impact our ability to send 300+ POAO products incl. baby food and c. 5,000 parcels in NI as we currently cannot segregate our products going into NI. While the derogations cannot be a long-term solution, we would like to see permanent easements put in place so we can continue providing a range of products into NI.
- A trade war with the EU would aggravate the climate of uncertainty and further hinder business planning and investment.

1. (3) What would you identify as the main practical issues that have arisen in relation to the Protocol's operation, including both for GB and Northern Ireland-based businesses? To what extent have these issues been ameliorated or exacerbated over the past year?

1.1. Since the 1st January 2021, our business has incurred additional operational costs to manage the implications of trading between Great Britain (GB) and Northern Ireland (NI). For instance, we have already spent £250k of additional resources to manage the additional customs and border control requirements to trade from GB to both NI and ROI.

1.2. Thanks to the derogations to the implementation of the Northern Ireland Protocol (NIP), we have been able to manage the practical challenges and maintain overall product availability and consistency within our retail stores and community pharmacies that are based in NI. Nevertheless, we are dealing with many operational challenges regarding the supply of medicines and medical devices, and our e-commerce parcels.

Medicines

1.1. Since the implementation of the Northern Ireland Protocol (NIP), there has been a lack of operational and regulatory guidance for the stakeholders of the GB-NI medicine supply chain. As a result, our wholesale partner has already told us that he is expecting to stop distributing some products in NI partly because of some manufacturers' ongoing confusion over the rules, as guidance and derogations have changed many times over the last couple of years. This lack of clarity does not create a favourable environment for businesses to invest and maintain supply into NI.

1.2. Recently, we welcomed the adoption of the EU Directive to ensure continued supply of medicines to NI[1]. According to this piece of legislation, the Medicine and Healthcare Product Regulatory Agency (MHRA) will be

[1] Directive (EU) 2022/642 amending Directives 2001/20/EC and 2001/83/EC as regards derogations from certain obligations concerning certain medicinal products for human use made available in the United Kingdom in respect of Northern Ireland and in Cyprus, Ireland and Malta

able to authorise manufacturers located in GB to use a single pack and leaflet when supplying in GB and NI.

1.3. However, the derogations will only last three years (until 31 December 2024) and we have no clarity on the future of the medicine regulatory landscape in NI after that date.

1.4. Furthermore, the EU Directive does not cover products authorised by the centralised procedure of the European Medical Agency (EMA) which is the EU wide procedure for the authorisation of medicines. Centrally approved products (CAPs) already available in the UK were automatically converted into UK Market Authorised (MA) products effective in Great Britain and issued with a UK MA number on 1 January 2021. New CAPs now must obtain a new NI license by either the usual UK licensing route or the EU Decentralised and Mutual Recognition Procedures routes[2] because of the dual requirements for NI (UK registration and EU registration). Manufacturers would have to create both a GB specific pack and a NI specific pack with the NI pack having to meet the EU requirements (e.g. FMD). Given the small size of the NI market, this segregation will not be viable for many manufacturers who will likely decide to not supply NI at all. Wholesalers will also have to create additional space to segregate stock and manage the lines separately which will require significant investment.

1.5. Furthermore, we are aware that some manufacturers of "Specials" (unlicensed medication approved by the EMA) have now stopped supplying NI due to the customs and import requirements negatively impacting patients. Some of these manufacturers have continued to supply the NI market but the additional paperwork has led to delays in product getting to patients.

1.6. Finally, the amended Falsified Medicine Directive (FMD) is also a challenge as it implies that all products entering NI from GB need to be verified by wholesalers. This cannot be done with wholesalers' current operational structure. We also need to ensure and demonstrate the correct implementation and application of the FMD in respect of NI. This is reliant on manufacturers making packs available with the appropriate safety requirements.

Medical Devices

1.7. The sale of Medical Device in NI has also been impacted by the NIP. All our medical devices were CE marked at the time the UK left the EU with the marking remaining valid in the UK until the end of June 2023. However, all medical devices which have a UK legal manufacturer have had to appoint

[2] EU procedure to authorise medicines in more than one member states in parallel

an Authorised (EU) Representative, add their details to the labelling and register the Class 1 devices in an EU country. The estimated regulatory cost for this has been c. £10K per product initially with £5K per annum thereafter. In addition, our own brand medical device's suppliers from outside the UK have had to appoint a UK Responsible Person and register their devices with the MHRA which has increased our costs.

1.8. We are also challenged by the uncertainty regarding the compliance with the EU importer requirements. Based on a MHRA "letter of comfort", we are currently not complying with the EU MDR importer labelling requirements for either our own brand or proprietary medical devices sent to NI. Our own label devices have had ROI address added to artworks for products supplied into ROI but this is not possible for proprietary devices. We need cost-effective, manageable solutions for NI importer labelling such as a concession to accept an ROI importer address for NI and the use of a till receipt voucher for importer details. Otherwise our cost will significantly increase as we will have to establish and operate over-labelling of medical devices sent to NI. This may result in reduced product availability and price increases for our NI customers.

2. (4) Which aspects of the Protocol's operation are creating most difficulties? Which practical modifications to the operation of the Protocol would make it operate more effectively?

2.1. Following the full implementation of the NIP, we are forecasting that we will have to further:

- Change the operational structure of our store deliveries
- Increase our compliance and regulatory costs
- Manage reduced product availability and increased prices

Based on our ROI business's loss following the implementation of the EU–UK Trade and Cooperation Agreement (TCA), we believe that we face a financial impact up to £6m in NI. This represents c. 5% of our revenue in NI.

2.2. **POAO** - We are concerned about the introduction of full border control for Product of Animal Origin (POAO) when the derogations end. We have already switched off our supply of Boots branded sandwiches, salads, sushi, fruit and cakes in December 2020. We have also reduced our chilled food product lines and now only offer 30% of our existing lines that are available elsewhere in the UK. Any additional red tape for moving Sanitary and Physio-Sanitary (SPS) goods will impact heavily on product availability. Based on our experience in ROI, we believe that 300+ products could be impacted immediately. While these goods only represent 2.5% of our overall product lines, they can be critical for NI customers. For instance, we are forecasting that we will not be able to provide 22% of our existent food

supplement offer and 44% of our baby food offer. At minimum, we would like to see the current derogation kept as they currently are.

2.3. **Medicines** - As demonstrated in question 1(3), the inclusion of medicine regulation in the Protocol has started to hinder medicine supply into NI. While there have been positive developments with the introduction of the NIMAR system and the EU Directive on the continued supply of medicines, the lack of guidance and certainty over the future of the medicine regulatory landscape in NI disincentivise manufactures and wholesalers from investing and preparing for new requirements. Consequently, we are aligned with the UK Government's Northern Ireland Protocol Command Paper's proposal to remove all medicines from the scope of the Protocol entirely and build specific arrangements for this category of products.

2.4. **Dual marking** - The introduction of dual labelling CE/UKCA mark in a small market like NI is also an initiative which has created challenges for businesses. Wholesalers and Manufacturers will have to relabel products going into NI meaning they will have to invest to create specific supply routes adding costs to their supply chain. Some of our suppliers have already decided to switch off their Northern Ireland supplies as the cost of investment is higher than their commercial revenues in NI. In line with the British Retail Consortium (BRC) proposals, we would ask for a recognition of the CE mark across the UK so we can avoid NI specific labelling. To a lesser extent, the UK Government's Northern Ireland Protocol Command Paper's proposal to allow product which are either marked with CE or UKCA to circulate in NI could also be beneficial as it would remove the dual conformity assessment requirements.

2.5. **E-commerce** - The changes to the current easement on requirements for sending parcels to NI will also have a significant impact to our online retail business. Our current co.uk retail website is available for customers throughout the UK to purchase a wide and diverse range of products. We send on average c. 5,000 parcels each week to customers in NI. We will incur significant additional operating costs for managing customs declarations for all parcels we send to customers in NI. Our current system cannot segregate between customers based in NI and GB so we will need to make operational changes. We also anticipate that we may have to utilise customs brokerage services at an additional cost to help manage the increase in compliance requirements. Additional restrictions on POAO when sending via parcels will also add cost and complexity to our current business practices. We will need to implement restrictions for parcels being sent to NI only, e.g. weight limits for products eg. Baby formula being sent under personal allowances, as permitted by EU legislation.

2.6. We currently utilise the Royal Mail letter service for delivery of a large volume of our parcels to customers, as well as additional carriers. We are still waiting for guidance on upcoming restrictions to the NI market. While we are hoping for the easements to continue, we will require suitable timescales for any changes to be implemented so there is minimal impact on our NI customers.

3. (6) What is the impact of regulatory divergence between the UK (in respect of Great Britain) and the EU upon the operation of the Protocol and the ability to identify solutions to the current problems? Benefits and potential opportunities.

3.1. The political and legal uncertainty stemming from the regulatory divergence has already prompted manufacturers to signal that they will withdraw their products from NI because they are unclear about their legal status, and because they believe the current arrangements are commercially unviable.

3.2. We are also already seeing the impact of divergence regarding product safety. For instance, the ingredients "Lillial"[3] used in cosmetics was banned by the EU in March 2022 while the GB ban will start from December 2022. Similarly, Titanium Dioxide used in food supplements have been banned by the EU but still allowed in GB. This means that we were technically not allowed to sell the same products in GB and NI. Our supply chain doesn't allow us to separate NI from the rest of the UK so this has presented logistical and operational cost and complexity.

Medical Device

3.3. The MHRA is working on a new UK Medical Device regulatory system. New UK specific regulation presents several problems stemming from the potential divergence from EU regulations:

3.3.1. First, all devices will require a labelling change, with addition of a UKCA symbol on all medical devices sold in the UK. This includes the appointment of UK Responsible Person (RP) for non-UK manufacturer and UK Notified Body approval for above Class 1 devices[4]. This means that a device manufactured outside UK/EU will need: legal manufacturer address, EU RP address, UK RP address, UK importer/distributor address, EU importer/distributor address, CE mark and UKCA mark. Fitting all this information on a product label will entail additional packaging materials e.g. leaflet which will increase costs and reduce sustainability. Some EU suppliers may also

[3] butylphenyl methylpropional (BMHCA)
[4] Class 1 medical devices include "low risk" device such as band aid or stethoscopes

decide that the revenue level does not justify a second UK Notified Body approval for the UK. Therefore, we could see a reduction in class 1 medical devices available in the entire UK market.

3.3.2. We are also concerned that the UK Medical Device regulations could require different technical file contents requirements, post market surveillance reporting requirements etc… requiring nearly twice the regulatory workload of operating just within an EU/CE framework. The UK divergence is happening at a time when global regulatory convergence is being discussed. A further complication will be divergence of classification rules between UK MDR and EU MDR. As we sell above class 1 devices into UK and NI, then we will need to support costs and audits for two notified body approvals. We estimate the cost of compliance with UKCA at £5K per annum just for the certification of one product or the re-approval of an existing one by a UK Notified body. While this needs to happen by July 2023, we are worried we will not be able to meet the deadline as there is also insufficient UK Notified Body capacity to approve all the above class 1 medical devices currently sold on the UK market in time for the 2023 deadline. Altogether we risk reducing the range of medical devices available in the UK.

3.3.3. The best possible approach for businesses which supply into UK and NI would be the mutual recognition between UK and EU medical device regulations. This would allow continued use of CE marking in the UK and avoid the duplication of regulations.

3.4. So far, we have not been able to identify any benefits stemming from the UK divergence from EU regulations.

4. (13) What would be the political, legal and socio-economic impact if the UK Government a) brings forward domestic legislation in relation to the Protocol, and/or b) uses the safeguarding mechanism contained in Article 16 of the Protocol?

4.1. Since the departure of the UK from the EU, the ongoing, general environment of uncertainty has hindered business planning. As explained in previous points, the lack of guidance and certainty does not create a positive environment for business investment and the implementation of the new rules have incurred significant operational and compliance costs.

4.2. Over the last few years, businesses have battled huge supply chain challenges entailed by the Covid 19 crisis and the Ukraine war. Bringing domestic legislation in relation to the NIP or triggering Article 16 of the

Protocol will lead to a trade war with the EU and aggravate the challenges currently faced by businesses.

4.3. A trade war with the EU would be akin to the 'no deal' scenario that we faced some years ago so we would encourage the Government to avoid such a situation. Planning for a 'no deal' entailed mitigations for supply disruption – such as stockpiling medicines – and if the Government has concerns about this situation arising again then industry would welcome guidance on what we should do.

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