Walgreens Boots Alliance – Written evidence (FFT0028)

A response from Walgreens Boots Alliance

Walgreens Boots Alliance is the largest retail pharmacy, health and daily living destination across the U.S. and Europe. Walgreens Boots Alliance and the companies in which it has equity method investments together have a presence in more than 25 countries and employ more than 415,000 people. The company is a global leader in pharmacy-led, health and wellbeing retail and, together with its equity method investments, has more than 18,500 stores in 11 countries as well as one of the largest global pharmaceutical wholesale and distribution networks, with more than 390 distribution centres delivering to more than 230,000 pharmacies, doctors, health centres and hospitals each year in more than 20 countries. In addition, Walgreens Boots Alliance is one of the world's largest purchasers of prescription drugs and many other health and wellbeing products.

Boots UK operates the largest chain of community pharmacies in the United Kingdom. It is synonymous with pharmacy in the public mind and is one of the country's most trusted brands. Boots is also one of the largest beauty retailers in the UK which retails proprietary brands and Boots owned branded products.

Global Brands is a designated cross-divisional function who develops and sources a number of product categories from cosmetics, healthcare to general merchandise, electrical beauty and baby items. Our well known and loved brands include No7, Soap & Glory, Botanics, Boots Pharmaceuticals, Liz Earle, Sleek MakeUP, Boots own branded products and other brands "only at Boots" exclusive products.

Alliance Healthcare is the leading distributor and wholesaler of pharmaceutical, medical and healthcare products in the UK and offers tailored healthcare solutions for customers. It delivers twice daily to all of the nation's 16,500 dispensing points — community pharmacies, dispensing doctors and hospitals – and our network of distribution centres are the trusted partner for over 17,800 delivery points.

Response

Introduction

- Walgreens Boots Alliance (WBA) welcomes the opportunity to respond to this call for evidence on non-tariff trade barriers in the future trade relationship between the EU and the UK. A large part of our organisation has deep roots in the UK and Europe.

- We are concerned about the significant technical barriers that will arise with a trade agreement including customs control. The European Union is a deep and critical part of our supply chain. Boots UK and Ireland has c. 2,500 retail stores in the UK and Republic of Ireland (ROI) including 89 stores in ROI and 78 stores in Northern Ireland. We also sell c. 36,000 retail product lines sourced from more than 70 countries and work with c. 1,100 suppliers located in 35 countries. Our Global Brands function imports c. $60m from the EU and then exports about $20m to the EU across 2,000 lines.

- Without a frictionless trade agreement, we expect a number of technical barriers to arise which will deeply impact future trade in goods with the EU and significantly increase the costs of trading with Northern Ireland and the EU, in particular with the Republic of Ireland (ROI). It could significantly disrupt our supply chain and extensively increase compliance, operational and staff costs. We are also concerned that these technical barriers could result in a differentiated approach to consumer and environment safety and ultimately reduce consumer choice.

1. The key non-tariff, technical barriers affecting future UK-EU trade in goods and their likely impact on WBA operations and UK consumer landscape (questions 1,2 and 3)

1.1 Moving away from a single and aligned regulatory framework to separate regulatory frameworks and customs requirements for the UK will be our biggest technical barrier. Minimal regulatory divergences across all product classifications will be critical for UK businesses and suppliers to continue to operate seamlessly and provide consumer relevant, safe and innovative products on UK and EU markets. This will also help UK businesses to remain competitive by keeping their operating costs low and minimise delays in placing products on the market.

1.1.1 Non-collaboration with EU agencies

1.1.1.1 The potential lack of collaboration with EU agencies including on chemical, environmental, and pharmaceutical regulations will cause significant disruption to the supply chain. Timely and co-ordinated exchange of information about current regulation and future EU regulatory changes, such as EU environmental, chemical and digital legislations, between the UK and the EU is critical for trade to continue to operate as smoothly as possible.

1.1.1.2 The continuing collaboration of the UK with EU agencies is key to maintaining safety for both the consumer and the environment. We urge the Government to provide upfront and transparent information of possible regulatory changes, to share scientific assessment outcomes and

discuss regulatory discrepancies in order to find a common ground with EU agencies.

- For cosmetics, the close collaboration of the EU and UK scientific bodies on the assessment of cosmetic ingredients and chemicals reviews carried out by the EU will enable the industry to maintain and maximise safety for consumers and the environment. Exchange of information between the UK and EU competent authorities will enable the industry to continue to carry out post-marketing surveillance activities effectively to guarantee consumer safety cross border.
- With regard to chemicals, the exchange of information about concerns on chemicals will be key to ensure chemicals are managed safely and the impact on the environment is minimised. Due to geographical proximity and full regulatory integration, the UK and the EU should remain closely aligned on chemicals regulation and management.
- Regarding pharmaceuticals, it is critical we keep a close relationship with the European Medicines Agency (EMA) to allow patients to access newly-approved medicines more quickly through a centralised process of licensing. If the UK diverges from the EMA's common regulatory framework for clinical trials and medicines licensing, this risks delaying UK patient access to the best available treatments.

1.1.2 Divergence in regulatory standards

1.1.2.1 Example 1 - impact on cosmetic regulation:

- The UK cosmetic market is worth £9.7 billion[1]. The EU is the main trade partner for the UK cosmetics industry, with imports from the EU representing 66.2% (£2.8 billion) and exports to the EU 64.8% (£2.5 billion) of the UK's world trade. As a distributor, our Global Brands entity manages 4,000 lines across over 30+ countries and deals with 150 suppliers of all sizes across Health and Beauty.
- Differences in regulatory standards are likely to result in brands and products being removed from the UK market, which in turn would result in a price increase of products and less consumer choice. While Regulatory compliance is feasible, the costs stemming from the changes will need to be absorbed somewhere along the supply chain and ultimately impact prices. Some of our own suppliers, a large part of whom are UK SMEs, would struggle, and our EU ones may decide to stop selling in the UK to avoid unnecessary costs.
- As a result, it is critical that the new UK independent regulatory framework maintains strong alignment with the EU regulatory framework to ensure a fairer playing field for businesses, whilst also protecting consumers from potentially, products that are currently not deemed safe for the UK and the

[1] CTPA Annual Report 2018

EU. As the EU Cosmetic Products Regulation 1223/2009 (CPR) is seen as a "gold standard" across the world, we want the new UK regulation to implement current principles and standards of the CPR so we can continue to trade cosmetics with EU as well as with the rest of the world. If cosmetic products follow the same rules for formulation, labelling, safety assessment principles, together with online notification, our trade with the rest of the world will continue to be greatly facilitated. This is also important for product innovation to ensure that we continue to access the most up to date technologies to develop innovative products with continually improving ingredients – chemicals and raw materials.

1.1.2.2 **Example 2 - the impact on chemical regulation:**

- According to the Chemical Industry Association, in 2018, the bilateral EU27 – UK chemicals trade amounted to about €46 billion. With the UK chemical industry representing 6% of total EU28 sales and UK exports to the EU27 representing about 60% of UK sales in 2018, both sides are important markets to each other.
- REACH is a European Union regulation, adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry. It also promotes alternative methods for the hazard assessment of substances in order to reduce the number of tests on animals. Without UK/EU alignment on REACH, there is a severe impact on our operations both as a distributor of UK products as well as an importer of products from Europe and other countries.
- The cooperation and collaboration between the UK and the EU is highly necessary to enable marketing and use of chemicals in the European continent. Providing access to UK based companies on the European chemicals database (ECHA) for review purposes only will avoid companies duplicating existing registrations, therefore minimising the huge impact on cost and resources to companies, and reducing the risk of losing access to chemicals in both markets.

1.1.2.3 **Example 3 – Regulation of medicines and medical devices**

- The UK has been at the heart of developing regulatory policy for medicines and medical devices for over 50 years. The coronavirus pandemic has highlighted the extent to which the UK's supply of medicines and medical devices is embedded and entwined with EU and global supply chains and regulatory frameworks.
- Over the past five years, we have been implementing two major regulatory upgrades: the Falsified Medicines Directive (FMD), which brings in new safety features and pan-European databases to reduce the risk of falsified medicines reaching patients, and the Medical Device Regulation (MDR),

which updates legislation to address previous failings in the quality and traceability of devices, especially implantable ones. These affect our pharmacy and wholesale businesses in 14 EU/EEA markets. FMD came in to force in 2019 following a three-year implementation period. MDR was due to come in to force in stages from May 2020 but this has been pushed back a year due to Covid-19.

- UK-based businesses have spent millions of pounds on implementing FMD, despite the uncertainty caused by the EU referendum result. We spent £5.3 million and 50 colleagues were dedicated to the project. As the UK Parliament is now considering a Medicines and Medical Devices Bill, we need more clarity to what extent the new UK arrangements will simply duplicate EU legislation or how much the new systems will cost UK companies to implement.
- We are also concerned about the position of medicines and devices in Northern Ireland after the transition period ends. The Northern Ireland Protocol (Annex 2, Section 20) lists some EU legislation on medicinal products that must continue to apply. It is not clear if this includes FMD (Directive 2011/62/EU) or its associated Delegated Regulation (2016/161), neither of which is specifically listed. Since Northern Ireland represents less than 5% of the UK's total medicines market, any additional arrangement for NI would be challenging to implement. We call on the National Competent Authorities for the UK and EC to clarify this position with urgency.
- Creating a very small pool of "NI-only" products risks exacerbating shortages in NI. At present, stock sent to NI by wholesalers and manufacturers is, in effect, chosen from the entire UK-wide pool of products. Due to different medicines licensing regimes, there is very little direct north-south trade, with the vast majority of products being sourced and supplied through Great Britain. We would suggest that Northern Ireland is removed from FMD to ensure continuity of supply and patient safety across the UK.

1.1.3 New compliance and customs processes stemming from a divergent regulatory landscape will lead to significant supply chain disruption and increased compliance costs. For instance, companies are not currently subject to the licensing for pharmaceutical products or Products of Animal Origin (POAO). Doing so will entail the duplication of requirements and an increase in administration, staff and compliance costs at the border. We are also concerned that Safety and Security Procedures (S&S) will be required for all moving goods from the UK to the EU. While the UK Government has announced a phasing-in approach, the EU has said that this declaration will be required for all movements from 1st January 2021.

1.1.4 Finally, the loss of the current benefits we enjoy as a member the EU Customs Unions such as the EU Generalised Scheme of Preference (GSP)

scheme with developing countries means that costs of sourcing will rise but also that our ability to source products from a range of countries will be limited. For instance thanks to the EG GSP scheme, Boots UK gets duty relief for items from Pakistan, Korea and Japan. As we are leaving the EU, we will have to undertake a re-sourcing programme to purchase these products from a country with likely less favourable duty rates. These sourcing costs will increase our supply chain costs and this likely be reflected down the line on product pricing.

2. Minimising the cost of disruption for any required testing and compliance processes including conformity assessments and the importance of mutual recognition (Question 4)

2.1 We support the Cosmetic Toiletry & Perfumery Association (CTPA) proposal on REACH regulation which encourages regulatory cooperation with the EU and mutual recognition which will minimise our costs. Some of the principles include:

- For the UK to review information on chemicals on the ECHA database; access additional data on existing chemicals, if a specific concern is raised; and collaborate with ECHA in terms of technical and scientific assessment.
- The UK authority should be allowed to know which existing chemicals are available on the UK market.
- Regarding the registration system for new chemicals manufactured or imported into the UK above 1 tonne per year, there should be a possibility to register new chemicals under both EU and UK REACH by using the same dossier for registering the same chemical under EU and UK REACH.
- We also recommend that the UK REACH law includes provision for reducing the requirements for animal testing for low tonnage and low hazard chemicals, by means of a tiered approach to assessment; a review of deadlines; the assessment of chemicals shall be risk-based and different depending on tonnage level;

2.2 There should a mutual recognition regarding the Conformity assessment and CE marking, which would avoid test duplication while maintaining high level of product standards.

3. Rule of origin (question 5)

3.1 We support the CTPA position regarding the Rule of Origin for Cosmetic Products. The Change in Tariff rule will be our preferred option from a cosmetic manufacturing perspective, providing a bureaucratically less burdensome and straightforward way of obtaining origin.

3.2 This is also likely to allow EU companies currently manufacturing in the UK and UK companies currently manufacturing in the EU to continue to do so

post-Brexit, minimising disruption to their supply chain and business plans.

3.3 This rule will only confer originating status to a good when the final product does not include the same heading or sub-heading as inputs. Some parts of the industry may struggle to comply with this rule where the core ingredient shares the same 4-digits heading as the finished product. To mitigate against this and maximise its usefulness, a tariff shift at the sub-heading (6-digit level) would likely be most appropriate for manufacturing cosmetics. If this is not possible, increasing the tolerance clause to 15-20% would help manufacturers meet the rule. This tolerance clause allows a certain percentage (usually 10%) of the product to include non-originating inputs of the same heading/sub-heading. Tolerance level can also be determined by weight (as per the EU-Canada FTA) for specific types of products

4. Simplification of customs processes and documentation (question 6, 7 and 8)

5.1 There are a number of ways to simplify custom processes and documentation to ensure that trade between the UK and EU as well as between the UK and Northern Ireland remains as smooth as possible. As the compliance requirements will increase, it is important that custom processes remain quick and easy so that border frictions are limited.

5.2 The Government should ensure that customs and businesses can continue to use the same technology, keep potential new IT systems simple and maintain access to existing common databases so they can continue to share information with the rest of the world.

5.1 The ideal situation for UK businesses trading with the rest of the EU would be the continuation of Intrastat declarations for the majority of goods to ease the flow instead of the introduction of new customs entries. Intrastat is the system for collecting information and producing statistics on the trade in goods between countries of the EU and has been critical to demonstrate the movement of goods without the complexity of customs entries.

5.2 For example, a full customs entry requires the completion of more than 50 fields of data. An Intrastat declaration has less than 10 which means that while we have four full time people managing non-EU customs entries, we only need one colleague to manage Intrastat thanks to the automated process. We currently submit c. four Intrastat declarations per month for Export despatches from the UK, and Import arrivals in to ROI. Post-Brexit, we will need to report all of these movements on a shipment by shipment

basis which for ROI alone, will represent over 234 customs entries per month creating massive backlog, supply chain issues and significant payroll costs.

5.3 So that goods can flow easily across borders, we would also urge the use of technology and processes which help remove the obligation for freight vehicles to stop. For instance, the use of Automatic Number Plate Recognition (ANPR) which is a system capable of reading vehicle number plates without human intervention through the use of high speed image capture.

5.4 Regarding medicine supply, the use of "Green Lanes" which are priority lanes for freight transport of essential goods, including medicines, as authorised by the European Commission during the Covid-19 crisis would help facilitate the transportation and flow of medicine and avoid shortages of supply. The Government should also consider the fast-tracking of empty vehicles and vehicles carrying certain types of loads e.g. empty delivery units.

5.5 We would recommend that both the UK and EU remove complex additional codes on both sides such as the need for Meursing codes and additional quantities. This would mean fewer fields to populate, fewer errors when filling the customs declaration and as a result, fewer customs declarations rejected. While the UK has removed the obligation to declare Meursing codes, the EU has not.

5.6 We also recommend that UK traders with an "Authorised Economic Operator" (AEO) status who have demonstrated that they meet certain standards in their customs related activities, remain a trusted trader. Businesses should also be able to use their AEO Accreditation Number on frontier declarations instead of Safety and Security declarations. Regarding smaller businesses, we would recommend the introduction of a specific AEO scheme to help them become trusted traders without having to demonstrate the depth of compliance and process adherence that large companies do.

5.7 We have some specific concerns regarding the introduction of current proposed customs procedures for Northern Ireland border which will be costly and complex to implement. The lack of a tangible solution and clarity on import declarations into Northern Ireland from UK Mainland is worrisome and the technological solution mentioned by the Government has yet to be developed, implemented, and tested ahead of going live. Traders are not ready and this has the potential to hold up shipments if a live frontier declaration is needed upon import. An Intrastat style process would help ease flow and reduce additional software and process

development.

5. Impact of the absence of a UK-EU trade agreement at the end of the transition period (Question 9)

5.1 In the absence of a trade agreement and a transition to allow technology and other means to smooth the process, we expect significant delays of goods at border as exported and imported shipments will need to be cleared and inspected before they leave the country of departure. If both exporter and importer are not ready on a shipment by shipment basis this can stop goods moving and cause bottlenecks at the ports. With full customs declarations for all European movements, high volumes of entries will slow the systems and cause outages. This could impact the robustness of the pharmaceutical supply chain and lead to product shortages or see an increase in prices.

5.2 The Government needs to also consider the freight going back to the EU once they have brought their merchandise in the UK. For instance, if there are delays to out-bound goods at Dover, this could quickly strand large numbers of lorries, drivers and pallets on the wrong side of the channel, causing widespread problems to multiple supply chains, including food and medicines. Once lorries are stuck in queues it is very difficult to extract and prioritise different loads.

5.3 It is our understanding that a majority of our European suppliers and customers are not ready to become importers and exporters of goods to/from the UK in the belief that the UK should manage the burden of the new system. Without a smooth transition, they will switch away?

5.4 Our system infrastructure is also not ready with for instance the Customs Declarations System which has been delayed to later in 2021 but could be the portal of choice for NI imports which start on 1st January 2021.

5.5 Regardless of any agreements reached this year, the UK and EU should provide a period of implementation so that businesses from each side can implement the changes stemming from the new relationship. A phase-in period will allow readiness as companies and UK Competent Authorities will need sufficient time to adapt to the changes, in order to ensure compliance without impacting business continuity and availability of products to the consumer. For instance, we know that any amendment in legislation impacting healthcare licensed medicines will need an implementation period of minimum 24 months. This is because submissions to amend or transfer licences follow a strict process of submission and approval laid out by the Medicines & Healthcare products Regulatory Agency (MHRA) in the UK or the Health Products Regulatory Authority (HPRA) in Ireland which on average takes 18 months. Only then, products can be released for sale. Any period shorter than 24 months could lead to interruptions in supply and potential discontinuation of products.

5.6 While we welcome the recent Government announcement on a phasing in approach regarding custom controls for goods leaving the UK to the European Union, without a similar approach for goods entering the EU, we will face significant customs checks at the ROI and EU borders. We would urge the UK government to negotiate the phasing-in approach with the EU and the EU and UK competent authorities should provide common support and guidance to businesses to ensure equal implementations across both areas.

13 July 2020