# BIA and ABPI submission to the House of Commons Public Bill Committee's consultation on the Trade Bill

January 2018

## 1. Key points in this paper:

- The life science sector relies on existing EU trade agreements through supply chains, exports, and imports. Disruption to current trading arrangements would increase costs for companies and risk the supply of medicines to patients.
- EU FTAs are a key component of our sector's approach to global trade. Their key value to the sector lies in driving closer global alignment of rules and higher standards.
- It is vital that the UK adopts current EU trade agreements, and any trade agreements agreed by the EU and third countries during the implementation period, before the UK's formal exit from the EU. These agreements should be adopted into UK law with minimal changes.
- The Trade Bill does not mention a global market access strategy; this should be included to secure progress in tackling increasing protectionist measures within countries.
- As well as accession to the GPA, the UK should prioritise accession to other plurilateral WTO agreements; in this respect, the WTO Pharmaceutical Tariff Elimination Agreement underpins our sector's ability to trade tariff-free for most products.

## 2. About the BIA and the ABPI

2.1. The BioIndustry Association (BIA)[1] is the trade association for innovative life sciences organisations in the UK. The BIA members include emerging and more established bioscience companies, large pharmaceutical companies, academic research and philanthropic organisations, and service providers to the UK bioscience sector. Our goal is to secure the UK's position as a global hub and as the best location for innovative research and commercialisation, enabling our world-leading research base to deliver healthcare solutions that can truly make a difference to people's lives.

2.2. The Association of the British Pharmaceutical Industry (ABPI)[2] represents innovative research-based biopharmaceutical companies, large, medium and small, leading an exciting new era of biosciences in the UK. We represent companies who are researching and developing the majority of the current medicines pipeline, ensuring the UK remains at the forefront of helping patients prevent and overcome disease.

2.3. The BIA and the ABPI have worked closely together since the outcome of the referendum on the UK's membership of the European Union. Our objective is to ensure that the UK life

[1] www.bioindustry.org
[2] www.abpi.org.uk

sciences sector is in as strong a position as possible as the UK establishes a new relationship with the EU in the interests of public health and the economy.

2.4. Following the EU referendum in July 2016, the BIA and the ABPI published a report mapping out the key areas for the UK life science sector. The analysis was informed by over 50 hours of working group meetings with over 200 experts in 90 organisations. The issues identified are as follows:

- Scientific research;
- Regulation of medicines;
- Access to talent;
- Trade.

2.5. As trade is a key priority for the life science sector, the BIA and the ABPI welcome the opportunity to submit our views on the Trade Bill on behalf of the sector. The frictionless trade arrangements between the UK and EU, and the integrated UK-EU regulatory framework that underpins these trade arrangements, are essential to the life science sector's ability to discover, develop, manufacture, and provide medicines for patients across Europe.

2.6. In 2016, the UK exported €15,816 million of pharmaceutical products and imported €7,768 million. The UK imports around 54% of its pharmaceuticals from Germany, the Netherlands and Belgium. The UK exports 48% of its finished medicines to three EU countries: Germany, the Netherlands and France.[3]

2.7. Every month, 45 million patient packs of medicine move from the UK to the EU27/EEA, with 37 million patient packs moving from the EU27/EEA to the UK. Furthermore, over 2,600 final medicines have some stage of manufacture based in the UK.[4] Furthermore, 37% of the active substances processed in the UK are included in the World Health Organisation's list of essential medicines.[5]

## 3. Maintaining existing trade agreements

3.1. The Trade Bill seeks to provide the government with the powers to make necessary changes to ensure that current EU-third country agreements, once agreed by all parties, are fully implemented and can be ratified. However, we understand that changes may be necessary to ensure the agreements remain operable over time.[6]

3.2. The UK life science sector relies on these current EU trade agreements with third countries through global supply chains, exports, and imports. Disruption to current trading arrangements would increase costs for companies and risk the supply of medicines to patients. In addition, the complexity of changes to regulatory approvals, administrative

[3] Office of Health Economics, *Public Health and Economic Implication of the UK Exiting the EU and the Single Market, page 27*

[4] EFPIA, Brexit survey, November 2017 https://www.efpia.eu/media/288530/brexit-survey-outcome-08112017.pdf

[5] Office of Health Economics, *Public Health and Economic Implication of the UK Exiting the EU and the Single Market, page 27*

[6] TRADE BILL: DELEGATED POWERS – MEMORANDUM BY THE DEPARTMENT FOR INTERNATIONAL TRADE, https://publications.parliament.uk/pa/bills/cbill/2017-2019/0122/Trade-Bill-Delegated-Powers-Memorandum.pdf

burdens, intellectual property, data protection, and good manufacturing practises (GMP) means that the timescales to prepare for changes are considerable.

3.3. It is therefore vital the UK adopts current EU trade agreements, and any trade agreements agreed by the EU and third countries during the implementation period, before the UK's formal exit from the EU to ensure continuity for life science companies and patients' access to medicines. For the same reasons, it is equally important that the EU trade agreements are adopted into UK law with minimal changes. In addition, Mutual Recognition Agreement (MRAs) on the mutual recognition of good manufacturing practice (GMP) inspections and batch certification of medicines are important for the sector and are much faster to negotiate and implement then FTAs.

## 4. Trade Remedies Authority

4.1. The bill seeks to establish the Trade Remedies Authority (TRA), a new non-departmental public body, to provide advice and support on trade remedies and international trade disputes to both government and other organisations. The BIA and the ABPI welcome the establishment of the TRA.

4.2. Beyond defensive measures such as those outlined in the scope of the TRA, and indeed the focus on FTAs, the Trade Bill should prioritise development of a coherent strategy to tackle market access barriers in third countries. Noting the rise of protectionist measures globally, taking a more holistic approach – going beyond trade dispute mechanisms – would be a prerequisite for an effective UK trade policy.

4.3. We value life science representation with key bodies and departments, e.g. the Life Science Organisation within DIT and Office for Life Sciences within BEIS. This representation helps to highlight key issues for the sector and to build important relationships. The TRA and any related bodies should have similar life science representation to ensure appropriate understanding and interaction with the sector.

## 5. WTO plurilateral agreements

5.1. The bill seeks to ensure that the UK remain a party to the WTO Government Procurement Agreement (GPA). The GPA is an agreement between a number of countries (including all EU member states) that ensures that public procurement processes above a certain amount are opened up to bids from all signatories and follow standards to ensure open, fair, and transparent conditions of competition.

5.2. It is also a critical for our sector that the UK remains a party to another WTO Plurilateral agreement: the WTO Pharmaceutical Tariff Elimination Agreement (Zero-for-Zero Agreement).[7] For the life sciences sector, this is a fundamentally important agreement that underpins tariff-free trade among its signatories. The Agreement commits its signatories to

[7]The current signatories are the EU and its 28 member states, the United States, Canada, Australia, Japan, Norway, Switzerland and Macao (China). The UK is a signatory to the Agreement through the EU.

zero tariffs on medicines. Products essential to the manufacturing of medicines, such as active pharmaceutical ingredients (APIs), are only covered by the Agreement if they are listed in the Agreement's Annex.

5.3. Currently, the Annex covers only 7,000 products essential to manufacturing of medicines. While new products can be added to the Annex, this requires the consent of all signatories to the Agreement. The most recent update in 2010 added 735 new items to the Annex of products eligible for duty-free treatment. Given that the Annex has not been updated since, the Annex is substantially out of date for current and future life science trade.

5.4. Beyond accession to the Agreement, the UK should take a lead role in pushing for the Agreement to be updated, notably in terms of the Annex, in order for it to ensure the free flow of materials to support research, clinical research, the development and delivery of new and existing medicines.

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