BIA and ABPI response to the Public Bill Committee's consultation on the Taxation (Cross-border Trade) Bill

January 2018

1. Key points in this paper:

- The life science sector relies on integrated supply chains across Europe to discover, develop, manufacture, and provide medicines to patients in both the UK and Europe. Medicines may cross the UK-EU border many times during their manufacture.
- Any changes to these complex supply chains involve significant timescales. There is a risk delays at border controls for both unfinished and finished medicines could cause shortages of medicines.
- The Bill should therefore clearly reflect the need for a lengthy implementation period, where the UK remains aligned with the EU regulatory framework and vis-à-vis has easy access to its customs union.
- While the future customs arrangements with the EU are yet to be determined, it is important that the future arrangements are as frictionless as possible and that entry and exit simplifications are introduced for supply chains that are integrated throughout the EU and dependent on cross border movements.
- As VAT will become due on the import of goods into the UK and the EU, this could have significant cash-flow implications for life science companies and particularly SMEs. In addition, whilst finished pharmaceutical products are free of duty, the intermediates and raw materials are not, and this will add significant amounts to base costs.

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. 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.

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

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 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 Taxation (Cross-border Trade) Bill on behalf of the sector.

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. Implementation period

3.1. Clause 31 of the Bill relates to customs unions with other countries and territories. According to the Explanatory Notes to the Bill, the clause "could facilitate a Customs arrangement with the Crown Dependencies and/or an interim Customs arrangement with the EU".[6] The Explanatory Notes further clarify that other "provisions allow further regulations to be made for the purposes of implementing a Customs union arrangement, […] so that the legislative framework for Customs can be aligned between the UK and the territory with which the UK is

[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*

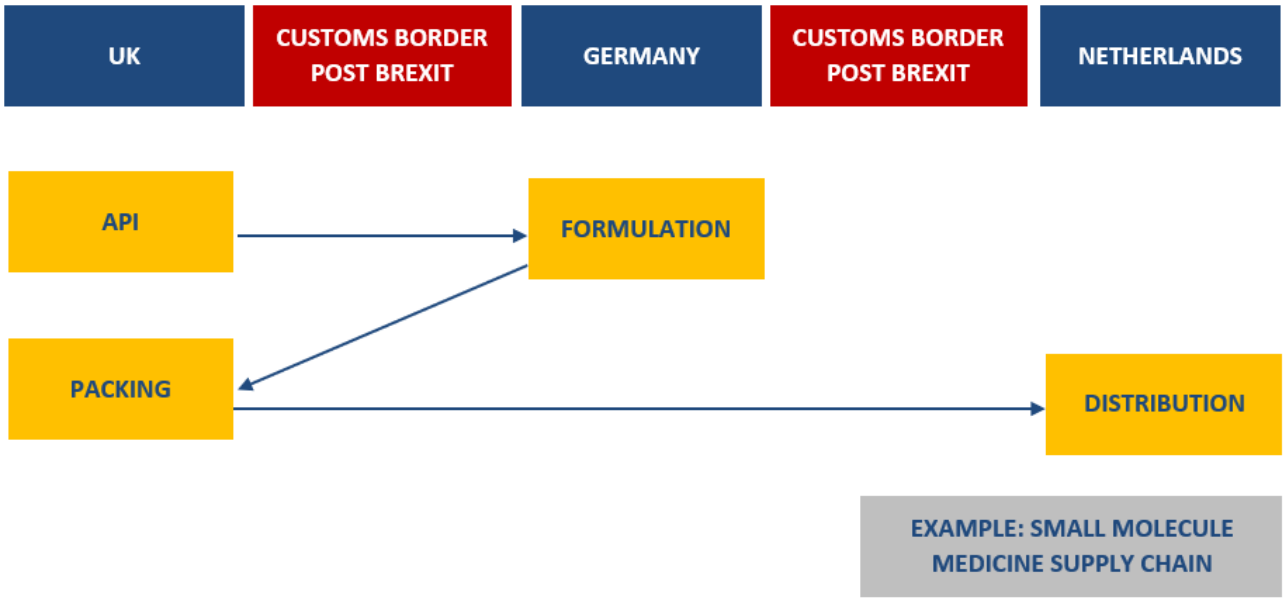
[6] Taxation (Cross-border Trade) Bill, Explanatory Notes, para. 136: https://publications.parliament.uk/pa/bills/cbill/2017-2019/0128/en/18128en.pdf

in a Customs union".[7] We welcome the Bill's flexibility to include alignment with the EU customs framework.

3.2. 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. Life science companies manufacturing medicines in the UK rely on supply chains integrated throughout the EU to supply medicines to both UK and EU patients. During its production, a medicine may cross the UK-EU border many times before being finished. These supply chains are complicated and take many months to plan, organise, find expertise and implement. See Figure 1 below for an example of how customs controls could slow down a small molecule medicine supply chain. Note there may be similar potential supply chain movements across borders of materials for manufacturers of the components of finished medicinal products, such as excipients and packaging materials.

3.3. The life science sector currently faces uncertainty over how their supply chains will be affected by the UK's post-Brexit trading relationship with the EU on issues such as custom controls, administration, and tariffs. This means that some companies have plans to re-map their supply chains and move their manufacturing, warehousing, R&D activity, and clinical trial activity to the EU27 to mitigate the effects of a cliff-edge Brexit or in the circumstance that the UK becomes a 'third country' to the EU. These companies include not only multinational companies but also SMEs and growing UK companies. With the risk of medicines being delayed in custom controls, a cliff-edge Brexit would also have severe implications for the supply of medicines to patients in the UK and the EU, causing a significant risk to public health.

Figure 1.



Example of how customs controls could slow down a small molecule medicine supply chain. The active pharmaceutical ingredient (API) is the part of the drug that produces its effects.

[7] Ibid, para. 137.

3.4. Recent research published by the Office of Health Economics underlines that in a scenario where significant customs delays were introduced in trade between the UK and the EU, there could be an "increased frequency of medicines shortages".[8] In this context, it particularly draws attention to the UK's specialism in the manufacturing, importation and batch release certification of advanced therapy medicinal products.

3.5. In the White Paper on the Bill, the government recognises the importance of an "interim period". The government is right in stressing an interim customs agreement "would help both sides to minimise unnecessary disruption and provide certainty for businesses and individuals if this principle is agreed early in the negotiations."[9] However, it is important that an interim agreement maintains current customs framework to minimise disruption so that the sector must only adjust to the final post-Brexit framework. It is also important to recognise that addressing uncertainty for life science companies not only requires assurance that the sector will have the time to make the necessary operational adjustments, but firstly, clarity over what the new framework will be to which we should transition. It is difficult to know the length of a journey without knowing the destination.

3.6. Life science companies across Europe are working on their risk mitigation planning on the basis of the guidance received by EU and UK authorities. Evidence suggests this timeframe of decision-making falls between Q4 2017 and Q2 2018. However, for some companies this deadline is long past and for some products, supply chain changes would have had to have started ahead of the Referendum vote to be ready for March 2019. The complexity of the changes and the necessary regulatory approvals necessary means that the timescales to prepare are considerable.

3.7. It is imperative that an implementation period is urgently agreed between the UK and the EU and that this is clearly reflected in the Bill to ensure no more irreversible business decisions are taken and any subsequent agreement on transition arrangement are not without impact. These timelines are applicable to UK and EU life science companies, patients, and suppliers alike.

4. Future customs arrangements with the EU

4.1. The future customs arrangements with the EU are yet to be decided in the Brexit negotiations. While the Bill is designed to be flexible to account for a range of negotiating outcomes, there are a number of concerns with the government's intention to leave the EU and its comprehensive customs union. These include short timescales for business of all sizes to adapt to the new arrangements, the UK's infrastructure capacity to manage increased customs controls, and the capacity and readiness of the new Customs Declaration Service (CDS). We have strongly argued that the re-introduction of tariffs and customs controls with its associated burdens will impact UK and EU life science companies and the patients who rely on the medicines they produce.

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

[9] Customs white paper, para. 5.4.

4.2. In its White Paper on the Bill, the government made proposals to help facilitate customs arrangements between the UK and the EU. The proposal to negotiate a continued waiver from the requirement to submit entry and exit summary declarations for goods being moved between the UK and the EU would help to streamline trade. The proposal to remain a member of the Common Transit Convention (CTC) would also help with this objective. However, we recognise that both proposals must be agreed through the negotiations with the EU.

4.3. The proposal to negotiate the mutual recognition of Authorised Economic Operators (AEOs) with the EU to help reduce the risk of delays is also subject to the negotiations. However, it should be stressed that under the current requirements, it is difficult and expensive for UK companies to obtain AEO-status due to a burdensome and lengthy application process. This has led to low application by UK exporters and importers. These challenges may limit the impact of mutually recognised AEOs, unless the government reviews the requirements for obtaining the AEO status and thus makes AEO more accessible for UK companies. Despite these challenges, some form of 'trusted trader' system will be important in ensuring the smooth operation of a post-Brexit border. For the future trade of medicines under such a system, some form of mutual recognition will be needed, alongside reform of the requirement to obtain the AEO status.

4.4. In addition, the government also presented a proposal for the new customs partnership to rely on a tracking mechanism to determine the whether the end-user is in the UK or the EU. Members of the BIA and the ABPI are concerned this tracking mechanism would be very burdensome, both in terms of complexity, costs and administrative requirements. The integrated nature of life science supply chains across Europe would only increase these burdens. Scarcely resourced SMEs in particular would find these burdens challenging.

4.5. The other option of a repayment mechanism also presents challenges. Scarcely resourced SMEs in particular would find the repayment mechanism challenging if companies are forced to pay a higher up-front duty rate and seek settlements later. However, businesses of all sizes would likely find the repayment mechanism difficult to implement.

5. Value Added Tax (VAT)

5.1. The Bill provides for an amendment of existing VAT legislation. According to the Explanatory Notes, the Bill will "provide for the EU concept of acquisition VAT (for business-to-business intra-EU movements) to be abolished so that import VAT is charged on all imports from outside the UK".[10] The Bill is flexible to allow the VAT regime to function regardless of the outcome of the Brexit negotiations.

5.2. Without access to the Single Market, VAT will become due on the import of goods into the UK and the EU in the jurisdiction the goods are imported into. From a UK perspective, for most life science companies, import VAT should be recoverable and hence not represent a cost to the business. However, this could have significant cash-flow implications for companies and particularly SMEs. While the government is considering methods to reduce this potential cost

[10] Ibid, para. 19.

(e.g. by introducing a postponed accounting mechanism), it is important that solutions to cash-flow disadvantages are implemented before changes to the current VAT regime.

5.3. Sending products cross-border as consignment stock for example may also give rise to import VAT in the EU. While this would generally be expected to be recovered through a VAT registration in the relevant EU Member State, there may be instances where the EU refund mechanism for non-EU business would need to be used. This mechanism can significantly increase the time lag in receiving repayments and it is not uncommon for refunds to be refused.

5.4. Finally, the proposed EU Commission VAT reform package is likely to fundamentally change the VAT treatment within the EU supply chain process. These changes are not expected to come into force until 2022 and therefore outside of any potential transitional period. However, the access to any "One Stop Shop" mechanism may create an advantage to EU businesses over UK businesses. Consequently, full access to any future mechanism would be beneficial to the life science sector and should form part of any negotiations with regard to future trade within the EU.

Contact

Eric Johnsson
Policy and Public Affairs Executive
BIA
ejohnsson@bioindustry.org
0207 630 2197

Elliot Dunster
Head of External Affairs
ABPI
edunster@abpi.org.uk
0207 747 7168