BIA response to Department for International Trade's consultation on Free Trade Agreements

October 2018

UK BioIndustry Association

1. Executive summary

- The top priority of the life science sector is for UK patients to continue to receive their medicines as the UK leaves the EU. Given the high levels of uncertainty companies are currently facing, this remains an enormous challenge.
- The life science sector benefits from the EU regulatory system, deeply integrated supply chains, and the free movement of goods across the UK-EU border. For these reasons, it is crucial that post-Brexit UK-EU trade is as frictionless as possible.
- If the Government does not achieve its primary negotiating objective, its priority should be to negotiate a UK-EU FTA as soon as possible. Given that is unlikely that an FTA could be signed and ratified within a timeframe that ensures continuity post-Brexit, the Government should then seek to utilise a Mutual Recognition Agreement (MRA) in the meantime.
- The UK life science sector relies on EU MRAs and EU FTAs. These agreements must be grandfathered before March 2019 to avoid significant disruption for industry, including to supply chains could impact patients' access to medicines and business R&D investment decisions.
- The UK should become a signatory of the WTO Pharmaceuticals Tariff Elimination Agreement and work with the other signatories to update the agreement and introduce an ongoing update mechanism.
- For future FTAs, this paper sets out high-level principles on services, regulatory barriers to trade, customs and trade facilitation, rules of origin, mobility and people, science and collaboration, and intellectual property which are important to the sector.
- As the UK's post-Brexit relationship with the EU becomes clearer, so will the sector's ability to provide more detailed information of the its priorities regarding both UK's overall post-Brexit trade policy and specific FTAs. With the current uncertainty the sector faces, this is neither the right time nor a situation in which there is sufficient clarity to give detailed information for the proposed FTA negotiations.

About the BioIndustry Assocation (BIA)

The BioIndustry Association (BIA) is the trade association for innovative life sciences in the UK. 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.

We have more than 350 members, including:

- Start-ups, SMEs and scaling biotechnology companies
- Multinational pharmaceutical and technological companies
- Universities, research centres, tech transfer offices, incubators and accelerators
- A wide range of life science service providers: investors, lawyers, IP consultants, and communications agencies

Over 150 of our members have at least one R&D and/or manufacturing sites in the UK. Numerous members are also currently expanding existing R&D/manufacturing sites or opening new sites. Many of our members manufacture in the UK and export to both the EU and global markets from the UK.

We have engaged with the Government, including DIT, DExEU, BEIS, DHSC, and the Office for Life Sciences (OLS) on a regular basis on trade-related issues since the EU referendum, both with regards to UK-EU trade and the UK's future independent trade policy. As these two issues are deeply intertwined, we welcome the opportunity to submit a response outlining the sector's current trade priorities to DIT on its consultations on future FTAs.

2. Overarching trade issues

Day 1

Our top priority is for UK patients to continue to receive their medicines as the UK leaves the EU. Many products are produced in a "European hub" and cross multiple borders during manufacture. For instance, a BIA member with a small molecule supply chain currently moves an active pharmaceutical ingredient (API) from UK to Germany for formulation, it then comes back to the UK before going to the Netherlands for distribution. Post-Brexit, three customs border crossings will be introduced for this single product. Clinical trial supplies, samples, and R&D materials must also continue to flow – this is essential to both patients and the UK's R&D ecosystem. Urgent action is needed to **prioritise supply of medicines on day 1 on both sides of the border**, including ensuring there are no queues and no additional administrate burdens or paper work at the border.

Future customs / Facilitated Customs Arrangement

The **UK's future customs system should require as little change as possible**. Government should consider: minimising additional and duplicative administrative burdens; no new administrative burdens at borders; no divergence from EU rules/regulation during the transition period (this has become known as "regulatory alignment"); no expectation of a reliance on AEO (Authorised Economic Operator) certification; and rapid reimbursing for any VAT paid. The UK should re-accede to the Convention on Common Transit.

The system also needs to be able to adapt to the life sciences sector, and therefore needs to consider:

- Requirements for regulatory approvals for supply-chains changes.
- Moving clinical trial materials and samples which are non-standard and time critical.
- Balances SMEs and multinationals.
- Recognises that companies do not always know where their product will end up if they sell to a wholesaler.
- Reassures logistics suppliers, who may seek assurances or changes to legal requirements to ensure they would not be liable if incorrect duties were paid. This would be particularly onerous on SMEs, who can be solely reliant on logistics suppliers and have less resources and capacity.

3. Trading with the EU

As frictionless trade as possible

The priority for the life science sector remains the ability to trade freely with the EU, both in goods and services. The life science sector is supportive of Government's White Paper proposals for trade in goods with the EU and proposals for regulatory alignment that will enable that trade to occur. Further work needs to be done to ensure that services companies such as Clinical Research Organisations (CROs) are also able to main their core business activity in the UK.

UK-EU FTA and MRA

If the Government does not achieve its primary negotiating objective, its priority should be to negotiate a UK-EU FTA as soon as possible. Given that is unlikely that an FTA could be signed and ratified within a timeframe that ensures continuity post-Brexit, the Government should then seek to utilise a Mutual Recognition Agreement (MRA) in the meantime.

An MRA on product testing and GxP inspections could come into effect once the UK leaves the EU and would have the greatest impact on short term medicines supply. There are precedents for such MRAs, with other third countries including Japan, Australia, Canada and the US, which have frequently been adopted outside of FTA negotiations and thus could be delivered prior to the final agreement.

MRAs can be used to recognise the assessment work conducted in or by the UK and EU27. This could include re-testing on import and batch release, OMCL controls, GMP/GDP inspections performed by the UK and the EU 27, IMP and placebo supply and API manufacture. Given the starting point of full UK-EU regulatory alignment, an MRA has the potential to be ambitious, and could also include areas beyond those in the EU's existing MRAs. An UK-EU MRA could enter into force immediately following any transition period. This could potentially reduce the risk of disruption in the supply chain and support business continuity if a broader EU-UK FTA cannot be reached in a timely manner. An MRA could be agreed separately (e.g. EU's MRA with the US) – and in due course incorporated into any FTA that may be reached. Consideration should also be given to other mechanisms that could bridge the period between the UK's exit and the point in time when an MRA can be in place.

Continuity/access to EU MRAs

The life science sector utilises key areas in the EU's MRAs on Conformity Assessment with Japan, Israel, Australia, Canada (as incorporated into CETA), New Zealand, Switzerland, and the US. Like the majority of EU FTAs, these MRAs have been in place for several years, allowing UK companies to benefit from facilitated market access in the partner countries. These **MRAs are critical for industry and must be grandfathered in time for March 2019**.

Continuity of/access to EU FTAs

It is vital for industry that the UK maintains access to the FTAs that the EU has agreed. Without it there will be significant disruption for industry, including to supply chains which could impact on patient safety and access to medicines as well as business R&D investment decisions. We support Government's stated ambition to **grandfather existing free trade agreements** into UK law to ensure continuity with no time delay.

4. The WTO and future FTAs

WTO and tariffs

The life science sector supports Government's intention to mirror the EU's current WTO schedule. This will help provide a seamless transition and continuity for businesses trading with countries on WTO terms.

It is vital that the **UK becomes a signatory of the WTO Pharmaceuticals Tariff Elimination Agreement**. This is a non-binding agreement between key pharmaceutical producing countries to reduce duties to zero on certain pharmaceutical products. The agreement covers finished pharmaceutical products and specified APIs and intermediaries (biologic products are also typically included).

The agreement needs a significant update to the specified list of APIs and intermediaries that qualify for zero percent duties. This has not been updated since 2010 and a significant number of new APIs and intermediaries are not included. **The UK should work with other WTO members to update the agreement to reflect scientific advancements and introduce an ongoing update mechanism**.

The UK should work with trading partners to promote tariff liberalisation, particularly with less established countries. The UK should emphasise the many benefits of a well-functioning rules-based global trade system to all FTA and WTO partners.

Services

It is important that the UK is a signatory to the WTO Government Procurement Agreement and to ensure benefits apply to UK suppliers. Government should not allow limitation on access to government procurement markets.

Regulatory barriers to trade

Government should seek regulatory harmonisation, whilst not reducing UK regulatory standards. Medicines regulation in FTAs should not impact the ability of the UK's MHRA to have regulatory cooperation with the EU's EMA. There should be mutual recognition where possible and obligations on non-discriminatory regulatory treatment of imported products.

Customs and trade facilitation

The UK should develop a customs and excise regime that facilitates trade with all of the UK's trading partners and reduces the burden on companies importing to and exporting from the UK. Many life science companies have global supply chains, with different steps of the manufacturing process happening in different countries. An inefficient or burdensome customs and excise regime would make it significantly harder for industry to manage these global supply chains and ensure timely supply of medicines to patients.

Rules of origin

Rules of origin need to facilitate trade between the UK and trade partners, now and in the future. The rules need to fit with industrial conditions and the technological innovation encountered by each sector. Our industry requires **simplified, easy-to-handle and rational rules of origin based on common and defined chemical and pharmaceutical processing activities** that are easy for customs administrations to verify.

The burden of historical rules of origin is often too great for industry and does not reflect the manufacturing process, technology evolution, and global supply chains that industry work with today. Liberalising the UK

market with multiple rules to optimise UK manufacturing gains, simplifying, and streamlining the process with up-to-date ROOs while maintaining FTA objectives, will support Brexit activities positively.

As a result, industry promotes the use of manufacturing processes which come from WTO technical rules of origin. With industry advancements, these rules have not been included in EU FTAs, even though the European Commission has consistently used them for non-preferential origin and they have been known by all customs authorities for many years. When necessary, we advocate for slight changes due to technical updates or industry needs. Additionally, these origin-conferring rules are included in new, global FTAs while the use of set of rules is also a path to harmonise all standards in rules of origin.

Mobility and people

The ability for life science companies to attract and retain the best of international talent is a key factor in ensuring that the UK is a global leader in life sciences. The proportion of non-UK employees working for UK-based biopharmaceutical firms ranges from between 17-41%, a significant proportion of the overall workforce that brings vital innovative thinking to the UK sector. It is essential that the UK's future trade policy ensures frictionless access to talent and the ability to circulate employees internationally for regular business trips and development opportunities.

- *Business travel:* The easy circulation of employees for business travel and development programmes is essential to the operating of UK life sciences companies. For example, GSK staff make around 2500 trips between their UK and Belgian sites annually. It is essential that frictionless visa free business travel is ensured in the future.
- *Students:* to secure the future of the UK's STEM base, Government should ensure that students from around the world are able to come to the UK to study and work without hinderance.
- *Mutual recognition of professional qualifications:* The UK should seek to ensure mutual recognition of professional qualifications in future FTAs where appropriate (for example, for clinicians, pharmacists and Qualified Persons (QPs).
- *Intra-company transfers (ICTS):* no reduction in the ability for companies to use Tier 2 ICTs. Two additional measures should be proposed: Increasing the number of visa allocations to bring key talent to the UK; Remove quotas for ICT visas for non-UK citizens on assignments less than 12 months in duration.

Science and collaboration

The ability to collaborate internationally is key to the development of life sciences ecosystem in the UK. The Government should therefore seek how it could facilitate and enable science collaboration as part of FTAs. Within this the Government should also consider how SMEs in particular could build relationships across borders for future cooperation.

Intellectual Property

Life sciences companies in the UK benefit from the UK's world class IP system that helps to encourage and protect investment in innovation and R&D. The current system strikes a good balance between the rights of innovators and the needs of consumers and other parts of the industry; it should be maintained. **Future FTAs should seek to capitalise on the UK's strengths and encourage trading partners to adopt high standards of intellectual property protection and enforcement.**

The UK should work with trading partners to **encourage the harmonisation of IP systems globally**. Greater levels of harmonisation between different systems reduces the complexity and burden on industry and helps to facilitate trade.

The UK should ensure that all of its trade deals have suitable mechanisms for resolving trade disputes, this should include **strong mechanisms for enforcing intellectual property rights in partner countries**. The failure of FTAs and trading partners to provide for enforcement of rights can create barriers to trade.

The BIA cautions the adopting or evolving lesser protections than exist currently in the EU. Such action would reduce the attractiveness of the UK as a location for R&D investment and could incentivise companies to delay marketing authorisation applications in the UK to ensure there is no early generic market entry opportunity in the UK that could jeopardise wider EU market access for the innovator product.

In particular, the UK should ensure that FTAs seek to retain the following elements of the UK's current IP framework:

- Extended exclusivity periods to compensate companies for exclusivity time lost during the lengthy medicines development and regulatory process, such as is provided by Supplementary Protection Certificates
- Data exclusivity periods to reward the significant investment in non-clinical and clinical development programmes required to bring new medicines to patients
- Recognition of paediatric trials through specific extensions to intellectual property rights
- Recognition of investment in orphan products for rare disease through a 10-year market exclusivity incentive and other benefits

5. Considerations for specific FTAs

As UK Government pursues trading relationships with new partners, including the US, Australia, New Zealand, and the potential of joining CPTPP, they should consider the priorities of the life sciences sector. When companies are developing their international trade strategy they consider several factors. These include:

- Size of market – how many patients that may benefit from a medicine
- Tax system – what tax incentives exist, e.g. R&D tax credits
- Cost / reimbursement – is a sustainable price paid for a medicine and is it reimbursed
- Access / update – does the health system buy innovative new medicines
- First launch market – if a new product
- Where they have raised capital or want to raise capital – e.g. a UK company that has raised capital in the US and is seeking to launch their product there first. Alternatively, a genomics company may seek to raise capital in China.
- Overall government support for sector – e.g. Industrial Strategy and Life Sciences Sector deal
- Overall strength of the life science ecosystem

As the UK's post-Brexit relationship with the EU becomes clearer, the life science sector will be able to provide more detailed information of the sector's priorities regarding both the UK's overall post-Brexit trade policy and specific FTAs. With the current uncertainty the sector faces, this is neither the right time nor a situation in which there is sufficient clarity to give detailed information for the proposed FTA negotiations. As this paper sets out, the sector's current priorities on trade are to ensure the continued supply of medicines on day 1 through a as frictionless as possible relationship with the EU and continued access post-Brexit to current EU FTAs and MRAs.

These priorities are important foundations for the UK's independent trade policy post-Brexit. Only once these foundations are firmly in place should the Government focus on other trade agreements and it should consider firstly focusing on broader trade agreements, such as WTO agreements. Efficient UK participation in such broader agreements could bring more benefit to industry in the short-term compared to lengthy FTA negotiations.

6. Government export/investment support

The role of Office for Life Sciences (OLS), DIT and the HLB Cluster in supporting export/investment is important.

The UK is fortunate to have many SME and scaling companies. However, those companies often note the lack of support, and senior Government engagement, to encourage them to invest in the UK. Many of these companies have hundreds of employees working in R&D in the UK, are growing quickly, have raised funds that they can invest anywhere in the world, and are flexible and nimble. EU27 countries and the US have recognised the potential of many of these companies and Government needs to act to ensure that they continue to grow their UK footprints.

Government support and coordination at international biotech and pharmaceutical events is important. Our sector sees increasingly effective delegations from EU, US, China, and Japan at important international events. Support needs to recognise that benefits from engagement may not be immediate but are important for SMEs. The UK's presence at events including Biotech Showcase, BioEurope, BioEurope Spring, and the China Summit are important to support the future financing and exporting of the UK.

As the UK leaves the EU it is important the Government considers attending events where there is broader decision-maker/regulator presence and proactively engages, for instance DIA and TOPRA.

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