BioIndustry Association response to the Department for International Trade's consultation on UK-Japan trade

November 2019

UK BioIndustry Association

Introduction

1. 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.
2. Our members include:
    - Start-ups, biotechnology and innovative life science companies
    - Pharmaceutical and technological companies
    - Universities, research centres, tech transfer offices, incubators and accelerators
    - A wide range of life science service providers: investors, lawyers, intellectual property (IP) consultants, and communications agencies
3. The BIA's members are responsible for over 90% of biotechnology-derived medicines currently in clinical development in the UK and are at the forefront of innovative scientific developments targeting areas of unmet medical need. This innovation leads to better outcomes for patients, to the development of the knowledge-based economy and to economic growth. Many of our members are small, pre-revenue companies operating at the translation interface between academia and commercialisation.
4. The BIA welcomes the opportunity to submit a response into the Department for International Trade (DIT)'s consultation. Over the last couple of years, we have seen increased activity between UK life sciences SMEs and Japanese companies and investors.

Priorities for the life sciences sector in the UK's future trading relationships

5. The top priority for the UK life sciences sector as the UK leaves the EU is to ensure UK-EU trade remains as frictionless as possible and aligned on medicines regulation. The UK sector benefits from the EU regulatory system and has deeply integrated supply chains across the EU which rely on regulatory alignment and the free movement of goods and services across the UK-EU border.
6. The life sciences sector currently benefits from existing EU Free Trade Agreements (FTAs) and Mutual Recognition Agreements (MRAs) with key markets. It is vital for the sector that the UK rolls over the FTAs and MRAs that the EU has agreed, including the Economic Partnership Agreement (EPA) and MRA with Japan. Without these agreements, or if there is a gap between the UK leaving the EU and rolling over the agreements, there will be significant disruption for the sector, including to supply chains which could impact on patient safety and access to medicines as well as business R&D investment decisions.
7. As the UK Government seeks to negotiate FTAs with third countries post-Brexit, it is crucial that the first FTA to be negotiated sets high standards for the benefit of the UK economy, as it is likely that the FTA will become a model for future negotiations. It is also important DIT builds transparent and efficient

means of communication with industry to inform negotiating positions. If multiple trade negotiations are taking place simultaneously, this communication becomes even more important.

8. Overall, the priorities of future FTAs outlined in BIA's submission to DIT in October 2018 on IP, tariffs, science and innovation collaboration, regulatory cooperation, mobility of people, and rules of origin remain unchanged.[1]

Priorities for UK life sciences in Japan

9. With its advanced economy, high levels of R&D investment and growing biotech sector, Japan offers many opportunities for UK life sciences companies. Its pharmaceutical and healthcare market is the third largest in the world and with a rapidly ageing population, the market is set to grow further.[2] However, the opportunities Japan offers the UK life sciences sector go beyond selling existing products; many Japanese life sciences companies are actively looking for international R&D partnerships and collaborations.

10. Japan is a highly innovative country. Public and private R&D investments in Japan is around 3.2% of GDP, well above the OECD average of 2.4% and much higher than the current UK levels at around 1.7%.[3] This high level of R&D investment feeds the innovation pipeline, from basic research through to commercialisation. Indeed, Japan is ranked as Asia's number one country for biotech and pharma patents (3,748 patents listing at least one Japanese inventor).[4]

Intellectual property

11. 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 trade deals should seek to capitalise on the UK's strengths, harmonise global IP systems, and encourage trading partners to adopt high standards of IP protection and enforcement.

12. In general, Japan has an innovation-friendly IP environment, and the Japan-EU FTA has helped establish a high degree of alignment in approaches to IP. The UK and Japan would therefore be starting from a positive position for negotiations with regards to IP.

13. However, there are significant weaknesses in two IP provisions of the Japan-EU FTA that are of concern and that the UK could seek to strengthen to benefit innovators in both the UK and Japan:

    a. Article 14.35 in the IP chapter obliges the parties to provide a patent term extension to compensate for the reduction of effective patent term resulting from regulatory requirements, however, it contains no detail as to what that compensatory term should be. A potential UK-Japan FTA would give the UK the opportunity to seek to agree text which specifies a formula that would result in a term equivalent to the term of extension in the UK today. We urge the UK Government to do so.

[1] https://www.bioindustry.org/resource-listing/bia-dit-consultation-response-pdf.html
[2] EU Business in Japan (2019): 'Biopharmaceuticals': https://www.eubusinessinjapan.eu/sectors/biotechnology/biopharmaceuticals
[3] OECD (2018): 'Gross domestic spending on R&D': https://data.oecd.org/rd/gross-domestic-spending-on-r-d.htm
[4] GEN (2017): 'Top Eight Asia Biopharma Clusters 2017': https://www.genengnews.com/a-lists/top-eight-asia-biopharma-clusters-2017/77900935/?q=japan

It is important that such a formula should be expressed to be the minimum term that should be provided, so that either party should be free to increase incentives for innovation by providing a longer term. Further, the EU text provides that the compensatory term be based on the time during which the patented invention cannot be used due to the 'marketing approval process'. This could be interpreted as meaning that the compensation should be related only to the period between the application to a regulatory authority for a marketing authorisation and the grant of the authorisation (this is the approach taken in Singapore). The UK should seek to ensure that the whole R&D process required to satisfy requirements necessary to obtain authorisation to market a pharmaceutical or agrochemical product prior to the application being made is considered. Text that specifies this would align more closely with the current UK policy on patent term extensions.

b. Article 14.37 in the IP chapter requires the parties to prevent second or subsequent applicants for authorisation of certain pharmaceutical products from relying on or referring to undisclosed tests or other data submitted to the regulatory authority by the first innovative applicant for 'a certain period of time' counted from the date of approval of the innovative product. No term of protection is specified. Again, we urge the UK Government to seek to agree text which would result in a term equivalent to the term of protection in the UK today and again we believe it is important that this should be expressed as a minimum term.

Science and innovation collaboration

14. As an advanced country with a growing biotech sector, Japan is an attractive location for international R&D collaborations. There is a strong track-record of alignment in scientific interests and partnership between UK and Japanese life sciences companies, particularly in regenerative medicine. For example, in 2012 Japan's Shinya Yamanaka and UK's John Gurdon were jointly awarded the Nobel Prize for Physiology or Medicine for their stem cell research. The UK has a strong cell and gene therapy sector which is well-placed to build on and commercialise breakthroughs in basic research, such as the joint Nobel Prize. One example of this is UK SME company and BIA member Mogrify, which is developing life-saving cell therapies building on Yamanaka and Gurdon's research, and raised $16 million in October 2019. There is clearly a strong foundation and motivation for expanding our partnership with the Japanese innovation ecosystem through an FTA.

15. To promote these types of partnerships, this year the BIA and the Forum for Innovative Regenerative Medicine (FIRM), a Japanese trade association, jointly published a directory of member companies engaged in regenerative medicine, translated into English and Japanese.[5] The BIA and FIRM hope that the shared directory will enable UK and Japanese companies to work cooperatively to solve problems and accelerate mutual commercial outcomes that generate health and wealth gains for our countries.

16. The directory was completed without any support or involvement from DIT. As the UK builds on its trade relationship with Japan, it is important that DIT enables these types of science and innovation collaborations between the two countries. For example, this could include free translation services for similar projects and the development of case studies of UK-Japanese partnerships.

17. It is also important that DIT has a strong presence at international conferences in Japan to promote the UK and its life sciences sector. These conferences are key networking opportunities for businesses and investors to explore new opportunities and potential partnerships. However, DIT currently does not

[5] https://www.bioindustry.org/resource-listing/bia-firm-directory-final-pdf.html

have this presence. For example, there was no DIT/UK stand at the recent BioJapan, held in October 2019. DIT engagement and presence at these types of conferences in the future are central to improving UK-Japan trade and should be pursued in addition to trade negotiations.

Regulation

18. The UK Government should seek regulatory harmonisation, whilst not reducing UK regulatory standards nor impairing the MHRA's ability to have close regulatory cooperation with the EU's EMA. The EU-Japan MRA currently removes duplicative requirements and additional costs for life sciences companies in both countries. It is welcome that the UK and Japan have exchanged letters on mutual recognition of conformity assessments, which maintains the effect of the operational aspects of the EU-Japan MRA.
19. While many UK life sciences companies are interested in expanding into Japan, many companies do not have a comprehensive understanding of the Japanese regulatory environment and the regulations that affect their products. This is acting a barrier to UK-Japan trade and cooperation. DIT should take an active role in tackling this barrier by helping UK life sciences companies better understand Japanese regulations, for example through case studies and technical workshops.

Market access

20. As Japan implements its new health technology appraisal (HTA) system, it is important that the UK Government emphasises the importance of transparent processes and stakeholder engagement. The current system has lacked transparency and predictability and the Japanese approach to calculating quality-adjusted life years (QALYs) has diverged from international and UK standards which has made it difficult for UK life sciences companies looking to invest in or access the Japanese market. We would like to see Japanese reforms go further, however, and explicitly include patient engagement which is currently missing from the Japanese HTA process. The Japanese HTA system should look to NICE and, in particular, the Scottish Medicines Consortium for evidence of how to involve patients in the HTA process.
21. Excluding budget impact from value calculations: Japan should dispense with the 'tokurei kakudai saisantei' which applies automatic price cuts to products which have exceeded sales projections, even when the original list price was clearly approved for reimbursement. This policy significantly penalises and undervalues breakthrough therapies which may have near-term costs but clear long-term value.

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