BioIndustry Association response to the International Trade Committee's inquiry on UK trade with China
October 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, 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 Committee's timely inquiry. Over the last couple of years, we have seen an increased activity between UK life sciences SMEs and Chinese companies and investors.

Summary

- With its large healthcare and pharmaceutical market and emerging excellence in science, China offers many opportunities for UK life sciences companies. These opportunities encompass big data, new healthcare systems, digital, diagnostics, genomics and new medicines, which will all be at the heart of the new healthcare landscape that is emerging in China.
- In the last two years China has made a concerted attempt to, and has delivered, fundamental changes to key aspects of its healthcare market, including new approaches to medicines regulation, reimbursement of drugs, talent, and capital and public markets. Ties between UK-Chinese institutions, especially regulators, must be strengthened to maintain UK influence in global affairs.
- Recent rule changes on the Hong Kong Stock Exchange has enabled pre-revenue biotech companies to float on the exchange. Buoyed by domestic market growth and new scientific opportunities, there is a significant pool of capital in China seeking to invest in biotech and related innovative healthcare. These investors and companies are increasingly interested in UK biotech and

life sciences. In 2018, UK biotech companies received over £140 million[1] in venture capital investment through deals involving Chinese investors.

- The BIA is committed to building strong links between the UK and Chinese innovation systems. In 2018, we established a China Biotech Special Interest Group together with the China-Britain Business Council. In the past two years, we have attended and led delegations of UK SMEs to several major conferences in China. This year, the BIA has also hosted two delegations in London, including one delegation from the Hong Kong Stock Exchange and another of the Xiamen Municipal Government.
- Intellectual property (IP) theft and enforcement of IP rights in China has historically been a concern for businesses operating in the country. The situation is improving with the Chinese Government and courts increasingly recognising the importance of upholding IP rights to support investment, business activity and innovation. However, a future trade agreement should seek to put in place robust protections for foreign companies' IP when operating in China.

Opportunities for UK life sciences in China

1. With its large healthcare and pharmaceutical market and emerging excellence in science, China offers many opportunities for UK life sciences companies. These opportunities are much broader than merely selling existing products in China. Rather, the opportunities for UK life sciences encompass big data, new healthcare systems, digital, diagnostics, genomics and new medicines which will all be at the heart of the new healthcare landscape that is emerging in China.
2. In the last two years China has made a concerted attempt to, and has delivered, fundamental changes to key aspects of its healthcare market. These changes are part of a broader government push to improve healthcare for the nation and become a world leader in biotech. The changes fall into four areas: medicines regulation, reimbursement of drugs, talent and capital and public markets.
3. This section explains the changing environment for life sciences companies, outlines the opportunity of the Chinese market and provides some recent examples investment deals and other agreements between UK and Chinese life sciences companies.

Medicines regulation

4. Since 2017, the Chinese regulator, the National Medical Products Administration (NMPA) has dramatically revamped its processes to eliminate hurdles that previously slowed approvals of non-Chinese drugs. For example, there is no longer a requirement that foreign drug-makers can only apply to start clinical trials in China after it has at least entered Phase 2 trials elsewhere. In addition, foreign drug-makers can file for a new drug approval using data from international, multicentre trials, so long as those trials include China as a study site.
5. The NMPA has also joined the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and is keen to take a key role in the global discussions about the future of medicines regulation. There have been recent discussions between the UK regulator, the Medicines and Healthcare products Regulatory Agency (MHRA) and the NMPA, and it will be

[1] BIA analysis of Pitchbook data (2019). However, we believe this data is not comprehensive and that the amount invested is higher than £140 million.

important for ties and cooperation to be strengthened to ensure the UK remains at the forefront of global regulatory policy and innovation as China increases its influence.

Reimbursement for medicines

6. Two decades ago, the Chinese drug market was relatively small. Today, however, a paradigm shift to the Government's reimbursement system means the system covers 1.4 billion people. Over the past few years, key changes have been made to the National Reimbursement Drug List (NRDL), which aims to provide basic medical coverage to China's population and typically covers well-established and relatively cheap medicines. The changes to the NRDL mean that equal importance is now attached to both Chinese and foreign drugs. For example, the UK's AstraZeneca have benefited from these recent developments and are now the second largest pharmaceutical company in China.

Talent

7. For over a decade, China has offered significant incentives for Chinese talent to return from overseas to set up and run innovative companies. This has resulted in a lot of talent moving to China-based biotech companies and life science financing roles companies from world-leading biotech clusters in California and Massachusetts. Many management teams benefit from Chinese executives with international experience that can win support from investors.

Capital and public markets

8. In 2018, the Hong Kong Stock Exchange introduced new rules which allowed pre-revenue biotech companies float on the exchange. Since then, around ten companies have floated but there is a pipeline of more IPOs expected. There is also a clear desire from the Shanghai Stock Exchange to go in a similar direction. We anticipate this driving rapid growth in the Chinese biotech sector.

Increasing interest in UK life sciences

9. The Chinese life sciences investment market is not dissimilar to the US or UK markets in the late 1990s: confident, expecting growth and increasing in sophistication but still young and growing. Buoyed by domestic market growth and new scientific opportunities, there is a significant pool of capital seeking to invest in biotech and related innovative healthcare.

10. These investors and companies are increasingly interested in UK biotech and life sciences. In 2018, UK biotech companies received over £140 million in venture capital investment from deals involving Chinese investors.[2] In addition, Chinese pharmaceutical companies are actively seeking licensing deals with UK companies, which has become a new form of funding option for UK biotech companies. However, a 10% Withholding Tax on capital outflow from China is a current trade barrier that should be examined.

11. Some recent announcements of Chinese investment into UK companies and agreements between UK and Chinese companies include:
    - ReNeuron, a UK-based leader in cell therapies, licensed rights to two of its cell therapy programmes to Fosun Pharma for payments of £80 million in April 2019.[3]

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[2] BIA analysis of Pitchbook data (2019). However, we believe this data is not comprehensive and that the amount invested is higher than £140 million.

[3] 'ReNeuron partners with Fosun Pharma in China', 9 April 2019: http://4965zs3ha2l125fk78zkozo3.wpengine.netdna-cdn.com/wp-content/uploads/ReNeuron-Fosun-Pharma-deal-press-release-Apr-2019-FINAL.pdf

- Congenica, an SME based in Cambridge that provides a diagnostic decision support platform, has a strong footprint in China. Congenica recently announced two partnerships with Chinese companies to enable the company's platform to be used in China to further genome sequencing and genome medicine.[4] In April 2019, the company announced that it had raised £23.3 million in a Series B, part of which were from Chinese investors.[5]
- In March 2018, DNA sequencing company Oxford Nanopore announced a £100 million fundraising round from global investors, including Chinese CCB International.[6]
- In February 2018, Trinity College and Tus Park agreed a £200 million joint venture that will catalyse a new phase of renewal and investment in Cambridge Science Park, which is home to many life sciences companies. The collaboration will include the development of a new Biohub which will provide labs and offices for early stage companies and inventors working on a wide range of healthcare products and technologies.[7]
- Eight Great Technologies (8GT), a UK venture capital fund, and Tsinghua University's venture capital fund signed an agreement in 2018 to create a £560 million fund for emerging technologies, such as regenerative medicine and synthetic biology, in the UK and China.[8]

12. These investments and agreements between UK and Chinese companies come as a result from recent trade missions between the two countries. For example, the then-Prime Minister Theresa May's visit to China in February 2018 resulted in several healthcare agreements being signed.[9] One of the BIA's ongoing priorities is to build strong links between the UK and Chinese innovation systems. We are working to lead the way for life sciences SMEs to explore the opportunities that China offers.
13. Since 2018, the BIA has attended and led delegations of UK SMEs to several major conferences in China, including the China Healthcare Summit in Shanghai 2018, the Wuxi Healthcare Forum in Shanghai and the Boao Forum in Hainan Province. We have also supported the establishment of AstraZeneca's Wuxi International Life Science Campus in September 2019 (see case study 1 below for more information). In November 2019, we will lead another delegation of UK SMEs to the China Healthcare Summit 2019, where we are hosting a special 'UK Biotech Track' which will allow companies to tell their stories to leading Chinese investors and corporate executives.
14. This year, the BIA has also hosted two delegations in London. In June, we hosted the key movers from the Hong Kong Stock Exchange to discuss the recent rule changes on the Exchange (see para 8 above) as part of a strategic push to enable global investors to get to know the opportunities in UK

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[4] 'Congenica Signs Strategic Digital Health Contracts During Official UK-China Trade Mission', 1 February 2018: https://www.congenica.com/2018/02/01/congenica-signs-strategic-contracts-uk-china-trade-mission/; 'Congenica Announces Market Access Partnership with Digital China Health to Enable Genomic Medicine in the Chinese market', 17 September 2018: https://www.congenica.com/2018/09/17/congenica-announces-partnership-digital-china-health/
[5] 'Congenica Raises Additional £13.25M ($17.1M) to Reach Total of £23.3M ($30.1M) for Series B Funding Round', 30 April 2019: https://www.congenica.com/2019/04/30/congenica-raises-additional-13m-for-series-b-funding-round/ '
[6] 'Oxford Nanopore announces £100 million ($140M) fundraising from global investors', 20 March 2018: https://nanoporetech.com/about-us/news/oxford-nanopore-announces-ps100-million-140m-fundraising-global-investors
[7] 'Landmark joint venture at Cambridge Science Park', 1 February 2018: https://www.trin.cam.ac.uk/news/landmark-joint-venture-at-cambridge-science-park/
[8] 'Launch of Eight Great Technologies China UK Fund - a collaboration with Tsinghua University's VC Fund Leaguer International', 1 February 2018: https://www.eightgreattechnologies.com/single-post/2018/02/01/Launch-of-Eight-Great-Technologies-China-UK-Fund---a-collaboration-with-Tsinghua-Universitys-VC-Fund-Leaguer-International
[9] 'Strong UK-China collaborations in healthcare', 14 February 2018: https://www.gov.uk/government/news/strong-uk-china-collaborations-in-healthcare

biotech. In September, we hosted a delegation from the Xiamen Municipal Government, including the Xiamen Mayor, to discuss the investment and business opportunities between UK and Xiamen and to establish relationships with our member companies who have interests in making investment or having a business presence in Xiamen.

15. In addition, in 2018 we established a China Biotech Special Interest Group together with the China-Britain Business Council (CBBC), and supported by the Department for International Trade (DIT), to provide a discussion platform for BIA and CBBC members in the life sciences sector, exploring the opportunities for business growth in and with China via trade and investment. The group's objective is to increase the number of UK biotech companies collaborating with, generating revenue from, and receiving investment from the Chinese market.
16. The country is rapidly opening up and it is becoming easier to do business in China. However, UK companies still experience considerable difficulties operating and it is all but essential to have a local partner (a Chinese consultant and/or local business collaboration) to help navigate the business, regulatory and political landscape.

Case study 1: The Wuxi International Life Science Campus

On 7 September 2019, AstraZeneca, in partnership with the Wuxi Government, officially opened the Wuxi International Life Science Innovation Campus (I·Campus). At the opening, the BIA signed a signed a memorandum of understanding with the I·Campus and AstraZeneca in China.

The I·Campus is situated in the Wuxi National High-tech District in Jiangsu, China, and brings together innovative 4D (Drug, Device, Diagnosis and Digital) companies, government, and medical and academic institutions together via an open collaboration platform, helping to accelerate healthcare innovation and sciences in China. The state-of-the-art campus will enable UK SMEs companies to easily explore, partner and engage with China's rapidly expanding healthcare innovation market. The I·Campus will also serve as AstraZeneca's new China headquarters.

Steve Bates OBE, Chief Executive of the BIA, commented on the opening of the campus:

> "This is a key initiative for the BIA to make it easier for UK life sciences SMEs to do business in China. The opening of the Wuxi I·Campus will do much to de-risk and de-mystify China for UK companies. Wuxi is a city renowned for manufacturing and being at the centre of the 'internet of things' in China. The I-·Campus will build on Wuxi's innovation heritage and be a significant landing pad for UK biotech companies looking to expand and collaborate in China."

Intellectual property

17. Life sciences companies in the UK benefit from the UK's world class intellectual property (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. A trade deal with China should seek to capitalise on the UK's strengths and encourage trading partners to adopt high standards of IP protection and enforcement.

18. 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.
19. The UK should ensure that all of its trade deals have suitable mechanisms for resolving trade disputes, this should include strong mechanisms for enforcing IP rights in partner countries. The failure of trade agreements and trading partners to provide for enforcement of rights can create barriers to trade.
20. The BIA cautions the adopting or evolving lesser protections than exist currently. Such action would reduce the attractiveness of the UK as a location for R&D investment. In particular, the UK should ensure that trade agreements 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
    - Regulatory 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
    - Ability to obtain preliminary injunctions (with appeal) against generics that launch at-risk
21. China currently operates a basic patent regime. There are no R&D incentives that provide longer exclusivity terms, such as those available in the UK described above. However, the Chinese Government has indicated in intention to introduce regulatory data exclusivity and orphan medicine incentives. Expediting their implementation should be a priority in any trade deal.
22. IP theft and enforcement of IP rights in China has historically been a concern for businesses operating in the country. Companies operating in highly regulated sectors, such as biotech, are particularly prone to IP theft as they are asked to disclose large amounts of data and technical information. The situation is improving with the Chinese Government and courts increasingly recognising the importance of upholding IP rights to support investment, business activity and innovation. However, a future trade agreement should seek to put in place robust protections for foreign companies' IP when operating in China. In particular, a mechanism should be established to obtain preliminary injunctions (with appeal) against generics that launch at-risk to prevent erosion of innovators market share.

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