

Summary of the DIT/Canning House Brazil Life Science Roundtable

On 20 September 2018, the Department for International Trade (DIT) and Canning House co-hosted a roundtable on the life sciences sector in Brazil. This event brought together businesses that had experience in, or had expressed an interest in exploring and investing in the life sciences market in Brazil. This document summarises that discussion.

Introduction and purpose of the roundtable.

- DIT described the conclusions of the UK-Brazil Joint Trade Review and that the life sciences sector has been identified as a key sector for further policy co-operation. The UK and Brazil agreed to identify opportunities to improve trade in the sector at the Joint Economic and Trade Committee (JETCO) in March 2018 with recommendations for Ministers ready for the next JETCO in 2019.
- Building on the Trade Review, officials are developing a programme of work on trade facilitation and improving regulatory coherence and convergence, some of which will be delivered by HMG's Prosperity Fund.
- DIT also highlighted work to develop a mechanism for UK and Brazilian companies to engage in direct dialogue with each other and with both governments to further identify areas for cooperation.

The below reflects the views of life science companies discussed under the Chatham House rule, and do not indicate HMG policy positions:

Perspectives on the life science market in Brazil

- Companies acknowledged that Brazil is one of the most highly regulated countries in Latin America but said that they felt a lack of technical staff in the Brazilian Government means that the regulations are often not properly understood, with inconstant application and a lack of clarity around the goal.
- However, firms said that they felt Brazil's approach to regulation does seem to be moving in the right direction for facilitating improved international trade.

Barriers to trade

- Businesses cited an unstable macro-economic climate as a significant hindrance in the market but felt that the fundamentals were improving.
- Firms had limited experience of securing patents in Brazil and therefore did not see patent issues as a barrier, though some described how a lack of trade mark protection had caused problems when securing entry into the market.

- Local manufacturing requirements vary between states in Brazil and are quite often subject to negotiation. This offers a degree of flexibility for firms, but the lack of clarity adds complexity and makes it hard for firms navigate the issue.
- In some instances, the Brazilian Health Regulatory Agency (ANVISA) required a huge number of safety and other tests requested beyond what would be required in other markets, and firms wanted to see this fall to a proportionate level. If Brazil were to recognize a CE mark on the product this would reduce the number of required tests and would prevent delays.
- One firm reported that they were told that it could take between 2-5 years to obtain the Good Manufacturing Practice (GMP) certification and final ANVISA registration. They successfully used the Medical Device Single Audit Program (MDSAP) to accelerate the process but the firm still had to pay c. \$40,000 for the cost of a physical site inspection from ANVISA despite the inspection not being performed.
- The requirement and process to establish local partnerships was also identified as a barrier. It is difficult for firms to identify potential partners and perform the required due diligence because of the lack of information available.
- The process of securing a local partner is also associated with substantial legal fees; the cost of which is increased significantly by the need to use local law firms given the restrictions on foreign firms practicing law.
- The tendering process is much less transparent in Brazil than in other Latin American countries which adds to the problem. As an example, information about the successful and unsuccessful bids in a tender is not publicly available in Brazil, where as this information is available in neighboring countries.
- The degree of local preference is also often not stated. This prevents international companies from making informed decisions about whether to put in a bid.
- On customs, the companies present did not report any significant issues.

Next steps

- DIT will take forward the results of this discussion during conversations with the Brazilian government and seek further views as we agree recommendations.
- The UK-Brazil Business Dialogue (UKBBD) in 2019 will bring together UK and Brazilian businesses in a range of sectors alongside government officials, and we hope to use the UKBBD to seek further views and provide a progress update to the business community in advance of the next JETCO.