The UK's Life Sciences sector exposure to Brexit

Hertfordshire Chamber of Commerce

Life Sciences Summit

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- COVID-19 has rightly dominated the news and our thinking but on 31st December 2020 the transition period ends.
- This will have immediate and significant effects but we are still unclear on the nature of the deal.
- Michel Barnier Press Statement – Round 6 negotiations 23rd July 2020 -

'The EU has always insisted that an economic partnership with the UK must include robust level playing field rules and an equitable agreement on fisheries.

This means that, by its current refusal to commit to conditions of open and fair competition and to a balanced agreement on fisheries, the UK makes a trade agreement at this point unlikely.'

Pharmaceutical Annex

- Comprehensive Free Trade Agreement (CFTA) – UK Objectives
  - Facilitate trade in medicinal products and support high levels of patient safety.
  - Mutual recognition of certificates of Good Manufacturing Practice (GMP)
  - Acceptance of batch testing certificates issued by a manufacturer based in either party, in line with provisions in EU-Canada Free Trade Agreement (CETA).
  - Cooperate on pharmacovigilance
  - Comprehensive confidentiality agreement between regulators, in line with agreements between the European Medicines Agency and Swiss, US and Canadian authorities.
  - Information sharing and enable regulators to act promptly to safeguard patient safety and public health, such as by responding to urgent adverse drug reactions.
  - Annex could also cover procedures relating to vaccines and other biological medicinal products, and clinical trials.
- No longer part of EMA centralised authorisation procedure & EMA now moved to Amsterdam
- MHRA commitment from its Annual Report:
  '*to make the UK one of the best places in the world to develop life sciences projects, protecting health and improving lives, here and around the globe.'*

Chemicals Annex

- CFTA – UK Objectives
  - Facilitate trade in chemical substances and related products
  - Ensure high levels of protection for the environment and human and animal health.
  - It could provide for cooperation between UK and EU authorities, including on implementing the Global Harmonised System of Classification and Labelling of Chemicals.
  - In order to ensure high levels of protection and to support UK and EU businesses to meet the separate regulatory requirements of the two markets, the parties could agree data and information sharing mechanisms, in line with the relevant provisions set out in UK and EU regulation and existing third-country mechanisms.
  - This annex should also include a commitment to develop a memorandum of understanding (MOU) to enhance cooperation further, similar to the MOUs that the European Chemicals Agency has agreed with Australia and Canada.
- System creates EU-REACH and UK-REACH. How this works in practise will have a significant long term effect on the Chemicals industry which is a vital part of the Life Sciences Sector. CIA estimate bilateral trade at €46bn for chemicals.
- Due to international nature of chemical industry rules on Tariffs and Rules of Origin will also be critical.

Skilled Workers

- EU nationals currently working in the UK need to apply for settled and pre-settled status – deadline for applications is 30th June 2021.
- Post 31st December 2020:
  - Australian point based immigration system.
  - EU nationals assessed on an equivalent basis to other international applicants.
  - One option remains Sponsorship:
    - Company can obtain approval to Sponsor individuals who meet minimum criteria and a market labour test for the role.
    - Process is expensive and relatively bureaucratic.
  - Recruiting international staff will be more difficult and expensive.
- Life Science sector has always had skills challenges and the exit will make these shortages a greater challenge.
- In this area the situation is clear with little uncertainty.

Border & Trade Friction

- The Chancellor of the Duchy of Lancaster, Michael Gove - 10th February 2020:

  "The UK will be outside the single market and outside the customs union, so we will have to be ready for the customs procedures and regulatory checks that will inevitably follow.

  As a result of that we will be in a stronger position, not just to make sure that our economy succeeds outside the European Union but that we are in a position to take advantage of new trading relationships with the rest of the world."

- Gove also confirmed that the policy easements put in place for a potential 'no deal' exit will not be reintroduced as businesses have time to prepare.
- Mitigation plans for 'No Deal' exit may need to be considered for 1st Jan 2021.
- Need an EORI number and consider having a customs agent.
- David Watson ABPI Interim Executive Director for Commercial Policy - 4th August 2020:

  "Pharmaceutical companies have worked around the clock to make sure medicine supply chains have held up during this pandemic. With this pressure likely to continue over the coming months, it is imperative that the Government works closely with them to provide the support they need to plan for the end of the transition period.

  While this letter means that preparations can proceed, detailed guidance is still urgently required from Government on issues like freight capacity, ferry routes and the Northern Ireland Protocol."

- For companies like Pharmaron difficult to stockpile materials such as Solvents will be the greatest concern.

GDPR

- From 1st January 2021 UK will become a third country for EU GDPR.
- UK has implemented Data Protection Act 2018 (DPA 2018) and the UK GDPR which provide equivalent protections.
- UK Government stands ready to assist the Commission in undertaking an assessment to allow the adoption of adequacy decisions for the UK and Gibraltar.
- Ahead of any adequacy decision EU GDPR data must be covered by Standard Contractual Clauses:
    - Article 26(2) of Directive 95/46/EC, which provides flexibility for an organisation wishing to transfer data to third countries, and Article 26(4), which provides for standard contractual clauses, are essential for maintaining the necessary flow of personal data between the Community and third countries without unnecessary burdens for economic operators. Those Articles are particularly important in view of the fact that the Commission is unlikely to adopt adequacy findings under Article 25(6) for more than a limited number of countries in the short or even medium term.

Northern Ireland & International R&D

- Northern Ireland – BBC News 7th August
  - Government to spend £355m on a new system for moving goods into Northern Ireland from the rest of the UK.
  - From 1 January, goods entering NI from GB will need customs declarations.
  - The Trader Support Service (TSS) will effectively see the government acting as a customs agent on behalf of businesses.
  - Cabinet Office Minister Michael Gove gave details of the plan on a visit to Portadown, County Armagh, on Friday.
  - The TSS is due to be up and running in September and will be free to use.
  - Initially traders will register with the service and receive advice on what Brexit will mean for their business and the next steps they should take.
- International R&D
  - Under the Withdrawal Agreement, the UK will continue to participate in programmes funded under the current 2014-2020 Multiannual Financial Framework (MFF) until their closure
  - UK Objectives
    - Consider a relationship in line with non-EU Member State participation with the following programmes: Horizon Europe, Euratom Research and Training, and Copernicus.
    - Consider options for participation in elements of Erasmus+ on a time limited basis, provided the terms are in the UK's interests.

Impact on Pharmaron

- Pharmaron UK has a number of core focuses:
  - Chemistry, Manufacturing and Control services supporting preclinical to Phase II of drug development.
  - Drug Discovery services.
  - Manufacture and distribution of 14C and 3H labelled compounds.
  - Conduct of DMPK, e-fate and plant metabolism studies to support the Pharmaceutical, Animal Health, Agrochemical and Chemical industries.
- For the Pharmaron businesses the key direct impacts/risks are:
  - Disruption to shipping and trade arrangements while new arrangements bed down. >70% of sales are exported and lots of raw materials are imported.
  - If Batch release certificates and UK QP qualifications not accepted this will be disruptive in supporting EU trials. This may favour our continental competitors when bidding for EU projects.
  - Potential disruption to access to key raw materials due REACH or shipment issues.
  - Greater difficulties and expense with international recruitment.
- Pharmaron had a French CIR registration while we were in the EU. This will no longer be available to us and so will make us less competitive for French clients.
- Overall impact will be negative but should be manageable assuming a sensible compromise is reached.

Overview

- Life Science Sector needs to adapt to the coming changes.
- If UK achieves its negotiating objectives then with sensible contingency planning for the start of 2021 the industry can adapt.
- In the event of moving quickly to ‘Australian’ trading arrangements (new language for old ‘no deal’) we will potentially face significantly more disruption and bureaucracy.
- Thanks to CIA, BIA and other sources of information used.
- Did not cover phytosanitory arrangements, ...
- Life Science industry must continue to lobby hard for minimising the regulatory and other burdens arising from our exit.
- Opportunities for benefits from trade agreements with US, Japan....