Potential impact of Brexit outside the UK/EU

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There is hardly a shortage of views, forecasts and estimates of the impact of Brexit – hard, soft or otherwise – on the UK and EU generally, and on life sciences in particular; but less thought has been given to potential ramifications further afield, whether for developing or mature countries. In this article we touch upon some of the possible impacts, whether at geopolitical or life sciences-industry levels, with a focus on the Association of South Eastern Nations (ASEAN) region.

SIMON JOHNSON, former chief economist of the IMF, in a January 2019 article headlined "Brexit Does Not Matter", concluded that whilst Brexit may have an impact on British growth, it will not cause significant disruption to regional, let alone global, trade. In his view, the global economy's current uncertainty is due to a far greater extent to the political climate in the US.

However, beyond the level of global trade, some commentators take a broader view. In the aftermath of the UK referendum, Indonesia's trade minister at the time, Thomas Lembong, stated that he considered Brexit to be, not only a 'wake-up call' for the EU but also for ASEAN (Malaysia, Indonesia, Thailand, Philippines, Singapore, Brunei, Vietnam, Laos, Cambodia and Myanmar). He said that "Transnational unions cannot be allowed to become a project of the elites... We are failing to bring along our own people on the benefits of globalisation and international trade, even of international finance." He concluded

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that ASEAN could take lessons from Brexit on identifying and addressing the challenges of regionalism in the face of national priorities.

Conversely, some have looked at Brexit and concluded that any damage it – and the developments in other countries such as Italy, Greece and Hungary – does to the EU in reversing the 'ever closer union' logic, will benefit other regions such as ASEAN. It has been argued that the effect of the UK's exit from the EU might be to bolster ASEAN's desirability, centrality and its influence on potential trade and strategic partners.

Currently, the UK's withdrawal from the EU will deprive it of the benefits of existing Free Trade Agreements between the EU and non-European countries. For instance, the EU and Singapore have just negotiated and (in October 2018) signed a Free Trade Agreement intended to improve trade for goods such as pharmaceuticals. It is also negotiating deals with Vietnam, Indonesia and Malaysia. These would need to be renegotiated by the UK in the event of its departure from the EU.

Europe's international life sciences support

The European Commission, through the European Medicines Agency (EMA), is highly regarded internationally and has assumed a global role in seeking to assist less well-resourced regulatory agencies. For instance:

- Under Article 127 of Directive 2001/83/EC (on medicinal products for human use), the EMA issues certificates of medicinal products, based on World Health Organization recommendations, on behalf of the European Commission scheme to any country outside the EU. Such certificates confirm the marketing authorisation status of products and the good manufacturing practice (GMP) compliance status of the manufacturing site(s).
- The Agency also certifies products under Article 58 of Regulation (EC) No. 726/2004 (on the centralised procedure) by way of a scientific opinion, for the evaluation of certain medicinal products intended exclusively for markets outside the European Community. Such opinions are drawn up by the Committee for Medicinal Products for Human Use (CHMP), after consultation with the WHO, following a review of the quality, safety and efficacy data, analogous to the review undertaken via the centralised procedure.
- On a broader level, the EMA also plays a key role in harmonisation of worldwide regulatory standards. It is one of the three agencies that make up the International Conference on Harmonisation.
- The EMA and many other EU national medicines regulatory authorities are involved in the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S). This is an international cooperation between pharmaceutical inspection authorities in the field of GMP. The PIC/S develops international GMP standards and quality systems of inspectorates in human and veterinary medicines and assesses national inspectorates and facilitates cooperation between national regulatory authorities. In practical terms, this means that if a country joins PIC/S they will recognise GMP inspections and assessments carried out by other PIC/S member countries, without the need for another inspection.

Several ASEAN countries are among the 72 countries that have authorised medicines evaluated through the Article 58 process. Indonesia, Malaysia, Singapore and Thailand also belong to PIC/S.

Questions have arisen in the light of the well-publicised teething problems of the EMA's move from London to Amsterdam and the likely loss to the EMA of the resources of the UK Medicines and Healthcare products Regulatory Agency (MHRA). The MHRA is reported to play a bigger role than any other national agency, carrying out some 30 percent of EMA assessments, vigilance and licensing work. However, whilst the EMA acknowledges that its role at an international level, such as on the harmonisation of global medicine regulation, will be temporarily scaled back to a more reactive level, it has stated that it

BIOGRAPHY

PAUL RANSON is a consultant at Morgan Lewis who focuses on the regulatory and commercial needs of the pharmaceutical, biotechnology and medical devices sectors. Paul's regulatory experience covers both marketing authorisation-related matters and market access, pricing and reimbursement issues. His commercial work is concentrated on transactions with a high degree of industry specificity including collaborations and outsourcing transactions.

will continue to process product-related requests and supply-chain integrity and procedures under Article 58. The suspension and scaling back of work is expected to last until 30 June 2019, but a decision will be taken this month as to when a full programme of work can resume.

Some effects for third countries of the UK's departure

The position of the European Commission is that any marketing authorisation or other licence, which is a legal requirement under EU laws held by a UK-based entity, will require a transfer to one based in the EU27. Similarly, any UK holder of a regulatory role such as a responsible person for manufacturing or pharmacovigilance purposes, or a responsible person for distribution purposes, must be replaced by an entity based in the remaining states. Additionally, the EU Pharmacovigilance System Master File (PSMF) must reside within an EU Member State.

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Moreover, the current system, whereby the batch release of a product imported into the EU may take place in any of the EU28, will no longer apply within the UK. It will therefore make little sense for an importer of drug product into the EU to batch release in the UK. Instead, a separate batch release would be necessary for the EU27, and then again for the UK.

With medical devices, under the Medical Device Directives (eg, 93/42/EC) and the new Medical Device Regulations ((EU) 2017/745 and 746), a manufacturer not based in the EU is required to have an authorised representative located inside the EU. In addition, Notified Bodies, charged by the Commission with awarding CE-marking to approved devices, is dependent on EU location. Accordingly, those manufacturers using UK-based Notified Bodies will have to transition to Notified Bodies based within the EU27.

The free flow of medicinal and medical products between the UK and the EU27 would also end and third-country importers would need to deal with different, albeit possibly mirrored, requirements for the UK and the rest of the current EU.

As to the acceptability of UK medicines and devices for import; that would be a matter for local regulatory authorities, although it is worth noting that the MHRA is commonly accepted under the Article 58 procedure as an appropriate reference authority.

The future for third-country trade with the UK

The UK is the third largest biopharmaceutical cluster outside the East and West Coast of the United States. Its leading universities have excellent intellectual capital for third countries seeking to develop medicinal products and medical devices, making it unlikely that the research base will wither any time soon.

However, from a trading perspective, Brexit fundamentally alters Britain's relations with trading partners outside Europe. There are contrasting positions regarding the impact of Brexit on trade between the UK and the rest of the world, which might be said to encapsulate the 'Remainer' and 'Brexiteer' perspectives.

Some argue that Brexit substantially weakens the UK's position in global trade. The country would cease to enjoy the collective bargaining power of the EU and would stand alone in trade disputes before the World Trade Organization, due to the fact that, at present, withdrawal from the EU necessitates the UK's withdrawal from the European Union's common external tariff regime.

Others consider that Brexit strengthens the international trading position of the UK, allowing it to enter bilateral trade agreements with the rest of the world, rather than having to accept trade deals negotiated by Brussels. In particular, this camp would point to deals with China and India, stalled by the agricultural and other protectionist lobbies.

Only time will tell who has correctly interpreted the future but at the time of writing, the UK Government and Parliament continue to wrangle as to whether to pursue a soft Brexit (continuing to be closely tied to the EU) or a 'clean break' (leaving without any deal with the EU). The coming hours, days, weeks, months or even years may see a resolution.