Assuring the Interests of the UK in Global Pharmaceuticals - What role does the EU play?

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- What role does the EU play?

Executive Summary

This paper intends to present a balanced view of the UK pharmaceutical industry in the context of its myriad current pressures. Its need to conduct a business that delivers safe and effective medicines, deliver a return on its high-risk investments at a time when patient expectation is escalating as fast as healthcare systems' budgets are shrinking and all with a backdrop to exiting the EU.

We consider serious commercial concerns to Brexit and the vulnerability of UK patients to the rational business interests of a global industry.

We review the strengths of the UK in relation to global price referencing its synergy with NICE Guidance. How current developments in the UK could conspire with Brexit to damage investment.

The paper describes an exciting future for the UK's Medicines and Healthcare Products Regulatory Agency (MHRA), a world-class regulator, outside the EU but also the risk of a chasm of time between exit and realising those opportunities.

A future industrial life sciences strategy needs to consider how bi-lateral benefit for the UK and EU can be secured by retaining the 'working parts' of the current single/regulatory market arrangements and, in so doing, minimise damage to economies.

The UK may have chosen a new political relationship with the EU and it is in the interests of both parties that the new relationship functions to maximise mutual benefit.

Introduction

In some UK industries, leaders are anxious to leave the EU, while in others such as the pharmaceutical industry, the perceived negative consequences of leaving have overshadowed the opportunities that might emerge or be created in the future.

It is well documented that the UK pharmaceutical industry is a major contributor to the economy, healthcare delivery and employment, so it's important to understand this major difference in outlook. In order to do so, we need to fully comprehend the priorities of a pharmaceutical industry that is global in its strategic thinking and ask how the UK will be valued alongside the priorities of the decision makers. And finally, get a realistic view of what opportunities for the UK really could exist beyond a market where, currently, one licence gives it the freedom to operate across 28 Member States.

Firstly, a number of fundamentals make the pharmaceutical industry distinct from most other industries:

- The stringent regulations surrounding the development and approval for marketing pharmaceuticals

- The perception of the industry by governments, payers and media, since pharmaceuticals are paid for by publicly funded bodies

No one in the pharma industry would disagree that the development and marketing of pharmaceuticals should be highly regulated. Regulation protects patients, HCPs and the industry itself from those who place profit ahead of efficacy, safety and true innovation.

Nevertheless, the ever-growing complexity of regulation contributes to the huge escalation in the cost of development. The progression of medicines from being organ-based to cell-based entities means they are more targeted, often improving benefit in smaller patient populations, as well as in a range of new indications. In turn, these breakthrough innovations will require the development of more complex regulation.

Longevity is now an expectation amongst today's populations, but it also involves polypharmacy and longer treatment regimens. The ability to do more stimulates an ever-increasing level of public expectation and has significant implications for the financial stability of advanced health systems.

There is an equivalent pressure on pharmaceutical companies to maximise their profitability – they are businesses after all. Innovation in healthcare would soon evaporate if investors were not to get a return on their high-risk investment.

However, the principle of pharmaceuticals funded from the public purse is used to pressurise companies to lower their prices and make the pricing process more transparent.

Industry might argue that while health systems are publicly funded, the NHS and other commissioners can be slow to adopt innovative processes and technologies that could help them achieve longer-term system efficiencies and cost savings.

The UK Market

We will now consider the UK in some detail:

- How the cost of medicines is controlled in the UK
- The UK in the context of global markets
- The UK as a member of the EU
- How the UK compares with the adopters of new medicines – both inside and outside the EU

There are four ways in which the cost of branded medicines is controlled in the UK:

- The Pharmaceutical Price Regulation Scheme (PPRS)
- The Statutory Regulations
- The Department of Health Commercial Medicines Unit – soon to become the Strategic Commercial Unit at NHS England
- Patient Access Schemes (PAS)

The PPRS - The PPRS is a voluntary agreement between the Department of Health (DH) and industry and is renegotiated (mostly) every five years. The aim of the Scheme is to control the medicines bill and also the profit that pharmaceutical companies make from their prime customer, a publicly funded NHS.

In previous schemes, the industry agreed to a percentage price cut in the list price of its medicines. New Chemical Entities (NCEs) launched during the five years of a new Scheme were exempt from a price cut; the aim, to encourage innovation.

The current Scheme covers the period 1st January 2014 to 31st December 2018 and, instead of a price cut, the industry agreed to fund a cap in growth of the medicines bill in each of its five years: 2014 – 0%; 2015 – 0%; 2016 – 1.8%; 2017 – 1.8%; 2018 – 1.9%.

This means that list prices remain unchanged and pharmaceutical companies fund the cap through rebates paid quarterly to the Department of Health. When the industry cut its prices in previous Schemes, NHS prescribers and budget holders could immediately see the benefits, as their costs fell. Now, under the current scheme, the rebates are paid to the DH.

Because there is little transparency on how the 'savings' are fed back to the NHS, prescribers and budget holders complain they see no direct benefit from the PPRS.

Unlike in Scotland and Wales, where the PPRS rebates are flagged clearly to contribute to a New Medicines Fund.

Nonetheless within this scheme, list prices remain unchanged - this is a benefit to companies and the UK economy due to International Reference Pricing (this will be discussed later).

The Statutory Regulations - As stated previously, the PPRS is a voluntary agreement. For companies that choose not to join the PPRS, the Statutory Regulations apply. Companies subject to the Statutory Regulations had to drop their list prices by 15%.

The Department of Health Commercial Medicines Unit (CMU) - The CMU conducts tenders for branded medicines in a range of therapeutic classes and these discounted prices provide a direct benefit to the NHS of an estimated several hundred million GBP every year. Companies do not disclose these discounts in detail because of the competitive and confidential nature of such pricing.

Patient Access Schemes (PAS) - It has been confirmed that c. 60% of NICE Technology Appraisal Guidance is accompanied by a Patient Access Scheme, which will involve a significant price discount. It is reasonable to reflect that the remaining 40% of Technology Appraisal Guidance technologies have been found to be cost effective at their list price.

The UK in the Context of Global Markets

The UK represents c. 3% of the global market for branded medicines i.e. excluding generics. As with many other countries, the UK continues to search for financial savings, so has rationed and sought cost reductions on most of the more expensive medicines and devices.

As stated previously, it may therefore not be surprising that c. 60% of all National Institute for Health and Care Excellence (NICE) Guidance is now associated with a PAS, where a company will provide a confidential discount on its medicine in order to reach a cost effectiveness threshold that is acceptable to NICE.

Two factors of significant importance to pharmaceutical companies are:

- NICE is a highly respected and influential Health Technology Assessment (HTA) body
- The UK is used as a reference price state by 55% of major global markets, including many EU countries

While a positive signal from NICE is recognised internationally, a NICE ‘No’ can have dire consequences, triggering other countries to negotiate downwards on price.

These two factors create a synergy for the UK that benefits companies (and the UK) by enabling them to compromise on only 3% of their global business via a PAS while positively impacting, via reference pricing, on 55% of major global markets because their UK list price is remains unchanged.

This makes a strong case for global pharma decision makers to invest in the UK by launching new medicines and even setting up the initial European presence here. The prime advanced global pharmaceutical markets by share are:

- US 45%
- EU (28) 20% - EU (5) 15%
- Japan 8%

The context is that the UK, when separated out from the EU market at only c. 3% of the global market, is small and becomes an isolated player in a very large pond instead of quite an influential player amongst equals. Therefore, it is understandable that, for many in UK pharma, the critical factors are to retain access to the:

- EU single market
- EU regulatory framework
- People with appropriate knowledge and skills

The Global Use of New Chemical Entities (NCEs)

Understanding the global use NCEs will add weight to the above points. The global adoption and use of New Chemical Entities is the lifeblood of the pharmaceutical industry.

Before considering the 'opportunities in Brexit' for the UK, it is vital to recognise why the pharmaceutical industry needs access to the EU market in these ways.

There are UK industries that, once free from EU control, anticipate they will prosper in BRIC (Brazil, Russia, India, China) and TM (Turkey, Mexico) markets. This may well be so.

However, global pharmaceutical markets vary enormously in size and nature e.g. the Chinese market is almost as large by value as the Japanese market but is not as advanced as the Japanese market in terms of its use of newer medicines.

If we consider the global share of newer medicines across the main EU markets [1]:

[1] Proportion of normalised cumulative 5-year list price sales of New Active Substance (NAS) by country, based on 120 New Active Substances launched in that period. QuintilesIMS Data.

- 5.5% Germany
- 4.5% France
- 2.6% Italy
- 2.5% Spain
- 2.2% UK

By contrast, the total share of the BRIC + TM countries is 2.1% - even less than the UK. BRIC + TM markets are focused on older medicines and generics.

So the question is, by stepping outside the EU 20% share of global pharmaceuticals, will the UK become just a 3% market and therefore less important? This could become a reality if the rest of the EU do not recognise the UK regulatory framework and a separate approval system has to be negotiated - and paid for - by global pharma. It may mean that the UK could become assigned to second tier status, reserved for smaller and less important markets. It could then follow that significant new cancer medicines could be launched in mainland EU some years ahead of the UK.

Would UK based pharma companies need to consider launching in a EU, that excludes the UK, perhaps two years before launching in their home market?

This potential challenge is compounded by the UK limiting access to global pharma people with the necessary skills. Pharma is noted for moving its people internationally to gain experience in the primary markets.

There are a number of 'chickens' that may begin to come home to roost all at once:

- The UK reputation for having the lowest prices in the EU
- The intention of NICE to charge for Technology Appraisals in 2017
- The NICE/NHS E Consultation to allow NHS England to delay (no mention for how long) implementation of NICE Guidance as well as introduce a widely-regarded unrealistic QALY threshold for Highly Specialised Technologies where there currently isn't one
- The Health Service Medical Supplies (Costs) Bill which proposes to introduce a 'tax' on all new medicines and make future 'voluntary' Pharmaceutical Price regulation Schemes (PPRS) very challenging to negotiate
- The challenges for companies working with NHS England and particularly its Clinical Priorities Advisory Group

Mitigating the Risks of Brexit while Exploring the Opportunities of Exiting the EU

The opportunities for the UK in exiting the EU have been discussed and published in the EMIG paper '**UK Biopharma - Adapting to a changing landscape to deliver a better global**

future' which should be read in conjunction with this paper and is available for download on the EMIG website www.emig.org.uk.

Below, is an extract from the paper that focuses on the opportunities for innovation in pharmaceutical and medical device technology and, in particular, the UK's world class regulator, the MHRA.

Areas for consideration – Impact, Risk Mitigation and Opportunities

The Current Regulation of Medicinal Products

For a medicinal product to be placed on the EU market it must have a Marketing Authorisation (MA). An MA may be granted on a 'centralised' basis whereby the European Medicines Agency (EMA) appoints a Rapporteur and Co-Rapporteur to review the application and make recommendations to the European Commission**.** The product may then be sold throughout the EU. This route is compulsory for most biotechnology products and orphan medicines and generally followed with other high technology products.

Alternatives are the decentralised or mutual recognition procedures whereby an application is considered by a 'reference member state' residing in the EU and once assessed or approved by that country, the other EU 'concerned member states' should, in principle, grant consistent national approvals. Issues arise as to whether the UK could continue to be the reference member state for authorised products after it leaves the EU. An MA applicant or holder must be 'established' in the EU.

In addition the sponsor of a clinical trial in the EU, who is not established in the EU, is required to appoint a 'legal representative' with responsibilities for managing the trial locally. Similarly, a sponsor of a medicine with orphan drug designation will need to be established in the EU.

In addition, the import of medicines into the EU requires an import authorisation; manufacture within the EU requires a manufacturing authorisation and these allow the holder to release the product for supply throughout the EU. Similarly, those distributing or brokering the supply of medicinal products are required to obtain authorisations to do so. Imported products also need a release site within the EU.

Finally pharmacovigilance (PV) requirements mean that the Qualified Person for PV must be established in the EU and that the PV database and master file must be accessible from within the EU.

Planning for Regulation Post-Referendum

The EMA and other EU organisational and licensing arrangements are restricted to EU and EEA members so the UK, if outside the EEA, will be excluded.

Indeed, the EMA will be expected to move its headquarters out of the UK and relocate in one of the remaining EU countries. Further, rapporteurs from the UK will not be accepted.

The EMA is likely to regret the loss of the UK competent authority, the Medicines and Healthcare Products Regulatory Agency (MHRA).

This is because it is one of the most respected member state competent authorities and the most-used Rapporteur under the centralised system and Reference Member State under the mutual recognition and decentralised systems.

However, it is clear that the prospect for the EMA itself of moving from the UK is not welcome. The EMA has been quoted as saying it would take at least two years to move the agency away from London to ensure recent improvements in approval times to not stall, or move into reverse. Guido Rasi, Director of the EMA, has stated that this could make Europe less attractive to pharma and biotech countries considering investing in the region.

The EMA could lose expertise as well as focus on its pricing and enforcement commitments to a fragmented Europe. A staff survey presented to the agency's Board showed about 50% would leave if the EMA moves to an undesirable city. The EMA employs almost 900 people – but also faces a large loss of capacity in the event of a move.

These challenges for the EMA could be an opportunity for the UK in any negotiations.

As part of the forthcoming negotiations, it might seem sensible for the UK to agree a Mutual Recognition Agreement (MRA) - such agreements already exist between the EU and Switzerland, Canada and Australia. In the event of a Mutual Recognition Agreement, it is doubtful that a world-leading Agency, such as the MHRA, would be willing to simply "rubber-stamp" others' opinions. We would therefore strongly encourage the MHRA to be enabled to develop national policies in key areas where there are currently regulatory bottlenecks, which, when mature, could be applied more globally.

Examples include;

The Clinical Trials Directive*;* looking objectively at where it could be reformed to reduce or remove areas of overt bureaucratic burden on all organisations that conduct clinical research. Since its introduction, the requirement for "paperwork" has often been cited as a cause of escalating costs and declining attractiveness to both the UK and the wider EU as a place to site clinical research…or…."Europe's gift to America", as an FDA official once put it.

Drug/device combination products; these products are at the borderline between being medicinal products and medical devices, where currently two sets of non-aligned regulation exist. The MHRA should be allowed to explore creating regulations that bring together elements from both to give clear guidance for companies.

The regulation of companion diagnostics; A key issue amongst regulators across Europe is whether companion diagnostics and other medical devices should be regulated in similar ways to medicines, particularly with regard to in-vitro diagnostic (IVD) tests. Traditionally the regulation of medical devices has remained separate from pharmaceuticals. With the trends towards personalised medicines, Health Technology Assessment (HTA) bodies are investigating combinations of individual medicines and IVD tests for detecting those patients most responsive to them.

These assessments, however, do not cover the design, materials and manufacturing process of the equipment – which would potentially affect the accuracy and reliability of the equipment. New proposed European regulations will look to harmonise the assessment, to resolve these issues. (http://www.pharmtech.com/regulation-medical-devices-and-companion-diagnostics)

Advanced Therapy Medicinal Products (ATMPs); are medicinal products which are either a gene therapy or somatic cell therapy medicine or a tissue engineered product. These types of products evolve at a very fast rate. Currently, the EU regulation for these types of products is complex. The EMA's Committee for Advanced Therapies (CAT) is responsible for assessment and following scientific developments in the field. There is potential for simplification of this regulation, using the MHRA as a national lead on these types of products as an exemplar pilot. The MHRA should be able to develop regulation to reduce the 'norm' of use by hospital exemptions whereby unlicensed ATMPs can be made available in the UK for a specific patient.

The UK should build on the presence of the Cell and Gene Therapy Catapult, the independent centre of excellence for the UK cell and gene therapy. With the USA, for example, unable to conduct research using pluripotent stem cells, the UK should continue success in this area in bridging the gap between scientific research and commercialisation, with the role of regulators crucial in this process.

The use of 'Real world' evidence (RWE); the use of data generated in normal clinical practices, used in conjunction with data from randomised clinical trials, will become increasingly important in demonstrating the value of a new medicine. The MHRA should be able to define a national regulatory policy to allow RWE to be used to support registration. See also section 3.1.

Relatedly, consideration could be given to permit biopharmaceutical companies and research charities to access patient-level data in the Clinical Practice Research Database to facilitate clinical trial design and implementation.

The role of regulatory science; maintaining and expanding the role of regulatory affairs expertise is crucial for the development and approval of medicines. The MHRA needs to remain at the forefront of this development to strengthen the support provided to the UK's pharmaceutical industry. In particular the National Institute for Biological Standards and

Control (NIBSC) should be able to further develop its global leadership in the field of biological medicines.

Training the world's emerging regulatory agencies; The MHRA is already frequently asked to provide training and to conduct inspections in countries that are developing their regulatory skills. The MHRA should be enabled to develop this example of leadership much further.

A key opportunity for the MHRA; The evolution of the Early Access to Medicines Scheme

In 2014, the Government established an 'Early Access to Medicines Scheme' (EAMS) which held the promise of new, ground-breaking medicines being made available to patients 'several years before licensing' (https://www.gov.uk/government/news/cutting-edge-drugs-to-be-fast-tracked-to-patients).

However, EAMS is allowed to exploit flexibilities that exist only within current EU regulatory legislation: the current scheme is not, therefore, as flexible as it could be in order to deliver the potential range of new treatments for patients, including drug/medical device combinations, cell therapies and genetic treatments. Extending EAMS to these treatments could see their use in the UK years before other countries in Europe.

The opportunity of such a system becomes even greater when considering the challenges that the licensing of technologies, that are just appearing on the horizon, pose to existing EU medicines legislation.

These include drug/medical device combinations, cell therapies and genetic treatments. A great deal of the scientific excellence to develop these treatments, which hold the potential to cure genetic diseases such as cystic fibrosis, is already here in the UK. There are therefore, obvious opportunities available to a UK regulator, able to operate in a simpler and more streamlined way.

Indeed, it is not an overstatement to say that the UK could have *cured* a large number of genetic disorders whilst the EU is still *treating* them.

There have been criticisms of EAMS from industry, including the fact that it is unfunded. So how could it be improved? While its initial "promising innovative medicine" (PIM) designation stage is both useful (e.g. to encourage investor confidence for SMEs) and relatively easy to navigate, the later "scientific opinion" stage of the current EAMS is direct cost and resource-intensive for companies.

Also, the medicine is provided free by the pharmaceutical company until an opinion is provided by NICE which, if positive, should be the signal for NHS England to commission the medicine formally.

Reducing the timelines between regulatory approval, cost-effectiveness assessment by NICE and NHS commissioning is a primary objective of EAMS, but it is still too young a scheme to know if this will be the reality. A future scheme could be made to guarantee rapid adoption by the NHS, following a positive cost-effectiveness assessment, and be made more "enabling" in terms of its regulatory flexibilities earlier on, That is when a case could more justifiably be made for the company to provide the medicine without charge during the scheme. In this way, it would be a great example of how the public and private sectors could collaborate effectively to share risk and reward for patient benefit.

Additionally, the constraints of the current scheme arise because it simply exploits flexibilities for a national approval that exist within current EU regulatory legislation i.e. it is not "new" legislation. We need to be considering, therefore, the potential ability of the MHRA to design bespoke regulation for the UK. While it would be the MHRA's discretion to determine the detail of what this would look like, given its globally recognised status, it should be expected that where the MHRA leads, others in the world might follow.

So, what could this mean for patients? The scheme could incorporate new national regulation to cover, for example, the aforementioned areas of drug/device combinations, cell-based therapies and genetic treatments - the science-base for this already exists in the UK.

It could also incorporate the smarter use of real-world evidence to inform the regulatory approval of new treatments. Under existing legislation, the ability for UK regulators to make smart use of 'real-world evidence' – i.e. data that comes from sources other than randomised control trials – is heavily constrained. The EMA is already exploring the use of real-world evidence in its 'adaptive pathways approach pilot' (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000601.jsp), but this work has been criticised by other bodies in Europe – including the German health technology assessment body, IQWiG, which argued in August 2016 that it is "high time to pause for a moment and rethink the whole concept" (http://www.pmlive.com/pharma_news/germanys_iqwig_perplexed_by_emas_adaptive_pathways_plan_1096728).

Ultimately for patients, it would mean their physicians would have the potential for "earlier approvals to use" a larger range of innovative treatments than exist today. It is "potential" because patients' ultimate access to them would also depend on them being assessed as cost-effective and then bought by the NHS! So, as with so many other opportunities we have, it would only become real if we work consistently as a single, joined-up, delivery system.

How Could Meaningful 'Special Arrangements' Look for Pharmaceuticals?

The likelihood of an extended negotiation period means there may be little material change for at least two years and, perhaps, substantially longer.

However, it would be appropriate to identify all applied for or granted marketing authorisations, clinical trial approvals or legal representative status, orphan designations and supply chain licences held by UK affiliates. Additionally, any key regulatory functions performed by them, including qualified or responsible persons and siting of databases.

A hard Brexit would mean MA approvals under the centralised route would need to be nationally implemented, as they would not apply automatically in the UK.

In addition, the MHRA would have to transfer marketing authorisation applications, for which they are either rapporteur or the reference member state, to other member state regulatory authorities.

Were the UK to choose the Swiss route or WTO, much of UK life sciences law is derived from EU law either through Directives implemented nationally in the UK or through EU Regulations that have direct effect. Accordingly, transitional measures could well be brought in to ensure that both the UK implementing laws and the EU Regulations would remain in force until amended or revoked.

A solution for some aspects of regulation might be a series of mutual recognition agreements in relation to both medicinal products and medical devices. Since UK governance in both sectors is widely respected throughout Europe, there is little reason (other than possibly political mischief making) why this could not be achievable.

It would be particularly important for the continuity of the supply chain to ensure importers and manufacturers could release product for EU supply – and vice versa. By way of precedent, Switzerland has an agreement with the EU mutually recognising GMP licences to facilitate this.

Similarly, UK notified bodies can point to existing mechanisms in place for non-EU countries including mutual recognition agreements involving the US, Canada, Australia, Switzerland and Japan.

Negotiations are likely be drawn-out, challenging and uncertain, so it will be important for business not to take precipitous action since, at worst, any regulatory approvals, licences or functions could be transferred to an affiliate within the EU prior to the effective date of the UK actually leaving the EU.

Indeed, from conversations held recently with the MHRA leadership and statements from the MHRA website (https://www.gov.uk/government/news/medicines-and-healthcare-products-regulatory-agency-statement-on-the-outcome-of-the-eu-referendum), we are highly encouraged that it is "business as usual" for the MHRA in terms of its routine regulatory work.

This will be at least for the short and mid-term future, whilst the Agency works with the UK Government, industry and other EU and international regulators to consider and take forward the results of the UK referendum. This is also recognised and endorsed by its EU partners and EMA leadership.

Analysis

Technologies currently in research, particularly cell and gene editing therapies, will test existing regulatory approaches to the limit.

For example, gene editing therapies will often be specific to humans – limiting the use of animal safety studies – and will target some of the rarest diseases where there are too few patients to conduct traditional clinical trials. The most advanced technologies in development will be designed – 'lego-like' – to treat individual patients, and clinical trials will be impossible to run in each case.

The most forward-looking regulators around the world, including the Food and Drug Administration in the United States, are already considering what impact these new technologies will have on their own regulatory approaches (https://www.healthra.org/download-resource/?resource-url=/wp-content/uploads/2016/06/Gene-Editing-Worshop-Summary.pdf).

Similarly, Japan's MHLW has introduced its own SAKIGAKE Designation System, designed to promote R&D in Japan by achieving early practical application for innovative pharmaceutical products, medical devices, and regenerative medicines (http://www.mhlw.go.jp/english/policy/health-medical/pharmaceuticals/140729-01.html).

Outside the pan-European medicines licensing system, UK regulators would be free to do likewise, possibly to include working more collaboratively with these leading regulators – increasing the attractiveness of the UK both as a location for research investment and as a place to launch new technologies first.

Balancing Interests

It has been said that, in the context of leaving the EU, the UK cannot have its cake and eat it. It is certainly understandable that, in the complex politics of exit negotiations and the need

for the EU to avoid further fractionation, there may be a natural urge to make an example of the UK.

Unfortunately, this could lead to the EU 'cutting off its nose to spite its face' when there is a need to take a broader perspective of the future stability of the EU than just the UK decision to exit, momentous as it is.

One the one hand, it is estimated that 48% of UK exports are to other EU Member States. On the other, the UK is the EU's single largest export market in goods at 16% of all goods exported from the EU (i.e. treating the UK as being outside the EU).

The United States is a close second at 15% of exports to non-EU countries. Over the last ten years, on average only three Member States – Ireland, Luxembourg and Malta – did not have a trade surplus with the UK. These are hard commercial statistics that should not be dismissed and no one on either side will be thanked for winning the battle of politics and losing the war of economics, resulting in damage to economies.

There is a suggestion of a middle way that might form the basis of a discussion between the EU and the UK negotiators – at least for targeted industries such as the pharmaceutical industry.

Bruegel is a Brussels based economic think tank with a very distinguished international Board and Scientific Council http://bruegel.org/about/board-and-scientific-council/.

In the summer of 2016, Bruegel published 'Europe after Brexit – A proposal for Continental Partnership' http://bruegel.org/2016/08/europe-after-brexit-a-proposal-for-a-continental-partnership/.

The paper explains that the alternative models of partnership with the EU, EEA and EFTA, would be unsuitable and that a Free Trade Agreement would be no basis for the deep economic integration for participation in a single market.

The Bruegel paper proposes a EU-UK relationship considerably less deep than EU membership, but closer than a simple free-trade agreement. It would involve a Europe of two concentric circles with the supranational EU and the euro area at its core together with an outer circle of countries in a structured partnership. The outer circle could encompass countries such as the UK where trade would take precedence over constitutional union.

There would be no legal right to free movement for workers, so the UK requirement for controlled labour mobility would be satisfied.

The Paper outlines two ways of characterising the EU single market, a deeply integrated market, as functional and constitutional.

The functional characteristic would be of greatest potential interest to the UK and its central functional elements would involve:

- The absence of tariffs
- A single set of rules or minimum standards
- Enforcement of those rules and standards under shared, supranational jurisdiction
- A single competition policy and state-aid control
- The contribution to shared public goods, including through EU budget

The Continental Partnership would need to include:

- Participation in selected common policies, consistent with access to the Single Market
- Participation in a new system of inter-governmental decision making and enforcement
- Contribution to the EU budget
- Close cooperation on foreign policy, security and, possibly, defence matters

These are the requirements where compromise would be needed on both sides.

Conclusion

A future UK industrial strategy that includes life sciences needs to consider how bi-lateral benefit for the UK and EU can be secured by retaining the 'working parts' of the current single market arrangements and, in so doing, minimise damage to economies.

The UK may have chosen a new political relationship with the EU and it is in the interests of both parties that the new relationship functions to maximise mutual benefit.

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