Response to the Call for Evidence on the Government's Review of the Balance of Competences between the United Kingdom and the European Union - Trade and Investment

August 2013

Association of the British Pharmaceutical Industry
7th floor, Southside, 105 Victoria Street, London SW1E 6QT
t +44 (0)870 890 4333 abpi@abpi.org.uk

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ABPI Response to the Call for Evidence – Review of the Balance of Competences (Trade and Investment)

About the Association of the British Pharmaceutical Industry (ABPI)

The ABPI represents large, medium and small research-based biopharmaceutical companies, leading an exciting new era of biosciences in the UK. Our members are a major contributor to the economy of the UK, and supply 90% of all medicines used by the NHS. Member companies are researching and developing over two-thirds of medicines currently in development, ensuring that the UK remains at the forefront of helping patients prevent and overcome diseases.

ABPI Response to the Call for Evidence

ABPI welcomes the opportunity to respond to your call for evidence on the EU Balance of Competence Review – Trade and Investment. This response should be read in conjunction to previous associated responses from the ABPI to both the Health and R&D Call for Evidence.

The ABPI firmly agrees that trade and investment are central to both the UK and EU agenda to create sustainable economic growth and jobs. In particular we have, and continue, to welcome the UK Governments' promotion of free and fair trade and open markets, enabling businesses to be well connected to the main sources and regions of global growth. We hope the general remarks below are a useful contribution to your call for evidence on behalf of the UK based biopharmaceutical industry.

The research-based biopharmaceutical industry can play a critical role in restoring both the UK and Europe to economic growth, ensuring future competitiveness in an advancing global economy. In 2012, it invested an estimated € 30,000 million in R&D in Europe. It directly employs 700,000 people and generates three to four times more employment indirectly – upstream and downstream – than it does directly. However, the sector faces real challenges.

Besides additional regulatory hurdles and escalating R&D costs, the sector has been severely hit by the impact of fiscal austerity measures introduced by governments across much of Europe since 2010.

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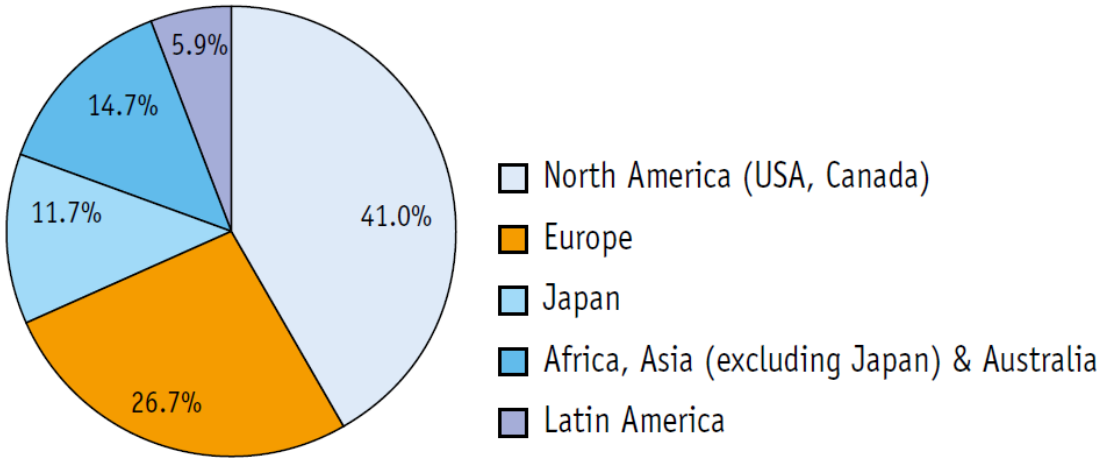
In particular, the rapid growth in the market and R&D environment in emerging economies such as Brazil, China and India, is leading to a gradual migration of economic and research activities from Europe to these fast-growing markets. For example, in 2012 the Brazilian and Chinese markets grew by 16% and 21% respectively compared to an average market growth of minus 2% for the five major European markets (source: IMS Retail Drug Monitor – February 2013).

The world pharmaceutical market was worth an estimated € 667,653 million ($ 857,800 million) at ex-factory prices in 2012. The North American market (USA & Canada) remained the world's largest market with a 41.0% share, well ahead of Europe and Japan.

BREAKDOWN OF THE WORLD PHARMACEUTICAL MARKET – 2012 SALES



Note: Europe includes Turkey and Russia
Source: IMS MIDAS, 2013 (data relate to the 2012 audited global retail pharmaceutical market at ex-factory prices)

In addition to the dominance of North America with regard to the world pharmaceutical markets, it is particularly noteworthy to appreciate that 62% of sales of new medicines (the life-blood of the innovative bio-pharmaceutical sector) launched during the period 2007-2011 were in the US market, compared to only 18% in the European market.

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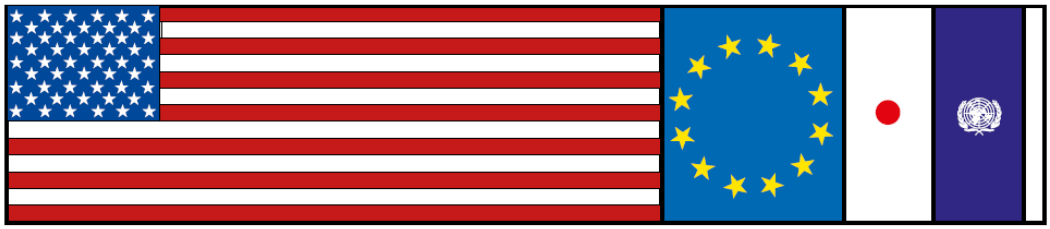
GEOGRAPHICAL BREAKDOWN (BY MAIN MARKETS) OF SALES OF NEW MEDICINES LAUNCHED DURING THE PERIOD 2007-2011



Note: New medicines cover all new active ingredients marketed for the first time on the world market during the period 2007-2011
Pharmerging comprises 17 countries ranked by IMS Health as high-growth pharmaceutical markets (Argentina, Brazil, China, Egypt, India, Indonesia, Mexico, Pakistan, Poland, Romania, Russia, South Africa, Thailand, Turkey, Venezuela, Vietnam and The Ukraine)

Specifically in the UK, pharmaceutical R&D and manufacturing create and sustain many highly skilled jobs – as well as supporting local communities and economies. This contribution is made not only by global pharmaceutical companies, but also by numerous SMEs based across the UK.

The pharmaceutical industry employs around 68,000 people directly in the UK – 23,000 of which are in highly-skilled research and development roles[1]. The pharmaceutical sector has, over the past decade, consistently generated a large trade surplus for the UK – £5bn per annum, according to the latest figures. This is greater than any other industrial sector in the UK[2]. In fact, in 2011, the pharmaceutical sector's contribution to the balance of trade was the greatest of 9 major industrial sectors, up from 5th in 1975 and 3rd in 1990[3].

[1] OHE calculations based on ONS, *Business Enterprise Research and Development (2008, 2009, 2010, 2011)*, accessed March 2013
[2] HM Revenue and Customs, *UK Trade Info 2012*, February 2013
[3] OHE figures based on HM Customs and Excise data

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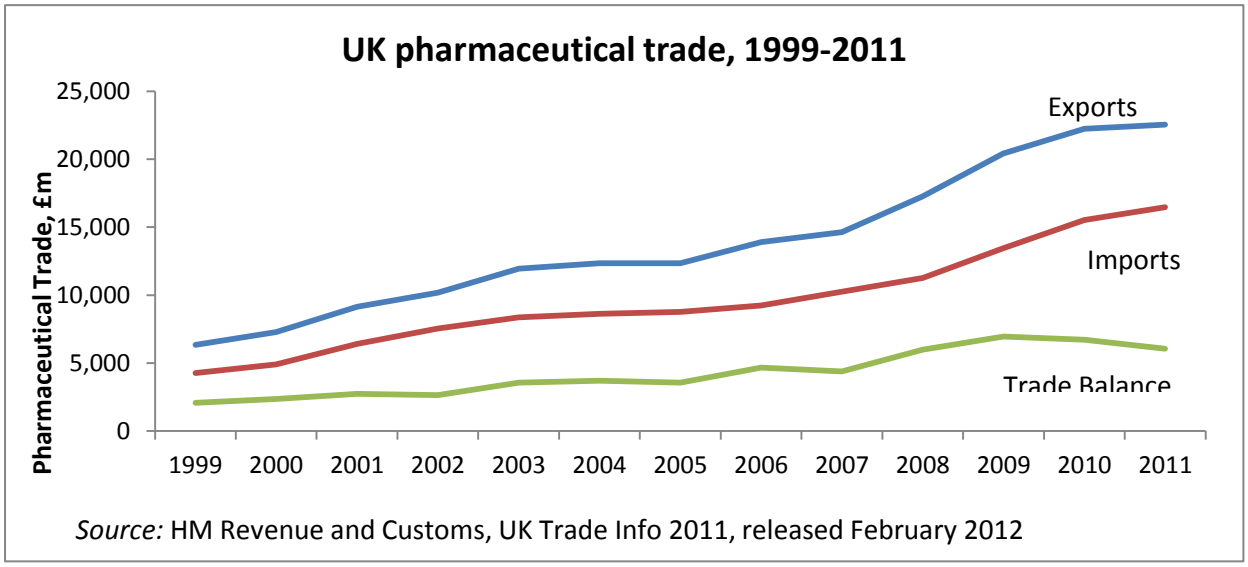

Source: HM Revenue and Customs, UK Trade Info 2011, released February 2012

The pharmaceutical sector's relative importance becomes even more obvious when looking at the productivity – or Gross Value Added (GVA) - generated by each employee. According to the latest figures, this shows that GVA per employee in the industry was £210,000[4] – significantly higher than high and medium-high tech sectors such as chemicals, motor vehicles and computer products.

[4] ONS, *Annual Business Survey 2011 Provisional*, November 2012 (Section C, Manufacturing)

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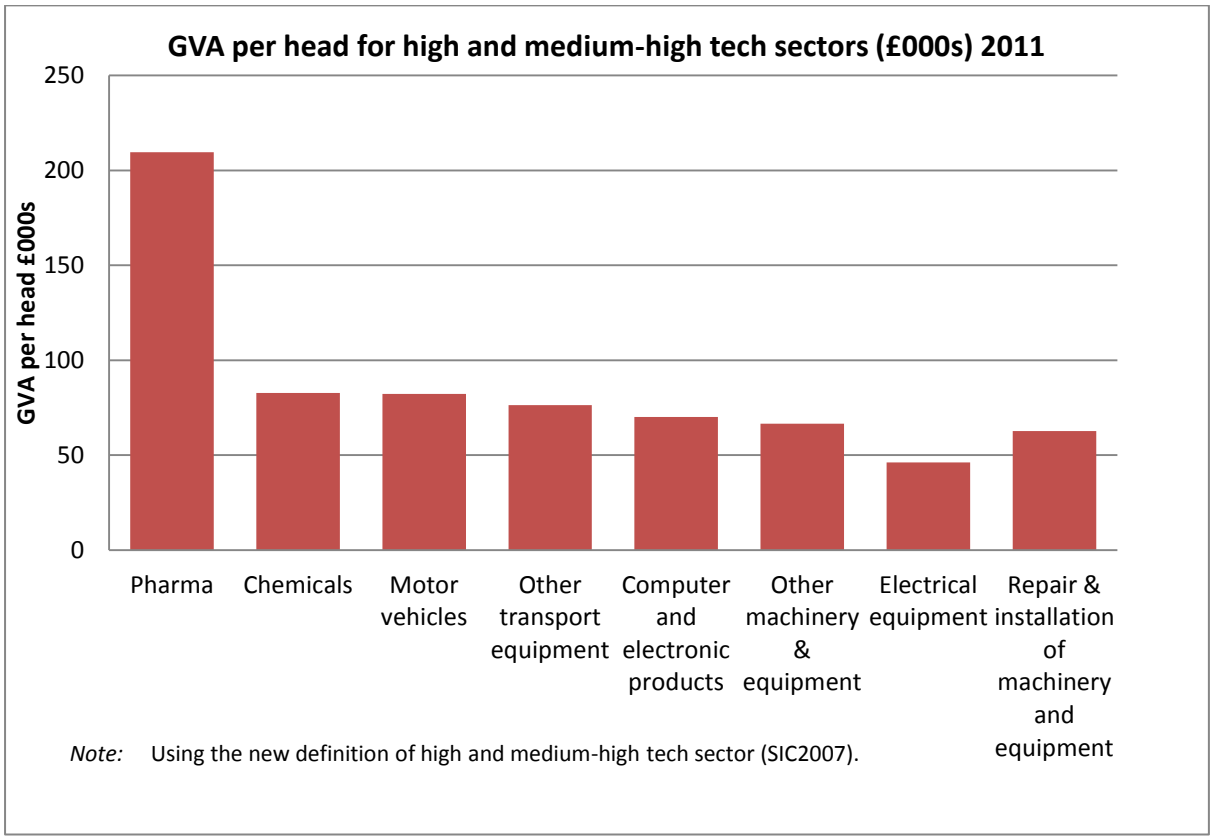

Given the current economic situation, these figures highlight the vitally important contribution of the pharmaceutical industry to the UK's economic recovery.

In addition, the industry generates thousands of jobs in related sectors across the life sciences, including biotechnology, medical technology and diagnostics.

The UK's pharmaceutical sector invests approximately £13.3 million every day in R&D[5]. In fact, the pharmaceutical industry invests more in R&D in the UK than any other industrial sector[6].

These investments not only benefit the pharmaceutical companies that make them, but investments by one pharmaceutical company often stimulate innovation elsewhere in the sector, or the economy more widely.

Knowledge generated by R&D also flows from one organisation to other companies in the same sector. At the simplest level, scientists employed by the pharmaceutical sector share knowledge at congresses and in publications. In many cases, the flow of cutting-edge knowledge benefits other business sectors as well as public, academic and charitable

[5] ONS, *Business Enterprise Research and Development 2010*, November 2011
[6] ONS, *Business Enterprise Research and Development 2010*, November 2011

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organisations. The industry is part of a much wider ecosystem which extends across the NHS, universities, charities, research bodies and numerous collaborative projects and networks across the UK.

This spill-over effect to the rest of the economy generated by pharmaceutical R&D is estimated to be more than double the return that is captured by the company actually making the pharmaceutical R&D investment[7].

However, the success of the pharmaceutical innovation model relies on a holistic approach across the life-cycle of medicines development, from high-risk up-front investment, through actual usage of product, to delivery of efficiencies upon loss of exclusivity.

There are three distinct stages to this cycle:

1. Innovation – this is capital intense and high-risk. Only 1 in 10,000 molecules screened ever reaches the market

2. Value creation – during this stage, manufacturers benefit from intellectual property protection and can recover a fair return on their investment

3. Efficiency – this model has in-built efficiencies. After loss of exclusivity, genericisation follows with consequent price reductions

At present, the UK innovation life-cycle is being 'squeezed' on all sides. The UK medicines market is already very efficient, with branded medicines prices among the lowest in Europe[8].

Companies are finding the UK commercial environment increasingly challenging and this is demonstrated in a number of ways:

- Between 2000 and 2010, the UK's global share of patients in clinical trials fell by 14%[9]

- The UK's position as the country of origin of the leading 100 global medicines by sales declined between 2004 and 2011[10]

[7] Garau M and Sussex J *Estimating Pharmaceutical Companies' Value to the National Economy Case Study of the British Pharma Group*, OHE 2007
[8] Department of Health, *PPRS Report to Parliament*, 6th, 10th and 11th reports, 2002, 2009 and 2012
[9] Centre for Medicines Research (www.cmr.org); Global Clinical Performance Metrics Database; Kinapse report
[10] Department of Health, MISG, *Pharmaceutical Industry: Competitiveness and Performance Indicators* 2009

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- The UK is an early launch market in global pharmaceutical launch sequences but companies are starting to consider delaying launches in the UK because of the challenges they face

- Uptake of innovative medicines is poor

- Prescribing savings pressures in the NHS are significant and have increased

We also need to recognise that the business environment in the UK is very challenging – and the external perception of the UK as a place to invest is not always a positive one. Critically the UK continues to lag behind in the adoption of new medicines compared to many other European countries and the UK's global share of clinical trials has fallen in recent years. The pharmaceutical industry in the UK is now at a crucial moment and we must reverse these trends if we are serious about maintaining the UK's position.

The importance of maximising both EU and UK support to the pharmaceutical industry cannot be underestimated if our historic contribution to both health and wealth is to be continued. Several initiatives are worthy of note and reflection.

EU Innovative Medicines Initiative (IMI)

ABPI was pleased to welcome the recent launch by the European Commission of the Innovative Medicines Initiative 2 (IMI2) research funding stream.

IMI is a public-private partnership between the European Commission and EFPIA, the European Federation of Pharmaceutical Industries and Associations. Under the new EU framework programme Horizon 2020, IMI2 will carry on the collaborative spirit of IMI by bringing together the pharmaceutical industry, European government, and health research partners and patients to advance scientific research and development for a healthy European society.

Using a similar model to IMI, IMI2 is to be jointly funded by EFPIA and health research industry partners and the European Commission's innovation investment package, and provide a strategy to support public-private partnerships in EU-funded research. IMI2 aims to advance trends in personalised medicines; to further R&D in areas of unmet medical need; and to address the regulatory context in hopes of speeding translation from research to innovation. EFPIA particularly welcomed the Commission proposal's intent to cut the red-tape that can impede progress of EU research, an essential step in improving patient access to innovation in Europe.

IMI has already delivered tangible results and has proved to be competitive to other global funding schemes. It has demonstrated that in biomedical research, Public Private Partnerships work and can deliver tools to address bottlenecks in medicines development and reduce attrition rate. It also addresses key healthcare challenges and unmet needs in

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areas like antimicrobial resistance, neurodegenerative diseases, chronic pain, complications of diabetes and mental health.

The Innovative Medicines Initiative has delivered new solutions to increase safety and efficacy of medicines. IMI has already identified new treatment opportunities and developed new and more predictive tools to predict toxic effects of potential candidate medicines, as well as non-invasive methods of detecting disease progression or effects of medicines. Through proactive engagement with regulators, payers, patients, health professionals, IMI also makes sure that the new methods and standards are considered in the regulatory and clinical practice, as well as in companies' R&D processes.

Free Trade Agreements

The EU's size and open market approach to trade has allowed it to be a lead advocate for trade and investment liberalisation using both multilateral and bi-lateral relations and negotiations. The ABPI remains supportive of multilateral and bi-lateral negotiations, in particular with fast growing emerging economies where there are increasing opportunities for;

- Opening new markets for goods and services
- Increasing investment opportunities
- Making trade cheaper - by eliminating substantially all customs duties
- Making trade faster - by facilitating goods' transit through customs and setting common rules on technical and sanitary standards
- Making the policy environment more predictable - by taking joint commitments on areas that affect trade, such as intellectual property rights, competition rules and the framework for public purchasing decisions

The prospect of multiple Free Trade Agreements (FTA's) between the EU, US and key trade partners, such as Canada and Japan, is very positive. Specifically, such agreements will not only improve the business environment for both the UK and EU, but also strengthen bi-lateral cooperation when engaging with third countries and establish the development of global rules.

The recently commenced negotiations on the EU/US Transatlantic Trade and Investment Partnership (TTIP), in particular, provide an excellent opportunity to remove duplicative requirements and enhance regulatory convergence and harmonisation.

ABPI supports an ambitious and comprehensive agreement that addresses regulatory compatibility initiatives, intellectual property protections, market access and investment

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provisions, customs and trade facilitation and public procurement measures. In particular, we support:

Greater regulatory convergence:
We strongly support continued efforts to address regulatory differences and duplicative requirements that can impede efficiency in global drug development. The alignment of regulatory processes can reduce redundant testing and optimise use of limited regulatory agency resources. This will speed up patient access to new, innovative medicines. Further harmonisation of EMA and FDA practices would pave the way for economies of scale for the industry and particularly help the entrance of smaller companies into the market. The active engagement of regulators in moving these negotiations forward is essential.

TTIP should build on longstanding cooperation at bi-lateral and multi-lateral level and on current efforts by both EMA and FDA in harmonising their procedures. TTIP can serve to harness these efforts and introduce new approaches to institutionalise the outcome. Our priorities include: mutual recognition of Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP) inspections in the EEA, US and third countries; extend parallel scientific advice towards a joint advice applicable to all medicines; greater regulatory compatibility for submitting single pediatric plans; efficient parallel assessment of Quality by Design applications; amongst others.

We acknowledge that not all regulatory divergences can be eliminated at once: TTIP should provide for a built-in agenda allowing for progressively greater regulatory convergence against defined targets and deadlines. To this end, we strongly support the creation of a Working Group on Biopharmaceuticals, which can provide a venue to discuss implementation issues and address joint approaches to future compatibility topics.

Improved alignment on protection of Intellectual Property Rights (IPRs) and their enforcement:
Seeking increased harmonisation in the protection of IPRs and the mechanisms for their enforcement would secure our innovative industry with a conducive environment to develop and bring new medical treatments to patients. While both regions provide for strong IP protections, TTIP can foster greater alignment on patentability standards, regulatory data protection, patent enforcement, use of trademarks and data disclosure; amongst others.

Furthermore, TTIP provides the opportunity to reaffirm a number of high-level intellectual property principles and to set out a globally consistent set of IP protections as a means of encouraging growth and trade.

Enhanced transparency concerning market access for pharmaceuticals:
The TTIP should ensure that government pricing and reimbursement policies do not create obstacles to EU-US pharmaceutical trade. To this end, a devoted Annex on pharmaceuticals,

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drawing on the specific annex included in the EU-Korea FTA and in line with the EU Transparency Directive, should address key issues relating to government pharmaceutical pricing and reimbursement policy and procedures. Particular emphasis should be put on delivering greater transparency and adequate reward for innovation.

Investment environment conducive to greater innovation:
EU and US investments are the real driver of the transatlantic relationship, contributing to growth and jobs on both sides of the Atlantic. It is estimated that a third of the trade across the Atlantic actually consists of intra-company transfers. This agreement should help foster an innovation-friendly investment framework set also to promote larger public and private research and development initiatives, which would benefit our innovative industry.

Enhanced coordination in global trade agenda:
As noted above, this agreement should also lay the basis for a coordinated approach when engaging with third countries. By developing a common understanding and joint approaches on priority areas – namely, regulatory harmonisation, transparency measures, intellectual property protection standards, or tariff elimination – both Parties could address their trade objectives in a more effective and efficient manner. For our industry, this would ensure that the highest quality medicines could be duly accessible to patients and citizens globally.

UK Life Sciences Strategy
The life sciences industry is rightly recognised by the Prime Minister and current coalition Government as a strategic priority and the UK's Life Science Strategy is a welcome package of commitments that enables a holistic industrial policy that is joined up across UK Government departments (BIS, DH and HMT).

Due to its global nature and the fact that R&D investment decisions are largely made by decision-makers outside of the UK, it is critical that the UK continues to be recognised as an innovation driver and that large flagship initiatives (e.g. Stratified Medicines, Immuno-Inflammation), and tax credit benefits (e.g. Patent Box) are visible on the global radar of companies. Equally critical is the visibility and cross-cutting culture of collaboration supporting research (e.g. NIHR Clinical Networks and Health Research Authority) and the clear encouragement for the adoption of technological innovations (e.g. NHS Innovation Scorecard).

In its submission on Life Sciences for Growth – Spending Round 2013, the ABPI highlighted the following key points;

- **The science budget should be sustained and protected against inflation.** This means an increase in the 2015/16 spending round, as the science settlement in the current CSR was not inflation-indexed and therefore it must recover from the real term decrease by the end of the CSR period. Additionally, at 2% GDP, the UK lags behind the OECD and EU targets, of investment in R&D at 3% GDP, while other countries

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such as the USA, France, Germany and emerging economies have increased investment in R&D to underpin economic growth.

- **The science budget must continue to be ring-fenced** - both in the BIS (Research Councils, TSB, Funding councils) and DH (NIHR) budgets.

- These actions are necessary to maintain UK's **global competitiveness in science and for inward investment**. And to enable implementation of government's Life Science Strategy for economic growth.

- Investment decisions by companies are taken over the **long-term**. Therefore a **stable** environment underpinned by a sustained science budget is crucial.

- Each £1 of public funding of biomedical research **generates a return** equivalent to 39% per year in perpetuity.

- Public sector investment and the modern way in which this is approached, **leverages industrial participation** e.g. industry-academic partnerships such as the MRC-ABPI Immuno-inflammatory initiative (RA, COPD), likewise in Diabetes, Neurodegenerative disease, and Stratified Medicine across disease areas have drawn in substantial participation across disease areas from many biopharmaceutical companies, including disease area units based outside the UK. The Immuno-inflammatory partnerships were stimulatory factors in AZ and GSK working with University of Manchester to set up a collaborative centre for inflammation research, with £5M from each partner over 3 years.

- Widen scope of **Biomedical Catalyst Fund** to include a broader spectrum of companies which include pharmaceutical companies.

Conclusion

The industry stands ready to be a continued driver for economic recovery, but our message is simple: the industry needs to be supported and nurtured at both EU and UK level. To generate growth and nourish innovation, different elements need to be right in terms of the fiscal, R&D and the commercial environment affecting pricing, access and use of medicines by patients. This means that both the EU and UK needs to ensure that innovative medicines are reimbursed at a fair price and used rapidly and consistently. A failure to act will make global pharmaceutical companies think twice before investing here and launching the most modern medicines - and this could potentially impact on patients and the wider economy.