
Maintaining and growing the UK's world leading Life Sciences sector in the context of leaving the EU

"It is hard to think of an industry of greater strategic importance to Britain than its pharmaceutical industry"

Rt. Hon. Theresa May MP, 11th July 2016

UK EU Life Sciences Transition Programme Report, for the UK EU Life Sciences Steering Committee, 6th September 2016

Final Version

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i. Foreword

Less than a week after the referendum vote on June 23 2016, the UK life science sector committed to the then Life Science Minister George Freeman that it would come together and rapidly produce its initial thoughts on how to maintain and grow the UK's world leading Life Sciences sector in the content of leaving the EU for the new government as it formed in the autumn.

As the process got rolling, politics moved faster still. A new Conservative government formed within a month, new departments were set up and new faces appointed to Ministerial positions.

Knowing we are a diverse sector within a vibrant ecosystem, we've worked hard across the summer to engage members, experts and stakeholders in a rapid and professional process. This includes companies large and small, charities, device and diagnostics as well as research councils.

In July and August we've held over 50 hours of working group meetings focusing on: regulation, people, manufacturing and supply, R&D, Intellectual property and fiscal and trade. Over 150 experts in 90 organisations engaged, supported by PwC, who provided their own expertise and an out of sector perspective on key areas like people and tax. We want to thank in particular the MHRA who attended every workshop. Overall, expertise and engagement from everyone involved has been outstanding.

The process in itself has also played a role in providing a focus for the sector at an uncertain moment and, as such, we hope has helped to enable companies develop their thinking faster than it would have done without it.

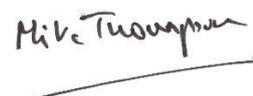
The outputs – the following Executive Summary two page report and the detailed report - capture the positive approach and can do attitude of all participants and reflect the desire to make a success of the opportunities ahead of us. It's a record of a snapshot in time of our developing thinking rather than as a completed manifesto for the years ahead.

Whilst the report outlines some preferred positions, we have also shared alternatives and remain flexible. Although we have developed a strong understanding, the key defining lines of what Brexit will look like in more detail, lies in the weeks and months to come.

We were delighted to be able to present our thinking to Ministers and the UK EU Life Sciences Steering Group on the 6 September and that they found the report excellent and the discussion and engagement valuable. This is of course just the start of the journey. It's a first contribution to an on-going engagement with government as well as a framework for continued dialogue as the UK negotiates its new relationships.



Steve Bates, CEO BIA



Mike Thompson, CEO ABPI

ii. Executive Summary

This Executive Summary and accompanying report is the collective response of the UK Life Sciences sector to the Government's request to understand **how to maintain and grow the UK's world leading Life Sciences sector in the context of leaving the EU**. Although an industry report, it has been produced through wide consultation* and is intended to form a starting-point for ongoing engagement with the new Government. As a wide ranging sector, our constituents see the opportunities as the UK exits the EU, and potential challenges, through different lenses, but **we are already seeing the opportunity to work concertedly and across sectors in partnership with government to drive an effective and impactful Industrial Strategy** for the UK, in which Life Sciences is a key pillar.

The contribution of the UK Life Sciences sector

The Life Sciences sector makes a significant contribution to the UK's strength in innovation, which is a critical success factor for modern economies. The sector **invests more than any other in the UK on R&D** (£4bn, 2014)¹, creating high skill jobs, stimulating partnerships/ collaborations with academia and other sectors, and driving value for the UK.

The UK Life Sciences sector has a turnover of **more than £60bn a year**², and generates **exports and a trade surplus worth £30bn** and **£3bn**, respectively³. It **sustains high quality jobs across the UK** – two-thirds of the sector's **220,000 jobs** are outside London and the South East. Pharmaceutical manufacturing **employees have the highest Gross Value Added** (GVA) of any high-technology sector – over £330,000 per employee⁴, delivered in part by **commercialising new technologies** such as genomics, personalised healthcare and Advanced Therapy Medicinal Products (ATMPs). **25% of the world's top 100 prescription medicines were discovered and developed in the UK**⁵, and the largest pipeline of biotech products in Europe are under development in the UK.⁶

Pharmaceutical R&D and products for diseases such as dementia and oncology support the Government's drive to improve UK healthcare outcomes. They also underpin its commitment to address global health challenges such as antimicrobial resistance (AMR), HIV/AIDS, and malaria. Medical technologies, including emerging digital technologies and devices, are creating substantial opportunities to improve NHS efficiency and deliver improved UK healthcare⁷.

Life Sciences are driving a medical revolution, as the scientific discoveries of recent years are translated into patient treatments and products. The next wave of medical technologies[†] creates the opportunity to bring **further investment, new highly skilled jobs, and improved healthcare** to the UK. The UK is already a global leader in Life Sciences which is why it should be at the heart of the government's Industrial Strategy.

Managing Risk and Creating Opportunity – Priorities for the Sector

The sector's contribution is no accident – the UK is one of the most attractive destinations for Life Sciences investment and activity globally⁸. This is the result of the UK's ecosystem of leading universities, NHS collaborations, entrepreneurial biotech start-ups and international pharma companies, allied to a supportive policy framework and deep financial markets. EU membership and adoption of its legislation have reinforced the UK's global attractiveness. At the same time EU Court judgements like the Brüstle case have hampered cell therapy development and leadership by the UK was needed to defeat damaging European Parliament amendments on clinical research data protection.

In a period when many countries are seeking industry investment and, given that investment is mobile, it is important that the UK's strengths are reinforced, that the full implications of EU exit are addressed and that as far as possible a predictable operating environment is maintained. The Life Sciences sector is confident this can be achieved.

Negotiating EU Issues

The UK Life Sciences industry has identified four key areas for the UK to address as it negotiates exit from the EU. Addressing these will bring significant benefit and opportunity. We set out below our proposals for the priority responses to secure the best outcome for the UK, having considered a range of options.

1. Long-term, predictable funding for scientific research, and continued ability to collaborate at scale

Challenge: the UK government has long-recognised the importance of significant, predictable research funding, but the UK has also been a major net beneficiary of EU funding for research. The UK benefits disproportionately from the collaboration opportunities offered by EU programmes (e.g. Horizon 2020). In addition, the UK Venture Capital (VC) ecosystem is reliant on EU funds (e.g. European Investment Bank (EIB) and European Investment Fund (EIF)).

Opportunity: the sector welcomes the recent Government announcement to guarantee funding for projects under the Horizon 2020 initiative, while the UK remains a member of the EU, but a long-term solution still needs to be found. Access to EU R&D **funding could be retained**, for example, through the UK gaining "associate member" status for Horizon 2020 and its successor (as achieved by Switzerland and Israel). This would also allow UK-based academics to lead and participate in EU-wide collaborations. The most effective way equity for VC can be maintained is through

* Workshops were held with 150 experts from industry, trade associations, Non-Governmental Organisations (NGOs) and public sector organisations covering pharmaceuticals, biotech, medical technology, consumer health, animal health, support services

† The term "medical technologies" is used throughout this report to refer to: pharmaceuticals, medical devices and in-vitro diagnostics (IVDs)

securing continued participation in the EIB and EIF, including shareholding, financial contributions and a seat at the Board. Beyond EU funding, the UK government could also provide the long term investment and support as part of a home-grown Industrial Strategy for Life Sciences.

2. Ability to trade and move goods and capital across borders

Challenge: on leaving the EU, trade between the UK and EU could be subject to customs duties, import VAT, and the added bureaucracy and complexity of import/export declarations and inspections. This would cause significant disruption and cost. The result could hinder UK access to medical technologies, increase NHS costs, impact exports, and produce a less attractive environment for companies looking to maintain current or make future investments, and manufacture products, in the UK.

Opportunity: the UK should maintain **free trade with the EU** on terms equivalent to those of a full member of the EU customs union and EU common system of VAT. These terms would minimise cost and disruption by preventing customs duties, non-tariff barriers to trade or import VAT being imposed. The UK would also retain access to EU negotiated Free Trade Agreements (FTAs) with third countries. The ability to move capital should also be maintained.

3. A common regulatory framework with Europe

Challenge: the UK benefits from a common regulatory framework and market with the EU, to which UK expertise has materially contributed. The single regulatory system **provides the scale and certainty required to bring innovative, effective and safe medical technologies to UK patients quickly**. The two globally significant regulators, the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) cover markets comprising 32% and 25% of global pharmaceutical sales respectively⁹. Their dominant position means they are the first choice markets for new products and the long tail of economic benefit in the form of industry investment that brings. Creating a stand-alone UK regulator, would require significant resource, time and expertise, and, by lowering its priority, would likely still leave the UK behind the US and EU for new product launches, to the detriment of UK patients. There are concerns that the current state of uncertainty may already be leading to a loss of UK influence in Europe in key scientific and regulatory discussions and decisions.

Opportunity: **commonality with the EU regulatory system, alignment of current and future regulations and participation in European processes**, could be achieved through **a regulatory cooperation agreement** negotiated with the EU. This would allow the UK to remain a key participant in European regulatory procedures and decisions, retain influence and benefit from the scale of the common regulatory framework.

4. Access to the best talent

Challenge: the UK benefits from the mobility of talented individuals. Access to relevant talent enables the **brain circulation critical to developing the next generation of innovators and commercial talent**. The UK must remain accessible and attractive to the world's best talent and UK must retain the ability to work in the EU and beyond.

Opportunity: **continued ability to secure the most talented people for UK science can be delivered through an immigration system which facilitates ease of movement for talented students, researchers and workers**. This should be needs-based, straightforward, and rapid – providing certainty of outcome. In the short term, action is needed to ensure that highly skilled EU citizens already in the UK can continue to work and study here.

UK Industrial Strategy

The following policy actions will enable the UK to capitalise on its potential to be a global leader in Life Sciences:

- **Making the NHS an innovation engine** – capitalising on the unique potential of the NHS for clinical trials, leveraging the benefits of a single healthcare system, developing real world evidence capabilities. Also essential is improving the NHS's innovation uptake, e.g. via the Accelerated Access Review (AAR). Currently for every 100 EU patients who receive a new medicine in its first year of launch, only 15 UK patients receive the same medicine¹⁰.
- **Delivering value-adding innovation** – investing in the technology, capabilities, skills and enablers requires to improve the development and commercialisation of medical technologies of the future (e.g. genomics, ATMPs).
- **Targeting future UK talent development** – identifying key skills areas in which the UK wants to excel, and tailor funding, curriculums and apprenticeships/industrial placements accordingly.
- **Maintaining a supportive tax system** – supporting innovation, entrepreneurship and the UK's competitive edge, e.g. Patent Box provisions, R&D tax credits and opportunities for direct UK government funding.

Such an Industrial strategy for Life Sciences will help attract investment to the UK, stimulate the growth of our domestic industry, deliver effective and efficient healthcare for future generations, and demonstrate that the UK is open for business.

The Life Sciences sector stands ready to work with the new government through an unprecedented period. **Making the right choices today will build on existing strengths and position the industry and the UK for an even more successful future.**

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iii. Introduction

This report is the collective response of the UK Life Sciences industry to the Government's request to understand **how to maintain and grow the UK's world leading Life Sciences sector in the context of leaving the EU**. Although an industry report, it has been produced through wide consultation with the sector* and is intended to form a starting-point for ongoing engagement with Government throughout the UK's process of EU exit.

The UK Life Sciences industry has identified four priority areas for the UK to address as it negotiates exit from the EU – **innovation, trade, regulation and people**. Each of is discussed in turn below. Within each area, content is organised with the following structure:

- **Summary box:** an overview of the priority area and the industry's recommended way forward
- **What is at stake as a result of leaving the EU:** an overview of the current position and the potential implications as a result of EU exit
- **The industry's recommended way forward to achieve the best outcome for the UK:** detail on the industry's priorities and the enablers required to achieve them. The industry recognises the challenge faced by government in negotiating the UK's new relationship with the EU. Therefore, other options were considered, these are referenced in this report where relevant
- **Benefits for the EU:** a review of any areas where the industry priority is likely to also bring benefits to the EU
- **An invigorated UK Life Sciences Industrial Strategy:** proposals on measures that the UK government can use to drive an effective and impactful Industrial Strategy for the UK in which Life Sciences is a key pillar

iv. Priority Areas

Innovation – Long-term, predictable funding for scientific research, and continued ability to collaborate at scale

The UK has a long history of global leadership in Life Sciences, having discovered and developed 25 of the top 100 prescription medicines globally¹¹. R&D and products for diseases such as dementia and oncology support the Government's drive to improve UK healthcare outcomes. They also underpin its commitment to address global health challenges such as antimicrobial resistance (AMR), HIV/AIDS, and malaria.

Life Sciences is on the cusp of a medical revolution. Personalised medicine, genomics and emerging digital technologies and devices are transforming patient care. The unique window of opportunity to take a global leadership role is now.

Research leadership requires long-term funding certainty, the brightest talent and the ability to collaborate at scale. Commercialisation of this research requires an end-to-end funding ecosystem to support small and medium enterprises (SMEs) from inception to sale or Initial Public Offering (IPO) – an area in which the UK already excels. Funding and talent are globally mobile and the UK must work hard to maintain these, particularly in light of current uncertainty.

The industry welcomes the guarantee the Government has provided for Horizon 2020 funding. However, a longer-term solution is needed which recognises both the role EU-wide programmes play in funding, but also in providing both the scale and collaborations needed to tackle the most challenging public health issues.

* Over 50 hours of workshops have been held, with 150 experts from industry, trade associations, NGOs and public sector organisations, covering pharmaceuticals, biotech, medical technology, consumer health, animal health and support services

1.

The UK should seek continued access, long-term, to European funding and collaboration programmes, through:

- Reaching an agreement to maintain access to Horizon 2020 and its successor (e.g. “associate member” status akin to Switzerland, Israel and Turkey)
- Seeking continued participation in the EIB and EIF, including shareholding, financial contributions and, as a result, a seat at the Board

What is at stake as a result of leaving the EU

The UK Life Sciences ecosystem facilitates collaboration between industry, academia and health systems, stimulating innovation and bringing investment, jobs and benefits to UK patients.

Losing access to research funding will damage UK innovation.

HM Treasury’s commitment to underwrite funding for Horizon 2020 projects secured while the UK is an EU member provides important short-term reassurances that the UK science base is a secure partner for EU projects¹⁴. However, access to EU research funding beyond the Horizon 2020 round of funding, is still unknown. ***Life Sciences has a long research cycle, and requires a long-term funding solution.*** Lack of European Research Council (ERC) funding would discourage top scientists from conducting their research at UK institutions, whilst the removal of translational research grants could also reduce the number of UK start-ups. Even if the UK retains access to Horizon 2020 funding, other funding sources will be lost following the UK’s departure from the EU. For example, the European Structural and Investment Funds (ESIF) – invested in projects such as Cardiff University’s Brain Research Imaging Centre.

If the UK is not eligible to lead EU-wide research collaborations, this will erode the UK’s position as a global research leader.

Collaborations are increasingly essential to reach the necessary scale for breakthrough discoveries. The UK currently plays a leading role in EU-wide collaborations; for example, leading the highest number of IMI projects¹⁷ (which speed up the development of better and safer medicines for patients, boosting innovation in Europe). Non-EU countries may also now target their collaborations outside of the UK if they believe European scale is critical to success.

There is a positive correlation between government spending on medical research and private R&D spending. A 1% increase in government spending on medical research is associated with a 0.7% increase in private R&D spending¹⁹. A decline in public funding could also trigger a fall in R&D spending in the UK by pharmaceutical companies.

The UK has the most developed funding pipeline in Europe. The UK VC ecosystem is critical to commercialising and growing SMEs, providing £630m in 2015 to Life Sciences SMEs²¹. ***VC’s are heavily reliant on EIB and EIF funding***, which often make up 25-40% of VC funds and plays a role in catalysing further private investment²². Loss of access to EIB/EIF funding will result in reduced VC funding for UK SMEs, and ultimately fewer start-ups in the UK. Further, the loss of EU passporting rights for financial institutions would limit their ability to raise funds across Europe. In addition, the UK is attractive for investors due to the strength of the IPO market and openness to Foreign Direct Investment (FDI) and mergers and acquisitions.

The UK is one of the largest recipients of research funding in the EU

The EU Horizon 2020 framework, has a total budget of €75bn (2014-20) for all EU member states¹²

Between 2007 and 2013, the UK secured a **total of €8.8bn in R&D funding**, €3.4bn more than contributed, including:

- **€1.9bn** in ESIF funding
- **€1.7bn** from the ERC
- **€1.1bn** from Marie-Curie¹³

KEY FACTS

The UK produced **19% of the world’s most cited academic publications** in the Life Sciences, (2012)¹⁵

60% of UK internationally co-authored papers are with EU partners¹⁶

KEY FACTS

In 2014, pharmaceutical companies invested **16% of their European R&D budget** in the UK. This compared with **9.4% of European sales** in the UK¹⁸

KEY FACTS

Every €1 of EIF investment attracts a further €6 of private funds, totalling €16.1bn between 2011 and 2015²⁰

KEY FACTS

Initiatives which are underway to further improve the funding pipeline (such as patient capital and evergreen funding) may also be affected.

Pan-European research is supported, in part, by data sharing across the EU. In order to maintain its leading position; **the UK must remain aligned with the EU on Data Protection** or future data sharing will be restricted – the current UK Data Protection Act is insufficient to enable data sharing.

Intellectual Property (IP) protections and other exclusivities are key to incentivising the lengthy, risky and expensive process of Life Sciences innovation. (This topic is covered in the Regulation section).

The industry's recommended way forward to achieve the best outcome for the UK

The UK should seek to retain long term access to European funding and collaborations, through:

- Reaching an agreement to **maintain access to Horizon 2020 and its successor** (e.g. “associate member” status akin to Switzerland, Israel and Turkey)
- Seeking continued participation in the EIB and EIF, including shareholding, financial contributions and, as a result, a seat at the board

The UK should **negotiate reciprocal passporting rights** for financial institutions to enable pan-European trading and keep full access to the common financial market.

The UK should align with the EU data privacy system. Specifically, the UK should continue with the implementation of **the EU General Data Protection Regulation (GDPR)**. This should ensure confirmation from the EU Commission that the UK has an adequate level of protection.

The industry also discussed options for the UK government replacing lost EU funds with domestic funding in the long term e.g. through a government backed venture fund. There is a real opportunity – in the context of home-grown Industrial Strategy – for the UK government to provide long term investment and support for UK Life Sciences of the scale and scope of the US National Institute for Health. This would however not facilitate collaborations or, without significant cost to the Treasury, be able to provide the scale of EU funding.

Refilling the Biomedical Catalyst, a successful government policy that has “crowded in” private sector investment into UK Life Science in recent years, is an action the UK government should take this year as a first step.

Benefits for the EU

Maintaining access to current funding and collaboration frameworks will enable the EU to continue to access the UK's world-leading Life Sciences academic institutions (e.g. UCL, Imperial, Oxford, Cambridge). Europe's position in Life Sciences benefits from close collaboration with the UK as a result of a “*halo effect*” on Europe's global positioning in Life Sciences.

The EIB/EIF greatly benefits from access to the advanced financial markets of the UK. In particular, the early stage funding market is a “poster child” of the EIB/EIF, with great learnings for Europe.

An invigorated UK Life Sciences Industrial Strategy

Making the NHS an innovation engine – The NHS is a unique selling point for the UK. There is the opportunity to capitalise on the potential of the NHS to act as a ‘single healthcare system’ for clinical trials and innovative research; one that offers access to a large and diverse population, with data across the entire patient journey – especially valuable in the era of personalised healthcare. Improving coordination and integration of patient records will allow the NHS to become a global leader in trials using real world data. The UK should actively push towards specialising in innovative trial design and building upon its informatics/data analytics capabilities. In addition, R&D structures in the

NHS should be supported to ensure continuity in the capacity to run clinical trials. In order to ensure innovative treatments developed through clinical trials benefit UK patients, it is essential that the UK accelerates the approval and reimbursement of innovative medical technologies to improve uptake of these products within the NHS. It is hoped that the AAR will take positive steps to address this.

Delivering value-adding innovation – The UK has an opportunity to lead in medical technologies of the future, e.g. genomics, digital health and ATMPs. To realise these opportunities, the UK will have to invest in new technology capabilities and skills. This should be with the goal of improving the development and commercialisation pipeline for new innovative medical technologies –enabling research breakthroughs to develop into commercial successes. A centrally coordinated translational medicine environment would involve stimulating early-stage innovation through both academia-industry and UK-overseas collaboration, for example by making clear and extending the role of university Technology Transfer Organisations (TTOs) as creating value for tax-payers. The UK should build upon the successes of schemes such as the Biomedical Catalyst, Cell and Gene Therapy Catapult and Precision Medicine Catapult to commercialise discoveries. A UK manufacturing hub could be created to incubate excellence in manufacturing of advanced products, in particular ATMPs.

Commercial and Trade – Ability to trade and move goods and capital across borders

Life Sciences is a global industry reliant on a stable business environment and the ability to move goods and capital across borders. As an open trading nation with a competitive fiscal environment, the UK has attracted companies to use it as a base.

The Life Sciences industry has streamlined and integrated supply chains. These often involves inter- and intra-company cross-border process, goods and value flows. The current harmonised regulatory environment and lack of border controls facilitate this movement of goods.

Trade between the UK and EU could now be subject to customs duties, import VAT and border controls (import/export declarations and inspections/goods' testing). This would cause significant disruption and increased costs. Ultimately, this could hinder UK patient access to medical technologies and lead to an increased NHS drugs bill. Such changes would also make it less attractive for companies to make future investments or stay in the UK.

The UK should seek to maintain free trade with the EU, ideally on terms equivalent to those of a full member of the EU customs union and EC common system of VAT (VAT union), i.e. no tariff (duties), import VAT, or non-tariff barriers (inspections, import/export declarations) to trade. Terms should also include the UK maintaining access to the EU's FTAs with non-EU countries.

2. The ability for capital to freely flow between the EU and UK should be sought (e.g. through access to existing EU directives, in particular the Parent-Subsidiary and Interest & Royalties Directives).

In addition, maintaining a supportive tax system will help offset current uncertainty (e.g. direct tax measures such as reduced headline corporation tax, more generous qualifying criteria for Patent Box or a higher rate for R&D credit).

What is at stake as a result of leaving the EU

Medical technologies for UK patients* are sourced from around the world. The UK is also a significant contributor to global supply. In 2015 the UK imported approximately £29.7bn in Life Sciences goods, and exported £29.5bn, of which 44% went to the EU²³.

The UK's trade environment is driven by **indirect taxation (customs duties and VAT), embedded throughout the manufacturing and supply chain**, including both cashflow costs (arising from the

* The term patients is used in this report to refer to human patients and also animals in the case of veterinary medicines

delay between paying out VAT and entitlement to recover the input VAT) and irrecoverable costs (including customs charges and the administrative costs of compliance). **These costs are currently minimised in relation to UK/EU trade.** The current **aligned regulatory environment** and **lack of border controls** facilitates ease of trade, as does the minimisation of the costs of transferring capital across borders by the EU **Parent-Subsidiary and Interest & Royalties Directives**, which have been critical in the costs of UK business trading in the EU. **Significant disruption, costs, and cashflow impacts to trade could now arise** if: trade between the UK and the EU becomes subject to customs duties and import VAT; border controls in the form of import/ export declarations and inspections/ goods' testing are introduced; the UK does not introduce VAT simplifications.

In addition, pan-European cooperation is **essential to help reduce the risk of falsified medicines reaching UK patients**. This risk would increase should the UK opt out of fully implementing the planned European Falsified Medicines Directive (FMD).

The UK could **lose access to FTAs negotiated by the EU** (in place with countries such as Switzerland and South Korea, and under negotiation with countries including the USA). Loss of the Swiss FTA, in particular, will have significant impact on Swiss-based Life Sciences companies who operate in the UK. A bilateral deal is needed as a priority to address these concerns.

Such changes would also **make it less attractive for companies to make future investments or stay in the UK** as integrated supply chains that rely on ease of movement of goods and capital across borders are challenged. If foreign investment in the sector and exports to the EU decline, the industry will be unable to sustain current employment levels and **the number of jobs in the Life Sciences industry may fall**.

The result of such changes **could hinder UK patient access to medical technologies and lead to an increase in the cost to the NHS**.

The industry's recommended way forward to achieve the best outcome for the UK

The UK should seek to maintain free and simplified trade with the EU on **terms equivalent to those of a full member of the EU Customs Union and EC common system of VAT (VAT union)**. This would result **in no increases in UK duty rates and no import VAT** being assessed against trade between the UK and the EU. Terms should also include the **UK maintaining access to the EU's Free Trade Agreements (FTAs) with non-EU countries**.

For manufacturing and supply, the need for **import/export declarations** or the introduction of **border controls** (e.g. for inspections) **should be avoided**. Achieving the latter would require the UK to not only have full EU customs union membership benefits but to also **maintain aligned Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) standards with the EU and reach an agreement that allows UK-based Qualified Persons (QP) decisions and inspections to be recognised between the EU and UK**. (This topic is covered in more detail in the Regulation section).

VAT simplifications (such as triangulation) should be retained and no VAT cashflow costs or administrative requirements should be additionally introduced. The UK should also seek to reach agreement with the EU to maintain the benefits of the **Parent-Subsidiary and Interest & Royalties Directives**.

Currently, the UK is a WTO member in its own right. However, as a member of the EU Customs Union, terms of trade between the UK and the rest of the world (e.g. general customs duty rates assessed against imports into the UK) are agreed by the EU. Depending on the negotiation outcome, **the UK may need to establish its own terms with the WTO**, including also its adoption and implementation of WTO agreements currently signed and implemented in the name and terms of the EU, not the UK independently.

The industry also discussed options if the UK was unable to maintain trade with the EU on terms equivalent to those of a full member of the EU Customs Union. In such circumstances, the **UK will need to create a supportive environment for trade** to mitigate increased costs and risks and should aim to provide for a significant transition period. Various options could be considered, including not adopting customs duties rates that exceed those currently set by the EU, signing and implementing industry critical WTO agreements (e.g. implementing the WTO Pharmaceutical Agreement on an accelerated basis for candidate APIs to encourage early stage drug development) and negotiating FTAs with non-EU countries independently.

Benefits for the EU

The negotiation with the EU should **focus on merits of EU Customs and VAT Union for both EU and UK companies**. This includes unfettered access to each other's markets, and avoidance of indirect tax costs, cash flow impacts and additional administrative burdens. Ultimately, this will ensure the continued **security of supply of essential medical technologies for UK and EU patients**.

An invigorated UK Life Sciences Industrial Strategy

Maintaining a supportive tax system – The UK government has a number of opportunities to support activities across the Life Sciences value chain and help **offset near-term uncertainty and reduced business confidence**.

Investment can be incentivised through direct tax measures, such as a reduction in the headline Corporation Tax rate, more generous qualifying criteria for Patent Box and a reduced Patent Box rate, a higher rate for R&D credit, delaying certain Base Erosion and Profit Shifting (BEPS) related measures to align with the timetable in other European countries and the removal of stamp duty charge on transfers to depositories, as examples.

Depending on the terms of any trade agreement, the UK may also have **increased freedom as a result of a release from EU state-aid laws**. This creates an opportunity to directly fund industry at the government's discretion (for example, as the National Institute of Health's Small Business Innovation Research program does in the US). An application in the UK could be subsidising scientific advice given to SMEs on orphan drugs to match the EMA scheme.

If the UK is not able to gain access to a customs and VAT union (a non-preferred outcome), the UK government would have **freedom to amend UK VAT legislation to benefit the Life Sciences industry**. For example, application of zero rating to new institute builds used for shared academic and commercial research to enable better collaboration between industry and academia or the introduction of a simplification to avoid import VAT cashflow costs for clinical trial sponsors.

Regulation – A common regulatory framework with Europe

The UK and EU benefit from a highly sophisticated regulatory system (including the regulation of medicines, devices and IVDs), jointly built over the last 50 years. The system provides industry with the scale and certainty to bring innovative, effective and safe medical technologies to patients.

The UK's Medicines and Healthcare products Regulatory Agency (MHRA) is a leading regulator within the European system, undertaking a significant proportion of EMA workload and contributing expertise in the most advanced areas. Without the MHRA the European system would be lacking in both capacity and expertise. Lost capacity of UK Notified Bodies and the Veterinary Medicines Directorate (VMD) will impact the EU system in a similar way.

For the UK, the resource, time and expertise required to build and legislate for a stand-alone regulatory model would be significant – *and not in the interests of UK patients or industry*.

No longer being within the European regulatory system could result in:

- Delayed or no regulatory submission to the UK for new medicines, due to the UK effectively becoming a “second priority” launch market, resulting in delayed (relative to European patients) or no access to new products, for UK patients
- Disruption to the supply of life saving medical technologies as a result of border inspections for products going to or from Europe
- Falsified medicines reaching UK patients if the UK is not part of EU-wide monitoring systems

Due to the potential impact on public health, the industry believes, it is in the mutual interests of the UK and EU to reach agreement on maintaining regulatory alignment.

The industry recommends maintaining alignment with the EU regulatory system, including for current and future regulations and long-term participation in European processes.

- 3. This could be achieved through a regulatory cooperation agreement, under which the UK would benefit from being able to be an active participant in European regulatory procedures and decisions, ideally continuing to influence future policy, guidance and legislation.**

What is at stake as a result of leaving the EU

The way in which the UK Life Sciences industry researches, develops, manufactures and brings medical technologies to patients is regulated by the EU. The regulation of medical technologies benefits from consistency and scale. ***There is considerable risk to patients associated with the UK divorcing itself from the sophisticated system of EU regulation.*** This robust regulatory system is critical to deliver safe, effective medical technologies and ***has been built with considerable UK influence*** and expertise.

The industry believe the EU regulatory system for medical technologies is highly effective and industry is broadly supportive of the current system – there is no appetite to add regulatory bureaucracy by losing European scale and consistency.

If UK regulations were to diverge from those of the EU; duplication of processes, increased costs and a divergence in standards will make the UK ***a less attractive place to develop, manufacture and launch new products***. Even a UK system designed to improve upon current EU regulations, if separate from the EU, will lead to increased costs and considerable delay or no regulatory submission to develop new medicines in the UK. Additionally, ***the UK will become a second priority market for new products***. This will result in innovative, generic and biosimilar products being made available to UK patients later than those in the EU. For global companies, the UK market is not sufficiently large to justify significant additional costs, at ***just 3% of global pharmaceutical sales***.²⁴

Leaving the European regulatory system for medicines, medical devices and IVDs will result in an unprecedented level of disruption, potentially threatening the ongoing availability of medical treatments and products to patients. The shock to the European system caused by losing MHRA, Notified Bodies and VMD capacity and expertise will be significant.

The ***loss of influence for the UK within the European system*** will have long-term impacts on the UK, with talented regulatory experts being less attracted to live and work the UK, and EU regulations becoming less favourable to UK interests in the future. In addition, the EMA will re-locate from its current base in London, representing a further loss of influence and attraction for top regulatory talent.

Patient safety may be compromised. No longer having UK involvement in European pharmacovigilance (PV) and future medical device (EUDAMED) databases and integrated EU vigilance processes will impact the quality and coverage of the systems used to detect side effects and manage safety issues. In addition, the UK losing access to the European Centre for Disease Control (ECDC), could impede the UK's ability to produce medicines used to manage pandemics and delay vaccine manufacturing and supply.

In addition, **effective regulation of animal medicines is vital to ensure human safety.** Of 1,500 infectious diseases, almost two thirds are able to pass between animals and humans. Furthermore, around 75% of emerging infections affecting humans originate in animals²⁵.

KEY FACTS

In 2015 the MHRA was a rapporteur in **15%** of Pharmacovigilance Risk Assessment Committee (PRAC) and Committee for Medicinal Products for Human Use (CHMP) procedures and over **25%** of Good Manufacturing Practice (GMP) certificates for sites outside the EU were issued as a result of MHRA inspections*.

The MHRA also made significant additional contributions to EU processes in licensing, pharmacovigilance and inspection and enforcement standards (IE&S), contributing a significant proportion of overall European Medicines Agency (EMA) workload.

The new Clinical Trials Regulation (CTR) for medicines is currently being implemented and is expected to be in force by 2018. It is designed to encourage and streamline the approval of pan-European trials with a single application designed to deliver speed and efficiency, with a simplified process where the investigational product poses less risk. Should the UK choose not to implement the CTR, **the UK could become a less appealing location for clinical trials in Europe; impacting the UK innovation base and the opportunities for UK doctors and academics to conduct trials in the UK.** In addition, clinical trial placement is linked to the uptake of innovation within a health system. Participation in this common regulatory framework is pivotal for maintaining investment in R&D, which benefits the NHS and UK patients.

The loss or reduction of Intellectual Property protections would disincentivise the development and launch of medical technologies in the UK. Protections are key to incentivising the lengthy, risky and expensive process of pharmaceutical and biotech innovation. Europe benefits from a high standard of IP incentives in the form of Supplementary Protection Certificates (SPCs) (essentially compensating for the amount of patent term that is lost during the lengthy development process of a pharmaceutical product), regulatory data protection (RDP), orphan designation (for rare diseases) and rewards for investigations into paediatric uses and formulations. EU pharmaceutical incentives are currently being reviewed and it is important that the UK actively participates in that review, prior to leaving the EU, to prevent IP incentives being weakened.

The industry's recommended way forward to achieve the best outcome for the UK

The industry's preferred position is for the UK to maintain **continuity with the EU medicines, medical devices and IVD regulatory systems; including full participation in EU regulatory processes and alignment of regulations.** This would include:

- A continued role and active **participation in relevant EU committees[†]**, with the ability to **influence medical technologies policy, guidance and legislation**
- Active participation in all EU **Marketing Authorisation Application and Maintenance** procedures and continued participation in EU **Pharmacovigilance and device vigilance systems and processes**, including the ability for the Qualified Person Pharmacovigilance (QPPV) to remain situated in the UK

* The equivalent figure for the Veterinary Medicines Directorate (VMD) was acting as a Reference Member State in 43% of Mutual Recognition Procedures

† Including: Committee for Medicinal Products for Human Use (CHMP), Pharmacovigilance Risk Assessment Committee (PRAC), Paediatric Committee (PDCO), Committee for Orphan Medicinal Products (COMP), Committee for Medicinal Products for Veterinary Use (CVMP), European Commission medical devices committees

- Continued implementation of: The **Clinical Trials Regulation**, new **Medical Device Regulations**, **In-Vitro Diagnostic (IVD) Device Regulation**, **Falsified Medicines Directive (FMD)** and adoption of the European Medicines Verification System (EMVS)
- Maintained alignment with **IP protections** (RDP, SPCs, Orphan and Paediatric), and ensure the UK is able to maintain standards of IP protection that are at least as high as they are today
- A Mutual Recognition Agreement (MRA) on the **alignment of GMP and GDP standards and Qualified Person (QP) decisions and inspections recognised** between the UK and EU
- **A Medical Devices MRA** including: the UK maintaining Notified Body and Competent Authority status, continued participation in CE-Marking activities related to medical devices, continued ability for UK Notified Bodies to certify manufacturers and review Technical Documentation related to medical devices
- Maintained access to and continued participation in and develop **EU databases***
- Continued guarantee of all **existing and accrued marketing authorisations and IP protections and other exclusivities**

The industry is therefore recommending an overarching regulatory cooperation agreement negotiated with the EU in the context of a broader UK/EU special relationship. This should be a **long-term, permanent agreement** given the complexity, cost and requirement to provide consistent and stable regulation. The industry considered alternatives and believe that a transitional period (of 5 to 10 years) would be preferable to no cooperation agreement at all.

The industry appreciate that **the UK may adopt a stand-alone regulator model**, however this would be non-preferable and has significant disadvantages associated with it. The resulting additional regulatory burden will add cost for industry and the UK government. **The UK would be deprioritised as an early launch market**, delaying patient access to innovative products and offsetting expected benefits from the AAR. To mitigate this, **the MHRA and VMD would need to effectively recognise EU authorisation for the majority of products**, aiming to use the same file, same timeline and ensure a quick, pain-free process for industry. **There is no appetite from industry to fund the MHRA or VMD to undertake stand-alone approvals for all products.**

Benefits for the EU

Continuing to be part of EU regulatory processes provides significant public health benefits for both the UK and EU. For example, the contribution of the UK to EU vigilance databases and to integrated EU vigilance processes enhances the quality and coverage of the vigilance system for Europe as a whole.

Maintaining **the ability for the MHRA and VMD to take part in EU procedures is essential to ensure sufficient capacity and expertise in the EU regulatory system**, ensuring ongoing timely access for patients to new medical technologies. Further, UK based Notified Bodies undertake a significant proportion of CE marking for medical devices and IVDs. Loss of their capacity would impact the availability of medical devices and in IVDs across Europe.

The National Institute for Biological Standards and Control (NIBSC), part of the MHRA, is an Official Control Authority for batch release of biologicals and vaccines whose testing is recognised across Europe. If NIBSC batch release were no longer recognised, as a result of a UK exit from the EU, duplication of testing will result in increased effort by industry and health authorities. This will also give rise to potential differing test results, possibly leading to non-release decisions. The initial set-up time for tech transfer can result in delays of release to market as labs need to be fully validated to perform control batch testing.

* Including: EudraVigilance, PSUR repository, IDMP/Article 57, Submissions gateway, EudraGMP, EUDAMED

People – Access to the best talent

The UK's position as a leader in Life Sciences is underpinned by the ability to attract, develop and retain a highly skilled workforce. A key feature of this has been the ability for talented people to move and collaborate freely – this brain circulation is critical for developing the next generation of innovators and businesses talent.

The UK's leading institutions attract the brightest students from around the world. This talent pool provides the fuel for UK start-ups. Big pharma are drawn to this combination of a thriving start-up ecosystem and skilled workforce - one reason that the UK currently “punches above its weight” as a base for global pharma companies within Europe. In a virtuous cycle, this further drives the UK's highly-skilled Life Sciences talent base.

The next wave of medical innovation will create new, highly skilled roles across the value chain, from R&D to advanced manufacturing. Taking advantage of this opportunity places a renewed imperative on developing the UK talent pipeline for the skills of the future. However, there will always be a need to access talent from abroad. The inability to do this would be a fundamental challenge to the UK's position as a world-leading Life Sciences environment, ultimately risking the long term erosion of the UK science base.

Uncertainty is already making it difficult to attract and retain talent, partly by creating a negative impression that the UK is closed to international workers. The right agreement on migration is critical.

4.

The government should develop an immigration system which facilitates ease of movement for talented/ skilled students, researchers and workers. The system should be needs-based, straightforward, rapid and provide certainty of outcome.

In the short term, immediate action is needed to ensure EU nationals can continue to work and study in the UK. This is important to address concerns that the UK is an unattractive environment for foreign workers.

What is at stake as a result of leaving the EU

Ease of movement across the EU enables the sector to attract the talent it needs. This is particularly crucial in skills gap areas such as clinical pharmacology and bioinformatics. In the future, the ability to attract top talent will be critical if the UK is to become a leader in emerging skills areas (e.g. device technologies, digital health, physiological modelling, genomics and ATMP manufacturing). Being able to attract the top students from around the world is vital to ensure UK research institutions remain world class.

Barriers to attracting and retaining the right talent pose a ***fundamental risk to the UK's position as a world-leading Life Sciences environment***, putting the entire Life Sciences ecosystem in the UK at risk and ultimately risking long term erosion of the UK science base. Currently, non-UK EU nationals make up around 17% of Science, Technology, Engineering and Mathematics (STEM) academics at UK research institutions²⁶.

Uncertainty over the position of EU workers to remain in the UK and the UK's future immigration policy is already making it difficult to attract and retain talent²⁷. Additionally, it is creating the negative impression that the UK is closed to foreign workers, making it harder to market the country as an attractive destination for the talent essential to the industry.

The UK is often the ***European HQ location of choice*** for global pharmaceutical companies, with over a dozen based in the UK including Eli Lilly, Gilead, Astellas, Takeda, Eisai and Otsuka. GSK and AstraZeneca also have their Global HQ's in the UK. MSD, Amgen and Pfizer also have significant UK R&D or manufacturing operations. ***This has helped foster a deep talent base across the value chain in areas including research, development, regulatory, manufacturing and commercial skills.*** These skills find homes within a range of organisations in the UK Life Sciences sector

including regulators, industry, research institutes and support services. However, as the UK's position as an attractive gateway to Europe is challenged, there is a risk that these operations will move to Europe –eroding the UK Life Sciences ecosystem and resulting in lost jobs and economic contributions.

The industry's recommended way forward to achieve the best outcome for the UK

The industry recommends the government develops ***an immigration system which facilitates ease of movement for talented/ skilled students, researchers and workers***. The system should be needs-based, straightforward, rapid, avoid additional costs to industry and provide certainty of outcome. Any new UK immigration system should have ***reciprocal agreement with Europe*** whilst also improving the current system for immigration from the rest of the world. The Intra-company Transfer process should remain and be uncapped to at least allow movement of people currently employed.

In the short term, ***immediate action is needed to ensure EU nationals can continue to work and study in the UK***. This is important to address concerns that the UK is an unattractive environment for foreign workers.

The UK should seek a reciprocal agreement on student tuition fees, enabling UK and EU students to benefit from 'local' country tuition fee levels. This will ensure the attractiveness and reputation of UK universities continues and that UK-educated talent is retained. Further, the UK should seek to ensure the validity of professional qualifications gained within the EU (e.g. medics, pharmacists, Qualified Persons (QPs)).

Any potential change to the current system, will require a ***significant transition period*** to ensure industry does not face a skills shortage in the short term, as new systems are set up.

Benefits for the EU

Both the EU and UK benefit from the brain circulation that ease of movement for students, researchers and workers provides. ***The strength of the UK's academic institutions and the breadth of the Life Sciences industry is to the benefit of the EU as a whole***. This allows EU workers who spend time here to develop and gain skills which they then infuse into their home countries and EU companies to benefit from the ability to recruit UK talent.

An invigorated UK Life Sciences Industrial Strategy

Targeting future UK talent development – There is a renewed imperative for the UK to grow and develop a thriving home-grown Life Sciences talent base. This will involve identifying key skills areas in which the UK intends to excel, (e.g. device technologies, digital health, physiological modelling, genomics and ATMP manufacturing) then tailor funding, curriculums and apprenticeships/industrial placements accordingly. Building general schemes to promote STEM education and training should also be supported.

v. Conclusion

This report and the Executive Summary that it appends represents the collective response of the UK Life Sciences industry to the Government's request to understand **how to maintain and grow the UK's world leading Life Sciences sector in the context of leaving the EU**. The core summary of the sector's contribution, priorities and suggested UK policy actions are summarised in the Executive Summary, but a summary of priority areas is also included below.

Although an industry report, it has been produced through wide consultation and is intended to form a starting-point for ongoing engagement with the new Government. As a wide ranging sector, our constituents see the opportunities as the UK exits the EU, and potential challenges, through different lenses, but **we are already seeing the opportunity to work concertededly and across sectors in partnership with government to support wherever possible**.

<i>Summary of Priority Areas</i>	
1.	<p>Innovation – The UK should seek continued access, long-term, to European funding and collaboration programmes, through:</p> <ul style="list-style-type: none"> • Reaching an agreement to maintain access to Horizon 2020 and its successor (e.g. “associate member” status akin to Switzerland, Israel and Turkey) • Seeking continued participation in the EIB and EIF, including shareholding, financial contributions and, as a result, a seat at the Board
2.	<p>Commercial & Trade – The UK should seek to maintain free trade with the EU, ideally on terms equivalent to those of a full member of the EU customs union and EC common system of VAT (VAT union), i.e. no tariff (duties), import VAT, or non-tariff barriers (inspections, import/export declarations) to trade. Terms should also include the UK maintaining access to the EU's FTAs with non-EU countries.</p> <p>The ability for capital to freely flow between the EU and UK should be sought (e.g. through access to existing EU directives, in particular the Parent-Subsidiary and Interest & Royalties Directives).</p> <p>In addition, maintaining a supportive tax system will help offset current uncertainty (e.g. direct tax measures such as reduced headline corporation tax, more generous qualifying criteria for Patent Box or a higher rate for R&D credit).</p>
3.	<p>Regulation – The industry recommends maintaining alignment with the EU regulatory system, including for current and future regulations and long-term participation in European processes.</p> <p>This could be achieved through a regulatory cooperation agreement, under which the UK would benefit from being able to be an active participant in European regulatory procedures and decisions, ideally continuing to influence future policy, guidance and legislation.</p>
4.	<p>People – The government should develop an immigration system which facilitates ease of movement for talented/ skilled students, researchers and workers. The system should be needs-based, straightforward, rapid and provide certainty of outcome.</p> <p>In the short term, immediate action is needed to ensure EU nationals can continue to work and study in the UK. This is important to address concerns that the UK is an unattractive environment for foreign workers.</p>

Appendix

vi. Process for developing this report

Overview and Objectives

Following the outcome of the EU referendum, George Freeman MP, the then Life Sciences Minister, announced the **formation of the UK EU Life Sciences Steering Group, under the auspices of the Ministerial Industry Strategy Group, to oversee and manage the transition for the Life Sciences sector**. The Steering Group asked the ABPI and BIA to set up the UK EU Life Sciences Transition Programme to do this work, and ensure the work covered the views of the entire Life Sciences Industry, including medical devices, over the counter medicines, generics and animal health. ABPI and BIA have been supported by PwC in completing this work.

The **overarching objective** of the transition programme is to determine how to **create a world-leading Life Sciences environment in the UK outside of the EU**. This includes:

- Identifying **optimal positions** for the Life Sciences sector **against potential exit scenarios**, and generating ideas for agile **approaches to overcome barriers and mitigate risks**
- **Identifying opportunities** to make the UK domestic landscape as strong and attractive as possible for the Life Sciences industry
- **Providing options for how the UK can negotiate** with the EU and relevant EU Life Sciences bodies to obtain the optimal outcome for UK and European industry, health systems and patients
- Ensuring a **framework for a continued dialogue** between the **Life Science industry and the government** on these issues

This report represents the Life Sciences sector thoughts on these topics.

Work structure and Timetable

The need to rapidly generate a Life Sciences industry point of view means the timescale for the work has been condensed, and has been run as an intense nine week programme during July and August.

Work was structured across **six workstreams: Regulation, Research & Development, Intellectual Property, Manufacturing & Supply, People, Fiscal & Trade**. Content for each workstream was developed through broadly workshops as well as through the authoring of expert reports by PwC for the People and Fiscal & Trade workstreams. Each topic workstream was co-chaired by an industry representatives from both the ABPI and BIA. These co-chairs also participated in a full-day **Strategy workshop**, where each of the six workstreams were discussed together, in order to identify and prioritise key topics and discuss, and consolidated into four priority areas.

Stakeholder engagement and Governance

In total, over 50 hours of workshops were held, attended by 150 individuals from nearly 90 organisations. Workshop outputs were also open for comment and review by a broader group of invited stakeholders, who were not able to attend the workshop on the day. In addition, feedback has been received on the work through two “Townhall Meetings” of ABPI and BIA members, as well as through comments received online through MyABPI, via BIA Board discussion, direct emails in response to BIA Newscast mailings from SME members, and through fortnightly steering calls with a Members Leadership Group (MLG).

Organisations Involved
Life Sciences companies AbbVie, Actavis, Allergan, Ammirall, Amgen, AstraZeneca, Astex, Bayer, Biogen, Boehringer Ingelheim, Bristol-Myers Squibb, Celgene, Covance, CRL, Eagle, Eisai, Eli Lilly, Envigo, GSK, Imanova, Johnson & Johnson, Leo, Lonza Biologics, Medimmune, Mentholatum, MSD, Novartis, Perrigo, Pfizer, Reckitt Benckiser, Sanofi, Shire, Skyepharma, Takeda, Teva, Tusk Therapeutics, UCB, Vectura, Vertex

NGOs / Charities
AMS, Cancer Research UK, CaSE, Faculty of Pharmaceutical Medicine, MRC, Royal Society, Wellcome Trust
Trade Associations
ABHI, ABPI, AMRC, BGMA, BIA, BIVDA, CBI, CCRA, EMIG, NOAH, PAGB
Public Sector
Department for Business, Energy and Industrial Strategy, Department of Health, HRA, Innovate UK, IPO, MHRA, NICE, NIHR CRN, NOCRI, OLS, Scottish Manufacturing Advisory Group, Standards Development Team (BIS)
Others
Abingworth Venture Capital, Confluence Tax, CPI, National Biologics Manufacturing Centre, CT Catapult, Fieldfisher, FTI Consulting, One Nucleus, BioNow, MediWales, BioPartner, Kilburn and Strode LLP, N+1 Singer, NHS Blood and Transplant, Osborne Clarke, Powell Gilbert LLP, ProPharma Partners LLP, PwC, Quintiles, Simmons and Simmons, Slaughter and May LLP, SV Life Sciences

vii. Glossary

Term	Explanation
AAR	Accelerated Access Review – aims to speed up access to innovative drugs, devices and diagnostics for NHS patients
AMR	Anti-Microbial Resistance – Antimicrobial resistance is resistance of a microorganism to an antimicrobial drug that was originally effective for treatment of infections caused by it
API	Active Pharmaceutical Ingredient – the ingredient in a pharmaceutical drug that is biologically active
ATMP	Advanced Therapy Medicinal Product – including medicines which are based on genes, cells or tissues
Associate Member	A non-EU member state with access to the Horizon 2020 funding programme on par with EU member states
Biosimilars	A biologic medical product which is almost an identical copy of an original product that is manufactured by a different company
CHMP	Committee for Medicinal Products for Human Use – committee at the EMA responsible for preparing opinions on questions concerning medicines for human use
COMP	Committee for Orphan Medicinal Products – committee at the EMA responsible for reviewing applications seeking 'orphan-medicinal-product designation'
CVMP	Committee for Medicinal Products for Veterinary Use – committee at the EMA responsible for preparing opinions on questions concerning medicines for veterinary use
DCP	Decentralised procedure – procedure for authorising medicines in more than one EU Member State in parallel. It can be used for medicines that do not need to be authorised via the centralised procedure and have not already been authorised in any Member State
ECDC	European Centre for Disease Prevention and Control – independent agency of the EU with a mission of strengthening Europe's defences against infectious diseases
EIB	European Investment Bank – the EIB is the European Union's bank. It is the only bank owned by and representing the interests of the European Union Member States, working closely with other EU institutions to implement EU policy
EIF	European Investment Fund – a specialist provider of risk finance to benefit small and medium-sized enterprises (SME) across Europe, part of the EIB
EMA	European Medicines Agency – the EU agency for the evaluation of medicinal products
EMVS	European Medicines Verification System – the IT system used to underpin the serialisation aspects of the FMD
ERC	European Research Council – European body for funding of scientific and technological research
EU DPR	European Union Data Protection Regulation
EU Horizon 2020	Current EU Research and Innovation programme with nearly €80bn of funding available over 7 year (2014 – 2020)
EU MAA	EU Marketing Authorisation Application – the licensing application made by the developer of a pharmaceutical product to bring this product to market
EudraCT	European Union Drug Regulating Authorities Clinical Trials – the European Clinical Trials database for all clinical trials of investigational medicinal products with at least one site in the EU
EudraVigilance	European data processing network and management system for reporting and evaluation of suspected adverse reactions during the development of new drugs and for following the marketing authorisation of medicinal products

ESIF	European Structural and Investment Fund – With a budget of €454 billion for 2014-20, the ESIFs are the European Union's main investment policy tool
FMD	EU Falsified Medicines Directive – introduces tougher rules to improve the protection of public health with new harmonised, pan-European measures to ensure that medicines are safe and that the trade in medicines is rigorously controlled
GDP	Good Distribution Practice – a code of standards ensuring that the quality of a medicine is maintained throughout the distribution network, so that authorised medicines are distributed to retail pharmacists and others selling medicines to the general public without any alteration of their properties
GLP	Good Laboratory Practice – a code of standards concerning the testing of medicines in laboratories during their development
GMP	Good Manufacturing Practice – a code of standards concerning the manufacture, processing, packing, release and holding of a medicine
GVA	Gross Value Added – the measure of the value of goods and services produced in an area, industry or sector of an economy. GVA is output minus intermediate consumption; it is a balancing item of the accounts' production account
IDMP	Identification of Medicinal Products – set of five ISO norms which has been developed in response to a world-wide demand for internationally harmonised specifications for medicinal products
IMI	Innovative Medicines Initiative – a Public Private Research Partnership between the EU and industry
IPO	Initial Public Offering
IVDs	In-Vitro Diagnostics – a device which, whether used alone or in combination, is intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility
MHRA	Medicines and Healthcare products Regulatory Agency – executive agency of the Department of Health which is responsible for ensuring that medicines and medical devices work and are acceptably safe
MISG	Ministerial Industry Strategy Group – brings together government and the bio-pharmaceutical industry. The purpose of the group is to jointly consider how to promote a strong and profitable UK-based bio-pharmaceutical industry. The group is co-chaired by the Secretary of State for Health and the Chairman of the British Pharma Group
MRP	Mutual Recognition Procedure – any national marketing authorisation granted by an EU Member State's national authority can be used to support an application for its mutual recognition by other Member States
NIBSC	National Institute for Biological Standards and Control – global leader in the field of biological standardisation, part of the MHRA
NIH's SBIR	National Institute of Health's Small Business Innovation Research program – also known as America's Seed Fund, one of the largest sources of early-stage capital for technology commercialisation in the USA
Notified Bodies	A notified body in the EU is an entity in a member state to assess whether a product to be placed on the market meets certain preordained standards. For example, a notified body may designate that a medical device conforms to the EU Medical Devices Directive, enabling the device to be labelled with a CE mark
Orphan Medicines	Medicinal products intended for diagnosis, prevention or treatment of rare diseases/ disorders
Patent Box	Tax incentive allowing for a lower rate of Corporation Tax on profits earned from patented inventions and certain other innovations
PDCO	Paediatric Committee – the committee at the EMA that is responsible for assessing the content of paediatric investigation plans and adopting opinions on them
PRAC	Pharmacovigilance Risk Assessment Committee – committee at the European Medicines Agency that is responsible for assessing and monitoring safety issues for human medicines
PSUR	Periodic Safety Update Report – pharmacovigilance document intended to provide an evaluation of the risk-benefit balance of a medicinal product at defined time points post-authorisation
PV	Pharmacovigilance – the practice of monitoring the effects of medicines after they have been licensed, especially in order to identify and evaluate adverse reactions
QP	Qualified Person – A QP is legally responsible for certifying that each batch of a medicinal product is suitable for release for sale or for use in a clinical trial, and will be named on the manufacturer's authorisation
QPPV	Qualified Person Pharmacovigilance – the named individual responsible for ensuring a company meets its legal obligations for monitoring the safety of a medicinal product
Rapporteur	One of the two members of an EMA committee or working party who leads the evaluation of an application

RDP	Regulatory Data Protection – intellectual property right available for a limited duration which protects an innovator’s proprietary safety and efficacy data for its product. Prevents any other party, during the RDP term, from relying on the innovator’s proprietary data in order to obtain marketing authorisations and market follow-on generic products
RMS	Reference Member State – the Member State which evaluates the marketing authorisation application dossier and prepares the assessment report on behalf of the Concerned Member States in MRP and DCP
SPC	Supplementary Protection Certificate – an intellectual property right which extends exclusivity for a maximum of 5 years after a patent has expired
STEM	Science, Technology, Engineering and Mathematics
Translational Research	A rapidly growing discipline in biomedical research and aims to expedite the discovery of new diagnostic tools and treatments by using a multi-disciplinary, highly collaborative, "bench-to-bedside" approach
VC	Venture Capital
VMD	Veterinary Medicines Directorate – an executive agency, sponsored by the Department for Environment, Food & Rural Affairs, the VMD protects animal health, public health and the environment
WTO	World Trade Organisation

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