1. Who we are

1.1 The Association of the British Pharmaceutical Industry (ABPI) represents innovative research-based biopharmaceutical companies, large, medium and small, leading an exciting new era of biosciences in the UK. We represent companies who are researching and developing the majority of the current medicines pipeline, ensuring the UK remains at the forefront of helping patients prevent and overcome disease.

1.2 The products of the human life science sector are unique. Access to medicines support patients in Wales, the UK and across Europe to live longer lives that are more productive. However, Brexit presents a significant challenge to the development, clinical research, regulation, supply and trading of medicines.

1.3 Since the outcome of the referendum on the UK's membership of the European Union, the ABPI has worked closely with our members and colleagues across the sector. Our objective is to ensure that the UK life sciences sector is as strong as possible as the UK establishes a new relationship with the European Union (EU) in the interests of public health and safety, and that the medicine a patient needs is available to them where and when they need it.

1.4 From July 2016, the ABPI and BioIndustry Association (BIA) worked with the UK Government to establish a joint industry and Government forum to discuss the impact of the UK leaving the EU on UK life sciences - the UK EU Life Sciences Steering Group. The Steering Group published a policy report mapping out the key policy areas for the biopharmaceutical industry. The issues identified were:

- Trade and supply;
- Scientific research;
- Regulation of medicines;
- Access to talent.

2. Wales' future relationship with the European Union

2.1 Overview

2.1.1 The UK's membership of the EU has provided much of the scientific, regulatory and trade infrastructure for the pharmaceutical industry in Wales. As such, the negotiations that determine Britain's new relationship with the EU will be critical to medicines delivery to patients across our nation, and the future success of the pharmaceutical industry.

2.1.2 The impact on the supply chain for medicines in both the UK and EU of the post Brexit trading relationship on issues such as custom controls, tariffs and non-tariff barriers is uncertain. This has the potential to affect NHS Wales, its clinicians and patients.

2.1.3 Further, the implications on the timely access of patients' to new medicines and technologies will largely depend on the ability of the UK Government to secure their stated objective of retaining ongoing cooperation between the UK and EU on the regulation of medicines.

2.1.4 Ensuring that Wales has the right people available to undertake the research, development and basic science required for Life Sciences is fundamental to our nation's thriving health and wealth. It is imperative that the UK negotiates an agreement with the EU that facilitates ease of movement for highly skilled talent.

2.2 Trade and supply

2.2.1 The UK is a significant contributor to global medicines trade and supply. In 2015, the UK imported approximately £29.7bn in Life Sciences goods, and exported £29.5bn, of which 44% went to the EU. Europe and the UK have profoundly integrated supply chains, which affects both finished medicinal products and component products.

2.2.2 Should trade between the UK and EU be subject to customs duties, import VAT and border controls (import/export declarations and inspections/goods' testing), this would cause significant disruption to the medicine supply chain, i.e. customs delays have the potential to impact on the availability of medicines for patients. This is particularly relevant for medicines that are time and temperature sensitive, such as cutting-edge cell and gene therapies. With the importance given to such medicines by the Welsh Government – and, of course, patients, the UK Government should

take into account the specific requirements of pharmaceutical products when negotiating new customs and trade arrangements with the EU.

2.2.3 Separate to the EU Customs Union, is the World Trade Organisation (WTO) Pharmaceutical Tariff Elimination Agreement. The agreement enables exports to signatory countries for many pharmaceutical products (including biologicals and monoclonal antibodies) at 0% tariff. Unlike medicines, APIs, intermediates and starting materials are only covered by the agreement for zero duty if they are listed in an Annex to the Agreement. The last update was in 2010 and included 735 new products. Should UK-EU trade rely on WTO arrangements post-Brexit, the agreement must reflect all finished and component pharmaceutical products.

2.2.4 Due to the complexity of import/export declarations and inspections, and the existing integrated nature of supply chains, the UK should seek to negotiate the ability to maintain frictionless trade and movement of goods and capital across borders with the EU for pharmaceuticals and medical supplies, through;

- Maintaining trading terms for Life Sciences goods and services that are equivalent to those of a full member of the EU Customs Union and EC common system of VAT;
- Continued alignment of Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) standards with the EU, and reach an agreement that allows batch testing, Qualified Person (QP) certification and regulatory inspections to be mutually recognised between the EU and UK;
- Reaching an agreement with the EU to maintain the benefits of the Parent Subsidiary and Interest & Royalties Directives;
- Current discussions on the WTO Pharmaceuticals Agreement should be urgently concluded and updated to cover all finished and component pharmaceutical products;
- Fully explore new opportunities for trading, including opportunities to consider wholesale customs valuation reform.

2.3 Scientific Research and Collaboration

2.3.1 The UK has been 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 states between 2007 and 2013,

the UK received a total of €8.8bn, including €1.9bn in ESIF funding, €1.7bn from the ERC and €1.1bn from Marie-Curie.

2.3.2 The ABPI welcomes the UK Government's commitment to underwrite funding for Horizon 2020 projects secured while the UK remains an EU member. However, access to EU research funding beyond the existing Horizon 2020 round of funding is unknown. The UK's eligibility for EU-wide research collaborations also enhances its position as a global research leader, i.e. leading the highest number of Innovative Medicines Initiative (IMI) projects, which speed up the development of new medicines in Europe.

2.3.3 The UK's ability to adopt the new Clinical Trials Regulation for medicines is also likely to impact on the availability of new medicines to UK patients' post-Brexit. The regulations, due for commencement in 2019, are designed to encourage and streamline the approval of pan-European trials, with a single application designed to deliver speed and efficiency. Wales and the UK will become less appealing for clinical trials if they do not have access to the EU clinical trials portal and database. Participation in this common framework is also important in ensuring our patients have access to new medicines and treatments.

2.4 Medicines regulation

2.4.1 The ABPI warmly welcomed statements by the UK Government indicating that achieving cooperation between the UK and EU is an objective of negotiations. We also welcomed the inclusion of cooperation in the Government's recent Collaboration in Science and Innovation and of "grandfathering" in the Continuity in the Availability of Goods for the EU and the UK.

2.4.2 The UK Medicines and Healthcare products Regulatory Agency (MHRA) was Rapporteur for about 20% of centralised procedures for marketing authorisation and performed over 30% of GMP inspections coordinated by the EMA. UK-based legal entities hold approximately 1,000 centralised licences, which would have to transfer to an EU-based legal entity if there is no agreement on retaining ongoing cooperation with the EU on the regulation of medicines. Additionally, regulatory procedures for which the UK MHRA is the lead assessment agency would reassign to an EU Member State agency. The processes for making these changes will add significant burden to companies and regulators' capacity to progress regulatory activities related to medicine quality, safety and efficacy.

2.4.3 ABPI shares the MHRA and UK Government's ambition for patients to have continued access to best and most innovative medicines through a close working relationship with Europe, underpinned by the strongest regulatory framework and the sharing

of data. We shall continue to work towards this. However, if such cooperation is not achievable, we welcome the MHRA's intent to take a pragmatic approach. Planning for this scenario requires further detail, and further highlights why a realistic implementation period needs to be urgently agreed. For patients and the public there are very real consequences of failing to get this right and ABPI will continue to work with our members, regulators, governments and the Commission to mitigate these risks.

2.4.4 It is also crucial that the UK honours intellectual property protections. Any loss or reduction of intellectual property protections would dis-incentivise the development and launch of medical technologies in the UK – an area of particular interest for the Welsh economy. Protections are key to incentivising the lengthy, risky and expensive process of pharmaceutical and biotech innovation. Europe benefits from an a standard of intellectual property which promotes innovation, in the form of Supplementary Protection Certificates (SPCs), regulatory data protection (RDP), orphan designation (for rare diseases) and rewards for investigations into paediatric uses and formulations. EU pharmaceutical incentives are currently under review and it is important that the UK actively participates, to ensure that Europe as a whole retains a supportive environment for innovation in medicines.

2.4.5 A standalone UK medicines regulatory system, with inherent duplication of processes, increased costs and divergence of standards will lead to increased considerable delay or no regulatory submission to develop new medicines in the UK. For global companies, the UK market - 3% of global pharmaceutical sales - is not sufficiently large to justify significant additional costs. There is a risk that this would lead to the UK becoming a second priority market for new products.

2.4.6 For the mutual benefit of patients and the life sciences sector, the UK should seek to negotiate alignment and commonality with the EU for the regulation of medicines, through:

- Seeking a regulatory cooperation agreement between the UK and EU or a mutual recognition agreement with the European Medicines Agency;

- Agreeing continued alignment of current and future regulations;

- Ensuring continued UK participation in EU regulatory and medicines safety processes.

2.5 Access to Talent

2.5.1 Currently, non-UK, EU nationals make up around 17% of Science, Technology, Engineering and Mathematics (STEM) academics at UK research institutions. Underpinning the UK's position as a leader in Life Sciences is the ability to attract, develop and retain a highly skilled workforce. This is particularly crucial in skills gap areas such as clinical pharmacology and bioinformatics. The ability to attract top talent will be critical if Wales is to become a leader in emerging areas e.g. device technologies, digital health, physiological modelling, genomics and advanced manufacturing. There needs to be a UK immigration system that is needs based, straightforward and rapid – not just for EU but also for other workers.

2.5.2 The UK should seek to negotiate an agreement with the EU that facilitates the ease of movement for highly skilled talent in Life Sciences, through:

- Agreeing a reciprocal arrangement with the EU that facilitates ease of movement for scientists, researchers and highly-skilled workers, maintaining current systems such as the Intra-company Transfer process;

- Guaranteeing the rights of scientists, researchers and highly skilled EU citizens already in the UK, alongside securing the rights of UK citizens working and operating in the EU.