Thank you for the opportunity to provide our views on the implications for Wales of Britain exiting the European Union. We appreciate that, in particular, the Committee would welcome views on the following questions:

- What should be the top priority for Wales in advance of the UK Government triggering of Article 50 (which starts the formal process of exiting the EU)?
- Can you provide examples of where the UK's proposed approach to transferring the acquis communautaire (the body of European law), through the proposed Great Repeal Bill, into domestic law might have particular implications for Wales?

Our submission will concentrate on the second of these questions.

Who We Are:

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.

Our industry, a major contributor to the economy of the UK, brings life-saving and life-enhancing medicines to patients. We represent companies who supply more than 80 per cent of all branded medicines used by the NHS and who are researching and developing the majority of the current medicines pipeline, ensuring that the UK remains at the forefront of helping patients prevent and overcome diseases.

Globally our industry is researching and developing more than 7,000 new medicines.

The ABPI is recognised by government as the industry body negotiating on behalf of the branded pharmaceutical industry for statutory consultation requirements including the pricing scheme for medicines in the UK.

Contact Details:

This submission is made on behalf of The Association of the British Pharmaceutical Industry by:

We would be happy for this submission to be made public.

We would be happy to provide further evidence – either oral or written – if the Committee would find this useful.

Can you provide examples of where the UK's proposed approach to transferring the acquis communautaire (the body of European law), through the proposed Great Repeal Bill, into domestic law might have particular implications for Wales?

1. The members of the Association of the British Pharmaceutical Industry (ABPI)[i] do not want to see Brexit derail progress and investment in the pharmaceutical and life sciences sector in Wales - or indeed across the rest of the UK. We want to ensure that patients in Wales benefit from the health and wealth achievable from strengthening the research, development, manufacture and use of novel medicines and treatments. Moreover, we want to see the research partnerships, manufacturing and jobs from our industry continue to grow in Wales.

2. In Wales, according to Welsh Government figures[ii], the life sciences sector employs around 11,000 people based at more than 350 companies and delivers a turnover of circa £2bn per year. These include companies in the ground-breaking fields of medical technology – biopharmaceuticals, regenerative medicine, diagnostics, e-health and biotechnology. Recognising this inherent strength and potential, the Welsh Government has established initiatives such as the Life Sciences Hub[iii] and Life Sciences Research Network Wales[iv] to ensure ongoing development of the sector in Wales, which is expected to deliver significant (over £1bn) economic impact by 2022.

3. However, with so much of the research, regulation and manufacture of medicines closely tied to arrangements established at the European level, the challenge for the whole United Kingdom will be to work together to understand the issues and take advantage of the opportunities that Brexit presents.

4. Representing the research-based pharmaceutical industry across the UK, the ABPI responded quickly to the outcome of the Referendum, and worked with the then UK Minister for Life Sciences, George Freeman, to establish a task force for the life sciences sector. Together with our trade association colleagues at the BioIndustry Association

(BIA)[v], we were charged with the task of bringing together industry experts from across our membership and the wider life sciences sector (including medical technology, diagnostics, over-the-counter medicines, generic medicines and animal health) to summarise the key needs and opportunities that must be addressed in future negotiations.

5. This work provides the basis for discussions with Governments across the UK, and stands as a resource for industry, stakeholders across the healthcare ecosystem and policymakers for the months and years of negotiations to come. It is available at http://www.abpi.org.uk/our-work/library/industry/Documents/UK-EU-Steering-Group-Report.pdf

6. What is clear is that it will take years to complete the journey. With forty years of medical regulation and rule-making to be untangled, there is no doubt that the challenge of establishing Britain's future relationship with Europe – and the rest of the world – will be daunting and complex. To successfully navigate this, and reset the entire United Kingdom as a place for business and research in life sciences, we will need to understand our priorities – and after conducting the initial work with our members and partners, we broadly identified four.

7. Firstly, we need to reinforce our strengths in research and innovation. The UK and Wales has a proud heritage of excellence in the life sciences, and we will need to reassert our science community as both a contributor and leader in international networks both through the practicality of funding and membership in research platforms, as well as through exploration of new opportunities for partnership. If Governments are confirming that "the UK is open for business"; we should also ensure that "the UK is open for innovation", exploring opportunities to continue collaboration, translational mechanisms and adoption for science to directly benefit patients and society.

8. Secondly, we need to agree on a roadmap to develop or at least sustain the regulation that we need to discover, develop, manufacture and supply medicines for patients. The EU-wide framework of regulation that ensures benefits and safety for patients and enables effective innovation in life sciences has taken decades to achieve – and it remains a work in progress.

9. Britain's regulator, the Medicines and Healthcare products Regulatory Agency (MHRA)[vi], has been a leading contributor to this shared regulatory framework. As such, we see the value in exploring opportunities with it, whilst also recognising the importance of regulatory cooperation and harmonisation with the EU, which has delivered valued clinical research, new medicines and a medicines safety system for the benefit of patients in the UK and across Europe. A reset of our regulatory relationship with Europe in this particular instance does not have to involve a revolution. However, care is needed to ensure that the result does not leave UK, including Welsh, patients out in the cold.

10. Medicines are developed, manufactured and distributed on a global basis, with complex supply chains established to follow demand and trading arrangements. To minimise disruption and the cost of delivering medicines for patients in the UK, we look to the Government to negotiate the best possible opportunities to trade freely and move goods and capital across borders. From financial services to the automotive industry, we know this is a sentiment shared by many sectors of the economy. However, this has particular importance for medicines when we consider the additional impact on public health.

11. Given the clear imperative to resolve these matters for patients and public health, ABPI, again working in partnership with BIA, is engaging with different Government departments in a series of "deep dive" working groups. These will map out both the transition plans for the years leading up to our exit from the EU and the challenges for "Day 1"; as well as the strategic plans for what comes next for the discovery, development, manufacturing and delivery of medicines for our health service, patients

and the broader community of the UK. We will draw this work together with the critical industrial strategy planning upon which the UK Government is now embarking.

12. As we have begun to identify, addressing the challenges and realising the opportunities that Brexit presents for the research, regulation and manufacture of medicines will be complex. Yet, despite all of this, we must look to make it a success. In our sector, this is not just important for the economy, but is crucial for patients, for their families and for the future of the NHS.

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[i] http://www.abpi.org.uk/Pages/default.aspx
[ii] http://gov.wales/topics/businessandeconomy/sectors/life-sciences-sector/?lang=en
[iii] https://www.lifescienceshubwales.com/
[iv] http://www.lsrnw.ac.uk/
[v] https://www.bioindustry.org/home/
[vi] https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency