

Cyflwynwyd yr ymateb i ymgynghoriad y [Pwyllgor Iechyd a Gofal Cymdeithasol](#) ar y [effaith pandemig COVID-19, a'i reolaeth, ar iechyd a gofal cymdeithasol yng Nghymru](#)

This response was submitted to the [Health and Social Care Committee](#) consultation on [the impact of the COVID-19 pandemic, and its management, on health and social care in Wales](#)

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Ymateb gan: | Response from: Association of the British Pharmaceutical Industry (ABPI) Cymru Wales

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The impact of the COVID-19 pandemic, and its management, on health and social care in Wales – ABPI Cymru Wales Response



Who We Are:

The Association of the British Pharmaceutical Industry (ABPI)ⁱ exists to make the UK the best place in the world to research, develop and use new medicines. We represent companies of all sizes who invest in discovering the medicines of the future. Our members supply cutting edge treatments that improve and save the lives of millions of people. We work in partnership with Governments and the NHS so patients can get new treatments faster and the NHS can plan how much it spends on medicines. Our members are playing a leading role within the UK and globally in responding to COVID-19, which we will discuss later in this submission.

Thank you for the opportunity to respond to your inquiry on the impact of the COVID-19 outbreak, and its management, on health and social care services in Wales. We hope that this response, as well as helping you to consider the impact on staff, patients and others receiving care or treatment in both clinical settings and the community will also give you some insight into how our industry has been supporting NHS Wales. If there are specific questions about the efforts of our members or any aspect of this submission, please get in touch.

The Life Sciences sector in Wales employs around 11,000 people in well-paid, high-quality jobs and has exports of approximately £980mⁱⁱ. Two ABPI members have significant manufacturing facilities in Wales: Norgineⁱⁱⁱ (in South Wales) and Ipsen^{iv} (in North Wales). Other members have field presence across Wales, and some are working collaboratively with the Welsh Government, NHS Wales, third sector and/or academia^v.

Since the start of the pandemic, the pharmaceutical industry has been committed to working with governments and partners around the world to make COVID-19 treatments and vaccines available and affordable for the patients that need them^{vi,vii}. Working collaboratively^{viii}, we have aimed to support the health and social care systems across Wales, with priorities focussed on:

- Researching and developing safe and effective treatments and vaccines for COVID-19
- Securing the supply of medicines for patients
- Supporting the NHS in responding to the crisis, by drawing on our member's expertise

Researching and developing safe and effective treatments and vaccines for COVID-19

The global R&D effort in response to the COVID-19 pandemic has been unprecedented in terms of scale and speed. Multiple companies and partnerships have looked at the development and manufacturing of COVID-19 vaccines and therapies, some of which have now been successfully rolled-out across the globe. Even now, in January 2022, there are a further 137 vaccine candidates in clinical development, with 194 in pre-clinical development^{ix}. These new candidates are based on different technologies or investigate new routes of administration or dosing regimens.

The global response to COVID-19 has seen the usual timescale for vaccine development significantly condensed. This has been due to factors, including:

- International **collaboration** on a scale never seen before, between industry, national governments, and academia
- Building upon decades of **knowledge and experience** with similar diseases like MERS and SARS, and directing this towards developing COVID-19 vaccines
- **Rapid genomic sequencing** of the virus when it was first discovered, enabling better understanding of its genetic blueprint, and providing a clearer target for research and development efforts
- Regular **communication and dialogue** between vaccine developers and regulators, to identify and address barriers in the research and development process
- Prioritisation of promising COVID-19 research through the establishment of Urgent Public Health Studies^x in the UK (and similar initiatives abroad), which enabled the **quick approval and set up of clinical trials** and supported **large scale patient recruitment** over a short period of time
- Undertaking stages of **development in parallel** rather than sequentially to increase efficiency, despite this approach posing significant financial risk to companies

Vaccine manufacturers worldwide are now producing 1.5 billion doses per month, and this is expected to continue growing. 12 billion vaccines were anticipated to be produced by the end of 2021 and, if there are no major bottlenecks, by June 2022 total vaccine production is estimated to reach over 24 billion by which time vaccine supplies will most likely outstrip global demand^{xi}.

With multiple COVID-19 vaccines now authorised for use in the UK, and potentially others to follow, it is important that the public continues to recognise that the speed of development is the result of unprecedented 'at-risk' funding, collaborative research efforts, the use of new

technology and analytical tools, the involvement of thousands of people in clinical trials, and crucially, running stages of development in parallel rather than sequentially. This is equally relevant – and critical – for ensuring confidence in COVID-19 therapeutics.

Since the beginning of the pandemic, companies have been developing new medicines, sometimes called therapeutics, specifically designed to treat COVID-19 and its symptoms across all stages; from prophylaxis for people exposed to the virus, to patients with early or mild symptoms, to critically ill patients, as well individuals dealing with symptoms of long-COVID. Given these are tailored medicines, they could potentially have a significant impact on patient groups and remain critical for those who are currently not advised to come forward for vaccination. Researchers around the world are investigating 650 therapeutic candidates (antivirals and treatments)^{xii,xiii} in addition to those which are becoming regularly available^{xiv}. It is key that sufficient support and prioritisation is given to facilitate all phases of trials for such novel therapeutics, but that this is extended across all therapy groups when appropriate.

In 2018 (the last year for which figures are currently available and before the impact of the COVID-19 pandemic), expenditure by the pharmaceutical industry on research and development in Wales amounted to £37m^{xv}. The integration of clinical research as part of service delivery and treatment for COVID-19 patients has been rapid and effective. ABPI have previously argued^{xvi} that Welsh Government should take the learnings from this ‘fast-tracked’ integration to expand the adoption of non-COVID clinical research at scale within service delivery and initiate new trials at pace within NHS Wales, to make it a more attractive and progressive location to undertake clinical research in the future^{xvii,xviii}. This should include allowing managed access to system wide analytics and moving towards the routine use of digital technology for data collection and monitoring; building on the use of telemedicine; and the use of e-consent. Improved understanding and experience with virtual communication systems throughout COVID-19 opens the door for improved engagement with patients, home nursing, and for some clinical trials, could enable patient involvement without regular visits to a hospital or trial site.

Securing the supply of medicines for patients

Core to our ability to support patients throughout COVID-19 has been ensuring the pharmaceutical supply chain remains strong and resilient. Over decades, pharmaceutical manufacturers have carefully built robust global supply chains to ensure patients in Wales, the UK and around the world have ongoing access to medicines.

The need for global supply chains is four-fold, to ensure that:

- i. Medicines and vaccines are manufactured through internationally recognised regulatory standards to ensure both their quality and safety
 - ii. Companies can manufacture according to national demand at the scale needed to provide the volume of medicines and vaccines to serve all patients across the globe
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- iii. Supply chains are robust and resilient, with diversity key to the success of supply chains, enabling manufacturers to adjust as needed to ensure stability and avoid potential shortages or disruptions
- iv. Medicines and vaccines are distributed fairly and equitably to all health systems, including NHS Wales

There has undoubtedly been extraordinary international demand for certain medicine classes, but pharmaceutical business continuity plans have proven to be remarkably resilient. International coordination and information sharing within global companies, and an enormous effort on behalf of industry to ramp up and where necessary redirect manufacturing has ensured patients in Wales have continued to be able to access the critical medicines they need.

Of the more than 12,000 different prescription medicines used by NHS Wales, during the COVID-19 response period only a small number triggered an NHS 'supply disruption alert'. In each of these cases, the potential negative impacts were limited by careful co-ordinated management by suppliers and the NHS whilst instigating the sourcing of alternative supplies or through publishing clinical advice on the management of affected patients when necessary.

In support of the NHS, throughout the pandemic ABPI members have prioritised the supply of medicines, vaccines, and health technologies to patients, mitigating any impacts by tweaking their global supply and manufacturing efforts. The global supply chain proved to be resilient, and the pharmaceutical industry was overwhelmingly able to continue to meet the exceptional demand for prescription medicines throughout the pandemic. Looking to the future, we would encourage greater consideration of the impact clinical, geographical, and behavioural changes can have on the supply of medicines. Understanding demand is a critical component of a resilient supply chain and it is vital that pharmaceutical companies and trade associations receive advance notice of any expected impact on medicines or vaccines supply, to ensure planning, preparations and contingency arrangements can be put in place, where required.

As the COVID-19 threat emerged in 2020, the Medicines & Healthcare products Regulatory Agency (MHRA)^{xix} very quickly sought to engage industry on regulatory agilities that would secure supplies of critical medicines to the NHS intensive treatment units (ITUs) and allow pharmaceutical companies to concentrate their resources on the development of vaccines and therapies. There was international regulatory cooperation to lower barriers to access across borders and with MHRA leadership in the harmonisation on reviews of safety data as the clinical trials unfolded. Throughout the pandemic, the MHRA has developed new ways of working, rapidly responding to changing circumstances. The experience of the MHRA during the crisis demonstrates that there are a range of new ways of working and policy changes

that can deliver a forward-looking, agile regulatory environment with patient protection at its core.

Similarly, from Spring 2020, the National Institute of Health and Care Excellence (NICE)^{xx} led the production of rapid guidance to respond to the challenges, delivered to colleagues across NHS Wales through the All Wales Medicines Strategy Group (AWMSG)^{xxi}, which offered an effective route to deliver the rapid re-start of clinical procedures. The learnings from this should be factored into the evolution of NICE methods^{xxii} and AWMSG activities to support patients receiving faster access to innovative treatments. The Committee should urge the Welsh Government to encourage the widespread use of new, innovative treatments and embed them at pace and scale to provide greater options for patients whilst increasing service effectiveness and efficiencies.

As the NHS begins to reintroduce services and procedures, it is critical that this effort is not confined to internal NHS planning and preparation to the exclusion of other stakeholders and contributors. Change in patient pathways and practices will impact on patients and other non-NHS partners in health, including the suppliers of medicines whose buy-in, planning and preparation is likely to be critical to overall success. Following experiences through COVID-19, the criticality of a co-produced and collaborative approach to delivery has become obvious. We do hope these learnings become recognised good practice in the provision of all aspects of healthcare into the future. We have considered aspects of NHS Recovery previously from an UK and Wales specific perspective^{xxiii, xxiv}.

Equal thought must also be given to cementing safe and effective changes in clinical practice, where innovative medicines used early in treatment pathways have been demonstrated to slow and prevent disease progression and/or minimise patients requiring secondary care or tertiary support. Examples have included moving patients requiring anti-coagulation away from warfarin, which necessitates extensive monitoring, and towards innovative, direct (or novel) anti-coagulants (DOACs/NOACs)^{xxv}. COVID-19 again created drivers for the expanded and fast-track use of innovation to minimise the risk associated with location-based care. Similar challenges will remain into the future as the NHS battles its way through extended and expanded waiting lists. It is critical that the early and widespread adoption of proven innovation continues to be recognised as a suitable and appropriate way forward.

Supporting the NHS in responding to the crisis, by drawing on our member's expertise

The pharmaceutical industry sees itself as a fully-fledged partner to the NHS in the provision of healthcare services. ABPI and its members understand that the pharmaceutical industry has been uniquely placed during the pandemic to respond through the development of new treatments and vaccines, the supply of medicine, and the use of our diagnostic testing expertise. This was actively demonstrated during the height of the COVID-19 pandemic,

when our members consistently contributed over and above their usual activities and functions, volunteering employees to directly help the NHS effort and donating treatments and equipment across our health service^{xxvi}.

As previously discussed, during and following the earlier waves of the pandemic, the ABPI is aware that some care and treatment pathways were augmented and fast-tracked, to better support patients. Similar challenges remain as the NHS battles its way through extended and expanded post COVID-19 waiting lists. It is critical that the early and widespread adoption of different models of care continues to be recognised as a suitable and appropriate way forward. The pharmaceutical industry is keen to play its part in supporting these changes.

Both early engagement opportunities and a clear demonstration of the NHS's willingness to collaborate would enable our members to identify areas where they can continue to support NHS Wales in the future. Since the start of the pandemic, everyone involved in the health system has talked more about innovation in, and transformation of, our services in Wales than at any other time. We've seen the way services are delivered in Wales evolve, sometimes beyond all recognition, and everyone is agreed that it sets us on the right path to deliver patient care, which is safe and sustainable across the whole of our country for the years ahead. We cannot afford to abandon or forget the developments that have enabled the health system under COVID-19 as the future challenges for post-COVID NHS recovery may be as great and longer lasting.

There has also been a recognition that the effective delivery of those services will benefit from greater collaboration across all sectors, something we would ask the Committee to support. This must be fundamental to the road to our recovery and the introduction of equitable services for the future. Collaborations between NHS Wales organisations, ABPI members, and other pharmaceutical companies can provide additional expertise and resources in the future and, working alongside the Welsh NHS Confederation, ABPI produced a Toolkit to support this^{xxvii}, which we've recently updated to take account of changes made to the latest iteration of the ABPI Code of Practice for the Pharmaceutical Industry^{xxviii}. The updated ABPI Code sets out new requirements for the pharmaceutical industry and supports our ongoing commitment to self-regulation and to working in a professional, ethical, and transparent manner.

Collaborative Working and Joint Working projects aim to deliver 'triple wins' in the form of benefits to patients, the NHS and the pharmaceutical company or companies involved and reinforce a key part of the Welsh Government's long-term plan for health and social care, A Healthier Wales^{xxix}. We hope that the published toolkit helps all our colleagues' aspirations to support patients, and health and care organisations; to deliver the very best services, wherever they are in Wales. We have committed to its continued development as we learn more, together, and can provide greater evidence of the benefits that can be derived for everyone of transparent and equitable collaboration.

In Conclusion:

Looking to the future, the ABPI and our members will continue to support the NHS in Wales, and our colleagues across all related sectors, to mitigate and recover from the impact of the COVID-19 pandemic.

During its ongoing inquiry, we would ask the Committee to consider:

- The important role that could be played by the greater integration of clinical research for all patients; to expand adoption of clinical research across service delivery and initiate new trials at pace within NHS Wales, making it a more attractive place to undertake clinical research in the future^{xxx}.
- Asking the Welsh Government to ensure that the impact of clinical, geographical, and behavioural changes in their policies fully consider the impact on the supply of medicines; that the vital role pharmaceutical companies can play is reflected in routine stakeholder engagement, ensuring early, advance notice of anticipated changes to medicines or vaccines supply requirements.
- The role that progressive regulation alongside safe and effective changes in clinical practice can play, where innovative medicines used early in treatment pathways have been advocated to slow and prevent disease progression and/or minimise patients requiring secondary care support.
- Encouraging Welsh Government to provide ongoing support for the widespread use of new, innovative treatments, embedding them at pace and scale to provide greater options for patients whilst increasing service effectiveness and efficiencies.
- The role that could be played by collaborations between NHS Wales organisations, ABPI members, and other pharmaceutical companies; the additional expertise and resources available to improve effective delivery of services on the road to our recovery and the introduction of improved services for the future.

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- i <https://www.abpi.org.uk/>
- ii <https://shubwales.com/>
- iii <https://norgine.com/>
- iv <https://www.ipson.com/>
- v <https://www.abpi.org.uk/media/8107/abpi-cymru-wales-spring-bulletin-2020-for-publication.pdf>
- vi <https://www.abpi.org.uk/covid-19/>
- vii <https://www.ifpma.org/resource-centre/pharma-joins-global-pledge-committing-to-work-together-to-beat-covid-19/>
- viii <https://www.abpi.org.uk/covid-19/what-are-pharmaceutical-companies-doing-to-tackle-covid-19/>
- ix <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>
- x <https://www.nihr.ac.uk/covid-studies/>
- xi <https://www.ifpma.org/resource-centre/momentum-of-covid-19-vaccine-manufacturing-production-scale-up-is-now-sufficient-for-step-change-in-distribution-and-opens-way-for-urgent-political-leadership-and-country-preparedness/>
- xii <https://www.bio.org/policy/human-health/vaccines-biodefense/coronavirus/pipeline-tracker>
- xiii Treatments include a large proportion of 'redirected' or 'repurposed' medicines, especially in the immunological/anti-inflammatory classes. A much larger proportion - 71% - of the antivirals have been targeted specifically at COVID-19.
- xiv <https://www.bbc.co.uk/news/health-52354520>
- xv <https://www.ons.gov.uk/economy/governmentpublicsectorandtaxes/researchanddevelopmentexpenditure/adhocs/11347researchanddevelopmentexpenditureinthepharmaceuticalsproductgroupperformedinukbusinessesbycountryorregion2018>
- xvi <https://business.senedd.wales/mgConsultationDisplay.aspx?id=398&RPID=1530682536&cp=yes>
- xvii <https://business.senedd.wales/documents/s101374/C18%20-%20Association%20of%20the%20British%20Pharmaceutical%20Industry.pdf>
- xviii <https://www.abpi.org.uk/covid-19/life-sciences-recovery-roadmap/>
- xix <https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>
- xx <https://www.nice.org.uk/>
- xxi <https://awmsg.nhs.wales/>
- xxii <https://www.nice.org.uk/news/article/nice-s-processes-of-technology-evaluation-presenting-a-case-for-change>
- xxiii <https://www.abpi.org.uk/publications/life-sciences-recovery-roadmap/>
- xxiv <https://abpi.box.com/s/4zsi2qllno4rsgnheiqzrrdd0iosttw6>
- xxv https://gov.wales/sites/default/files/publications/2021-02/directions-to-local-health-boards-as-to-the-statement-of-financial-entitlements-directions-2021_0.pdf
- xxvi <https://www.abpi.org.uk/media/1hqfh2i0/abpi-cymru-wales-summer-bulletin-2020-v3.pdf>
- xxvii <https://www.abpi.org.uk/publications/collaborative-working-and-joint-working-a-toolkit-for-industry-and-nhs-wales/>
- xxviii <https://www.abpi.org.uk/publications/code-of-practice-for-the-pharmaceutical-industry-2021/>
- xxix <https://gov.wales/sites/default/files/publications/2019-10/a-healthier-wales-action-plan.pdf>
- xxx <https://business.senedd.wales/documents/s101374/C18%20-%20Association%20of%20the%20British%20Pharmaceutical%20Industry.pdf>