

C 18

Ymchwiliad i effaith Covid-19, a'r modd y mae'n cael ei reoli, ar iechyd a gofal cymdeithasol yng Nghymru

Inquiry into the impact of the Covid-19 outbreak, and its management, on health and social care in Wales

Ymateb gan Gymdeithas Diwydiant Fferyllol Prydain

Response from Association of the British Pharmaceutical Industry

Welsh Parliament Health, Social Care and Sport Committee Inquiry – COVID-19

Background

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 in the wider, UK context. If there are specific questions about the efforts of our members or questions about any aspect of this submission, please get in touch.

The Association of the Pharmaceutical Industry (ABPI) represents pharmaceutical companies of all sizes who invest in researching and developing new medicines and vaccines. 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. The evidence provided in this submission therefore relates to medicines and vaccines developed and manufactured by the innovative pharmaceutical industry and may or may not apply to generic or over the counter medicines.

ABPI and its members understand that the industry is uniquely placed to respond to the current crisis through the supply of medicine, the development of existing treatments and vaccines and the use of our diagnostic testing expertise. In addition to these efforts the industry has volunteered its own employees to help the NHS effort and have donated treatments and kit to our health service.

Key points

- Over the last few months, NHS Wales has responded to COVID-19 with unprecedented speed to bring about complete repurposing of services, staffing and capacity. This achievement cannot be overstated and retaining positive changes in clinical practice and

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renewing NHS Wales systems can improve our resilience for future pandemic surges and support patients to live healthier lives with the need for fewer interventions.

- Our members are prioritising getting medicines, vaccines and health technologies to patients and are working hard to mitigate any impacts on their global supply and manufacturing efforts.
- The global supply chain has proven to be resilient, and industry has largely been able to continue to meet the exceptional demand for prescription medicines over the last few months. Of the more than 12,000 different prescription medicines used by the NHS, during the COVID response period only four products have triggered a ‘supply disruption alert’ to date. In each of these cases, negative impacts have been limited by sourcing alternative supplies or through publishing advice on the management of affected patients.
- Around 72% of confirmed active vaccine candidates in development are being led by private/industry developers with the remainder being led by academic, public sector and other non-profit organisations¹ – multiple projects are already in the human trials phase.
- The pharmaceutical industry sees itself as a fully-fledged partner to the NHS in the provision of healthcare services. This has been actively demonstrated during the COVID-19 crisis where our members have consistently contributed over and above the simple supply of medicines and vaccines. Early engagement and willingness to collaborate in joint-working would enable our members to identify areas they can support during the period of COVID-19 recovery on into the future,
- The integration of clinical research as part of service delivery and treatment for COVID patients has been rapid and effective. Welsh Government should take learnings on how to integrate clinical research at scale within service delivery and how to initiate new trials at pace within NHS Wales, to make it a more attractive place to undertake clinical trials in the future.

1. The role of the pharmaceutical industry in fighting COVID-19

To mitigate the impact of this unprecedented global health emergency, the innovative pharmaceutical industry has participated in coordinated, inclusive, and multi-stakeholder action across the world. Our members continue to play a key role in responding to this crisis, whether through:

- providing and prioritising delivery of critical products to tackle COVID-19, whilst also meeting ongoing needs from other existing health conditions,
- researching and developing new health technologies, and re-purposing those already existing, including preventive tools, diagnostics, treatments, medicines, and vaccines,
- ensuring there is capacity to “scale-up” production as necessary, re-directing manufacture of urgently needed products as required,

or other routine, and sometimes extraordinary, endeavours.

Research and Development activity to combat COVID-19 has mobilised at a scale and pace never seen before, building upon scientific advancements over many decades, and thanks to collaborative research activity from industry, academia, research charities and governments around the world. Around 72% of confirmed active vaccine candidates in development are being led by private / industry developers with the remainder (28%) being led by academic, public sector and other non-profit organisationsⁱⁱ. Multiple projects are already in the human trials phase, but whatever technology is used to create a vaccine, we need to be realistic about the timescales involved. New technologies have dramatically shortened the time it takes to decode viruses and develop potential vaccines, but there is no shortcut to the testing that is needed to make sure each vaccine is safe and effective.

Decisions will need to be made as to which patients' groups will have priority access and how vaccination can be used most effectively protect those at greatest risk. Achieving this will require the NHS to work with professionals across primary care and community settings. Efforts must also be made to understand and build public confidence so that any potential barriers to people coming forward for vaccination can be identified and addressed with the aim of achieving optimum levels of uptake in target populations.

Patient safety must always remain the number one priority. The industry recognises that its work will be central to life returning to normal. ABPI is constantly monitoring the R&D efforts of our members and regularly updates its websiteⁱⁱⁱ with examples of what is happening globally to combat the pandemic.

The Committee may wish to recommend that Welsh Government and NHS Wales continue to work proactively with government partners across the UK, and globally. This would include the pharmaceutical industry, academic institutions, and our citizens to ensure support for ongoing research and development to address the current pandemic.

2. Supporting NHS Wales Service Delivery

Since the outbreak of the pandemic, our members have made clear their desire to assist NHS Wales and the Welsh Government. Inputs have ranged from delivering vital medicines, vaccines, and health technologies through to offering the services of their employees, including clinical staff. At the end of March, the Welsh Government Chief Pharmaceutical Officer wrote to ask ABPI members to provide volunteers to support medicines delivery to the most vulnerable in Wales. We are pleased that this call has been answered by many of our members^{iv}.

However, core to our ability to support patients is ensuring the pharmaceutical supply chain remains strong. 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
- 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

To date, UK supply has held up remarkably well. The NHS uses over 12,000 different medicines and throughout the COVID crisis only four products have triggered a ‘supply disruption alert’ to date. In each of these cases, negative impacts have been limited by sourcing alternative supplies or through publishing advice on the management of affected patients^v. There have undoubtedly been challenges in certain medicine classes, driven by extraordinary demand, but through resilient supply chains and contingencies, international coordination and information sharing within global companies, and an enormous effort on behalf of industry to ramp up and where necessary redirect manufacturing, patients in Wales have continued to be able to access the critical medicines they need.

The role of co-morbidities, early diagnosis, treatment, and prevention has been highlighted during COVID-19, especially given the impact on patients with underlying conditions. To achieve an appropriate balance with ‘routine’ healthcare, it is essential that Wales pursues a sustained strategy of prevention. This strategy must incorporate both primary prevention approaches to risk factors like smoking and obesity (helping people safeguard and improve health) alongside secondary prevention (using innovation to slow or prevent disease progression). Medicines and vaccines can play an important role in both aspects of this agenda. A study of almost 17,000 people hospitalised with COVID-19 found more than half had at least one comorbidity, the most common of which were chronic cardiac disease (29%), uncomplicated diabetes (19%), non-asthmatic chronic pulmonary disease (19%) and asthma (14%).^{vi} Using innovative medicines could also help to slow or prevent disease progressions and protect NHS capacity by removing the need for ongoing chronic treatments.

The Committee may wish to reflect on the important role that the pharmaceutical industry plays in supporting patients and healthcare institutions across Wales and encourage Welsh Government and NHS Wales to pursue a sustained strategy of appropriate prevention and treatments, for the right patient at the right time.

The National Immunisation Programme

ABPI shares the Royal College of General Practitioners’ (RCGP) concerns about the risk of patients missing out on routine vaccinations due to COVID-19^{vii}. Although the Welsh

Government has asked NHS Wales to prioritise some vaccinations for children and at-risk groups during the pandemic, the impact on uptake is not yet clear^{viii}.

School based vaccination for HPV, Meningococcal ACWY, tetanus, diphtheria and polio has been completely suspended resulting in cohorts of adolescents who have not been able to access vaccination at all. Vaccines for older people, including shingles, have also been impacted. ABPI urges the Welsh Government and Public Health Wales to consider mitigating the risks of falling coverage across the immunisation programme and to implement any necessary “catch-up” campaigns.

An example of this is considering the impact of COVID-19 on the programme of Measles, Mumps and Rubella (MMR) vaccinations. It is over thirty-years since the MMR vaccine programme was introduced and it is estimated that the UK vaccination programme has prevented twenty-million cases and 4,500 deaths from measles, and 1,300 Congenital Rubella Syndrome births and 25,000 terminations^{ix}. Nonetheless, measles remains a serious illness that was once a common childhood infection in Wales. Before vaccination began in the UK in 1968, almost every child caught measles and around one-hundred died from the infection each year. Rubella was also once endemic. Whilst the flu season is still a number of months away, the effect lower rates of MMR immunisation could have for Wales, both in terms of current measles outbreaks and those in the future, has the potential to seriously impact not only people in Wales, but also our NHS.

Whilst flu season is some months away, ensuring good uptake of influenza vaccination this winter will be essential. Wales may wish to apply learnings from the southern hemisphere, which is currently in the flu vaccination administration period whilst implementing social distancing. Individuals particularly at risk from COVID-19 infection are also those at risk from flu. Reducing the chances of over-65s and at-risk groups falling ill and being hospitalised due to flu during the ongoing pandemic is critical. The impact of the pandemic on population demand for flu vaccination is unclear. Regardless, our industry is doing everything possible to meet global demand.

The Committee may wish to recommend that the Welsh Government and Public Health Wales consider the risks of falling coverage across the immunisation programme and implements any necessary “catch-up” campaigns, using evidence from other countries, where appropriate.

Secondary Care

Various reports have shown that there has been a pause in cancer screening and treatment across Wales^x. Unlike England, NHS Wales is yet to establish “COVID-free” cancer hubs to restart services to patients^{xi} and there is currently little information on how diagnostic testing, currently being used to support COVID-19 patients, will be reallocated to other specialities, including oncology. Similar data is not yet available for other conditions, but

health outcomes across all non-COVID disease areas will have been adversely affected to some degree.

To support the treatment of non-COVID disease areas, the ABPI is aware that some care and treatment pathways have been augmented through the crisis, to better support patients. Different models of care can allow patients to be treated closer to home, and include homecare models, virtual consultations with Healthcare Professionals and community-based diagnostics / monitoring (scans, bloods, community clinics etc) in areas as diverse as atrial fibrillation and inflammatory bowel disease. These kinds of approaches ought to allow NHS services in secondary care the opportunity to catch up on backlogs or pent up demand while also minimising the risk of infection for NHS Wales staff and patients. This is particularly the case with vulnerable patients that need to shield.

However, it is important that these are always done in a way that is safe, effective, and co-produced with patients and suppliers. These changes are sometimes being led - on a four-nations basis - by the Department of Health and Social Care at NHS England. In our experience, the changes that have been most effectively introduced have been those following appropriate early engagement with the impacted marketing authorisation holders, and we would encourage continued dialogue to assess the longer-term implications of these pathway modifications. Joint-working between NHS Wales' organisations and ABPI members may provide additional expertise to support this.

In meeting the future wave of pent up demand, we would also encourage consideration of the impact clinical, geographical, and behavioural changes will have on the supply of medicines. It is vital that 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.

The Committee may wish to encourage Welsh Government and NHS Wales to make appropriate arrangements to ensure that medicines and vaccines manufacturers receive advance notice of clinical, geographical, and behavioural changes so there is no impact on the supply of treatments.

Primary Care

As the NHS begins to reintroduce services and procedures paused during recent weeks, it is critical that this effort is not confined to secondary and tertiary care, although change in pathways and practices there will have an impact in other sectors. Therefore, equal thought must be given to cementing safe and effective changes in clinical practice, 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. Examples include moving patients requiring anti-coagulation away from warfarin, which necessitates extensive monitoring, and towards innovative, direct (or novel) anti-coagulants (DOACs/NOACs). The Welsh Government should continue to commit to the widespread use

of innovative treatments and technologies and embed them at pace and scale to provide more appropriate options for patients.

The Committee may wish to support the use of innovative treatments and technologies to support changes in practice across primary care, to help minimise patients requiring care in hospital environments, both now and in the future.

3. Ensuring continued supply resilience during the COVID-19 pandemic and into the future

From the daily conversations we have with member companies and those working in the healthcare sector we can assure you that everyone is working incredibly hard to ensure patients can continue to access the medicines and vaccines they need. However, it would be remiss not to acknowledge the tremendous pressure increased patient demand is exerting on supply chains and manufacturing. Our members are prioritising getting medicines and health technologies to NHS patients and are working hard to mitigate any impacts on their global supply and manufacturing efforts^{xii}.

More than ever, our industry welcomes measures which facilitate trade such as eliminating tariffs on medicines, and medical and protective equipment. However, it cautions against countries imposing protectionist measures such as export restrictions and/or stockpiling requirements that will disrupt already stretched global supply chains. Longer term, drastic policies mandating wholesale changes to global supply chains could fundamentally disrupt the manufacturing of medicines and vaccines for the NHS and patients. Nonetheless, UK Governments and industry should work together to identify opportunities to attract advanced manufacturing to the UK, but we should do this strategically, in a way that delivers benefits to patients and the NHS, supports innovation and drives economic growth.

The Committee could support opportunities to attract advanced manufacturing to Wales, and the UK, which will provide benefits to patients and the NHS, whilst supporting innovation and economic growth at this difficult juncture.

4. Research and Development (R&D)

The industry recognises the need for exploring novel and flexible approaches to support the R&D effort and to ensure that patients across the globe have access to a treatment and/or vaccine once one becomes available. Many of the priority vaccines and medicines being tested for COVID-19 exist today because of intellectual property and other incentives that drove their creation and development. Weakening intellectual property protections could do lasting damage –slowing recovery, undermining future innovation, and threatening our response to the next pandemic.

The integration of clinical research as part of service delivery and treatment for COVID patients has been rapid and effective. This is a welcome demonstration of the NHS as a research-focussed healthcare system. The ABPI's Clinical Trials Report 2019^{xiii} outlined seven recommendations for improving the UK's clinical research environment. These included simplifying the processes for setting up and running clinical trials, building a workforce fit for the future and harnessing the UK's data infrastructure. For COVID-19 studies, efficiencies have been developed in many of these areas, such as speedy Research Ethics Committees and Medicines & Healthcare products Regulatory Agency (MHRA) approvals.

We recommend that learnings are taken from this by Welsh Government on how to integrate clinical research within service delivery and how to initiate new trials at pace within NHS Wales. This should include allowing more flexibility, and moving towards use of digital technology as a routine for data collection and monitoring, building on the use of telemedicine, the use of e-consent, remote visits for patients, home nursing, and for some trials, enabling patients to take part without regularly visiting a trial site.

Further information about the rapidly changing R&D effort of our members is available from the ABPI website^{xiv}.

The Committee should recommend that Welsh Government and NHS Wales take the learnings from the current pandemic to enable the integration of clinical research within service delivery into the future.

ⁱ <https://www.nature.com/articles/d41573-020-00073-5>

ⁱⁱ <https://www.nature.com/articles/d41573-020-00073-5>

ⁱⁱⁱ <https://www.abpi.org.uk/medicine-discovery/covid-19/>

^{iv} <https://gov.wales/new-volunteer-prescription-delivery-scheme-support-those-shielding-or-self-isolating>

^v <https://www.cas.mhra.gov.uk/Help/CoronavirusAlerts.aspx>

^{vi} Features of 16,749 hospitalised UK patients with COVID-19 using the ISARIC WHO Clinical Characterisation Protocol (Preprint article published 28 April 2020 as part of a study funded by UKRI

^{vii} <https://www.rcgp.org.uk/about-us/news/2020/april/risk-of-serious-consequences-if-non-covid-conditions-unmanaged-or-untreated-warns-college.aspx>

^{viii} <https://gov.wales/sites/default/files/publications/2020-03/covid-19-response--continuation-of-immunisation-programmes.pdf>

^{ix} <http://www.wales.nhs.uk/sitesplus/documents/888/Measles%20Elimination%20Action%20Plan%202019-2021r.pdf>

^x <https://www.walesonline.co.uk/news/health/cancer-treatment-surgery-delayed-coronavirus-18185194>

^{xi} <https://www.bbc.co.uk/news/uk-wales-52522976>

^{xii} <https://www.abpi.org.uk/medicine-discovery/covid-19/what-impact-will-coronavirus-have-on-the-medicines-supply-chain/>

^{xiii} <https://www.abpi.org.uk/media/7607/rmi-0128-0919-clinical-trials-report.pdf>

^{xiv} <https://www.abpi.org.uk/medicine-discovery/covid-19/what-are-pharmaceutical-companies-doing-to-tackle-the-disease/>