

Welsh Parliament Economy, Infrastructure and Skills Committee



August 2020

About the ABPI

The ABPI 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.

Every day, we partner with organisations in the life sciences community and beyond to transform lives across the UK.

Background

Thank you for the opportunity to respond to the Economy, Infrastructure and Skills (EI&S) Committee's call for evidence on the effects of the Covid-19 pandemic in Wales. We are providing this response as the trade association for the branded pharmaceutical industry; but have also disseminated your call to our members who may choose to respond on an individual, company basis. We have concentrated our response on a small number of your consultation areas where we feel we have expertise. Other organisations and individuals will be better placed than us to accurately respond to many of the other topics.

We have worked across the Life Sciences Sector to produce a Recovery Roadmapⁱ, which has been shared with governments across the UK. A more focussed paper on the pharmaceutical industry in Wales, is attached as an appendix to this response.

Key Points

- Life Sciences are a core strength for the UK economy. It is a critical stabilising sector in a recession-hit economy and remains central to any long-term recovery centred on innovation, productivity and high-skilled, quality jobs.
- Increasing Research and Development (R&D) intensity, enabling and harnessing innovation, and attracting advanced manufacturing opportunities across the UK could be key components to help drive a rapid and sustained economic recovery.
- The pharmaceutical industry is more than simply a supplier to the NHS. It is also a partner in improving health outcomes and bringing economic and health security across all four nations. This approach to partnership and collaboration has been a constant commitment since devolution and responds to the actions in Welsh Government's A

*Healthier Wales*ⁱⁱ and *Prosperity for All*ⁱⁱⁱ as well as the *Life Science Industrial Strategy*^{iv} and subsequent Sector Deals^{v,vi}.

- The integration of clinical research as part of service delivery and treatment for Covid-19 patients has been rapid and effective. It is important, both in terms of healthcare and economic development that the Welsh Government take learnings on this greater integration of clinical research at scale within service delivery. Initiating new trials at pace within NHS Wales, could make our country a more attractive place to undertake commercial clinical trials in the future.

How has the industry been affected by Covid-19?

Research and Development (R&D), including clinical trials and skills provision

Vaccine development - 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 organisations^{vii} – multiple projects are already in the human trials phase.

Impact on non-Covid-19 research - The necessary focus on Covid-19 research, along with the impact of the virus itself, has had a significant impact on non-Covid-19 research. 55% of on-going commercial clinical trials across the UK were paused during the pandemic.^{viii} The impact of Covid-19 on our research base is significant and has put ambitions for R&D at risk. A full restart of activities, building on the steps already taken, must happen as soon as it is safe to do so.

Supply Chain

Resilient and flexible global supply chains - The medicines supply chain has proven to be resilient, in part, due to its global footprint, and industry has largely been able to meet the exceptional demand for prescription medicines. Of the 12,000 different prescription medicines used by the NHS, during the Covid-19 response period to date, only a very small number have triggered a 'Supply disruption alert'^{ix}. In each case, the potential negative impacts have been limited by sourcing alternative supplies or through publishing advice on the management of affected patients.

Cross-sector collaboration - Dialogue and collaboration between governments, the NHS, the Medicines and Healthcare products Regulatory Agency (MHRA), and the pharmaceutical industry has been critical in meeting the unprecedented demand for medicines. For example, these discussions precipitated the introduction of restrictions in parallel exporting^x, which increased the security of medicines intended for use across the UK.

Workforce

Resumption of industry and NHS partnership working - The pharmaceutical industry is playing a vital role in the research for vaccines, diagnostics, and therapeutic treatments for Covid-19 as well as a wide range of other clinical research activities within the NHS.

The wider Life Sciences sector can also play a significant role in supporting the NHS to address some of the backlog in patient care arising from the pandemic. To do so, it will need to be clear how industry staff can re-engage directly with frontline NHS organisations and staff safely. It is important that this engagement is appropriately maintained, and our industry can continue activities in an ethical, safe, and compliant manner.

The ABPI is not able to recommend what individual companies should do regarding promotional activities but we have flagged this issue with governments across the UK and will continue to monitor the situation as the Covid-19 picture evolves.

Trade Policy

Tariff changes - To help facilitate trade during the pandemic, many countries have eliminated tariffs on medicines and medical protective equipment used to detect, or in the treatment of, Covid-19. Despite initial delays, the UK Government adapted quickly to continue and initiate key trade negotiations which industry hopes will help to remove trade barriers in partner countries for UK Life Science exports.

What needs to be done to help Wales' recovery from the pandemic?

Next steps for R&D:

- **The strategy to restart clinical research** - There should be a clear, transparent and promoted plan to restart clinical research paused during the pandemic, with the goal of radically improving the way that trials are conducted to enhance Wales' existing science base. Any plan must articulate to clinical trial sponsors that Wales is open for clinical research and demonstrate that we have the necessary resilience to manage future waves of the pandemic. The ABPI's Clinical Trials Report 2019^{xi} 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 and would all be pertinent to the situation in Wales.
- **Embedding development** - The learning from the Covid-19 response should be factored into the evolution of a more agile All Wales Medicines Strategy Group (AWMSG)^{xii} and rapid National Institute for Health and Care Excellence (NICE)^{xiii} to support patients getting fast access to new treatments and technologies. Retaining positive changes in clinical practice and renewing NHS systems can help improve NHS resilience for future pandemic surges and support patients to live healthier lives with the need for fewer NHS interventions. This in turn will contribute to a stronger economy.
- **Skills** - Develop and fund skills development programmes to meet the future needs and workforce priorities of both the NHS and life science sector. This should be harnessed to a renewed focus on the Science Industry Partnership (SIP) 2030 Skills Strategy^{xiv} to support transformation of the Welsh economy.

- **Manufacturing capacity** – The Welsh Life Sciences Hub already supports the growth in Small and Medium-sized Enterprises (SMEs), amongst other priority areas, within Wales.^{xv} Greater targeted support for Welsh and UK manufacturing, particularly in advanced medicines, medical technology and diagnostics manufacturing alongside innovation funding for collaborative R&D for manufacturing and skill support, could help reinvigorate this sector in Wales. More information can be found at The Medicines Manufacturing Industry Partnership (MMIP)^{xvi}, which was established in 2014 to ensure that the UK is recognised by the global medicines industry as a world class, advanced centre for medicines manufacturing.

Next steps for medicines supply chain:

- **Enhancing supply chain resilience** – Supporting supply chain resilience is critical: where UK-based manufacturing is in operation, it will remain reliant on raw materials and components from across the globe; and benefit from un-hindered movement of finished goods across international borders. It is vital that the pharmaceutical industry be closely involved in discussions around resilience, to ensure proposals are practical and implementable. This will also ensure manufacturers can support increasing diversity of supply and flex its capacity to respond to variations in demand whilst managing international inventories, particularly after the EU-transition.
- **Procurement** - Working to support Value-Based Health Care (VBHC), future procurement of medicines should not be based on lowest cost alone, but rather consider value and where appropriate secure plurality of supply and multi-vendor approaches. Any move to focus on lowest price and single supplier contracts will result in manufacturing being driven to low-cost labour markets, threatening the resilience of supply. Value-based procurement processes need to be sustained, to improve robust, ethical, and sustainable supply chains and enhance contribution to the economy – something supported by Welsh Government policy^{xvii}.
- **Joint Working** - Governments should work together across the UK, with the NHS and industry, to develop a robust strategy for supply resilience for medicines and medical technology manufacturing. This should be delivered through the sub-groups of the Life Sciences Council, including the Health Technology Partnership (HTP) and Medicines Manufacturing Innovation Partnership (MMIP)^{xviii}.
- **VPAS** - The full potential of the Voluntary Pricing and Access Scheme (VPAS)^{xix} should be exploited to unlock improvements in the valuation of and uptake of new innovative medicines. Reforms paused due to Covid-19 should urgently continue or restart. A practical assessment of opportunities and challenges in the health technology procurement system should be undertaken.

Next steps for workforce

- **Early Engagement and Joint Working** - Willingness to collaborate in joint-working would enable our members to identify areas they can support during the period of, and post, Covid-19 recovery. The NHS should be encouraged to work with the Life Sciences Sector to create guidelines which must be implemented in a way that is sensitive to local needs but with a consistent framework for exploring new ways of working such as online tools and programmes for support and education.
- **The Science Industry Partnership 2030 (SIP)^{xx}** – The SIP model has the capacity to provide an overarching approach to skills for the entire life sciences sector, including careers outreach for young people. Alongside others who provide similar opportunities, it can also support those transferring from other sectors and people looking for work with transferable skills, post-Covid-19. Investing in these programmes to provide a range of workshops, learning strategies, guidance, and materials will be vital to the success of the sector.

Next steps for Trade Policy

- **Brexit** - Ensuring that trade partners work with the UK to promote global regulatory convergence for medicines and medical technologies is critical, particularly as the end of the EU exit transition period approaches. So too is a renewed commitment to strong intellectual property protection which encourages and supports innovation and provides transparent and predictable market access conditions while balancing fair and effective competition.
- **UK wide participation** - Welsh Government should participate in workstream groups across UK-wide conversations, to maintain full representation of Welsh interests. The Welsh Government should support the prioritisation of Life Sciences in future trade negotiations, to maintain the UK as a global hub for Life Sciences innovation.

Working with you

ABPI Cymru Wales are keen to support this work, by use of virtual meetings and additional written briefings. We can establish bespoke briefing sessions on any aspect of this paper, expanding upon the content in this briefing, and addressing your questions for the industry.

If you would like to set up a virtual meeting briefing session, please email jferris@abpi.org.uk or call 029 20 454297.

ⁱ <https://www.abpi.org.uk/publications/life-sciences-recovery-roadmap/>

ⁱⁱ <https://gov.wales/sites/default/files/publications/2019-10/a-healthier-wales-action-plan.pdf>

ⁱⁱⁱ <https://gov.wales/sites/default/files/publications/2019-02/prosperity-for-all-economic-action-plan.pdf>

^{iv} https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/650447/LifeSciencesIndustrialStrategy_acc2.pdf

^v <https://www.gov.uk/government/publications/life-sciences-sector-deal/life-sciences-sector-deal>

^{vi} <https://www.gov.uk/government/publications/life-sciences-sector-deal/life-sciences-sector-deal-2-2018>

^{vii} <https://www.nature.com/articles/d41573-020-00073-5>

^{viii} <https://www.nihr.ac.uk/documents/qanda-on-the-impact-of-covid-19-on-research-funded-or-supported-by-nihr/24467>

^{ix} <https://www.cas.mhra.gov.uk/SearchAlerts.aspx>

^x <https://www.gov.uk/guidance/parallel-export-and-hoarding-of-restricted-medicines>

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

^{xii} <http://www.awmsg.org/>

^{xiii} <https://www.nice.org.uk/>

^{xiv} <https://www.scienceindustrypartnership.com/home/>

^{xv} <https://lshubwales.com/working-industry>

^{xvi} <https://www.abpi.org.uk/medicine-discovery/new-medicines-data/medicines-manufacturing-industry-partnership-mmip/>

^{xvii} <https://gov.wales/sites/default/files/publications/2019-09/wales-procurement-policy-statement.pdf>

^{xviii} <https://www.abpi.org.uk/medicine-discovery/new-medicines-data/medicines-manufacturing-industry-partnership-mmip/mmip-news-and-publications/mmip-newsletter-july-2018/>

^{xix} <https://www.abpi.org.uk/new-medicines/medicine-pricing-in-the-uk/what-is-the-new-voluntary-scheme-on-branded-medicines/>

^{xx} <https://www.scienceindustrypartnership.com/>

Appendix

Leading Wales out of the Coronavirus Pandemic – Building Back Better



Background

- This paper is shared to provide an overview of the key opportunities and challenges for the pharmaceutical industry – part of the life sciences sector - as we look towards recovery and building a new partnership between the Welsh Government, NHS Wales, the third sector, academia and ourselves. It is intended to encourage further dialogue and delivery.
- The Association of the British Pharmaceutical Industry (ABPI)^{xxi} 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. Every day, we partner with organisations in the life sciences community and beyond to transform lives across the UK.

Introduction

- Our members are playing a central role in tackling the COVID-19 outbreak^{xxii}. The pharmaceutical industry has created new partnerships across the UK to:
 - Support the NHS to deliver care in a period of exceptional patient demand,
 - Lead the search for vaccinations and treatments to tackle the pandemic, and
 - Respond to increased demands for supply of medicines in challenging conditions.
- We have seen the future of healthcare in action; a scientific and technological revolution right across the sector. The use of AI and machine learning in research and development (R&D) through to novel manufacturing technologies and new treatment paradigms, all bringing real value to solving health challenges through new therapies and vaccines.
- The pharmaceutical industry is more than simply a supplier to the NHS. It is also a partner in improving health outcomes and bringing economic and health security across the four nations. This approach to partnership and collaboration has been a constant commitment in recent years, set out in the Welsh Government's *A Healthier Wales*^{xxiii} and *Prosperity for All*^{xxiv} as well as through the Life Science Industrial Strategy^{xxv} and subsequent Sector Deals^{xxvi,xxvii}.
- COVID-19 has proven that in order to have a thriving and successful life sciences sector in Wales, which can be mobilised for pandemics like COVID-19, the groundwork must be

The Association of the British
Pharmaceutical Industry

A company limited by guarantee registered
in England & Wales number 09826787

Address for correspondence

T: +44 (0)29 2045 4297
E: wales@abpi.org.uk

ABPI Cymru Wales, Floor 4, 2 Caspian Point,
Pierhead Street. Cardiff Bay CF10 4DO

T: +44 (0)207 930 3477
E: getintouch@abpi.org.uk

Registered office 7th Floor, Southside,
105 Victoria Street, London SW1E 6QT

laid in the normal day-to-day policy-making of the Welsh Government and operationally within our NHS and care sectors.

Working with you

ABPI Cymru Wales are keen to support this work, by use of virtual meetings and written briefings. We can establish bespoke briefing sessions on any aspect of this paper, expanding upon the content in this briefing, and addressing your questions for the industry. If you would like to set up a virtual meeting briefing session, please email jferris@abpi.org.uk or call 029 20 454297.

Five Key Areas

1) Transforming the partnerships between NHS Wales and the pharmaceutical industry to support greater joint-working in Wales

Building on and learning from the COVID-19 response, Welsh Government and the leadership of NHS Wales should actively consider the involvement of the pharmaceutical industry in work to support healthcare transformation. Our members have engaged to provide examples of where they could work across health and care to identify ways to retain and action positive changes in the adoption of innovation and digital solutions, embed new ways of working, harness the potential of data, bring healthcare to patients and diagnose and act faster. This could include,

- **Industry support for 'locking in' positive changes to clinical practice** - NHS Wales, alongside its partners, must take this opportunity to 'lock in' the co-produced changes that have been made during the pandemic.
- **Use of digital health technologies** - Digital technologies have shown great value in enabling new care solutions to relieve system pressures and have accelerated the adoption of a digital-first approach to healthcare. This fits with the aspirations of *A Healthier Wales*^{xxviii} delivering care close to home, wherever people live and whatever their circumstances.
- **Reducing the backlog** - Recent studies have illustrated the challenge that the NHS will face in restoring standards of care. This includes:
 - our ability to support cancer treatments^{xxix}, including those that rely on a genomic testing, increasing the complexity of embedding new genomics pathways and potentially reducing access to certain medicines.
 - routine vaccinations, for example vaccinations for the young (school-based) and older populations have been largely suspended.

It is crucial that diagnostic processes and our national immunisation programmes are restored quickly, safely and embedded within the new normal.

-
- **Improving early diagnosis, primary and secondary prevention** - Given the impact of co-morbidities, pursuing a sustained prevention strategy for conditions such as diabetes and heart disease will be essential. NHS data showing new patient initiations on treatments used for secondary prevention should be monitored closely as a leading indicator of improving health and resilience – something Wales could lead on with our ambitious plans for data and digital^{xxx}.

The pharmaceutical industry may be able to play a role in supporting NHS Wales to address some of the issues raised above. However, to do so, it will need to be clear how our staff members can re-engage directly with frontline organisations and staff safely and appropriately. A plan for the resumption of this activity could be created jointly between the NHS Wales and our sector, sensitive to local needs but with a consistent framework. This would echo previous work on joint-working, published by ABPI Cymru Wales and the Welsh NHS Confederation^{xxxi}.

2) Developing a comprehensive strategy to improve UK manufacturing capability and supply chain resilience in medicines

While supply chains have responded well in the crisis, additional resilience could be provided through improved demand forecasts and transparency along the supply chain, support for supply diversification, international inventory management and development of a strategic reserve of essential medicines. In parallel, there should also be a focus on targeted support for Welsh and UK manufacturing, particularly advanced medicines, medical technology and diagnostics manufacturing.

Governments should work together across the UK, with the NHS and industry, to develop a robust strategy for supply resilience for medicines and medical technology manufacturing. This should be delivered through the sub-groups of the Life Sciences Council groups, including the Health Technology Partnership (HTP) and Medicines Manufacturing Innovation Partnership (MMIP)^{xxxii}.

Areas for ongoing discussion could include:

- **Resilient and flexible global supply chains** - The global supply chain has proven to be resilient, and industry has largely been able to meet the exceptional demand for prescription medicines. Of the 12,000 different prescription medicines used by the NHS, during the COVID response period to date, only a very small number have triggered a 'Supply disruption alert'^{xxxiii}. In each case, negative impacts have been limited by sourcing alternative supplies or through publishing advice on the management of affected patients.
- **Cross-sector collaboration** - Dialogue and collaboration between governments, the NHS, the Medicines and Healthcare products Regulatory Agency (MHRA), and the pharmaceutical industry has been critical in meeting the unprecedented demand for medicines. For example, these discussions precipitated the introduction of restrictions in

parallel exporting^{xxxiv}, which increased the security of medicines intended for use across the UK.

- **Enhancing supply chain resilience** - Supply chain resilience is critical: where UK-based manufacturing is in operation, it will remain reliant on raw materials and components from across the globe. It is vital that the pharmaceutical industry be closely involved in discussions around resilience, to ensure proposals are practical and implementable. This will also ensure manufacturers can support increasing diversity of supply and flexibility in capacity to manage international inventories, particularly after the EU-transition.
- **Procurement** - Working to support Value-Based Health Care (VBHC), future procurement of medicines should not be based on lowest cost alone, but rather consider value and where appropriate secure plurality of supply and multi-vendor approaches. Any move to focus on lowest price and single supplier contracts will result in manufacturing being driven to low-cost labour markets, threatening the resilience of supply. Value-based procurement processes need to be sustained, to improve robust, ethical, and sustainable supply chains and enhance contribution to the economy – something supported by Welsh Government policy^{xxxv}.

The industry would welcome further discussions on supporting Welsh Government in the establishment of value-based procurement methodology within NHS Wales, supply chain resilience and greater collaboration.

3) Powering up the benefits of public spending on medical research to deliver bold policies that incentivise research investment

The announcement by UK Government of a doubling of R&D investment was welcomed by our industry. It remains a bold signal of the intention to deliver a science-based economy with world-leading research and should resonate across all UK nations.

This must be based on the continued funding and delivery of critical health data infrastructure for research alongside a ‘find and recruit’ clinical trial service. Welsh Government must also enable the continuity of third sector (charity-funded) research, recognising that the strength of the whole life sciences sector lies in its unique diversity; comprising funding from public bodies, medical research charities and industry. This could include,

- **Unprecedented research collaboration** - The scientific and research community has partnered at unprecedented speed and scale to research and develop new treatments, vaccines, and medical technologies against COVID-19. This response has shown how NHS, industry, academia, charities, and governments can deliver high quality research at pace and scale. Several innovative and flexible approaches to conducting trials have emerged during the pandemic and must be assessed in parallel with the resumption of clinical trials.

- **Collection and sharing of data** - Trial sponsors have been able to access COVID-19 data from registries and HDR-UK Research Hubs^{xxxvi} to support clinical research. New approaches to epidemiological research using very large datasets contained in NHS records have demonstrated they can quickly yield key clinical insights. There is an opportunity to explore how we can continue to expedite secure, anonymised access to health data for clinical research. Use of digital health technologies have generated real world evidence directly from patients and the public on a sustained basis to support the response to the pandemic. Wales' ambitions for its National Data Strategy and collation of self-reported outcomes (PROMs and PREMs^{xxxvii}) could provide vanguard data to support new indications, advice or claims for treatments and should continue to be adopted at scale and pace in Wales.
- **Third Sector / Medical Research Charities** - Medical research charities constitute a vibrant component of the UK's world leading R&D base, supporting science from basic research through to clinical trials and translation. In 2019, Association of Medical Research Charities (AMRC's)^{xxxviii} members collectively invested £1.9 billion in UK R&D. It is estimated that charity sector research investment faces a shortfall of between £252m - £368m in 2020/21^{xxxix}. This is the result of a collapse in charity fundraising income and the increased costs associated with paused/delayed research. It is important that Welsh Government considers how they can preserve the distinct contributions of medical research charities and the third sector to the research base and harness their role in supporting post-COVID-19 economic and social recovery.

4) Transforming Wales clinical research processes

COVID-19 has proven that Wales can do things differently. Now is the time for this to become the new normal by continuing rapid approval, set-up, recruitment, and delivery of research across NHS Wales, powered by new technologies and data. This new "normal" would ensure that Welsh patients are amongst the first in the world to benefit from breakthrough treatments and technologies, with the added benefit of cost savings and investment for NHS Wales.

As the UK steps into a new global role, it also has the potential to lead new work on pathways for emerging innovation such as cell and gene therapies. The Welsh Government has already published a statement of intent on precision medicines^{xl} and ensuring that we are globally relevant in this space will be fundamental to its success.

Areas for ongoing discussion could include:

- **The strategy to restart clinical research** - There should be a clear plan to restart clinical research paused during the pandemic, with the goal of radically improving the way that trials are conducted to enhance Wales' existing science base. Any plan must articulate to clinical trial sponsors that Wales is open for clinical research and demonstrate that we have the necessary resilience to manage future waves of the pandemic.

-
- **Impact on non-COVID-19 research** - The necessary focus on COVID-19 research, along with the impact of the virus itself, has had a significant impact on non-COVID-19 research. 55% of on-going commercial clinical trials across the UK have been paused. The impact of COVID-19 on our research base is significant and has put ambitions for R&D at risk. A restart of activities must be undertaken as soon as it is safe to do so.

5) Accelerating deployment of new and existing treatments and technologies where there are system and patient benefits

The COVID-19 response has shown that rapid scale-up of existing treatments and devices, new medicines, medical technologies, and diagnostics can significantly improve patient outcomes while making more effective use of NHS resources. There is an opportunity for decisive action to build on this to help NHS Wales address the backlog of care for non-COVID patients.

Wales needs to be positioned as a priority market for the launch of innovation, with broader measures of value that reflect the changing nature of treatments and a progressive ‘value based’ healthcare system. The learning from the COVID-19 response should be factored into the evolution of a more agile All Wales Medicines Strategy Group (AWMSG)^{xli} and rapid National Institute for Health and Care Excellence (NICE)^{xlii} to support patients getting fast access to new treatments and technologies. System partners should recognise the case for changing AWMSG and NICE’s appraisal methods so they can better consider the outcome focused value of new medicines. Senior level support will be required across Welsh Government, NHS Wales and industry to set out the level of ambition that can be supported to allow appropriate changes, potentially ahead of the first NICE Methods Review^{xliii} consultation in October 2020.

The full potential of the Voluntary Pricing and Access Scheme (VPAS)^{xliv} should be exploited to unlock improvements in the valuation of and uptake of new innovative medicines. Reforms paused due to COVID-19 should urgently continue or restart. A practical assessment of opportunities and challenges in the health technology procurement system should be undertaken.

Areas for ongoing discussion could include:

- **Rapid evolution of NICE methods and HTA for Wales** - The learning from the COVID-19 response should be an opportunity to be ambitious, to truly future-proof HTA in Wales for all medicines. Discussions are needed towards a more flexible approach to assessments, enabling new forms of real-world evidence and a wider definition of value.
- **Delivery of more flexible commercial and managed access arrangements** – Increasingly, centralised contracting has facilitated swifter introduction of vital new technologies. This should now be reviewed to see how these benefits could be maintained. Commissioning frameworks may need to incorporate more transparent criteria, identifying how patients will be prioritised for treatment. It is possible that, alongside this, Wales may wish to

explore the potential to incorporate the principles of value-based healthcare and encourage a reimbursement model based on patient outcomes and system efficiencies. Early engagement on these issues with the pharmaceutical industry would be welcomed.

- **Evaluating and embedding innovative changes in practice** - Changes to clinical pathways should be rapidly evaluated and positive changes should be confirmed across the health system. For instance, moving patients requiring anti-coagulation away from warfarin, which necessitates extensive monitoring, towards modern, easily managed direct anti-coagulants delivers a fundamental change in services. Consideration should be given to moving towards system performance and outcomes-based targets, to help drive integration of pathways and optimise patient care. This evaluation may represent a considerable change and is an area where our industry could provide extensive support through joint-working initiatives.
- **Develop a clear national strategy for the rollout of COVID-19 vaccines, treatments and diagnostics** - The life sciences sector will be critical in the manufacture and distribution of any COVID-19 vaccine that is developed. This will be a major logistical undertaking; it is critical that plans are developed in partnership with the world's leading vaccine manufacturers. Developing and implementing a COVID-19 vaccination programme should be on the Welsh Government's strategic agenda now. Efforts must also be made to understand and build public confidence so that any potential barriers to people coming forward for vaccination can be addressed proactively and optimum levels of uptake in target populations can be achieved.

^{xxi} <https://www.abpi.org.uk/>

^{xxii} <https://www.abpi.org.uk/medicine-discovery/covid-19/>

^{xxiii} <https://gov.wales/sites/default/files/publications/2019-10/a-healthier-wales-action-plan.pdf>

^{xxiv} <https://gov.wales/sites/default/files/publications/2019-02/prosperity-for-all-economic-action-plan.pdf>

^{xxv} https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/650447/LifeSciencesIndustrialStrategy_acc2.pdf

^{xxvi} <https://www.gov.uk/government/publications/life-sciences-sector-deal/life-sciences-sector-deal>

^{xxvii} <https://www.gov.uk/government/publications/life-sciences-sector-deal/life-sciences-sector-deal-2-2018>

^{xxviii} <https://gov.wales/sites/default/files/publications/2019-10/a-healthier-wales-action-plan.pdf>

^{xxix} <https://www.theguardian.com/society/2020/apr/29/extra-18000-cancer-patients-in-england-could-die-in-next-year-study>

^{xxx} <https://gov.wales/ps50-million-and-new-body-transform-digital-health-and-care-services-wales>

^{xxxi} <https://www.abpi.org.uk/publications/joint-working-a-toolkit-for-industry-and-nhs-wales/>

^{xxxii} <https://www.abpi.org.uk/medicine-discovery/new-medicines-data/medicines-manufacturing-industry-partnership-mmip/mmip-news-and-publications/mmip-newsletter-july-2018/>

^{xxxiii} <https://www.cas.mhra.gov.uk/SearchAlerts.aspx>

^{xxxiv} <https://www.gov.uk/guidance/parallel-export-and-hoarding-of-restricted-medicines>

^{xxxv} <https://gov.wales/sites/default/files/publications/2019-09/wales-procurement-policy-statement.pdf>

^{xxxvi} <https://www.hdruc.ac.uk/infrastructure/the-hubs/>

^{xxxvii} <http://www.wales.nhs.uk/promspremsandefficiencyprogramme>

^{xxxviii} <https://www.amrc.org.uk/>

^{xxxix} <https://www.theguardian.com/science/2020/apr/07/cancer-research-uk-to-cut-funding-for-research-by-44m>

^{xl} <https://gov.wales/written-statement-precision-medicine>

^{xli} <http://www.awmsg.org/>

^{xlii} <https://www.nice.org.uk/>

^{xliii} <https://www.abpi.org.uk/new-medicines/medicine-pricing-in-the-uk/what-is-the-nice-methods-review/>

^{xliv} <https://www.abpi.org.uk/new-medicines/medicine-pricing-in-the-uk/what-is-the-new-voluntary-scheme-on-branded-medicines/>