



2021 Manifesto for Medicine

ABPI Cymru Wales

The Association of the British Pharmaceutical Industry (ABPI)¹ 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.

Medicines are transforming our lives like never before. This manifesto gives political parties and the public a view from the ABPI's members of how to best capitalise on the UK's life science industry and improve the health of UK patients following the next election. We focus on two main themes:

- Making Wales the best place in the world for patients to benefit from innovative medicines and vaccines
- Building a thriving environment for medicine discovery, so that Wales is at the forefront of world-leading research and development of new medicines and vaccines

Medicines Spend is Under Control

The 2019 Voluntary Scheme for Branded Medicines Pricing and Access (VPAS)² is an agreement between the UK Government (on behalf of the devolved nations) and ABPI. The agreement supports NHS patients in getting new medicines quickly; helps to foster innovation in the pharmaceutical industry; and means that the NHS has complete spending predictability on branded medicines.

To do this, the scheme:

- Ensures NHS expenditure on branded medicines is capped to 2% growth a year for the next 5 years.
- Commits that companies pay back any expenditure over this amount to the UK - and then Welsh - Government.
- Aspires to see greater uptake of the most clinically and cost-effective medicines that provide significant health gain.

Patient Access to Medicines

Creating an NHS 'fit for the future' is about embracing cutting edge technology so all patients in Wales have access to world-class standards of care and disease prevention. Working together, the ABPI and the next Welsh Government can deliver patient access to the latest medicines and vaccines.

Continuation of the New Treatment Fund in Wales

- The ABPI welcomed the current Welsh Government's commitment to strengthen and speed up NHS patients in Wales' access to the very latest medicines. The progressive £80 million New Treatment Fund³ enables consistent routine adoption of all clinically and cost-effective medicines, whilst underpinning a new, collaborative approach to horizon scanning for innovative medicines in Wales. Whilst NHS Wales already receives funding for the adoption of medicines with positive approval from National Institute for Health and Care Excellence (NICE)⁴ and / or All Wales Medicines Strategy Group (AWMSG)⁵, the New Treatment Fund has facilitated service reconfiguration in the delivery of these innovative treatments when required.
- As the trade body representing the pharmaceutical industry, we have worked together with colleagues from across Welsh Government, NHS Wales, and our members to support the equitable implementation of the New Treatment Fund.
- The ABPI also accepted and responded to the challenge laid down by the Minister for Health and Social Services to support Health Boards' understanding of service and infrastructure planning requirements, to align with 'future' medicines. The ABPI supported the commissioning of extended applied research⁶ and continues to work with colleagues at the All Wales Therapeutics and Toxicology Centre⁷ to support their "Vault" information management platform.
- As we look ahead post-2021, the ABPI encourages the next Welsh Government to maintain and develop the New Treatment Fund policy. The ABPI believes this policy has benefited patients the length and breadth of Wales through quicker access to cost and clinically effective medicines and ensuring there is an appropriate uplift to reflect patient and service needs, based on horizon scanning and NICE / AWMSG advice.

ABPI Cymru Wales calls for the next Welsh Government to continue and regularise the ground-breaking, progressive New Treatment Fund.

Support collaborative working between the Welsh Government, NHS Wales, and Industry

- The ABPI supports the goal of the NHS Wales long-term plan “A Healthier Wales - our Plan for Health and Social Care”⁸ to create a service fit for the future, able to embrace innovation, improve the health and well-being of the population and provide world-class standards of care.
- We are working closely with NHS Wales and with NHS organisations across the country to highlight the broad contribution that our industry can and is making towards achieving this goal by encouraging ambitious, appropriate cross-sector collaborations, helping to develop an innovation-ready NHS and helping to maximise Wales’ health data assets. This has included our recent co-produced publication with Welsh NHS Confederation, which provides a toolkit to support joint working.⁹
- While it is essential for NHS organisations and industry partners to comply with legal and regulatory guidance when working together, compliance alone does not guarantee a successful outcome in collaborative working. Encouraging everyone involved in joint working to adopt the Welsh NHS Confederation / ABPI Cymru Wales toolkit would help facilitate a consistent, equitable approach to these projects.

ABPI Cymru Wales calls for the next Welsh Government to work with stakeholders, including the pharmaceutical industry, to reap the clear patient and health system benefits from working collaboratively.



Changes to AWMSG and NICE

- In January 2019, the Voluntary Scheme for Branded Medicines Pricing and Access (VPAS)¹⁰ was introduced across the UK, replacing the Pharmaceutical Price Regulation Scheme (PPRS)¹¹. Alongside the new agreement, there is a commitment that NICE will increase its capacity to appraise all new active substances and significant extensions to marketing authorisations. NICE has committed to achieve this by April 2020, which has implications for the future role of the AWMSG. Currently, NICE has limited appraisal capacity, meaning some new medicines or extensions to marketing authorisations are not appraised by NICE. In these circumstances the AWMSG has responsibility for providing clear advice to the NHS in Wales on the clinical and cost effectiveness of medicines.
- In a future where NICE appraise all new medicines, AWMSG will need to adopt a role which avoids duplication, whilst supporting the distinctiveness of the Welsh healthcare environment. This will include ensuring that no gaps appear, which could adversely affect patients and clinician's ability to access the latest innovative medicines.

ABPI Cymru Wales asks the next Welsh Government to ensure that any changes to either AWMSG or NICE remit or processes does not disadvantage Welsh patients accessing clinical and cost-effective medicines.

Data and Value-Based Healthcare

- The ability to track and optimise patient outcomes and care is essential to ensure a sustainable, innovative healthcare system in Wales. This can only be achieved through investment in the generation of timely, accurate real-world evidence from real-world data, to support both professionals and patients in the co-production of healthcare and encourage a more innovative, research-ready NHS. This change is predicated on a series of linked, interoperable real-world datasets, supported by appropriate governance, to encourage its delivery at scale and pace.
- A clear and coherent framework to encourage access to - and sharing of - healthcare data, whilst protecting privacy of personal data, is vital and should be underpinned by a recognised system, i.e. the F.A.I.R. (Findable, Accessible, Interoperable and Reusable) data principles¹².
- Without this change, the possibility for Wales to deliver value-based healthcare services will be severely compromised; data is the fuel that allows our healthcare system to optimise its resources, delivering the right treatment to the right patient at the right time.

ABPI Cymru Wales asks the next Welsh Government to build on the current Digital Strategy¹³ and National Data Resource¹⁴ to enable value-based decision-making to become a central tenet for NHS Wales to deliver the best possible patient outcomes.



Developing new medicines and vaccines

The pharmaceutical industry is critical to the health of our population and the success of our wider economy. The sector invests £4.3 billion in Research and Development (R&D) across the UK, more than any other sector, and employs 63,000 people¹⁵. The sector is fully behind the UK Government's aspiration to boost R&D investment to 2.4% of GDP by 2027, and up to 3% in the longer term¹⁶. Increasing investment in science will help provide the high-quality jobs and innovation that will drive the future of the Welsh and UK economy. Collaboration with industry will be essential to achieve this ambition.

The next Government should look to build on the excellence of the Welsh life science base and continue to be a world leader in the future by focusing on a broad range of policies to support the research and development of the next generation of medicines.

Support the development and roll-out of emerging technologies, including advanced therapies

- Collaborations with industry are key to delivering the treatments of the future. Health and Care Research Wales reported that in 2018-19 there were 212 active commercially sponsored studies in Wales¹⁷. Support – and expansion - of high-quality R&D has direct implications for the wider innovation and digitisation picture and should be actively encouraged.

- Similarly, encouraging the Welsh population to participate in high-quality research studies should be at the heart of our innovative health service. In 2018-19, from a population of 3.2m only 20,879 were recruited into a health or care research study – a little over 0.5%¹⁸.
- ABPI Cymru Wales agrees with the aims of “A Healthier Wales - our Plan for Health and Social Care”¹⁹ that Wales needs to become more agile in how we respond to emerging technologies such as precision medicine, genomics, cell therapies and Advanced Therapy Medicinal Products (ATMPs).
- In Wales, our journey towards these innovations has begun, but we need to embrace the opportunities offered to harness their potential. It is vital that we have a connected and collaborative approach towards advanced therapies.
- Realising the opportunity presented by biomedical innovation will depend on NHS Wales, life sciences and industry stakeholders collaborating more effectively than in the past to tackle health needs, prepare for major new developments such as the ATMPs, and develop integrated health data assets that allow outcome-based planning. Success will be derived from demonstrating the ability of innovative medicines and technologies to improve people's health in real-world settings and by scaling these improvements nationally. The prize will be a virtuous circle that delivers health and economic benefits to Wales from a thriving life sciences ecosystem.
- Supply chains and treatment pathways are well-established for traditional small molecule medicines, but ATMPs will require new systems and pathways to be designed, developed, and implemented. This includes the treatments themselves, as well as manufacturing facilities, IT systems, logistics solutions, support services and companion diagnostics.

ABPI Cymru Wales calls on the next Welsh Government to bring together industry and NHS Wales stakeholders to develop an adoption or implementation framework for key innovations. This should target year-on-year increase in both the numbers of commercially sponsored collaborations and studies attracted to Wales, and the number of people directly participating in research.





Prioritising patients and health security in future the UK – EU relationship

As the UK leaves the European Union, the next Welsh Government should prioritise building a new partnership that puts patients first and allows Wales to be a world leader in the delivery of new and innovative treatments.

The UK's membership of the EU has shaped and enforced much of the scientific, regulatory and trade infrastructure for the life sciences sector.

- Every month, 45 million packs of medicine move from the UK to the EU27, with 37 million packs moving the other way²⁰.
- Sharing information on medicine safety, controlling infectious diseases and cross-European clinical trial design has contributed to health security in the UK.
- Collaboration on regulating medicines also means that UK patients can be amongst the first in the world to use new medicines
- Our Member companies continue to do everything in their power to prepare for the UK to leave the EU. However, some things – such as border delays – are outside of their control. Leaving the EU with a deal in place is the best way to ensure there is no disruption to the supply of medicines. Going forward, supporting a relationship with the EU that maintains the free and frictionless trade of pharmaceutical supplies between the UK and EEA member states will help maintain this.
- Well-established cooperation on the regulation of medicines is important for our future, as is access to talent and ease of movement for the highly skilled talent in life sciences. Coupled with support for our science and innovation base, co-operation should be continued / facilitated through reinforcing collaborations in Horizon Europe.

ABPI Cymru Wales calls on the next Welsh Government to build a new partnership with the EU which puts patients first. This must prioritise health and medicines; the free and frictionless trade of pharmaceutical supplies, cooperation on regulation, access to talent, ease of movement and supports science and innovation.

COVID-19

COVID-19 will obviously be integral to the decisions made by the next Welsh Government, and for years to come. The 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.

Below are some key highlights for our industry, we would welcome the opportunity to build on these, if useful.

- 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 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 efforts²¹.
- 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 five products have triggered a 'supply disruption alert' to date²². 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 organisations – multiple projects are already in the human trials phase²³.
- 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
- Service re-design and integration of clinical research as part of service delivery and treatment for COVID patients has been rapid and effective. The next Welsh Government should take learnings on how to integrate clinical research at scale and pace 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.

Working with you

ABPI Cymru Wales are currently adhering to COVID-19 guidance around working practices. We are keen to support all colleagues through use of virtual meetings and briefings.

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



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- ³ Welsh Health Circular, The New Treatment Fund.
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- ⁵ All Wales Medicines Strategy Group. AWMSG in Relation to NICE.
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- ⁶ Welsh Institute for Health and Social Care, Horizon Scanning and Planning for the Future: New Medicines and NHS Wales.
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- ⁷ ABPI Summer Bulletin 2018. NHS Wales Securely Open for Business – the Vault workspace for commercially sensitive information.
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- ⁸ Welsh Government Health and Social Care Strategy. A Healthier Wales.
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- ⁹ ABPI. Joint Working: A Toolkit for Industry and NHS Wales.
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- ¹¹ ABPI. What was the PPRS?
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- ¹² FAIR Principles. Available at: <https://www.go-fair.org/fair-principles/>
- ¹³ Welsh Government Digital Action Plan 2017-2020.
 Available at: <https://gov.wales/sites/default/files/publications/2019-07/digital-action-plan-2017-to-2020.pdf>
- ¹⁴ NHS Wales Informatics Service. National Data Resource.
 Available at: <https://nwis.nhs.wales/news/latest-news/nhs-wales-to-create-world-leading-national-data-resource/>
- ¹⁵ ABPI. Manifesto for Medicine 2020, p.2.
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- ¹⁶ UK Government. Industrial Strategy White Paper, p.66.
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- ¹⁸ Health and Care Research Wales. Annual Report 2018-2019.
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- ²³ Nature article on COVID-19 research.
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