

Cafodd yr ymateb hwn ei gyflwyno i ymgynghoriad y [Pwyllgor Iechyd a Gofal Cymdeithasol](#) ar [Flaenoriaethau'r Chweched Senedd](#)

This response was submitted to the [Health and Social Care Committee](#) consultation on [Sixth Senedd Priorities](#)

HSC PSS 16

Ymateb gan: | Response from: [Cymdeithas Diwydiant Fferyllol Prydain, Cymru | British Pharmaceutical Industry Wales](#)

Blaenoriaethau cychwynnol a nodwyd gan y Pwyllgor Initial priorities identified by the Committee

Mae'r Pwyllgor wedi nodi nifer o flaenoriaethau posibl ar gyfer ei waith yn ystod y Chweched Senedd, gan gynnwys: iechyd y cyhoedd a gwaith ataliol; y gweithlu iechyd a gofal cymdeithasol, gan gynnwys diwylliant sefydliadol a lles staff; mynediad at wasanaethau iechyd meddwl; arloesi ar sail tystiolaeth ym maes iechyd a gofal cymdeithasol; cymorth a gwasanaethau i ofalwyr di-dâl; mynediad at wasanaethau adsefydlu i'r rhai sydd wedi cael COVID ac i eraill; a mynediad at wasanaethau ar gyfer cyflyrau cronig tymor hir, gan gynnwys cyflyrau cyhyrsgerbydol.

The Committee has identified several potential priorities for work during the Sixth Senedd, including: public health and prevention; the health and social care workforce, including organisational culture and staff wellbeing; access to mental health services; evidence-based innovation in health and social care; support and services for unpaid carers; access to COVID and non-COVID rehabilitation services; and access to services for long-term chronic conditions, including musculoskeletal conditions.

C1. Pa rai o'r materion uchod ydych chi'n credu y dylai'r Pwyllgor roi blaenoriaeth iddynt, a pham?

Q1. Which of the issues listed above do you think should be a priority, and why?

Thank you for the opportunity to provide our thoughts on your workload prioritisation. Whilst the following response focuses on your proposed inquiry into evidence-based innovation in health and social care, our work and that of our members touches all areas within your programme. Medicines and vaccines are transforming lives like never before. They have played a crucial role in increasing UK-life expectancy by eleven-years since 1960, doubling cancer survival rates since 1980, and transforming HIV/AIDS into a chronic, manageable condition. At ABPI Cymru Wales, we continue our commitment to play an active role, wherever appropriate, in your work.

Evidence-based innovation in health and social care inquiry

Introduction:



“Innovation” has become a catch-all in health and social care to describe a wide-array of projects and programmes whose ambition is to add value to patient treatment and/or experience. The use of this phrase has accelerated over the last sixteen-months, in response to the COVID-19 pandemic.

Every medicine or vaccine that is routinely funded by NHS Wales has to provide and prove its evidence-base multiple times. In the first case, extensive data is required by the licensing authorities, demonstrating a strictly monitored, evidence-based, development process, involving research in the laboratory, and testing in clinical trials. Licences are only granted if strict safety and quality standards are met and confirm the health condition the medicine should be used for and the recommended dosage. Whilst the development of new medicines and vaccines is uncertain, costly, and involves significant rates of failure, the pharmaceutical companies who produce them must base their work on the best global evidence available at the time.

Once the conditions required by the licensing authorities have been met, medicines routinely used in Wales have to successfully prove their clinical and cost-effectiveness evidence-base through assessment by one of two agencies: the All Wales Medicines Strategy Group (AWMSG)¹ or National Institute for Health and Care Excellence (NICE)². In the evaluation of new medicines, both agencies compare how much a treatment costs to buy for each extra Quality Adjusted Life Year (QALY) against an explicit threshold, which represents the limit of how much the NHS is willing to routinely pay.

The level of evidence required in the research and development of medicines and vaccines is high, and unlike some other innovations, the collation of information does not stop once the treatment starts being used in real-life. Continuous examination continues in the real-world, by our industry, the clinicians prescribing the medicines, and the patients who take them.

What impact or outcomes could be achieved through any work by the Committee?

As we described in our introduction, all innovative medicines and vaccines used in Wales already have to prove a strong evidence-base before becoming routinely available to clinicians and patients. As an industry, we have focused significant efforts over the last twenty-years to explain the evidence which supports public investment in our medicines and vaccines; we believe that the way in which our products are assessed has become the gold-standard for evidence-based innovation.

However, if Wales decides that we should continue to provide patients with prompt access to new medicines, AWMSG and NICE’s assessments may need to accept greater uncertainty in the evidence submitted to them. The current assessment processes can be inflexible, making it a challenge for some types of medicines, especially those used for treating specialist and rare diseases, to collate the expected evidence base and achieve approval for use by the NHS.

As the complexity of the medicines that the pharmaceutical industry is developing and researching through clinical trials have dramatically changed over the last ten years - from being predominantly treatments for long term chronic conditions and late stage cancers to those for

¹ <https://awmsg.nhs.wales/>

² <https://www.nice.org.uk/>

targeted therapies for complex, sub-diseases with increasingly smaller patient populations - it is imperative that the way the evidence-base is assessed evolves too.

For example,

- Advances in research and development mean more treatments are available earlier in the progression of the disease and, in some cases, these are curative. These medicines often address a very high unmet medical need because there are either no, or very few, other treatment options available.
- With medicines being increasingly developed for small patient populations, the pharmaceutical industry regulators are reducing approval timelines – making use of “fast-track” processes and “early access” initiatives, which result in medicines being assessed by AWMSG / NICE with ever more immature evidence packages. The assessment process has not kept pace, which needs to be addressed, to avoid inequitable delays to patient access.
- We must value patients’ lives more than ever before. The baseline cost effectiveness threshold currently used by AWMSG / NICE has remained unchanged for over 20 years and accounting for inflation, it has declined by 31%.
- The ‘simplistic’ QALY approach cannot be used to evaluate the full impact of new, innovative medicines on patients, their carers, NHS Wales, and wider society; the threshold needs to be applied much more flexibly.

Some of the issues above are currently being debated as part of the NICE Methods Review³ and we believe that NICE (and AWMSG) should also introduce a broader framework to assess the value of medicines in their evaluation methods, i.e., taking greater account of disease severity, rarity, and the full impact a new medicine has on patients and their family/carers. In discussing the evidence-base for health and social care in Wales, the Committee could consider the level of uncertainty that is appropriate or acceptable for the adoption of innovation in Wales.

Why is this important?

An inquiry of this nature could provide meaningful scrutiny of the way in which we evaluate whether an innovation will support Welsh patients and has an appropriate evidence-base. It will mean that NHS Wales invests its resources in innovations that have a real, demonstratable, opportunity to positively impact the lives of our citizens.

Gaining equitable access to new, innovative, and evidence-based treatments across Wales would result in improved clinical outcomes for NHS patients and help to deliver ambitions in health and care, including:

- improving outcomes in chronic diseases i.e., respiratory, and cardiovascular disease,
- treating thousands of children and adults with rare diseases, ensuring they gain access to the latest gene and cell therapies and medicines that can help transform their lives,

³ <https://www.abpi.org.uk/new-medicines/medicine-pricing-in-the-uk/what-is-the-nice-methods-review/>

- ensuring thousands of patients get access to the latest types of cancer medicines that can slow down or halt their cancer progressing,
- halting the decline in life expectancy and devastating impact on quality of life caused by diseases like dementia and Alzheimer's by adopting new medicines as soon as they become available.

Changes to the way in which we look at the evidence-base for innovation could also mean we can take full advantage of a virtuous circle that delivers health and economic benefits to Wales from a thriving life sciences ecosystem. This could help make NHS Wales an attractive healthcare system, globally recognised for using the newest, most effective, and evidence-based medicines and vaccines.

However, it is important to reflect on the evidence base required for all innovations adopted within NHS Wales, and whether there is a consistency or level playing field in the definitions and decision making in relation to 'innovations' in general. Is the evidence-base always scrutinised and evaluated to a level where appropriate clinical and cost-effectiveness is assured before funding decisions are made?

How the Committee might address the issue?

The Minister for Health and Social Services recently launched a new Innovation Programme for Health and Social Care⁴, which consolidates and strengthens some of the existing 'innovation activity' across Wales. This new innovation programme brings together all existing Welsh Government Health and Social Care innovation which includes, but is not limited to: Health Technology Wales, Intensive Learning Academies, Small Business Research Initiative, Research Innovation Improvement Coordination Hubs, Bevan Commission, Accelerate and Agor IP. Officials are also working across the health and social care sector; including all health boards and trusts in Wales, Regional Partnership Boards, Welsh universities, the third sector and industry⁵.

The Committee may choose to start their inquiry through scrutiny of this new Innovation Programme, drawing in other sectors with a proven record of patient and system benefit, but currently not directly referenced by the Minister (such as pharmaceuticals). It would provide a useful framework of ongoing developments across Wales, where the central importance of a proven evidence-base could be directed.

Whether there are any specific groups, communities, or stakeholders that the Committee should involve or hear from in any work?

As well as our industry, the response to the previous question outlines some useful contributors to the possible inquiry.

⁴ <https://gov.wales/written-statement-innovation-health-and-social-care>

⁵ <https://record.senedd.wales/WrittenQuestion/83118>

Blaenoriaethau allweddol ar gyfer y Chweched Senedd

Key priorities for the Sixth Senedd

C2. Yn eich barn chi, pa flaenoriaethau allweddol eraill y dylai'r Pwyllgor eu hystyried yn ystod y Chweched Senedd mewn perthynas â:

- a) **gwasanaethau iechyd;**
- b) **gofal cymdeithasol a gofalwyr;**
- c) **adfer yn dilyn COVID?**

Q2. In your view, what other key priorities should the Committee consider during the Sixth Senedd in relation to:

- a) **health services;**
 - b) **social care and carers;**
 - c) **COVID recovery?**
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Adfer yn dilyn COVID

COVID recovery

The pharmaceutical industry priorities in responding to COVID-19 have included:

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

The pharmaceutical industry is 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. We will continue to work with partners to support the NHS and governments moving forward.

Unrhyw faterion eraill

Any other issues

C3. A oes unrhyw faterion eraill yr hoffech dynnu sylw'r Pwyllgor atynt?

Q3. Are there any other issues you wish to draw to the Committee's attention?

The ABPI⁶ 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.

For background, the Life Sciences sector in Wales employs around 11,000 people in well-paid, high-quality jobs across the country and exports about £980m⁷. Two ABPI members have significant manufacturing facilities in Wales: Norgine⁸ (in South Wales) and Ipsen⁹ (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 academia¹⁰.

In 2018, expenditure by the pharmaceutical industry on research and development in Wales was £37m¹¹. This investment supports evidence-based innovation in health and social care and, whilst there are several areas in your proposed work programme where ABPI would wish to be actively involved, we would like to focus on this aspect of your proposed work in this response.

⁶ <https://www.abpi.org.uk/>

⁷ <https://lshubwales.com/>

⁸ <https://norgine.com/>

⁹ <https://www.ipsen.com/>

¹⁰ <https://www.abpi.org.uk/media/8107/abpi-cymru-wales-spring-bulletin-2020-for-publication.pdf>

¹¹

<https://www.ons.gov.uk/economy/governmentpublicsectorandtaxes/researchanddevelopmentexpenditure/adhocs/11347researchanddevelopmentexpenditureinthepharmaceuticalsproductgroupperformedinukbusinessesbycountryorregion2018>