



Health Bill Committee evidence submission

About the Association of the British Pharmaceutical Industry (ABPI)

The ABPI exists to make the UK the best place in the world to research, develop and access medicines and vaccines to improve patient care.

We represent companies of all sizes which invest in making and discovering medicines and vaccines to enhance and save the lives of millions of people around the world. In England, Scotland, Wales and Northern Ireland, we work in partnership with governments and the NHS so that patients can get new treatments faster and the NHS can plan how much it spends on medicines. Every day, our members partner with healthcare professionals, academics and patient organisations to find new solutions to unmet health needs.

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Background

In the context of the implementation of the 10-Year Health Plan (10YHP), the Health Bill has the potential to hardwire the conditions for delivery of the plan into the system itself. It can expand research participation, improve the adoption of innovation, enable effective partnerships with industry, develop workforce models suited to community-based care, enhance horizon scanning and the integrated use of medicines data, support the delivery of preventive medicines and vaccines, and ensure that strategic commissioning promotes health equity. The Bill should support not only the 10YHP, but other national health strategies, including the Cancer Plan.

These reforms, taken with the initiation of the Life Sciences Sector Plan and recent government commitments on medicines spending, should contribute to the shared aim with industry of making the UK a top destination for investment and growth, driving renewed confidence and supporting the government's ambition for the UK to become Europe's leading life sciences economy by 2030.

While the reforms offer the potential to strengthen strategic alignment, clarify accountability and improve oversight, there is also a risk that reductions in staffing and the consolidation of responsibilities could lead to the loss of critical clinical and operational expertise, particularly in areas such as vaccination.

The provisions of the Bill demonstrate the broader centralisation of authority and control of the NHS with direct responsibility and oversight being held by the Secretary of State (SoS), with the DHSC/NHSE Joint Executive Team serving as an important first step in this process.

As these reforms move into implementation and the NHS transitions to a new operating model, industry stands ready to act as a strategic partner to government. Through the Bill, we must ensure medicines and vaccines are adopted more consistently and equitably, support prevention and community-based care, and help build an NHS fit for the decades ahead that delivers better outcomes for patients and the UK's long-term prosperity.

Recommendations

Recommendation	Rationale
Strengthen safeguards around the use of the Single Patient Record by setting out explicitly in Clause 47 of the Health Bill that access should be solely for the purposes of delivering or improving individual or population health or care.	Whilst recognising the intention of Clause 47(2)(3), the ABPI does not feel that this is legally necessary and would be concerned about the risk of creating a broad gateway when the intended reassurance can be provided directly in the regulations.
Amend Clause 47(2)(6) to include specific reference to a minimum requirement for consultation, for example to include the National Data Guardian and the Confidentiality Advisory Group.	Such an amendment would improve public transparency about how the Single Patient Record is managed and used.
Additional clarity in Clause 6 of the Health Bill around how the Secretary of State will provide guidance or instruction to ICBs and regions on how to deliver their existing responsibilities to promote research and innovation.	The duty is real in that the language states 'must' rather than 'have regard to' but it is unaccompanied by any accountability mechanism, enforcement route or reporting requirement.
Amend Clause 22 to ensure ICBs forward plan includes: (a) the board's current capacity to support the delivery of clinical research, including commercial clinical trials, within its area; (b) the steps the board proposes to take to develop and maintain that capacity in accordance with the Secretary of State's duty under section 1CB.	This links the s.1CB innovation duty to an operational planning obligation. Given that the Bill removes the existing forward planning framework, this amendment provides the mechanism to ensure ICBs are required to address research capacity in planning.
Replacing text in Clause 19 (1)(b) to include “activities that the board considers to be beneficial to the health service or to the health, outcomes or wellbeing of patients and the public, including activities carried out in partnership with commercial organisations.”	The addition of 'patients and the public' as an independent purpose test, alongside the health service, removes the ambiguity that excludes industry partnerships whose primary beneficiary is the patient rather than the system. It is also consistent with the Bill's own stated objectives around patient-centred care.
Removing text in Clause 44 on ICB financial duties provision.	The current text creates the statutory hierarchy that currently does not exist between ICB financial duties and NICE implementation to ensure patient's access to treatments is protected.

An additional Clause that requires the Secretary of State to make an annual report to Parliament on the performance of routine, seasonal and targeted immunisation programmes.	Transferring vaccination commissioning to ICBs is the right way forward to enable more locally targeted, designed and implemented outreach to under-vaccinated communities – however monitoring is needed
Amend Clause 58 to clarify the provision allows the period within which a recommendation is to be complied with in individual and exceptional circumstances.	Determining funding variations from the standard 90-day implementation of NICE guidance (mandatory funding requirement under the NICE regulations) must not provide the power to alter the funding mandate itself. Individual requests from the NHS to alter the timeline should remain considered in exceptional circumstances only and through NICE's funding variation request process which includes multi-stakeholder input.

Data

The Bill presents a unique opportunity to enhance the use of data to improve patient care.

Single Patient Record

The Bill sets out provisions for the creation of a Single Patient Record, with the intention of improving patient access to their health and care information and improving the delivery of care. The Single Patient Record has real potential to improve patient care. Done well, it can transform individual care by ensuring clinicians have the right information at the right time. It should also enable responsible, well-governed research, helping to generate the evidence needed to improve the safe use of medicines and address unmet need by accelerating the development of new medicines for patients across the UK.

Realising these benefits depends on earning and maintaining public trust, patients need confidence that their data is handled securely, their privacy is protected, and there is clear transparency about how their information is used.

We note the clarification in Clause 47(2)(3) that processing of information in accordance with regulations yet to be made would not constitute a breach of any obligation of confidence owed. However, this clause is not legally required and risks creating too broad a gateway for subsequent regulations. The ABPI believes that such clarification to controllers about their legal responsibilities can be made directly in the regulations.

We welcome the recognition in Clause 47(2)(5) that clarifies that the Single Patient Record may be used for any purpose for which it could otherwise lawfully be processed, which would include secondary purposes such as health and care research.

Clause 47(2)(6) sets out the requirement for the Secretary of State to consult such persons as they consider appropriate before making regulations relating to the Single Patient Record. The ABPI regards this as a weak consultation requirement. Compare this with Schedule 7, clause 8(1)(c) of the Care Act 2014, which requires NHS England to seek advice from the Confidentiality Advisory Group before disseminating confidential information.

Recommendation: The ABPI recommend strengthening the safeguards around the use of the Single Patient Record by setting out explicitly in **Clause 47** of the Health Bill that access should be solely for the purposes of delivering or improving individual or population health or care. This would include use of the Single Patient Record for health and care research and for improved population health management, including the ability to share data across govt departments (e.g. DWP), but would exclude other forms of research that would be outside patient expectations.

Recommendation: The ABPI would welcome a commitment in the legislation to public transparency about how the Single Patient Record is managed and used. The ABPI recommends that **Clause 47(2)(6)** includes specific reference to a minimum requirement for consultation, for example to include the National Data Guardian and the Confidentiality Advisory Group.

Whilst recognising the intention of Clause 47(2)(3), the ABPI does not feel that this clause is legally necessary and would be concerned about the risk of creating a broad gateway when the intended reassurance can be provided directly in the regulations.

Promoting Research and Innovation

The Health Bill importantly does not remove the existing duties placed on ICBs under the 2022 Health and Care Act to promote innovation and research. This clarification is particularly welcome given the Model ICB Blueprint previously suggested that responsibilities for research, development and innovation would increasingly transfer to NHS regions over time. The Bill therefore provides important reassurance around the continued role of ICBs in supporting research adoption and innovation across local systems.

Strengthening research participation and health equity in primary care is essential if prevention and early intervention are to become routine rather than exceptional. Medicines and vaccines increasingly enable care outside hospital settings, but their impact depends on having the workforce, pathways and partnerships in place to deliver care safely and effectively closer to patients' homes, particularly in under-served communities.

The duty is real in that the language states 'must' rather than 'have regard to' but it is unaccompanied by any accountability mechanism, enforcement route or reporting requirement. The 2022 Health and Care Act inserted research duties onto ICBs via s.14Z45 of the 2006 Act. More specifically, this duty is on the Secretary of State, not on ICBs. It does not directly require any ICB to do anything. Whether it filters down through Mandate instructions, NHS Standard Contract conditions or NICE guidance is entirely at ministerial discretion.

The ABPI's 2025 [Translating Actions into Impact](#) report specifically highlighted the need for greater clarity around accountability and leadership for research and innovation between ICBs and regions.

Recommendation: The ABPI recommend additional clarity in **Clause 6** of the Health Bill around how the Secretary of State will provide guidance or instruction to ICBs and regions on how to deliver their existing responsibilities to promote research and innovation, specifically in a way that avoids unwarranted variation in the adoption and spread of innovation.

We welcome the responsibility placed on the Secretary of State to promote innovation in the provision of health services including the arrangements made for their provision but would like to see such guidance or instruction making explicit reference to commercial health and care research, as the importance of such research is not widely appreciated by ICBs currently.

ICB Research Planning Priorities

Sections 14Z52 to 14Z57 of the National Health Service Act 2006 provided the statutory framework through which ICBs set out their planning priorities jointly with partner trusts, including, in principle, priorities around research and innovation delivery. By omitting these sections entirely rather than replacing them, the Bill leaves a vacuum: there is now no statutory planning document in which commercial research capacity, clinical trial infrastructure or research workforce could be required to appear.

The innovation duty in s.1CB (Secretary of State must promote innovation) provides a statutory peg, but without a corresponding planning obligation on ICBs there is no mechanism to translate that duty into operational commitments at system level.

Recommendation: We therefore propose amending the Bill by inserting into **Clause 22** that the joint forward plan must include a statement of:

- (a) the board's current capacity to support the delivery of clinical research, including commercial clinical trials, within its area; and
- (b) the steps the board proposes to take to develop and maintain that capacity in accordance with the Secretary of State's duty under section 1CB.

This links the s.1CB innovation duty to an operational planning obligation. Given that the Bill removes the existing forward planning framework entirely, this amendment is not merely desirable, it is the only mechanism available to ensure ICBs are required to address research capacity in any planning document at all.

Strategic Commissioning

NHS and industry collaboration

To promote partnership working, the power of ICBs to provide assistance should extend beyond those conducting 'activities that the board considers to be beneficial to the health service.' This could be interpreted to mean directly operational activities such as through service delivery, pathway improvement and workforce development. Pre-commercial research, horizon scanning, capability building partnerships and innovative medicine access programmes that primarily benefit patients rather than the health service as an institution will be excluded unless this wording is changed.

Recommendation: The ABPI would therefore propose an amendment **Clause 19 (1)(b)** to leave out "*activities that the board considers to be beneficial to the health service,*" and insert "*activities that the board considers to be beneficial to the health service or to the health, outcomes or wellbeing of patients and the public, including activities carried out in partnership with commercial organisations.*"

The addition of 'patients and the public' as an independent purpose test, alongside the health service, removes the ambiguity that excludes industry partnerships whose primary beneficiary is the patient rather than the system. It is also consistent with the Bill's own stated objectives around patient-centred care.

ICB Financial Duties

The Bill tightens ICB financial duties so that ICBs must balance their books annually with less ability to carry forward deficits. Simultaneously, s.237(8A) potentially tightens NICE compliance timescales. These two provisions point in directly opposite directions.

ICBs already face structural deficits. NHS England's own planning framework for 2025/26 showed the majority of ICBs in deficit. High-cost NICE-approved treatments, particularly for rare diseases, oncology and advanced therapies is a large driver of ICB budgetary pressure. When an ICB must balance its books annually and also comply with a NICE funding requirement within 90 days, the financial pressure is acute.

Recommendation: The ABPI propose an amendment to **Clause 44** to move “*An integrated care board's obligations under [the relevant financial duties section] shall not be construed as a basis for the board to decline to fund services, treatments or medicines which the board is required to commission pursuant to guidance issued by the National Institute for Health and Care Excellence, unless the Secretary of State has issued a specific direction permitting such deferral.*”

This creates the statutory hierarchy that currently does not exist between ICB financial duties and NICE implementation to ensure patient's access to treatments is protected.

Vaccination and immunisation

The removal of Section 7A from the National Health Service Act 2006 (Clause 39) reflects a shift in how vaccination, screening and certain other public health functions may be delegated across the NHS system. Section 7A was the formal statutory conduit through which NHS England held vaccination and screening delegations from the SoS. Its removal means the underlying functions revert to the SoS and can be re-delegated under the new s.65Z5(1A).

While it is anticipated that commissioning of vaccination services will be delegated to ICBs¹, the provisions in the new s.65Z5 (1A) significantly expand the Secretary of State's ability to delegate to, or jointly exercise health service functions with, a wider range of organisations, including ICBs, local authorities, combined authorities and other prescribed bodies. The Secretary of State will remain ultimately accountable.

Transferring vaccination commissioning to ICBs is the right way forward to enable more locally targeted, designed and implemented outreach to under-vaccinated communities but it is not without risk, more so in the context of ICB headcount reductions and budget cuts.

Retaining the Secretary of State's ultimate accountability for vaccination programmes is therefore an important safeguard. Immunisation programmes are national and will always require strong central direction, support and accountability to ensure that vulnerability to

¹ <https://www.england.nhs.uk/long-read/direct-commissioning-update/>

infectious diseases is managed across all our communities. In the event of significant delivery challenges or system-wide failures this ensures the Government can intervene directly, re-centralise responsibilities where necessary, and provide stronger national direction and oversight.

Implementation will need to be carefully monitored to ensure ICBs are performing and the Secretary of State is intervening as appropriate. To support the Secretary of State, and to ensure effective delivery of things 'best done once' (such as developing national service specifications, liaising with the Joint Committee on Vaccination and Immunisation and developing/maintaining vaccination data reporting systems), national level immunisation operational expertise currently in NHSE must be retained in DHSC following the merger.

Recommendation: An amendment should be added to **Clause 39** that relates to s.65Z5 to require the Secretary of State to make an annual report to Parliament, published in a timely and comprehensive manner, on the performance of routine, seasonal and targeted immunisation programmes. The report must cover all eligible cohorts under the national immunisation programme, use consistent measures across programmes and include reporting that enables tracking of inequalities across geography and population groups.

This would help address current gaps in reporting, particularly for some at-risk adult cohorts, and would also create clearer pressure to improve reporting on areas such as HPV catch up coverage. There is also precedent for this approach in other areas.

Access

NICE Recommendation Timeline

The Bill contains provisions that would update the HSCA 2012 to enable the Secretary of State the power to agree variations to the standard 90-day period for implementing NICE guidance (as per the mandatory funding requirement under the NICE regulations). It needs to be clear this provision does not give the power to alter the standard 90-day implementation period through secondary legislation.

The process by which the Secretary of State would engage in and agree funding variations needs to be clarified with stakeholder input, including from industry. We recommend this aligns with the NICE process, which is outlined in NICE's health technology evaluation manual (changes to this process have been proposed and are currently being [consulted on](#)) and used only in exceptional circumstances.

Recommendation: The ABPI recommends inserting a clarification to Clause 58 to replace the current text with the following:

“(8A) Provision made under subsection (8)(b) may include provision about the period within which an individual recommendation is to be complied with (including provision for the period to be determined by NICE or the Secretary of State in exceptional circumstances)”.