Amgen UK

Response to Clause 58 of the Health Bill

Preserving Timely Patient Access Through the NICE Funding Mandate

Executive Summary

Amgen welcomes the Government's ambition to modernise the NHS and supports the structural reforms proposed through the Health Bill. We recognise that, following the abolition of NHS England, responsibility for agreeing variations to the statutory implementation period for NICE recommendations must transfer to another body.

We also recognise that there may be exceptional operational circumstances where implementation within the standard 90-day period is genuinely not feasible. In these limited situations, an appropriate funding variation mechanism is necessary to support the safe and effective introduction of innovative medicines.

However, Clause 58, as currently drafted, provides a broad enabling power without retaining the safeguards that underpin the existing funding variation process. While the Minister has confirmed that the power is intended only for circumstances where implementation within three months is "not realistic", this important limitation is not reflected in the legislation itself.

The statutory requirement to implement NICE Technology Appraisal recommendations within 90 days has been one of the defining strengths of the UK's health technology assessment (HTA) system. It provides certainty for patients, clinicians, the NHS and industry that medicines judged by NICE to be clinically and cost effective will become routinely available within a predictable timeframe.

Amgen therefore supports transferring the funding variation power but recommends that Clause 58 is amended to ensure that:

- the statutory 90-day funding requirement remains the default position;
- variations are restricted to clearly defined exceptional operational circumstances;
- affordability or wider NHS financial pressures cannot justify delayed implementation;
- decisions are transparent, evidence-based and subject to consultation;
- any variation remains time-limited; and
- appropriate Parliamentary oversight is maintained.

These safeguards would retain the operational flexibility sought by Government while protecting timely patient access, preserving confidence in the NICE appraisal system and supporting the UK's ambitions to become the leading life sciences economy in Europe.

About Amgen

Amgen is one of the world's leading biotechnology companies, committed to discovering, developing, manufacturing and delivering innovative medicines for patients living with serious illnesses. In the United Kingdom, Amgen works in partnership with the NHS, NICE, clinicians, researchers and patient organisations to improve patient outcomes and support the timely adoption of innovation across the healthcare system.

We share the Government's ambition to improve patient outcomes, strengthen NHS productivity and position the UK as a global leader in life sciences. A predictable and trusted pathway from regulatory approval through health technology assessment to routine NHS adoption is fundamental to achieving these objectives.

Background

Clause 58 transfers responsibility for determining variations to the implementation period for NICE recommendations following the abolition of NHS England.

Existing legislation already provides a mechanism for varying implementation timelines where exceptional budget impact considerations apply. Importantly, that process operates within a well-defined statutory and procedural framework, incorporating clearly defined eligibility criteria, transparent decision-making, stakeholder engagement, publication of supporting rationale and a defined maximum implementation period.

Clause 58 retains the power to vary implementation timelines but does not preserve these safeguards. As currently drafted, the legislation provides broad discretion without defining the circumstances in which the power may be exercised or the process by which decisions will be made.

Although the Minister stated during Public Bill Committee proceedings that the power would only be exercised where implementation within three months is 'not realistic', Amgen believes that this policy intent should be reflected explicitly within legislation or accompanying regulations to provide certainty for patients, clinicians, NHS organisations and industry.

Amgen's Policy Position

Amgen's response is founded on three core principles:

1. Protect timely patient access.
2. Preserve confidence in the UK's health technology assessment system.
3. Support the Government's ambitions for NHS reform and life sciences growth.

Principle 1 – Protect timely patient access

The statutory 90-day funding requirement is what gives practical effect to a positive NICE recommendation. Without timely implementation, medicines may be approved in principle but unavailable to patients in practice. Amgen recognises that exceptional operational circumstances may occasionally justify a longer implementation period. However, these situations should remain genuinely exceptional and should not alter the fundamental expectation that implementation occurs within 90 days.

Principle 2 – Preserve confidence in the NICE health technology assessment system

The NICE appraisal process already represents the NHS's comprehensive assessment of a medicine's clinical effectiveness, cost effectiveness and overall value for money. Once NICE has issued a positive recommendation, implementation should focus on delivering patient access rather than revisiting affordability. Clause 58 should therefore only address exceptional operational or service-readiness challenges and should not become a mechanism for managing affordability pressures after NICE has already determined that a medicine represents a clinically and cost-effective use of NHS resources.

Principle 3 – Support the UK's life sciences ambitions

The Government has set ambitious objectives through the 10-Year Health Plan and the forthcoming Life Sciences Sector Plan. Maintaining confidence in the statutory 90-day funding requirement supports timely patient access while reinforcing the UK's attractiveness for research, development and commercial investment.

What Clause 58 Changes

Current Framework	Clause 58 (as drafted)	Amgen Recommendation
90-day implementation is the statutory default	Implementation period may be varied	Retain the 90-day default
Defined funding variation process	Broad discretionary power	Restrict to exceptional operational circumstances
Defined eligibility criteria	Criteria not specified	Define criteria
Stakeholder consultation	No consultation requirement	Require consultation
Published rationale	No publication requirement	Publish reasons
Defined maximum implementation period	No statutory maximum	Introduce a maximum period

Amgen's Recommendations

- Preserve the statutory 90-day funding requirement.
- Restrict the variation power to exceptional operational or service-readiness circumstances.
- Explicitly exclude affordability, budgetary pressures and NHS financial performance as grounds for delay.

- Require consultation with patients, clinicians and industry.
- Require publication of supporting evidence, reasons and revised implementation timelines.
- Introduce a maximum implementation period.
- Maintain Parliamentary oversight through the affirmative procedure.

Suggested Legislative Drafting

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 only in exceptional operational circumstances where implementation within 90 days is demonstrably not feasible and where any variation is necessary to ensure the safe and effective introduction of the recommended intervention.

Conclusion

Amgen supports the Government's objective of ensuring that a funding variation mechanism continues following NHS structural reform. We also recognise that limited operational flexibility may occasionally be necessary to support the safe and effective implementation of innovative medicines.

However, the legislation should preserve, not dilute, the principles that have made the UK's health technology assessment system internationally respected. By embedding clear safeguards in primary legislation or regulations, the Government can retain the operational flexibility it seeks while protecting timely patient access, preserving confidence in the statutory 90-day funding requirement and supporting the ambitions of the 10-Year Health Plan, the Life Sciences Sector Plan and the UK's broader growth agenda.