ABPI position on the government's plans to develop a Single National Formulary in England

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The ABPI welcomes the government's intentions to accelerate equitable adoption of innovative medicines in line with the guidance produced by NICE. Overcoming long-standing barriers to adoption of new medicines that are clinically and cost effective is essential for improving equity of access and patient and NHS outcomes.

The Single National Formulary (SNF) could support achieving these goals, as well as the government's vision to be a leading life sciences economy and the terms of the UK-US agreement on pharmaceutical prices and tariffs, which has committed to increase spend on innovative medicines to 0.35% of GDP by 2028 and 0.6% thereafter. This will however be dependent on how the SNF is designed and implemented, which at this stage is not yet clear. This paper sets out the ABPI's views on what the SNF must and must not do if it is to deliver for patients, the NHS and the life sciences sector. Clarity is urgently sought from government on how the SNF will be an enabler for delivering more rapid and equitable adoption of innovative medicines.

Recognising the SNF is in the early stages of its design and the mechanics of how it will operate are being worked through, now is a vital time to ensure it is developed in a way that will support, not hinder, NHS patients accessing the most effective treatment options when they need them, no matter where they live. Getting this wrong would risk hindering clinician autonomy, patient outcomes, and would also undermine progress towards a globally competitive environment for innovation.

Very simply, the SNF should remove local barriers, translating NICE guidance into the NHS as a single-entry point for all eligible patients to access the medicines they need.

For the SNF to deliver for patients, the NHS and the life sciences sector,	
it must:	**it must not:**
1. be designed and implemented as a clinically led, patient outcomes-focussed, national framework that drives faster and more equitable adoption of medicines	1. weaken the funding mandate, create new barriers or bottlenecks, or further delay the adoption of new medicines and indications
2. be aligned with NICE guidance, strengthening the funding mandate to support widespread adoption of medicines within 1-3 years of NICE recommendation	2. be driven by a focus on cost containment or restrict clinical autonomy and patient choice for NICE recommended medicines, including by altering or reinterpreting NICE guidance
3. preserve clinician autonomy to ensure patient outcomes remain a priority	3. create barriers to entry for new innovations that address unmet need in therapy areas with low-cost standard of care
4. dismantle duplicative layers of prescribing guidance, reducing unwarranted variation and allowing resource and capacity to be diverted to other areas of NHS care, including innovation adoption and system readiness	4. run counter to the government's commitments to increase spend on innovative medicines as a proportion of GDP and improve life sciences competitiveness
5. support the government's ambitions for a more sustainable and competitive life sciences ecosystem that provides confidence, predictability and certainty on how the system will drive equitable adoption of medicines in line with NICE guidance	5. be designed and implemented without visibility and true partnership between industry, patient groups and NHS stakeholders

To support the above, clear metrics and milestones should be co-created with all relevant stakeholders to inform the SNF's design and determine how to measure its success and impact on patients and the NHS. Given the complexity of the task and potential enormity of its impact on patients, pilots and regular reviews of progress with all stakeholders should inform transparent decisions about how and if it should progress beyond concept.

The key metric for success should be whether the SNF can deliver significantly improved adoption of NICE recommended medicines. If this will not be possible, or practical challenges arise that are insurmountable, the SNF should not progress and alternative options for achieving this goal should be explored.

The Single National Formulary needs to be an enabler of the government's ambitions for the NHS and Life Sciences sector

The SNF has the potential to address issues in local variation and adoption of medicines, improving alignment with NICE guidance to measurably improve the pace and equity of adoption of new medicines and indications. The Life Sciences Competitiveness Indicators[1] demonstrate that the UK continues to fall short of the international average for medicines uptake.

To address this serious and long-standing issue, the SNF must be designed and implemented with a clinically led and truly collaborative approach that maintains clinician autonomy, patient choice, and focusses on patient safety. It must be made clear to stakeholders at all levels that it represents a key delivery mechanism for the government's priorities to improve the UK's competitiveness in attracting innovation and investment.

Failure to position the SNF in this way risks creating a more unpredictable access environment, which could impact on companies' ability to launch new medicines or discourage continued supply of innovative medicines in the UK. This would have unintended consequences for patient outcomes and would lead to the UK falling further behind comparable health systems in access to innovative medicines.

The Single National Formulary has the potential to reduce inappropriate variation, but must be safeguarded against restricting clinical and patient choice

Whilst the SNF can support best prescribing practice and consistency across the NHS in England, it should not prevent or disincentivise clinicians from making treatment decisions that are best for the individual patient in front of them. The SNF should avoid any misalignment with NICE guidance and should

instead strengthen implementation of the funding mandate for all NICE-recommended medicines to support their widespread adoption within 1-3 years of NICE recommendation.

Maintaining clinical autonomy and diversity of therapy area expertise should be carefully considered when devising the role of the proposed Formulary Oversight Board, which will need to make decisions in a robust manner that accounts for clinical nuances, evidence gaps, and the rapidly evolving innovation landscape.

Sequencing of medicines has been communicated as part of the SNF's prescribing tool ambition. In clinical pathways that have a lot of treatment options, this may be considered necessary to promote optimal patient care – decisions should be based on strong clinical rationale.

[1] Life sciences competitiveness indicators 2024: summary - GOV.UK. Comparator countries used to derive the UK's uptake ratio are Australia, Austria, Belgium, Canada, Finland, France, Germany, Ireland, Italy, Japan, Netherlands, Spain, Switzerland, Sweden, and USA.

Plurality of treatment choice will support supply chain resilience

As well as a clinical focus on decision-making for the SNF, supply chain viability and strength from a plurality of medicines and suppliers needs to be fully considered. Disrupting supply chains can create significant financial burden, as well as risks to patient safety and outcomes. To avoid such an unintended consequence, the SNF should avoid generating prescribing guidance which is overly restrictive and not reflective of the multitude of options recommended by NICE.

Design and implementation require a truly collaborative approach, in partnership with industry and other stakeholders

A collaborative approach in partnership with industry and other stakeholders will be critical to the success of the SNF. The ABPI is represented on an industry task and finish group (TFG) which is very welcome, but more connectivity is needed to the other TFGs, as well as the Working Group and future Formulary Oversight Board. Industry representatives bring a wealth of insight and expertise on how the SNF could impact supply chains, data, and patient outcomes.

Clinical and NHS commissioning and provider input is also

critical, as is that from patient organisations, to ensure the work is sufficiently capturing and addressing concerns and recommendations from these stakeholder communities. It is not yet clear how the patient community is being engaged, or how the SNF will support shared decision-making.

Clear principles and success metrics are needed

Metrics are needed for measuring the success of the SNF and mitigating against risks flagged by stakeholders during its design and implementation. These metrics should be co-developed with all relevant stakeholders, including industry, with clear milestones set for measurement, reporting, and publishing at a local and national level. The metrics should clearly assess whether the SNF is truly supporting faster and more equitable adoption of NICE-recommended medicines, whilst supporting clinician autonomy and shared decision-making.

Metrics could include the level of adoption of specific NICE-recommended medicines within 1-3 years, as well as the UK's uptake ratio as reported by the Life Sciences Competitiveness Indicators. The ongoing work on the Innovation Scorecard and development of a Local Formulary National Minimum Dataset should be able to support this – with a need for a baseline and targets in the short, medium and longer term.

Given the complexity of the task and potential enormity of its impact on patients, pilots and regular reviews of progress with all stakeholders should inform transparent decisions about how and if it should progress beyond concept.

The duplicative and resource intensive approach to formularies must be addressed

The SNF has the potential to generate significant resourcing and time efficiencies by dismantling duplicative layers of formulary work and decision-making. Local NHS stakeholders should be supported to implement and operationalise the SNF, for example through appropriate budget allocations and incentives.

We expect the SNF to be implemented alongside the evolving Model Region and Model ICB operating framework, clarifying the future role of existing medicines optimisation infrastructure, including medicines optimisation committees and local medicines evaluation groups. Resource efficiencies should be fully captured as a key part of the SNF success metrics, and there should be clear indication that efficiencies are being redirected into areas of the system which can further support patient care, including by improving system readiness and adoption of innovation. Resolving formulary variation is one part of a bigger picture issue; clinical pathways and services need to enable consistent, high-quality care and treatment opportunities across the NHS.

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