Briefing on the Innovative Medicines Fund

Key Messages

- The Innovative Medicines Fund is a proposed £340 million fund to give "quicker access to the most advanced, life-saving treatments". It is an extension of the existing Cancer Drugs Fund (CDF), which has already improved access to promising new oncology treatments. The IMF will expand coverage to other innovative medicines, including those for rare conditions and smaller patient populations.
- We welcome the potential for the IMF to support faster and earlier patient access to medicines, including those that need further data to be collected to address uncertainty in their evidence base. The gathering of additional data over an interim period will allow NICE to subsequently make a final recommendation on the use of the medicine through routine commissioning.
- However, we strongly believe there is an opportunity for the IMF to be more ambitious than presently proposed. If taken forward in the right way, the IMF can be a platform to test out and trial more innovative reimbursement approaches, beyond just traditional managed access agreements. We would urge NICE and NHSE to embrace this opportunity.
- To ensure the IMF is best set-up to respond to patient needs, ABPI recommends that:
    - **NHSE's horizon scanning processes should be used to determine how the IMF budget should evolve over time.** This will allow the fund to respond to the number of new medicines launching in any given year and remove the need for an expenditure control mechanism.
    - **Learning from the CDF, more flexibility on balancing risk is required when deciding which medicines are plausibily cost effective and should go into the fund.** The current bar is too high for many medicines the fund was intended to support, such as those for rare conditions and smaller patient populations.
    - **Accessibility of the fund should be improved.** The current proposed commercial criteria are too restrictive and will make it onerous for many companies to risk taking part in the fund, especially SMEs.
- The IMF will largely benefit medicines where there is short-term uncertainty at the time of their evaluation. Whilst this is welcome, innovative medicines face other challenges in achieving reimbursement which will require additional policy changes to be made. The IMF needs to be introduced alongside new NICE appraisal methods and processes.
- If improvements are made to the current proposals, the IMF stands to enable patients to have even better and more timely access to life changing medicines, whilst delivering on the ambitions set out in the UK's Life Sciences Vision and Rare Disease Framework.

What is the Innovative Medicines Fund?

- The IMF is a proposed £340 million fund, which was first promised in the Conservative Manifesto in 2019, alongside a commitment to ensure patients have access to the best available medicines.[i]
- Since 2011, England has operated a Cancer Drugs Fund (CDF), which provides funding for access to promising new cancer treatments. The IMF will be an extension of the CDF, adding a separate £340m pot that will provide coverage to patients with diseases other than cancer.
- The current CDF operates as a "managed access fund". Where there are significant uncertainties about the effectiveness of new cancer treatments that limit their ability to be positively recommended by NICE at the time of their evaluation, the CDF provides funding for a time-limited period whilst additional evidence is generated. The additional data is then able to support a NICE decision later (usually after 2-3 years).

Why do we need an Innovative Medicines Fund?

- NICE ensures we have a robust health technology assessment (HTA) approach in place for making decisions about which new medicines represent value-for-money and should be paid for on the NHS.
- However, some innovative medicines struggle to be approved when assessed by NICE because of their limited evidence base. In the ambition to make medicines available to patients in the UK as quickly as possible, there is a trade-off between the amount of data available from ongoing clinical trials and real-world data sources versus that needed to make an appropriate access decision. This challenge can often be amplified for medicines breaking into new therapeutic areas, and medicines and those treating smaller patient populations, such as rare diseases.
- The IMF is needed to support innovative medicines in all clinical areas with a limited evidence base whilst additional data is generated to support informed decision making. This will ensure that all clinically effective new medicines have the best possible chance of reaching patients.
- The IMF can also provide opportunities to test out more innovative and creative payment approaches where appropriate.
- However, the IMF is a time limited ring-fenced fund, and it can only solve certain problems such as dealing with short-term uncertainty and providing earlier and greater access to promising new treatments. Whilst this is welcome, innovative medicines can face other access challenges such as addressing long-term uncertainty in the evidence base for cell and gene therapies.

- Solutions are still needed for these challenges if the UK is to have a world-leading medicines assessment process, and wider changes are needed through the NICE Methods and Process Review as well as the IMF.

What is the NICE Methods and Process Review?

- NICE is finalising a two-year programme of work, reviewing its methods and processes for health technology evaluation. NICE will publish a new Programme Manual in early 2022 bringing together the changes. If ambitious evidence-based proposals are taken forward, this stands to improve patients' ability to access new medicines and other healthcare technologies.
- Specifically, proposals to introduce a new severity modifier, accept greater uncertainty in some circumstances (such as when evaluating particularly innovative technologies and rare disease medicines), and change the discount rate applied in economic evaluations to 1.5% all have the real potential to benefit patients.
- For more information please see our Methods Review briefing.

What should the IMF look like?

- To ensure that the Fund is optimised for the benefit of patients, there are several principles that must be followed:

Horizon scanning and Budget

- To ensure the IMF is flexible enough to respond to patient need, and the number of new medicines launching in any given year, NHSE's new horizon scanning processes should be used to set a forward annual budget. This will also remove the need for there to be an expenditure control mechanism on the fund.

Expenditure Control Mechanism

- The IMF should not include an expenditure control mechanism, such as the one that is currently in place in the CDF, given that all growth on branded medicines expenditure is already underwritten through the Voluntary Scheme (VPAS) and Statutory Scheme.
- The VPAS manages all spend on branded medicines to within agreed growth limits, with industry paying rebates on all expenditure over agreed levels.

Entry Criteria

- It will be important to get the criteria right for selecting which medicines can enter the IMF and to set out in a clear way who will be responsible for making these decisions, working closely with stakeholders including patient organisations.
- As proposed, there are new criteria beyond those which exist for selecting CDF medicines, for example, the need to determine whether a medicine will address an

"unmet need". Along with many of the other proposed criteria, this is subjective and depending who applies the criteria, this may risk unnecessarily restricting which medicines enter the fund in practice, depending on how the criteria are interpreted, and by whom.

- Normally, entry into the IMF should be possible for all non-cancer medicines which would benefit from managed access. Careful consideration needs to be given as to what data can be collected within a reasonable time frame. It will be essential to use the body of evidence gathered from global clinical trials programmes, large scale international registries, as well as that from UK registries and datasets. Data collection should minimise burden on patients and clinicians and be flexible enough to accommodate different timescales.

Commercial Commitments

- Commercial access agreements should be put in place which reflect the mid-point of the plausible cost effectiveness range (£25,000 per QALY), as determined by NICE. Delivering plausible cost effectiveness estimates within the standard threshold range of £20,000 to £30,000 (considering any QALY weightings applicable at the time) and not below this, represents the point at which a technology is considered to represent value for money for the NHS. This is an appropriate risk balanced approach between the company and NHSE.
- The commercial commitments that companies need to agree to upon entering the fund are more onerous than those for the CDF which may mean that some companies, particularly smaller companies, are simply unable to access the fund.
- For example, some companies will be unable to commit to offering free of charge supply of potentially life long chronic treatments if NICE is eventually unable to recommend a medicine for routine use on the NHS.

- The IMF has the potential to benefit many thousands of NHS patients, particularly those with rare diseases, if the proposals being consulted upon are modified to fully address the issues which have been identified.
- In addition to providing funding for 'conditionally approved' medicines, the IMF should provide interim funding for medicines positively appraised by NICE from the point of marketing authorisation to the end of the 90-day guidance implementation period. This will align with the arrangements in place for cancer medicines, where this option is already available.

What will the new IMF achieve?

- A well-designed IMF will support UK patients getting faster and earlier access to new medicines that might not otherwise have been possible. Coupled with meaningful reform of NICE's methods and processes, this will help ensure that:

- thousands of children and adults with rare diseases get access to the latest medicines that could help transform their lives.
- the decline in life expectancy and devastating impact on quality of life caused by diseases like dementia and Alzheimer's is reversed when effective new medicines become available.

- The IMF can also help make the NHS one of the most attractive healthcare systems globally and deliver on the ambitions of the Rare Disease Framework.
- However, we must remember that while the delivery of the IMF and the NICE Methods and Process will take us towards a more world leading system, broader policy and process changes are still needed, such as those to enable more innovative payment approaches to be adopted by the NHS.
- It will also be essential to connect the opportunity of the IMF with the joined-up approach across research, regulatory and access. This will provide an aligned system view on the risks and opportunities for early access to innovative new medicines, including through the Innovative Licensing and Access Pathway (ILAP), Project ORBIS and the ACCESS Consortium.

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[i] https://assets-global.website-files.com/5da42e2cae7ebd3f8bde353c/5dda924905da587992a064ba_Conservative%202019%20Manifesto.pdf