BIA response to NICE consultation on methods and processes for including NICE technology appraisal recommendations in guideline topic areas

The BIA has responded to the National Institute for Health and Care Excellence (NICE)'s consultation on methods and processes for including NICE technology appraisal (TA) recommendations in guidelines. For further details about the consultation, please visit the consultation page on the NICE website.

Consultation response

The BIA welcomes the opportunity to provide feedback on these proposals.

The BIA supports the proposals for the **incorporation** of NICE TA recommendations into the guideline topic area. We support NICE's objective "to bring together and make it easier for users to find all its guidance about a condition" and believe that incorporation will achieve this aim.

However, the BIA does not support the proposals for the **integration** of NICE TA recommendations. We are concerned that integration could have a number of unintended consequences, including reducing clinician and patient choice and damaging the attractiveness of the UK as a launch market.

We believe that NICE should not proceed with the pilots for integration and should instead focus on the incorporation of TA recommendations into guidelines. We understand that over time a rationalisation of NICE TA recommendations may be required to support clinical decision making but we have strong concerns that the current concept of integration has not been sufficiently developed, tested or consulted on.

The key reasons for our opposition to the proposals for integration are:

- The potential for the funding mandate to be removed as soon as three years after a positive NICE recommendation risks **damaging the attractiveness of the UK as a launch market for new medicines**. The business case for launching a medicine in the UK is based on a period of adoption following a positive NICE recommendation, but this would be severely undermined if NICE was able to restrict or remove TA guidance after

only three years. The risk of the UK becoming deprioritised as a launch market is also amplified in the current context of increasing fees for NICE appraisals and high rebate rates versus other European countries.

- The removal of clinically and cost-effective treatment options would **restrict clinician and patient choice**. This could result in the removal of treatments options that have become established standard of care in the NHS, and damage the stability of patient care. Medicines recommended by NICE have already been established as clinically and cost-effective for use in the NHS and this should not be reassessed or reinterpreted.
- **Innovative new medicines risk being disproportionately impacted** by the proposals, as they may be deemed less cost-effective than comparatively cheaper older medicines, despite offering higher clinical benefit. The UK is a leader in the development and manufacture of innovative medicines and in order to maintain this leadership it is important that the UK can provide long-term patient access to these treatments in the NHS.
- **Access to innovative treatments for rare diseases may be particularly impacted** by the proposals for integration as these treatments often have higher costs per patient and increased levels of uncertainty. Rare disease treatments already face challenges in the access and reimbursment process and these proposals risk creating further inequity for rare disease patients.
- The proposals are **unnecessary as a means of cost-control** because the voluntary and statutory schemes cap NHS spending on branded medicines.

About the BIA

The BIA is the trade association for innovative life sciences and biotech industry in the UK, counting over 500 companies including start-ups, biotechnology, universities, research centres, investors and lawyers among its members. Our mission is to be the voice of the industry, enabling and connecting the UK ecosystem so that businesses can start, grow and deliver world-changing innovation.

BIA represents the interests of its members to a broad section of stakeholders, from Government and regulators to patient groups and the media. We also work with organisations at an international level to ensure that UK biotech is represented on the global stage including EuropaBio, the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the International Council of Biotechnology Associations (ICBA).

BIA is the key thought leader for the sector, operating across a wide range of areas such as policy, finance, science, regulatory, legal, skills and talent as well as genomics, engineering biology and techbio.