

National Institute for Health and Care Excellence

NICE and the life sciences industries

We have an important relationship with the life sciences industry

1. Our primary responsibility is to help people who use the services provided by the NHS and social care and those who care for them to achieve the best possible outcomes, making the most effective use of the resources available. The recommendations we make in our guidance have an important impact on access to care and treatment, and so our focus, in developing our guidance, is very much on those who rely on the publicly funded health and social services.
2. We also have a longstanding relationship with the life sciences industry (pharmaceutical, biotechnology, medical devices and diagnostics), which has its origins in the earliest days of NICE. The need to gain the support and confidence of the industry, along with the medical, nursing and midwifery royal colleges, patient and carer organisations and the NHS more generally, has always been an important responsibility.
3. Because NICE operates at the interfaces between health and social care policy, science, patient and carer expectations, professional autonomy, industrial policy, all set in the broader context of the resources available to the health and care system, we have a complicated and sensitive task. The work of reconciling these sometimes incompatible and competing influences on the decisions we are asked to make takes place at NICE at a number of levels, but most obviously and publicly in the work of our independent advisory bodies.
4. The relationship we have with the industry has to align with both the Government's policies for the life sciences sector and the capacity of the NHS to absorb and pay for innovation in a sustainable way. We recognise that as we advise practitioners and patients on the most effective use of new health technologies and to ensure value for money for the taxpayer, we are also able to make a contribution to supporting a thriving life sciences sector.
5. This position paper sets out the ways in which we work with the industry, in the development of our guidance and through our participation in national and international policy. It concludes with a statement of the contribution we want to make to the development of a successful life sciences industrial policy, including the ways in which our contribution can be enhanced, as part of the implementation of the Government's industrial strategy.

Policy

6. NICE has engaged with the industry in Government policy, ranging from the Cooksey report in 2006 through to the Accelerated Access review in 2016, and the development of a life sciences industrial policy in 2017. Beyond these Government initiatives, we have worked with the industry, alongside evaluative and regulatory partners in the UK, to develop new approaches to evaluating new health technologies, such as the early access to Medicines Scheme and the recently reformed Cancer Drugs Fund.
7. Internationally, we have led projects focused on making optimal use of real world evidence and establishing best practice and infrastructure for the implementation of regulatory pathways to facilitate timely patient access to cost-effective medicines. We are establishing new research projects on the use of 'real world' data in collaboration with the life sciences industry, through the use of the European Commission Innovative Medicines Initiative public-private research funds.

Methods and processes

8. Through regular, structured reviews, workshops, consultations on significant changes and in regular bilateral meetings, we discuss and exchange views with the industry on how NICE should go about evaluating its products. We have collaborated on the development of methods for evaluating emerging technologies as well as existing therapies. In 2016, for example, we published a report on the assessment and appraisal of regenerative medicines and cell therapies. This report attracted international interest from the industry and is considered a ground-breaking contribution to understanding the issues and challenges around the evaluation, pricing and reimbursement of complex advanced therapy medicinal products.
9. Our medical technology and diagnostic evaluation programmes, with processes and methods tailored to the particular needs of these types of technologies, is also recognised as innovative. These programmes have demonstrated that robust health technology evaluation can help identify what these types of technologies can offer to improve both patient outcomes and system efficiency.

Scientific advice and market access

10. Through the Scientific Advice Programme and the Office for Market Access, we have created new opportunities for dialogue outside the processes of our guidance development programmes. By engaging in these ways, we have been able to inform companies' offer to the NHS and develop long term, constructive relationships with them. And our experience in face to face meetings with around

500 individual medical technology companies, beyond our evaluation programmes demonstrates that there is a high level of trust in, and growing respect for our work in the medtech sector.

11. As the NHS becomes more sophisticated in its approach to adopting new health technologies, our role in evaluating and making recommendations is providing the opportunities for us to work with companies, to help them better understand what patients need and what the NHS wants to invest in. And we are developing capacity and expertise to help companies and the NHS engage successfully, through data-driven commercial access arrangements which make medicines more affordable for the NHS.

Product evaluation

12. The life sciences industry is engaged to a greater or lesser extent in most of our main guidance, information and service programmes:

- Technology appraisals, highly specialised technologies and medical device and diagnostics
- Clinical and public health guidelines
- Interventional procedures
- Medicines practice guidance
- Evidence summaries for off license use of new drugs
- Commissioning support documents for NHS England

13. By making recommendations on new and existing products, we can have an immediate impact on their commercial prospects, in this country and internationally. It is in the nature of what we do that there will always be a tension between our evaluations and companies' ambitions for their products. However, we aim to make this tension constructive and always oriented towards the best possible outcome for patients while ensuring value for money for the taxpayer.

Our contribution to the life sciences industry

14. We want to reduce the risk for companies introducing products to the UK market by helping them focus their value proposition on the most compelling data. We want to work with companies and the NHS to design and manage novel evidence generation processes and new data-driven funding models for fast-track approval and reimbursement which provide benefits to patients and make the best use of NHS resources. Building on the international value of a positive NICE appraisal, we want to extend our support for companies by increasing the visibility and accessibility of the Office for Market Access and Scientific Advice Programme

outside the UK. And we want to support the UK in developing a world-leading approach to using data to track outcomes and manage early access to worthwhile new technologies.

15. Our vision for a thriving relationship between the industry regulators and the NHS is an environment which enables and promotes adaptive, integrated regulatory approval, followed by the fast, data-driven evaluation, reimbursement and adoption of compelling, affordable value propositions.
16. The contribution we believe that we can make is set out in the following section, which describes how we help companies improve their value propositions and in doing so, how, through *an enhanced contribution*, we can support UK economic and export growth, and the further development of the UK as a destination of choice for companies developing innovative technologies.

Improving product value propositions

- The Office for Market Access helps companies to develop their value proposition, navigate NICE and engage in commercial negotiations with the NHS
- The Scientific Advice programme helps innovators to develop targeted evidence early in clinical development and links the regulatory and HTA systems with joint advice
- The Technology Appraisal programme identifies new, potentially cost effective products which need active management at market entry, to ensure timely access and sustainable adoption
- *NICE's enhanced contribution: helping reduce the risk for companies by working with them to focus their value proposition on the most compelling data*

Contributing to UK economic growth

- Clear, predictable approaches to evaluating new products, reduces uncertainty and time-to-market for companies operating in the UK
- Effective collaboration with NHS England helps to manage financially challenging products into the NHS
- Timely identification and evaluation of the most cost-effective health technology innovations, incentivises companies to plan early market launch in the UK
- Support for the adoption of effective and cost effective new technologies, including the use of the funding directive helps to drive the uptake of recommended products
- *NICE's enhanced contribution: working with companies and the NHS to design and manage novel evidence generation processes and new data-driven funding models for fast-track approval and reimbursement of cost-effective technologies.*

Helping to position the UK as a premier global life sciences destination

- NICE Technology Appraisal guidance has a significant influence on the adoption of new technologies globally
- Recommendations from NICE are used by companies in the commercialisation of their products in overseas markets
- NICE methods and processes are regarded as a global gold standard and influence the development, application and use of HTA in health systems around the world
- *NICE's enhanced contribution: increase the visibility and accessibility of the Office for Market Access and Scientific Advice Programme outside the UK, to place the front door to NICE's advisory services closer to the headquarters of the global life sciences industry.*

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