NICE's position on negotiations on the UK's withdrawal from the European Union.

Introduction

1. NICE's role is to drive improvement, promote excellence, and reduce variation in the health and social care system. Using our knowledge of research and evidence, we develop guidance, standards and information on high-quality health and social care. We also advise on ways to promote healthy living and prevent ill health.

2. We believe a negotiation leading to the UK's withdrawal from the EU that maintains the sharing and movement of knowledge and skills, the alignment of regulations in medicine and research, and a negotiation that maintains our close scientific and academic collaborations would benefit both the EU and the UK. Such a partnership would have impact in the UK, the EU and in the rest of the world.

3. Withdrawal from the EU will affect NICE in a number of ways, in particular in research, regulation, and technology assessment. This paper sets out the key issues for these three areas, for consideration during the negotiation.

Research

4. Exchange of evidence, data and other forms of knowledge between the UK and the EU is mutually beneficial and is an important pillar in supporting the UK's science base which fuels the pharmaceutical and medical technology sectors.

5. After withdrawal from the EU, the UK should work closely with the union in research and innovation. This should include:

    - Continued access to European research funding streams relevant to NICE such as the Innovative Medicines Initiative, Horizon 2020

Regulation

6. Regulatory alignment with the European Union in research and medicine regulation benefits UK citizens. It helps in the development, manufacture and trade of safe medicines. To ensure trade in health technologies continues in the interests of both the UK and the EU, the Government should:

    - Secure an agreement with the EU that recognises the mutual value of a shared regulatory framework for health technologies
    - Maintain alignment between regulations in the EU and the UK after withdrawal from the EU with the European regulatory process for

medicines through European Medicines Agency (EMA) which allows early dialogue

- Guarantee the UK's early access to medicines
- Ensure early dialogue with European regulators
- Ensure any separate national process in the UK is easy for companies to navigate to authorise their products in the UK.

NICE's role in technology assessment

7. NICE is a world leader in assessing innovative medicines and other health technologies to ensure they are effective and that they offer value for money.

8. Our objectives also support a vibrant UK life sciences sector. Through active engagement with the industry and participation in UK life science strategy initiatives, such as the Accelerated Access Review, we aim to achieve win:win scenarios where important health technologies are adopted at scale and pace in a financially sustainable way. Aligned with this ambition is a clear need for early engagement with regulators in Europe with and without companies.

9. To do this, we need knowledge, sustained by high quality research and highly specialised staff. We support the Prime Minister's vision for the UK as "one of the best places in the world for science and innovation".

10. To maintain the UK's leadership in health technology assessment (HTA) and to support the UK's life science industry, the Government should:

    - Negotiate use of clinical trial data and arrangements for access to confidential regulatory information in both new EU arrangements and in the UK. Access should be available to the new EU Clinical Trials portal and database[1].
    - Seek to be a part of the new centralised system to ensure the country remains an attractive place to conduct clinical trials and wider life sciences research. The new regulation will create a single point of entry for companies that wish to carry out clinical trials in a range of countries across the EU.
    - Negotiate continued participation in EUnetHTA and on-going arrangements for collaboration in health technology assessment in Europe. Engagement in the HTA networks across Europe supports NICE in developing world-leading, robust, and efficient methods and processes for technology assessment.
    - Enable access to relevant research funding streams relevant to HTA.

[1] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000629.jsp

NICE's key points for the negotiating process

Research

i. The UK must protect and enhance opportunities for life science and clinical researchers in the UK and EU to collaborate and compete.

ii. After withdrawal from the EU, the UK should be an international partner with the EU in research and innovation.

Regulation

iii. The UK should secure an agreement with the EU that recognises the mutual value of a shared regulatory framework for health technologies.

iv. Medicine and research regulations should continue to be aligned with early engagement and dialogue.

v. Access to clinical trial data and arrangements for access to confidential regulatory information needs to be secured in both new EU arrangements and in the UK.

vi. The UK should join the new centralised system for regulating clinical trials.

Technology assessment

vii. We need to ensure that the important role of NICE health technology assessment is recognised and supported in the post Brexit environment.

viii. NICE should be able to maintain its European networks to ensure the UK continues to play a leading role in the development of robust and efficient methods and processes for technology assessment.

ix. The UK should contribute to and have access to research funding streams relevant to HTA.

A vibrant UK life sciences sector

x. Maintaining early access to medicines is vital to ensuring we provide patients with the best innovative treatments, attract investment and remain a global leader in life sciences.

xi. Any separate national process for medicines regulation in the UK set up as a result of EU withdrawal needs to be easy for companies to navigate to authorise their products in the UK.

xii. Continued access to collaborative mechanisms formed in Europe is essential.