

# National Institute for Clinical Excellence

## *A submission to the Health Select Committee*

### NEW INQUIRY: THE INFLUENCE OF THE PHARMACEUTICAL INDUSTRY

#### Health policy, research, prescribing practice and patient use

## 1 Introduction

- 1.1 The National Institute for Clinical Excellence (NICE) involves a wide range of stakeholders in the development of its guidance including NHS staff, healthcare professionals, patients and carers, the academic world and the pharmaceutical and medical devices industries. The pharmaceutical industry has the same rights and responsibilities as any other stakeholder.
- 1.2 We take a structured approach to our engagement with the pharmaceutical industry that enables companies to make an appropriate contribution to the development of guidance and encourages them to work transparently, alongside other stakeholders.
- 1.3 The purpose of this memorandum is to describe the role of the Institute, to outline the way we work with our stakeholders, and to set the contribution made by the pharmaceutical industry within this context.

## 2 The Institute

- 2.1 NICE was established as a special health authority in 1999. Our role is to provide advice to the NHS in England and Wales on the clinical and cost effectiveness of drugs and other treatments. Our advice is for people who rely on the NHS for their care and for health professionals. Further information about the work of the Institute can be found at [www.nice.org.uk](http://www.nice.org.uk).
- 2.2 A summary of the four main types of NICE guidance is set out below.
  - 2.2.1 *Technology appraisals*: recommendations on the use of new and existing medicines and other treatments (devices, surgical and other procedures, diagnostic techniques and health promotion methods).
  - 2.2.2 *Clinical guidelines*: recommendations on the appropriate treatment and care of patients with specific diseases and conditions, such as diabetes and schizophrenia.
  - 2.2.3 *Cancer service guidance*: recommendations on arrangements for the organisation and delivery of services for people with cancer.
  - 2.2.4 *Interventional procedures*: guidance about whether interventional procedures used for diagnosis and treatment are

safe enough and work well enough for routine use. An interventional procedure is one used for diagnosis or treatment that involves making a cut or hole in the body, entry into a body cavity or using electromagnetic radiation (including X-rays or lasers) and ultrasound.

- 2.3 We publish around 25 technology appraisals, 12 clinical guidelines and 60 pieces of interventional procedures guidance each year.
- 2.4 NICE guidance is a key component of the national standards to which the NHS is now expected to work. Technology appraisals and interventional procedures guidance are 'core' standards, which require immediate implementation, and clinical guidelines are regarded as 'developmental' standards, the implementation of which will take place over a longer period.
- 2.5 The Institute is based in offices in central London. It has a budget of nearly £20 million, which is largely provided by the Department of Health but also includes a contribution from the Welsh Assembly Government, to which the Institute is jointly accountable. The Institute directly employs around 100 people.

### **3 Working with stakeholders**

- 3.1 Since its inception, the Institute has taken the approach that those whom its decisions affect are entitled to express their views on how we go about our work and on the development of individual pieces of guidance. We define these groups as including, but not necessarily limited to:
  - 3.1.1 patients, carers and the public, and those who speak for them;
  - 3.1.2 healthcare professionals;
  - 3.1.3 NHS management;
  - 3.1.4 healthcare industries;
  - 3.1.5 the Government.

We recognise these constituencies as key stakeholders in our work alongside a much larger group including, for example, other NHS agencies with related functions, research organisations and trade unions.

- 3.2 We make sure that our stakeholders (sometimes called consultees) have clear and reasonable opportunities to engage with us when we are developing guidance on a particular topic. The arrangements we have put in place have evolved as our experience of working with a diverse community of interested parties has grown. The main elements of these arrangements are summarised below.

- 3.2.1 Our processes and methods are developed in consultation with our stakeholders and with the independent experts who sit on our advisory committees. Drafts of our process and methods documents are exposed to public consultation and the comments received, together with the final versions of the documents, are approved by the Board in public session.
  - 3.2.2 We consult with stakeholders on our interpretation (the 'scope') of the topics referred to NICE by the Department of Health and Welsh Assembly Government. These scopes form the basis of each guidance development project.
  - 3.2.3 All draft guidance is subject to consultation with stakeholders and the wider public through the Institute's website.
  - 3.2.4 All documentation associated with the development of guidance, other than where we have agreed to restrictions for reasons of commercial or academic confidence (see Section 4.5), is released into the public domain.
  - 3.2.5 Comments submitted to the Institute by stakeholders are made publicly available along with the Institute's response.
- 3.3 We take the view that those who rely on our guidance should be able to understand how it has been developed; in effect, they should be able to see an 'audit trail' from the evidence to the recommendations. It should be clear why our advisory committees reached their conclusions, where any changes – from the draft to the final conclusions – have been made and why. To this end each of our programmes displays a common set of characteristics, which are summarised below.
- 3.3.1 *Use of the best available evidence:* each programme secures a comprehensive evidence base, by contracting the work to an independent body or by undertaking the work in-house, and stakeholders are invited to check that all relevant evidence has been considered.
  - 3.3.2 *Involvement of clinical and patient experts:* ensuring that our advisory bodies have access to clinical expertise and patient and carer perspectives as they interpret the evidence is crucial both to the relevance of the recommendations and to their credibility.
  - 3.3.3 *Independent advisory bodies:* the guidance that NICE publishes is prepared by independent standing committees (for technology appraisals and interventional procedures) and individual development groups (for clinical guidelines). All our advisory bodies include healthcare professionals working in the NHS and people who are familiar with the issues affecting patients and carers. The standing advisory committees also include people who have current experience working in the healthcare industries. Under the Institute's policy on declaration of interests,

the members of our independent advisory bodies, who are mainly unpaid advisors, are required to register their interests and declare any interests they may have in the specific topic under discussion at the start of each meeting. If a conflict of interest is identified, the individuals are required to stand down and do not take part in the relevant decision-making process for that project.

3.3.4 *Genuine consultation*: all NICE guidance undergoes widespread consultation with stakeholders and the public. 'Genuine' means that our advisory bodies will respond to reasoned argument that can stand up to independent scrutiny and, if necessary, change their original thinking.

3.3.5 *Regular review*: technology appraisal guidance and clinical guidelines are reviewed at regular intervals to ensure that they remain current. Review dates are set on the basis of the advisory body's understanding of the anticipated pace of change in the evidence base.

## **4 Engaging with the pharmaceutical industry**

4.1 We regard the pharmaceutical industry as a stakeholder in our work. As such, they have the same rights and responsibilities as any other stakeholder. Organisations developing health technologies on which patients rely have knowledge about disease areas and the therapeutic value of their own technology. They also have access to important clinical data that the advisory bodies need to access. The pharmaceutical industry employs staff who are skilled in the interpretation of clinical trial data and the outputs of economic analysis and they make a valuable contribution to the development of high quality guidance.

4.2 However, the Institute is conscious of the conflict of interest that manufacturers of health technologies have when engaging with us – that their desire, ultimately, is to ensure a market for their products and a return for their shareholders. Our structured arrangements for engaging with companies ensure that this conflict does not inappropriately influence the development of guidance.

4.3 The pharmaceutical industry mainly engages with the Institute in the development of the technology appraisals guidance and clinical guidelines, and it is on this basis that the following details are provided. Our structured approach to engaging with the pharmaceutical industry in these programmes (as with all our other stakeholders) is summarised below.

4.3.1 NICE drafts a written consultation on the scope for a technology appraisal or a clinical guideline.

4.3.2 NICE invites relevant members of the pharmaceutical industry, alongside the other stakeholders, to a meeting at the start of the

development of a piece of guidance to discuss the scope, the approach to assembling the evidence base, and the key issues that will be addressed during the development of the guidance.

- 4.3.3 NICE consults on the evidence to be used by the advisory body and all stakeholders are given the opportunity to supplement the evidence base. Ultimately, the evidence that is taken account of is a matter for the advisory body, which sets out the rationale for the use or otherwise of the evidence submitted by all stakeholders.
  - 4.3.4 The advisory body prepares a written consultation on the draft recommendations, on two occasions during the development of a clinical guideline (where there is no appeal stage), and on one occasion during the development of technology appraisal guidance (where there is an appeal stage). Comments received from the pharmaceutical industry on draft documents, in common with responses from other stakeholders, are posted on the Institute's website.
  - 4.3.5 In the technology appraisal programme the relevant pharmaceutical company, alongside other stakeholders, has the opportunity to submit an appeal on the grounds that the Institute has exceeded its powers or has failed to follow its process, or that the guidance is perverse.
- 4.4 One aspect of the way in which we engage with the healthcare industries which does differ from other stakeholders is that manufacturers do not attend meetings of the technology appraisals advisory committee, whereas patient and carer groups and healthcare professionals do attend these meetings. In our view this an important part of minimising the risks associated with the potential conflict of interest referred to in Section 4.2.
- 4.5 Guidelines on the release of company data into the public domain during a technology appraisal were agreed between NICE and the Association of the British Pharmaceutical Industry (ABPI) in May 2004. This agreement acknowledges the importance of putting relevant information into the public domain to ensure the credibility of NICE guidance. These guidelines are helpful in achieving consistency of approach by the pharmaceutical industry, and they are a step towards our long-term goal of achieving unrestricted access to and publication of all relevant data for the development of our guidance (see attachment).
- 4.6 The pharmaceutical industry has an interest in monitoring the implementation of the Institute's guidance. Where individual companies or trade bodies have monitored the uptake of medicines or medical devices and have agreed to make this information publicly available, the Institute has published this information on its website alongside studies commissioned by the Institute itself and those provided by patient organisations.

- 4.7 We believe that this structured and transparent approach to our engagement with pharmaceutical companies enables us to take advantage of the knowledge and expertise of these companies and access to their data while shielding those who are formulating recommendations on behalf of the Institute from the potential distorting effect of an over-enthusiastic presentation of the benefit of a product.

## **5 Supplemental evidence**

- 5.1 A copy of the agreement made between NICE and the ABPI on the release of company data into the public domain and referred to in 4.5 is attached at Appendix A for information.
- 5.2 Members of the Health Select Committee are also invited to review the detail of our arrangements for engaging with the pharmaceutical industry and other stakeholders in the process documents for the technology appraisals and clinical guidelines programmes, which are enclosed as Appendix B and C for information.

## **6 Conclusion**

- 6.1 The pharmaceutical industry, alongside other stakeholders, contributes to the development of high quality, credible guidance that supports healthcare professionals and patients and their carers in making decisions about treatment and care.
- 6.2 The Institute takes a structured approach to the involvement of the pharmaceutical industry in the development of its guidance in order to manage appropriately the conflict of interest that the industry may have when dealing with NICE.
- 6.3 The Institute works with the pharmaceutical industry to encourage a consistent approach to placing relevant data in the public domain in order to support the transparency and credibility of guidance recommendations and enhance public knowledge.

## **National Institute for Clinical Excellence August 2004**

Encs Appendix B: Guide to the Technology Appraisal Process  
Appendix C: The Guideline Development Process: An Overview for Stakeholders, the Public and the NHS

## Appendix A

### **Agreement between the Association of the British Pharmaceutical Industry (ABPI) and the National Institute for Clinical Excellence (NICE) on guidelines for the release of company data into the public domain during a health technology appraisal.**

#### **Principles:**

1. NICE and ABPI acknowledge that it is in the interests of patients and health professionals for all relevant information about products being appraised to be put into the public domain. Both accept, however, that the legal rights of the owners of the data must be respected.
2. NICE has made a commitment not to place in the public domain any information provided to it as commercial-in-confidence during a technology appraisal prior to the launch of the product(s) into the UK market.
3. Any reference in this Agreement to abstracts shall assume the adoption of the CONSORT rules for the reporting of clinical trials, and an equivalent standard for reporting economic models.
4. In circumstances that warrant publication of data regarded by the data owner as confidential, or the non-publication of data normally available for publication in accordance with these guidelines, both parties will negotiate in good faith to seek to find a mutually acceptable solution, recognising the need for NICE to support its recommendations with evidence and the data owner's right to determine a global publication strategy.
5. It is recognised that in all cases the data owner retains the right to make a final decision in relation to the release of information into the public domain.
6. It is acknowledged that the principles in this document apply to licence extensions as well as new chemical entitles.

<b>Data</b>	<b>Position</b>
Clinical trial evidence	
- published	Any information, once published even in abstract form, can no longer be regarded as commercial in confidence (C in C).
- unpublished - design	ABPI policy encourages voluntary registration of specified information relating to the protocols of phase III trials involving patients in the UK and the current publication status three months after marketing in the first major market and prospective registration of phase IV and SAMM studies relating to the product.
- results	Companies will authorise NICE to quote publicly from either a full report, or an unpublished abstract, where the date of release, by NICE, of such data is not less than 12 months after the "sign-off" by the relevant company. This 12 month restriction shall be the

	subject of negotiation in good faith between NICE and the company in the event that the licensing authority “fast track” an application leading to NICE requiring earlier publication.
Price	Pricing information will not be released, by NICE, into the public domain before product launch in the UK. In cases where NICE commissions an independent economic model companies will normally provide – in confidence – the price (or range of prices) expected. It is acknowledged that the final price of a product is often only determined immediately prior to launch.
Draft SmPC & EPAR	Whilst both the SmPCs & EPARs are public documents, draft versions cannot be published as changes may take place even for the indications right up to the last minute.
Final SmPC & EPAR	Public documents
Economic analysis	
- published	Any information, once published even in abstract form, can no longer be regarded as C in C but only to the extent of the data in the public domain.
- unpublished	Companies will authorise NICE to quote publicly from either a full report or an unpublished abstract, where the date of release, by NICE, of such data is not less than 12 months after the sign-off by the relevant company. This 12 month restriction shall be the subject of negotiation in good faith between NICE and the company in the event that the licensing authority “fast track” an application leading to NICE requiring earlier publication.
- model	Companies shall normally agree to their economic models being available to an independent academic group, in electronic form, for the purposes of a NICE technology appraisal. The model will be supplied in confidence and subject to suitable intellectual property protection. The terms of Principle 4 above shall specifically apply to any decision about availability of economic models.  Similar arrangements apply to models produced as part of a NICE health technology assessment.
Budget/resource impact (including marketing/sales forecasts)	Companies are encouraged to supply data from any projections they have prepared of uptake of their products in the NHS, at their own discretion, indicating which data should remain as commercial in confidence.