NICE and the healthcare products industry: working together to enhance access and promote value

Singapore, July 2013
Kalipso Chalkidou,
Director, NICE International
On averages and increments…

“Debates about technological progress in health care often confuse two distinct issues. One concerns the average improvement in health—are we better off today than in the past? The other concerns marginal improvement—if we spend more on health care, how much better off will we be?

We believe that average improvements over time have been large, but that marginal improvements from the last dollars we now spend are small.

The progress medical science has made against coronary heart disease is striking, but it is not evidence that implanting a stent in patients with single-vessel, minimally symptomatic coronary disease is worth the cost.

Most proposals for the reform of health care financing and delivery would alter spending and incentives at the margin. They should be evaluated on that basis.”
"Our independent advisory committees specifically look for innovation in new drugs, but it is of course the case that being 'new' is not enough.”

"A new drug has to offer more to patients than existing treatments to justify its additional cost, and we work hard to help companies understand the need to make the case for their new drugs, using the evidence.”
Deliberation and engagement matter

- **Evidence** needs to be interpreted with, amongst other things, values.
- Evidence about **values** is often generated during **deliberative processes**, conditioned by reality, shaped by case law…
- **Processes** can drive useful evidence generation, strengthen institutions and help build capacity, locally.
Bringing together different stakeholders – NICE is established in 1999

- The National Institute's membership will be drawn from the health professions, the NHS, academics, health economists and patient interests
- NICE will create a new partnership between the Government, the NHS and clinical professionals...It will also inform the decisions of those commissioning care
NICE: what we do

• Issues evidence-based advice on best clinical and social care and public health practice, incl. health technologies.

• To make a decision it takes account of:
  – Comparative clinical effectiveness
  – Comparative cost-effectiveness: $\Delta \text{£}/\Delta \text{health benefit}$
  – Equity and societal values of the English and Welsh populations
  – EU and UK anti-discrimination and human rights legislation
  – Practicalities of implementation
  – Degree of uncertainty of estimates
More than 3,000 external experts, including patients, health professionals, academics, researchers, industry representatives and lay members of the public, offer their time and experience to NICE every year...
Assessing value is context-specific

- Health outcomes for patients
- Stakeholder views and experiences
- Impact on health system resources

Scientific and social value judgements
Industry as a partner

- Engagement in development and update of methods and processes
- Topic selection and scoping workshops for each product
- Submission of evidence: reliant on industry reviews for new products
- Expert testimonies by professionals and participation in meetings
- Consultation
- Appeal and judicial challenge
Technology information, with one record per indication, including mode of action, route of administration, formulation, dose, BNF class, likely comparators and whether the product has been selected for NICE review.

Clinical Trial information, with one record per study, including patient population, study design, primary objectives and outcomes.

Regulatory information such as status, date of submission, estimated license date, estimated UK availability.

Costs and budget impact, including proposed average dose, estimated length of treatment, drug cost range per patient per year/per episode, budget impact.
Committee Day

ERG = Evidence Review Group

45 - 55 participants
Managing Vested Interests: Code of Practice for Declaring Interests (NICE 2007)

• Applies to:
  – NICE employees, NICE Chairman & non-executive board members and their families
  – Chairs and members of the advisory bodies to NICE
  – Expert advisors testifying
  – Employees of organisations contracted by NICE (including academic and professional associations)

Apply for the role of member to the GDG on management of hyperglycaemia in acute coronary syndrome in patients both with and without diagnosed diabetes mellitus

NICE have been commissioned by the Department of Health to develop a short clinical guideline on management of hyperglycaemia in acute coronary syndrome in patients both with and without diagnosed diabetes mellitus. We are currently seeking to recruit the following healthcare professionals for the guideline development group (GDG):

- Consultant Cardiologist
- Consultant Physician in one of the following areas; Acute Medicine, Diabetology, Accident & Emergency
- Inpatient diabetes/cardiology nurse specialist
- Clinical Pharmacist/cardiology nurse specialist
- Clinical Pharmacist with specialist interest in patient safety
- GP
- Patient/Carer x2
Is there a personal pecuniary interest?

A personal pecuniary interest involves a current personal payment, which may either relate to the manufacturer or owner of a product or service being evaluated.

Example:
Any consultancy, directorship, position in or work for a healthcare industry that attracts regular or occasional payments in cash or in kind, both those which have been undertaken in the 12 months preceding the meeting at which the declaration is made and which are planned but have not taken place.
Judicial challenge

- “NICE’s decision to issue the final guidance may be challenged by applying to the High Court for permission for a judicial review. Any such application must be made within 3 months of publishing the final guidance.” NICE Guide to Appeals, Aug 2010
Judicial Reviews

• Over 600 individual decisions – 3 judicial reviews
  – Alzheimer’s Disease
  – Osteoarthritis drugs (1o and 2o prevention)
  – Chronic Fatigue Syndrome guideline

• NICE final recommendation held in all 3 cases – in 2 out of 3 cases the Appeal’s Court required:
  – changes in wording re dealing with population subgroups
  – sharing of models/evidence
  – reconsideration of the evidence base
Alzheimer’s Disease guidance

• NICE recommends the drugs only for patients with moderate disease
• The companies and patient organisations appeal the decision at the High Court
• NICE’s final guidance is upheld but NICE is asked to:
  – share an executable version of the economic model with industry
  – reword its guidance to ensure non-native English speakers and people with learning disabilities.
Appeals – a step before the Courts…

- Appeals are genuinely helpful in:
  - improving the final guidance
  - getting stakeholder buy-in
  - reducing legal challenge…
Right to Appeal

- **Patients and Carers**: National groups representing patient and carers
- **Professionals**: Healthcare professional organisations (Colleges and Associations)
- **Industry**: Manufacturer(s) or sponsor(s) of the technology
- **Government**: The Department of Health and the Welsh Assembly Government
- **Payers**: Specialised commissioning groups, primary care trusts and local health boards
NICE writes to DH: “Following the outcome of the Appeal Panel decision sent to you on 26 March 2007, I am writing to you to request confirmation of the position of the Department of Health in relation to the ‘risk-sharing’ arrangements proposed by Janssen-Cilag for the provision of bortezomib, within its licensed indication, for relapsed multiple myeloma, in the NHS in England and Wales.”
Value Based Pricing: another chance for engagement

• “We will pay drug companies according to the value of new medicines…” The Coalition: our programme for government, July 2010

• NICE is a world-leader in its field, and it will continue to have a central role, both in undertaking pharmaco-economic assessments and in providing advice to the NHS on the relative clinical and cost effectiveness of treatments”

Consultation document on VBP, December 2010
The deal provides for a straight 12.5 percent discount to bring the cost of Votrient to the NHS into line with that of Pfizer's Sutent, and also guarantees a financial rebate if Votrient proves inferior to Sutent in the clinical trial.

"We are moving in the direction where price is driven by value and value is driven by evidence, and therefore we can start to construct different sorts of arrangements where we can balance this off." Simon Jose, GSK
Bristol-Myers Squibb’s melanoma drug, Yervoy (ipilimumab), will face a tougher time securing UK reimbursement than Roche’s melanoma drug, Zelboraf (vemurafenib):

• Uncertain long term impact
• Inappropriate (for Europe/UK) comparator
• Lack of predictive biomarker

Roche and BMS will likely have to make serious pricing concessions or institute patient access schemes to attain reimbursement

The UK, along with Spain, France, Portugal and others, has passed or are considering legislation that would make it more difficult to prove drug value in order to secure reimbursement.
Making exceptions explicit and quantifiable

• “...the Government would set a range of thresholds or maximum prices reflecting the different values that medicines offer...

• there would be higher thresholds for medicines that tackle diseases where there is greater “burden of illness”: the more the medicine is focused on diseases with unmet need or which are particularly severe, the higher the threshold;

• there would be higher thresholds for medicines that can demonstrate greater therapeutic innovation and improvements compared with other products;

• there would be higher thresholds for medicines that can demonstrate wider societal benefits.”
NICE

“Just by having a price negotiation it could lead to delays in access...While the goal of the system is to improve access, it may actually do the opposite” Eli Lilly UK
Value Based Pricing – *take 2…*

- “…the government confirms that NICE
  - play an important part in the future value-based pricing of branded medicines
  - have a bigger role in evaluating drugs, through assessing a medicine’s benefits and costs”

“This will help make sure that the price the NHS pays for new medicines is more closely linked to their value to NHS patients and society.”

22 March 2013
• We have already made it clear that NICE will have a central role in the value based pricing system, including in undertaking an assessment of the costs and benefits of different medicines, drawing on its world-leading expertise.

• We can now go further, and confirm that NICE will be responsible for the full value assessment of medicines under the future system. Work to develop the new system builds on NICE’s existing technology appraisals processes, but it is also capable of incorporating a broader assessment of a medicine’s benefits and costs, taking into account factors such as burden of illness and wider societal benefits. Importantly, it imposes no requirements on companies to collect additional data.
Specialised Services

“Our decision to give this work to NICE from April 2013 means that...we have a robust, transparent and consistent process in place for assessing very high-cost, low-volume drugs.” Earl Howe, Minister for Quality

• Fast: <6 months
• Consultative: patient views
• Multidimensional: limited value in a cost per QALY
• Informing investment: NHS Commissioning Board decisions
HTA: a win-win…(when it has teeth)

- **Engagement:** payers, clinicians, patients, industry
- **Predictability:** methods (RC, λ); direction for national uptake
- **Flexibility:** End-of-Life, Patient Access Schemes, VBP?
- **Direction:** scientific advice, EMA pilot

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NICE: some numbers

- **80%**: evaluated drugs receiving a positive recommendation
- **One in ten**: ratio of technologies that get rejected
- **3 months**: time for payers to fund newly approved drugs
- **4-8 months**: average time between licensing and guidance
- **~2%**: tariff uplift due to NICE +ve decisions on drugs
- **~£1.5bn**: annual increase in the drugs bill due to NICE
Stronger drive for local compliance

“You have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are clinically appropriate for you.” Jan 2009

• Providers would lose the entire 2.5% Commissioning for Quality and Innovation payment if they do not comply with NICE rules on drugs and practice
• “We expect individual organisations to meet that [Nice rules] or explain why. But the emphasis is on complying” NHS chief executive Sir David Nicholson, Dec 2011
Public Local Formularies

Date: 9 August 2012

Gateway reference: 17879

To: SHA Cluster Chief Executives
    PCT Cluster Chief Executives
    CCG Leaders

INNOVATION HEALTH AND WEALTH
Publication of NHS Formularies

Dear Colleague,

• “I want to see all NHS organisations publish information which sets out which NICE Technology Appraisals are included in their local formularies…Clinical Commissioning Groups will need to take the lead in working towards publication by 1st April 2013 at the very latest. It will be important that the publications are online, and are clear, simple and transparent, so that patients, the public and stakeholders can easily understand them. From 1st April 2013, I also intend to make this a standard term and condition in NHS contracts.”
Adoption support for new technologies

“Deltex shares soar 30% after NICE report”

New Health Technology Adoption Programme to help support uptake of innovative products in the NHS

Digital Look and other media reports

4th October 2010

The CardioQ – ODM system can save around £1000 per patient

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New April 2013

Thursday 18 October 2012

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