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

Singapore, July 2013

Kalipso Chalkidou,
Director, NICE International

NICE International
www.nice.org.uk/niceinternational

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."

Saturday 03 March 2012

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NICE hits back over "drug delay" claims

"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"

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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

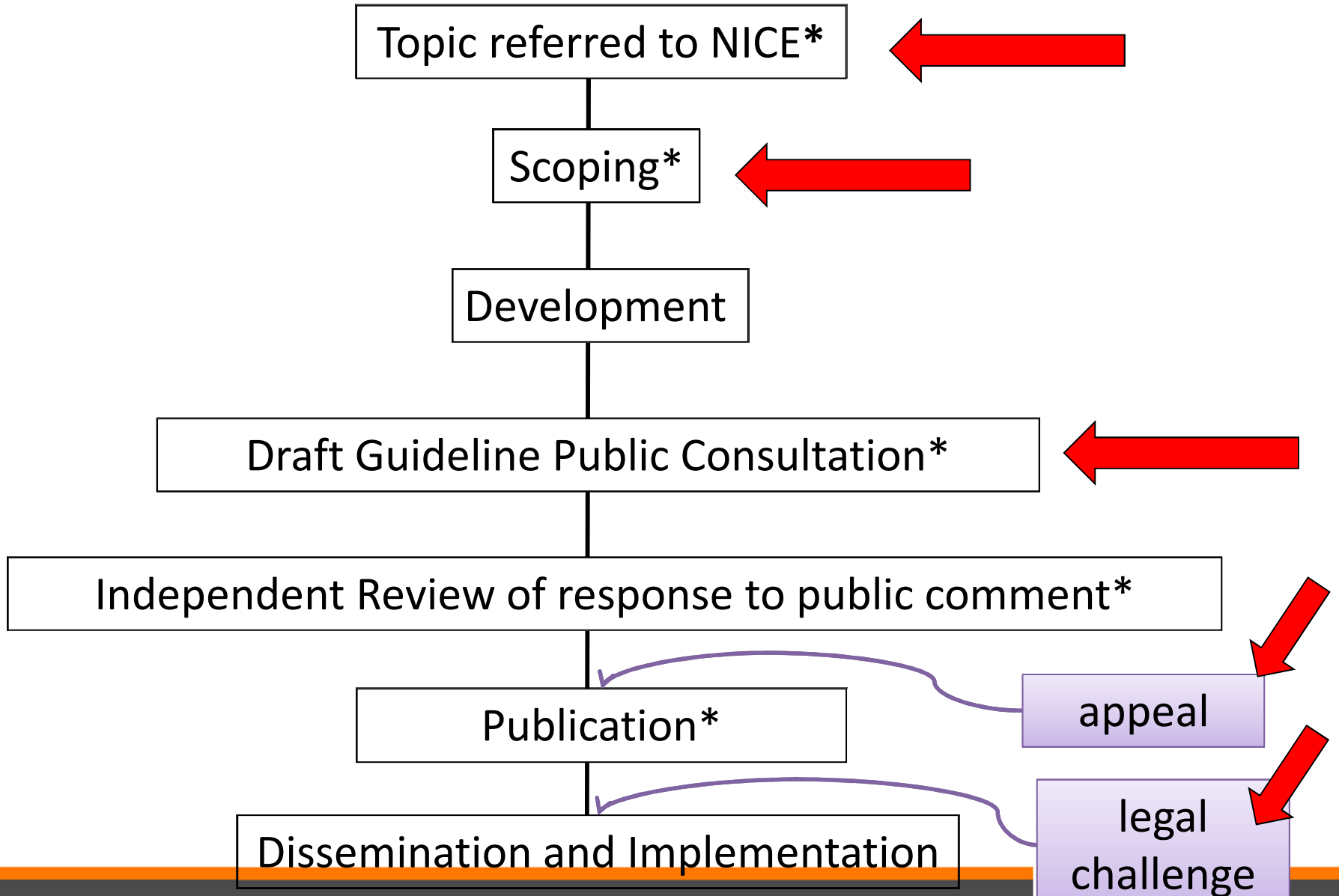
- The National Institute's membership will be drawn from the health professions, the NHS, academics, health economists and patient interests
- NICE will create a new partnership between the Government, the NHS and clinical professionals…It will also inform the decisions of those commissioning care

NICE: what we do

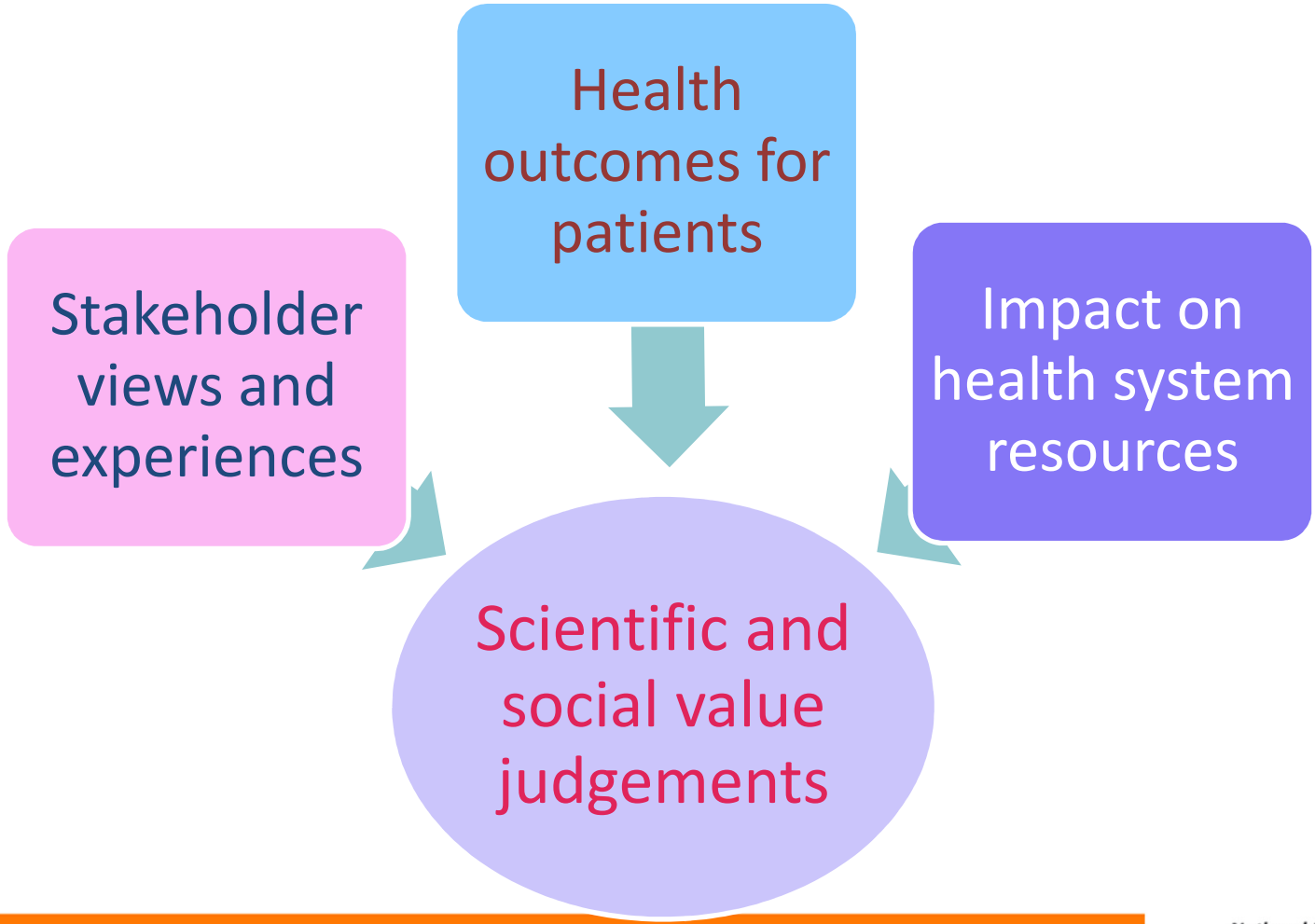
- Issues evidence-based advice on best clinical and social care and public health practice, incl. health technologies.
- To make a decision it takes account of:
  - Comparative clinical effectiveness
  - Comparative cost-effectiveness: Δ£/Δhealth benefit
  - Equity and societal values of the English and Welsh populations
  - EU and UK anti-discrimination and human rights legislation
  - Practicalities of implementation
  - Degree of uncertainty of estimates

Stakeholders

Stakeholder input



Assessing value is context-specific



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

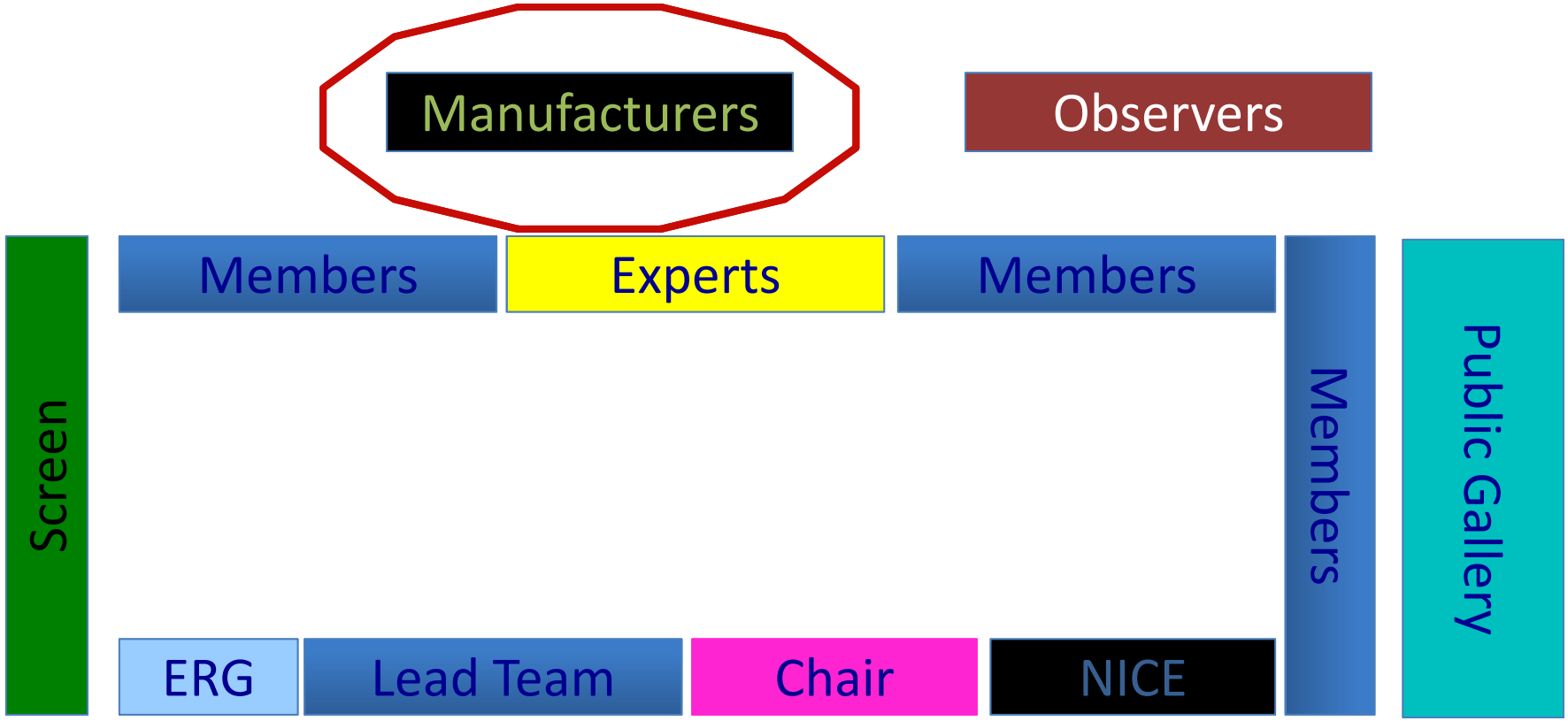
Appeal and judicial challenge

UK PharmaScan

developed and provided by NICE

- 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.

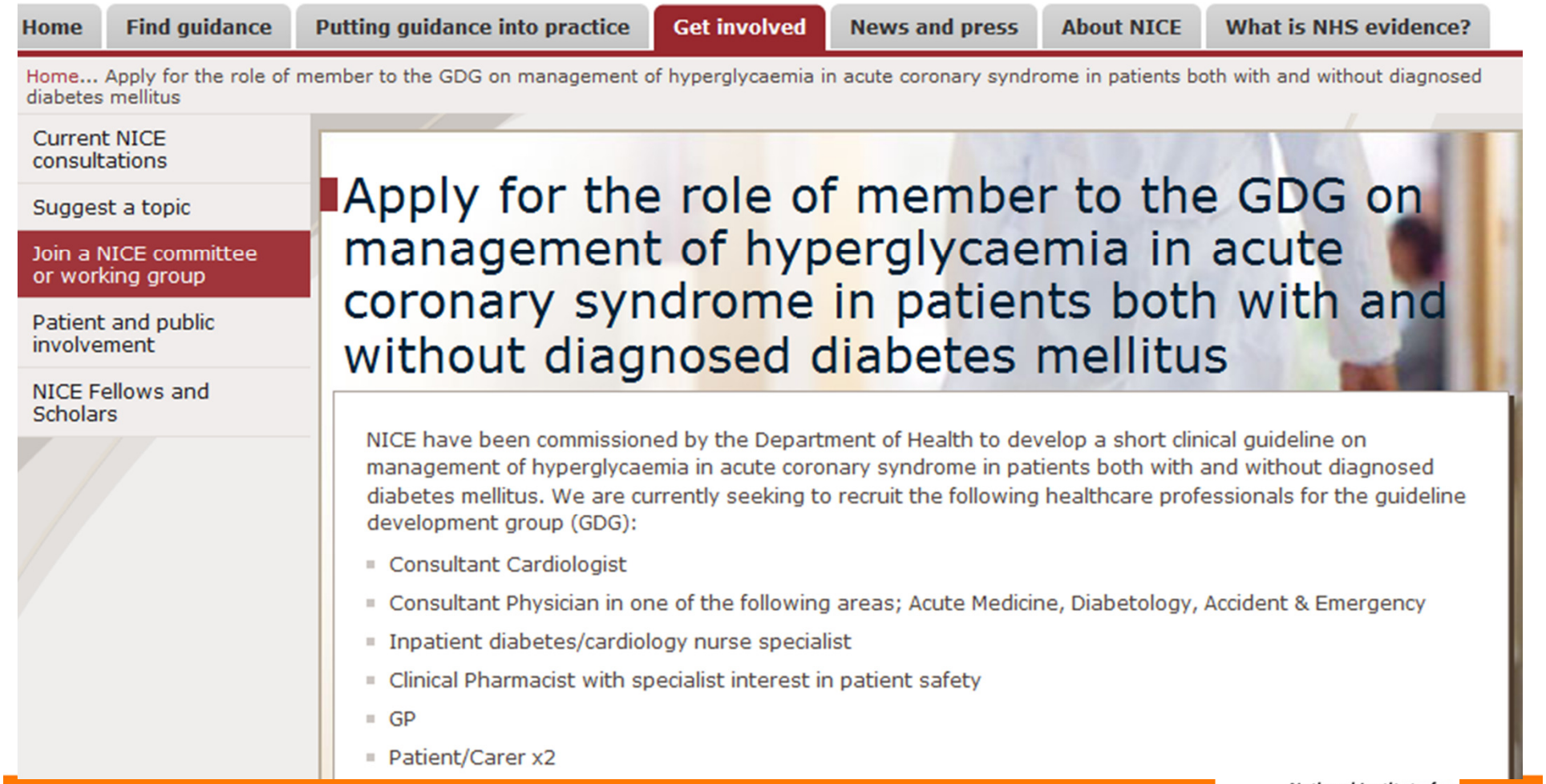
Committee Day



ERG = Evidence Review Group

45 - 55 participants

Managing Vested Interests: Code of Practice for Declaring Interests (NICE 2007)



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

MM and Velcade

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.”

- Patient Access Schemes and now Value Based Pricing are born…

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

GSK offers UK rebate if Pfizer cancer drug better

By
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a partial rebate from GlaxoSmithKline if the

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Link this

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

ft.com/frontpage UK All times are London time

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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

Proposed New Value Ba… …ricing A…

"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

Saturday 11 December 2010

The Telegraph

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Rosa Prince

NHS reforms could see patients miss out on groundbreaking drugs to cure Alzheimer's, Parkinson's

A leading drug company is threatening to delay the introduction of groundbreaking treatment for Alzheimer's, Parkinson's and schizophrenia in response to the Government's planned NHS reforms.

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Methods allow Committee to adopt a wide perspective on benefits and costs

…ultation on draft advice on whether a value based price claim is supported

Appraisal Committee reviews consultation comments and develops final advice

Final Advice submitted to Department of Health and published on NICE website for information

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"

Department of Health

REUTERS EDITION: U.S.

Britain puts NICE at centre of new drug pricing system

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LONDON | Thu Mar 21, 2013 12:24pm EDT

(Reuters) - Britain's health cost watchdog NICE will be responsible for assessing the full value of medicines under a value-based pricing system for new drugs due to take effect from 2014, the government said on Thursday.

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"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

GOV.UK

- 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.

Applies to: England

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


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NICE to assess high-cost, low-volume drugs

UK NEWS | JULY 24, 2012

LYNNE TAYLOR

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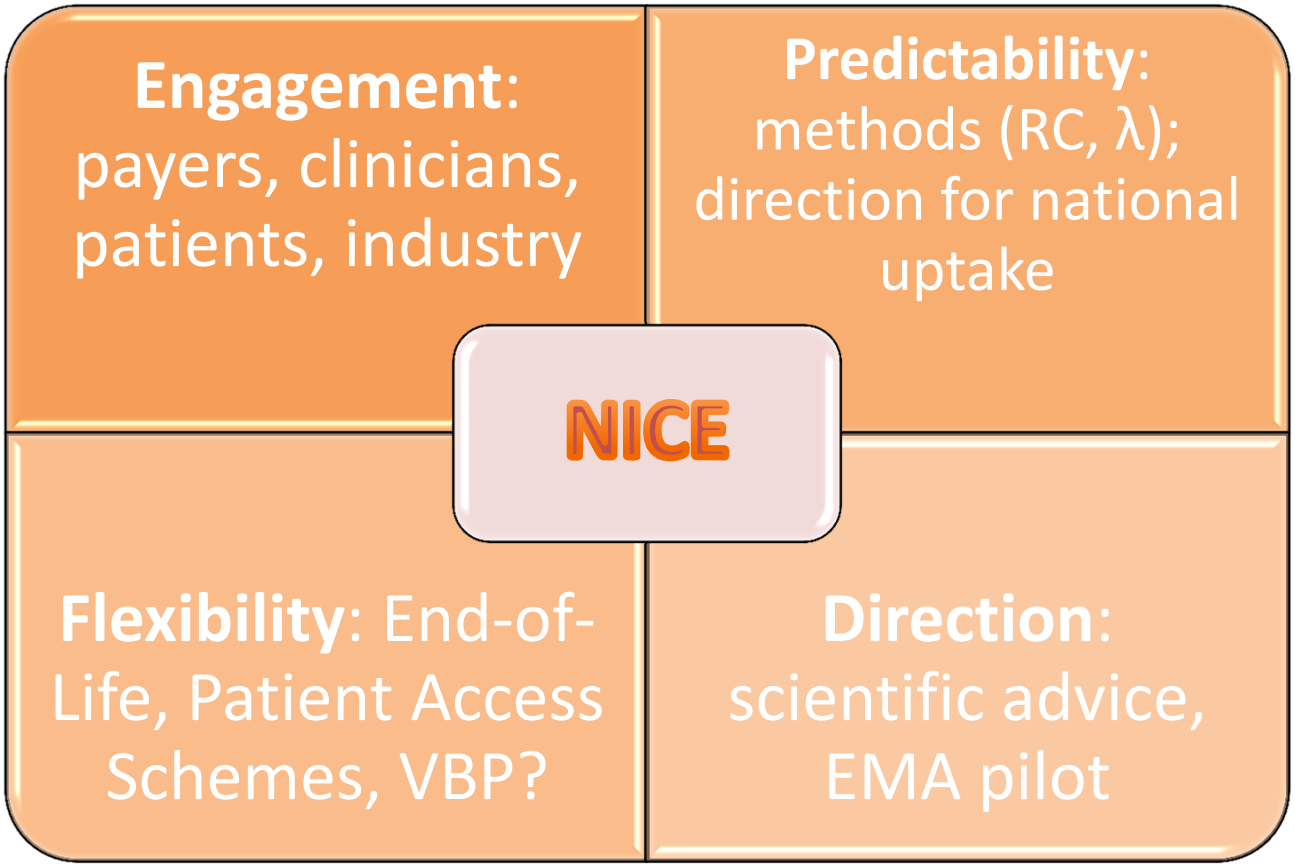
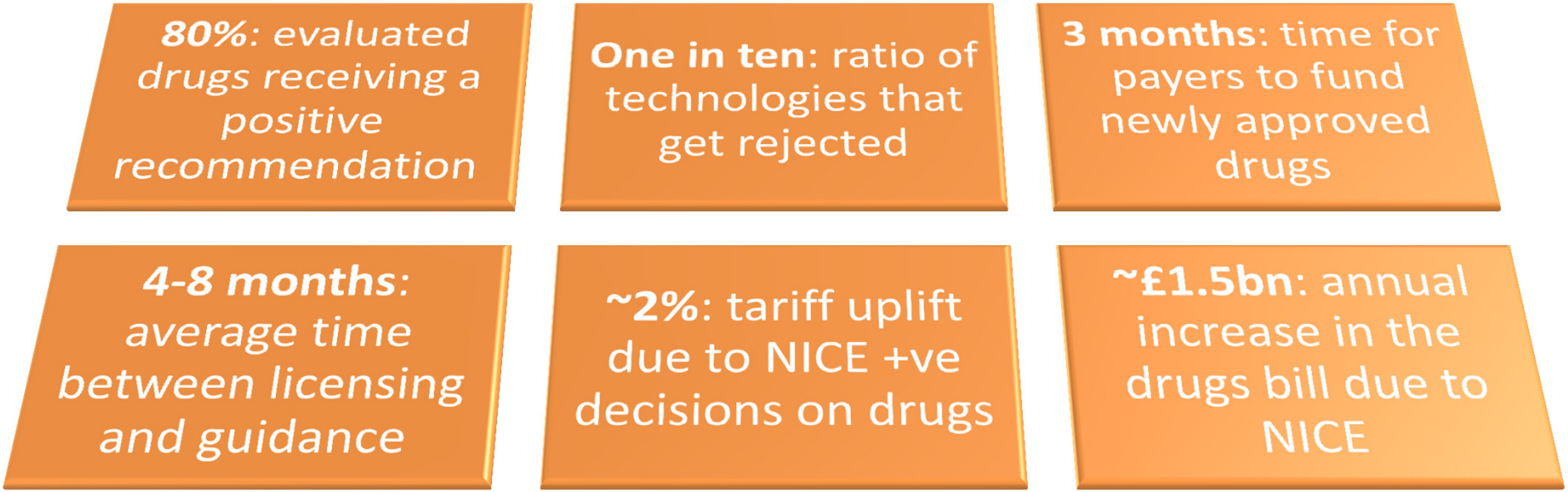
- Fast: <6 months
- Consultative: patient views
- Multidimensional: limited value in a cost per QALY
- Informing investment: NHS Commissioning Board decisions

HTA: a win-win…(when it has teeth)



NICE: some numbers



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

the NHS belongs to us all

ublic Local Formularies

Sir David Nicholson
NHS Chief Executive

Date: 9 August 2012

Gateway reference: 17879

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

DH Department of Health

Richmond House Nicholson
79 Whitehall
London
SW1A 2NS

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."

The Star

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Thursday 18 October 2012

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Adoption support for new technologies

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

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- Specialised drugs
- Social Care
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NICE Pathways

NICE National Institute for Health and Care Excellenc

Thank you!

kalipso.chalkidou@nice.org.uk