COST-EFFECTIVENESS ANALYSIS AND PHARMACEUTICAL INNOVATION

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Practice and experience in the British National Health Service

Presentation at American Enterprise Institute Conference:

"Does the U.S. need a NICE ?-
Perspectives on the UK Model for Drug Reimbursement"

Washington, D.C., 28th June 2006

by

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NICE

The National Institute for Health and Clinical Excellence

"responsible for providing national guidance on promoting good health and preventing and treating ill health in England and Wales"

[www.nice.org.uk].

FOCUS IN THIS PRESENTATION

ONLY on one of NICE's functions:

Technology Appraisal of medicines

especially on products that are internationally recognised as innovative.

NICE GUIDANCE

MULTIPLE SCLEROSIS MEDICINES :

"neither beta-interferon nor glatiramer acetate is recommended for the treatment of multiple sclerosis [MS] in the NHS in England and Wales"

[Technology Appraisal No. 32].

NICE APPEAL PANEL ruling:

" international opinion on clinical and cost effectiveness was not one of the criteria that the Institute was required to take into account when appraising health technologies."

[NICE, "Appraisal of the use of beta interferons and glatiramer acetate in the treatment of multiple sclerosis – Decision of the Appeal Panel", January 2002]

COST-UTILITY ANALYSIS

measures

QUALITY-ADJUSTED LIFE YEARS

[QALYs]

LENGTH OF SURVIVAL
combined with
QUALITY OF LIFE

RELATIVE TO COST

INNOVATIVE MEDICINES
FOUR CASE STUDIES

1. The 'MS CASE'
Beta-interferons and glatiramer acetate for
MULTIPLE SCLEROSIS

2. The 'CML CASE'
Imatinib for
CHRONIC MYELOID LEUKAEMIA

3. The 'PHOTODYNAMIC CASE'
Verteporfin for
WET AGE-RELATED MACULAR DETERIORATION

4. The 'OSTEOPOROSIS CASE'
Bisphosphonates, raloxifene and teriparatide for
SEONDARY PREVENTION of osteoporosis

FOUR CASE STUDIES

DURATION OF NICE PROCESS

from REFERRAL
to issuing of GUIDANCE

CASE	DURATION	
	Years	Months
MS	2	6
CML	1	5
Photodynamic	2	6
Osteoporosis*	2	10

[* Secondary prevention.
Primary prevention not yet concluded]

FOUR CASE STUDIES

RECOMMENDED NICE GUIDANCE

CASE	GUIDANCE: MAIN POINTS
MS	Against use in NHS except optionally for patients already on treatment or in clinical trials
CML	Recommended first-line treatment in chronic phase CML
Photodynamic	Recommended only for treatment of a small segment of patients
Osteoporosis	
Bisphosphonates	Recommended with restrictions for age segments among patients
Raloxifene	Recommended as second-line treatment for patients for whom bisphosphonates are unsuitable
Teriparatide	Recommended as second-line treatment at age 65+ with additional restrictions

QUESTIONS

NICE: PERFORMANCE?
Strong

NICE: CONCEPT?

MANDATORY NATIONAL GUIDANCE ON COST-EFFECTIVENESS OF INNOVATIVE MEDICINES:

Valid or unsound?
Helpful or burdensome?
Necessary or dispensable?

For INNOVATIVE MEDICINES

….coming to terms with the
UNCERTAINTY PRINCIPLE
in industry and health care

The place of
COST-EFFECTIVENESS ANALYSIS
as a useful analytical tool is limited:

- **Clinical limits**
- **Industrial limits**
- **Practical limits**

U.S. HEALTH CARE –

Pluralistic, competitive

EUROPEAN HEALTH CARE –

Public sector

‘Single Payer’ dominates

Both have advantages and weaknesses

If pharmaceutical innovation is to remain

a major objective

in industrial and health policy:

USE COST-EFFECTIVENESS ANALYSIS

as an optional decision-making tool

NOT WITH MANDATORY STATUS

for centralised national guidance

THE BRITISH HEALTH CARE SYSTEM IN OUTLINE

NATIONAL HEALTH SERVICE [NHS]

= public sector

Share of total health expenditure (2002)

	%
Public sector	83.4
Private health insurance, est.	3.2
Patient out-of-pocket, est.	10.7
Other, est.	2.7
	100

Funding of pharmaceuticals	%
Public sector, est.	74
Private sector, est.	26 *

[*of which >20 = otc/non-prescription]

NHS Prescription charge

April 2006: £6.65 [approx. $12] per item prescribed

Exemptions: about 84% of all NHS prescriptions

Prescription charge receipts = approx. 4% of NHS pharma expenditure

Thank you

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