JNIH 2014

5ème Journée Nationale des Innovations Hospitalières
Bordeaux – 26 Juin 2014

ESSEC BUSINESS SCHOOL

Panaroma de systèmes étrangers, mise en perspective avec la France

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RESEAU INNOVATION
Journée Nationale Des Innovations

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Agenda

- Australia: the first country in the world to adopt C/E
- United Kingdom and NICE: an avatar of the British Empire ?
- Sweden: a fair system ?

- The French perspective: topics for debate

Australian Health Care and the PBS

- Nationally publically funded health care
- Australians government pays for a majority of the drugs through the Pharmaceutical Benefits Scheme (PBS)
- But not all drugs are paid for:
  - The Pharmaceutical Benefits Advisory Committee (PBAC) is a group of experts who help to decide what drugs should be funded

Australia: the role of the PBAC

- Considers:
  - Comparative effectiveness, safety and costs (ie. versus the next best thing on the schedule, or placebo if nothing is available).
  - Formal considerations of Cost Effectiveness began in 1993
    - Total incremental treatment costs/total health gain
  - equity of access
- 18 member committee comprised of:
  - Physicians, health professionals, 1 health economist and 1 consumer representative

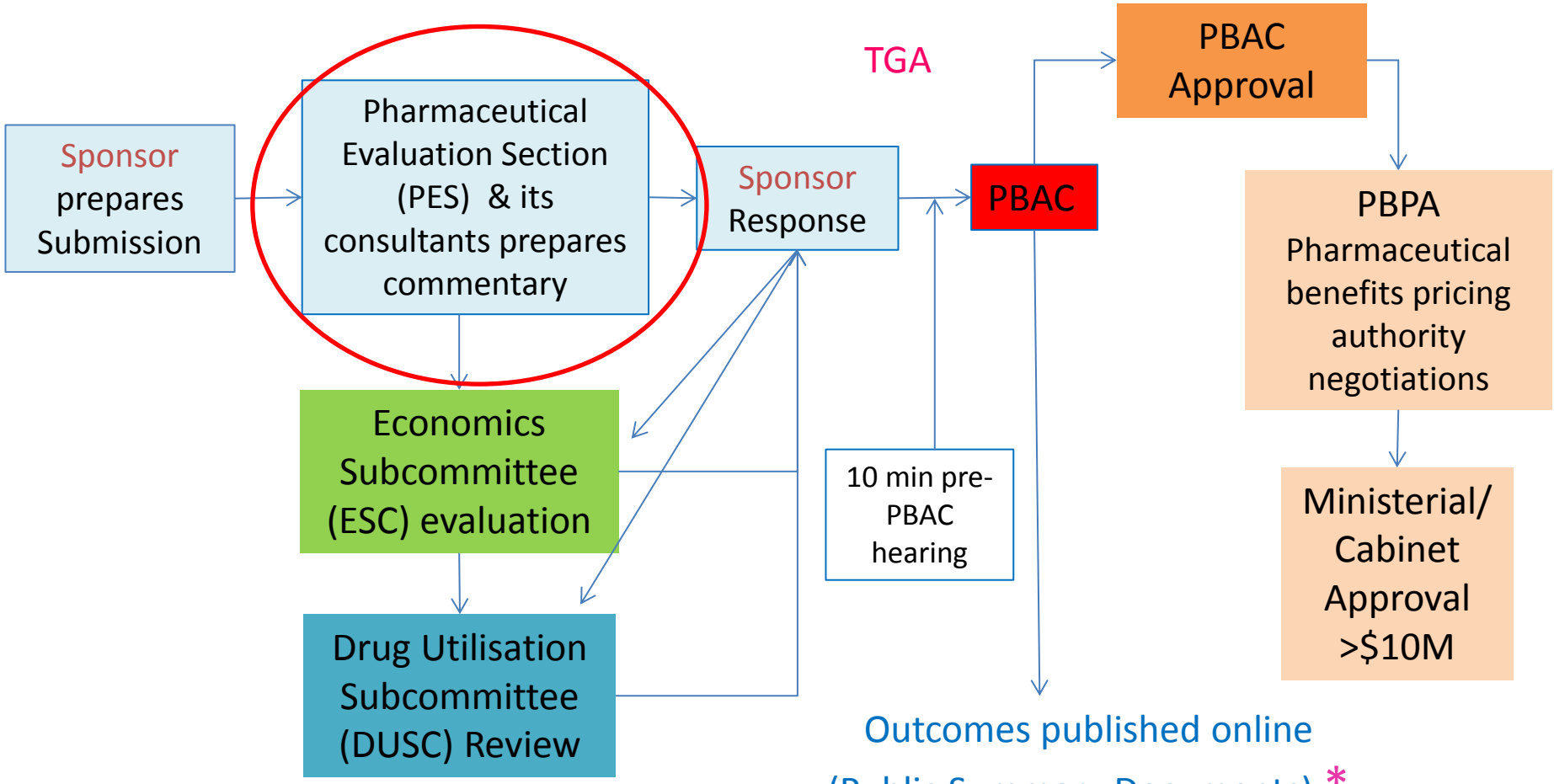
Australia: The role of PBAC (ctd)

- Minister can not list a drug on the PBS unless the PBAC gives it a positive recommendation

- In the case of negative recommendations
  - Sponsor can resubmit with new evidence or a lower price
  - No limit on number of resubmissions

- New drugs (or existing drug with new indication) can only be listed if:
  - Better (safety or efficacy) and of acceptable cost effectiveness
  - At least as good as (safety or efficacy) is of similar or better cost effectiveness

Australia: reimbursement process

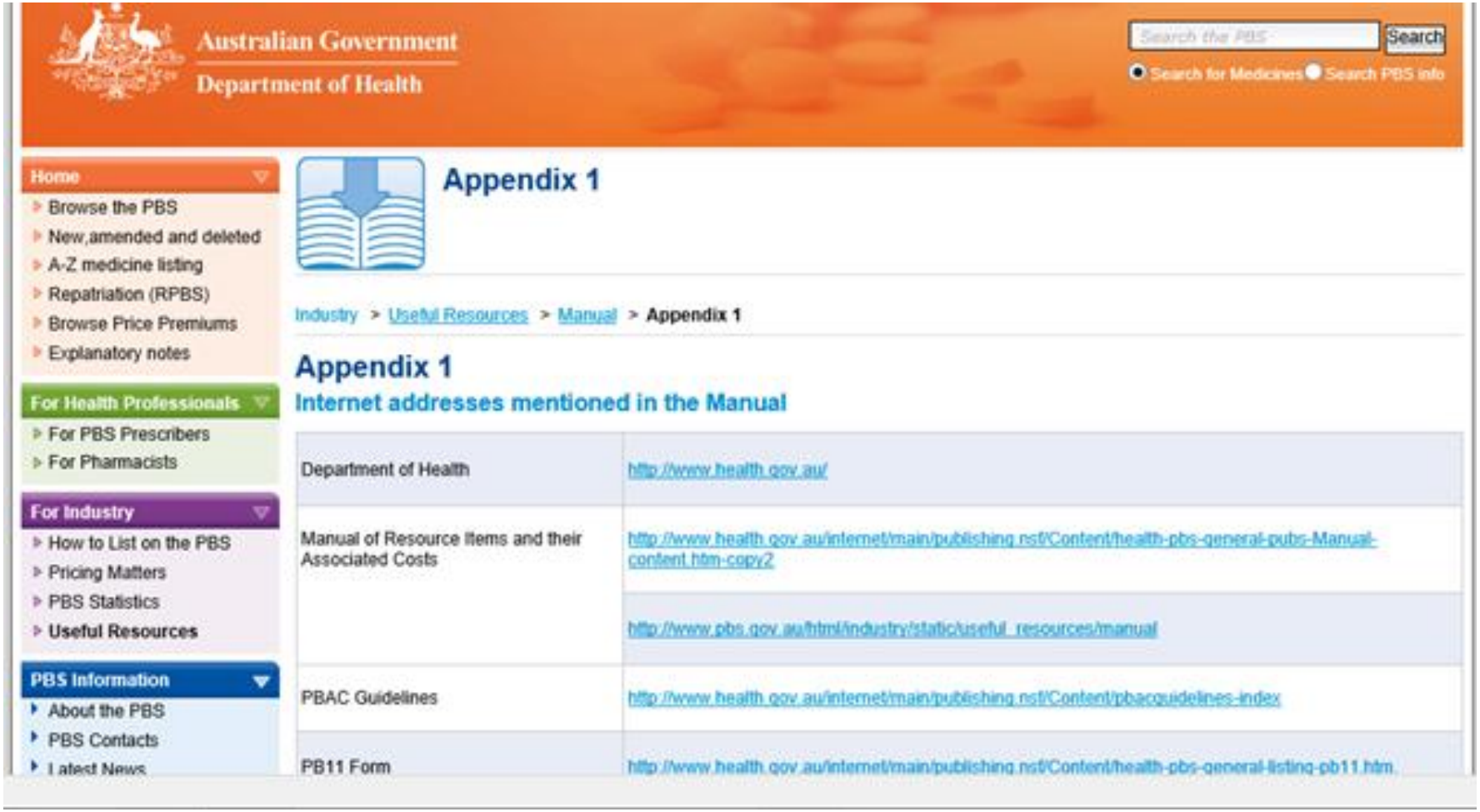


* only publically available info, all else commercial in confidence

Australia : 6 Sections to a major submission

A. Context
   - Restrictions and comparator
B. Clinical evaluation
C. Translating between trial and the modelled evaluations
D. Economic evaluation
E. Utilisation and financial implications
F. Optional
   - Quality use of medicines, risk-sharing arrangements and other relevant factors

Australia: guideliines and information sources for C/E analysis



http://www.health.gov.au/internet/main/publishing.nsf/content/pbacguidelines-index

Australia: decisions are made also on other considerations

- Positive recommendation by the PBAC necessary but not sufficient

- Other considerations and decisions steps:
  - Price negotiation with the Ministry for Health and Ageing
  - Scope for reimbursement finalized (possible restrictions)
  - Provision capabilities are verified
  - Government decision, according to expected budget impact (10 millions Aus $)and political priorities

UK: the historical PPRS

The Pharmaceutical Price Regulation Scheme (since 1949!)

- Voluntary agreement between the government (UK Department of Health) and the research-based pharmaceutical industry.
- Scheme allows **free pricing** of new products following a EU or UK marketing authorisation.
- Target level of profits (including part of the R&D costs) that companies can earn from supplying drugs to NHS: 21% return on capital (ROC) or 6% return on sales (ROS).

➔ *Ineffective system to control expenditure on branded drugs:*

- Very opaque and complex to administer (e.g. how to verify R&D costs sustained at international level?)
- It does not provide right reward to innovative drugs
- It allows high prices in comparison with EU for non assessed drugs

UK: the National Insitute for Clinical Excellence

- Established in 1999 to define best practices and to eliminate regional differences in access to drugs ("post-code" prescribing)
- Health Technology Assessment: recommendation for or against the use of comparable drugs based on clinical & pharma-economic data
  - Agenda defined by DOH
  - Single Technology Appraisal (STA) or Mutliple Technology Appraisals (MTAs): Evidence provided by manufacturer and evaluated by academic group. Decision considers also patient and clinical expert input (6 to 7 months / 14 months)
  - Compare the effectiveness and cost of new drugs vs comparable treatments from the **National Health Service perspective** .

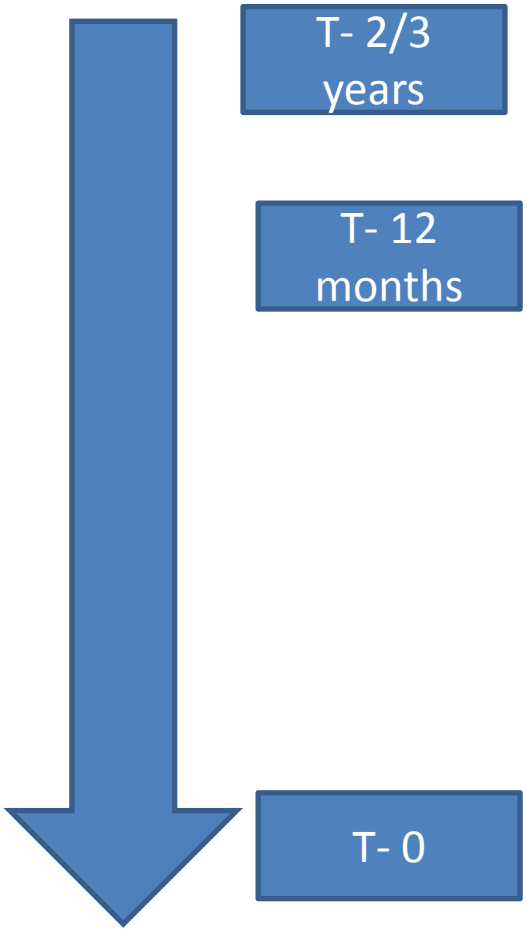
"In line with many other countries, in the UK, NICE currently accepts as cost-effective "Interventions with an incremental cost-effectiveness ratio of less than ***£ 20 000 per QALY*** *(quality adjusted life year) and that there should be increasingly strong reasons for accepting as cost-effective interventions with an incremental C/E ratio over* ***£ 30 000 per QALY".***

UK: very formalized and open to all stakeholders process

Example: Single Technology Assessment (STA)

1. Provisional appraisal topics chosen (Department of Health-DoH), based on the National Horizon Scanning Center research)

2. Consultees and commentators identified
3. Scope prepared (NICE/DoH)
4. Appraisal topics referred
5. Evidence submitted by manufacturers and other stakeholders
6. Evidence Review Group (ERG) report prepared
7. Evaluation report prepared
8. Appraisal Committee
An independent advisory committee considers the evaluation report and hears evidence from nominated clinical experts, patients and carers. Committee discussions are held in public.
9. Appraisal consultation document (ACD) produced
10. Final appraisal determination (FAD) produced with reassessment plan
11. Guidance issued



UK: the Threshold reference

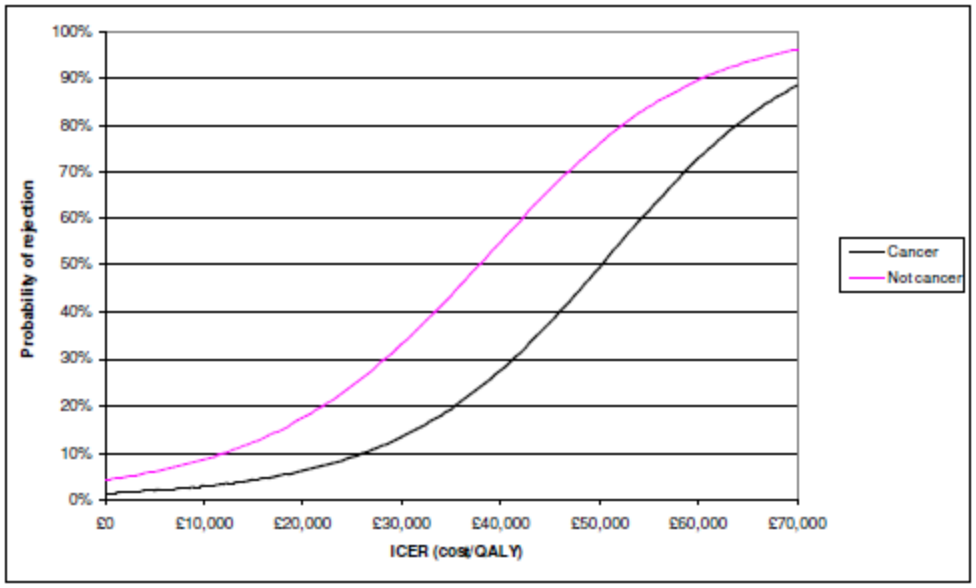
<£20k	£20k- £30k	> £30k
75% accepted; approval of full indication	55% accepted; but restricted	29% accepted; but highly restricted

Overall results show that ICER > $£20K are usually agreed without resctriction

However, the scope might be different in some areas …….

Source : Carmine Ornaghi, University of Southampton

UK: the threshold reference



- 'Cancer' dummy significant
- 102 cancer decisions included in the analysis
- 92 pre-EOL (38 no, 54 yes); 10 post EOL (7 no, 3 yes, of which 2 considered under EOL).

- The estimate of the threshold (probability of rejection = 50%) is:
  - £50,139 for cancer drugs
  - £37,805 for non-cancer drugs
  - NICE decisions reveal a willingness to 'pay' an additional > £10k per QALY gained by cancer patients

Source: NICE's cost effectiveness threshold revisited: new evidence of the influence of C/E andother factors on NICE decisions – Devlin and Coll, 2010

UK: adjustements to the reference thresholds

- **Flexible pricing** : a company can increase / decrease its original price in light of new evidence or when a different indication is developed –New evidence is then evaluated by NICE as part of an STA or MTA

- Recent changes for "**End-of-Life"** (EoL) treatment: life expectancy less than 24 months at least 3 months survival gain, small numbers of patients, higher cost/QALY threshold of (£50,000 to £60,000)

- **Patient Access Schemes** (PAS) : to facilitate patient access for medicines that are not found to be cost-effective by NICE ➔ NICE and PPRS are indirectly linked as companies consider the likely outcome of a NICE appraisal when setting drugs' prices

UK: adjustments to the reference threshold

Drug	Indication	Type of Scheme	Proposed Deal
Tarceva (Erlotinib) Roche	Non-small-cell lung cancer	Finance-based	Drug provided at a price equal to that of Sanofi-Aventis' Taxorete (docetaxel)
Velcade (Bortezomib) J&J	Multiple myeloma	Performance-based	Rebate the cost for patients that do not respond to treatment after four cycles
Sutent (Sunitinib) Pfizer	Renal cell carcinoma	Finance-based	The first treatment cycle would be provided free of charge

Tarceva: Easier scheme to use. Difficult to administer the discount on listed price as it comes as credit note

Velcade: Difficult to manage due to the need of measuring patient response. Refunds claims must be made within 60 days. Due to this strict timeframe, many hospitals admitted that they have lost out on claims.

Sutent: Difficulties in administering free cycle as many pharmacy computer cannot process free stock

Source : Carmine Ornaghi, University of Southampton

UK: Adjustments to the thresholds with PAS

List of technologies with approved Patient Access Schemes, recommended by NICE for use in the NHS.

TA Ref	Treatment	Indication	Company	Type
TA155	Ranibizumab (Lucentis)	Macular degeneration (Acute wet AMD)	Novartis	Simple discount
TA171	Lenalidomide (Revlimid)	Multiple myeloma	Celgene	Dose cap
TA162	Erlotinib (Tarceva)	Non small cell lung cancer	Roche	Simple discount
TA129	Bortezomib (Velcade)	Multiple myeloma	JC	Response scheme
TA265	Denosumab (Xgeva)	Skeletal related events in adults with bone metastases from solid tumours	Amgen	Simple discount
TA268	Ipilimumab (Yervoy)	Advanced melanoma, 2nd Line	Bristol-Myers Squibb	Simple discount
TA269	Vemurafenib (Zelboraf)	Metastatic mutation positive melanoma	Roche	Simple discount
TA274	Ranibizumab (Lucentis)	Diabetic macular odema	Novartis	Simple discount
TA276	Colistimethate (Colobreathe)	Pseudomonas aeruginosa for adults and children over 6 with cystic fibrosis	Forest Laboratories UK	Simple discount
TA276	Tobramycin (TOBI Podhaler)	Pseudomonas aeruginosa for adults and children over 6 with cystic fibrosis	Novartis	Simple discount
TA278	Omalizumab (Xolair)	Severe persistant asthma	Novartis	Simple discount
TA280	Abatacept (Orencia)	Rheumatoid arthritis, polyarticular juvenile idiopathic arthritis	Bristol-Myers Squibb	Simple discount

UK: impact of NICE recommendations

Impact on pharmaceutical companies

- Ex ante influences companies pricing strategies
- Generally accelerates the uptake of recommended drugs
- Cost-containement tool

Access at local level : Primary Care Trusts (PCTs)

- Have a statutory obligation to provide funding for drugs recommended by NICE
- Overspending in drug results in the cut back of other patient services
- PCTs have been known to wait to approve a product for use before receiving NICE green light

Drug uptake (NHS, 2009): **26 drugs positively appraised by NICE covering 13 technology appraisals (STAs and MTAs).**

- 12 STA : 7 drugs exceeded predicted use, 5 were lower

UK: Introduction of Value Based Pricing - the « Shrinking Reform »

- Department of Health planned to implement VBP in January 2014, but delayed up to Sept 2014…
- Wide assessment of the range of factors through which a medicine delivers benefits for patients and society
- Three key criteria discussed for the appraisal by NICE :
  - Wider Social Benefit (WSB) : abandoned …..
  - Burden of Illness (BOI)
  - Therapeutic Innovation and Improvement (TII): dropped ….
- PPRS system and price negotiation for each individual medicine has been finally maintained
  - Flexible pricing
  - Patients access schemes to be continued
- Consultation started in March 2014:"value based assessment"
  - Burden of Illness I ➔ QALY weighting
  - ICER threshold to be changed: £ 20 000 – 30 000 ➔ £ 20 000 – 50 0000

SWEDEN: the LFN

- Value Based Pricing: prices are fixed for reimbursable drugs (LNF established in 2002)
- The Dental and Pharmaceutical Benefit Agency (TLV) is a state agency charged with the task of deciding if a medecine or a dental procecure shall be reimbursed by society.
- Initiated to for out-patients drugs, extented to in-patients drugs
- Decisions based on 3 criteria:
  - Equal value of all human beings
  - Needs and solidarity
  - Cost-Effectiveness

We work to extract as much health as possible for each crown of public funds expended on medicines and dental care.

SWEDEN: the LFN (cdt)

- Key principles
  1. Societal perspective in order to consider cost offset in other sectors/budgets than the health care
  2. A threshold value, based on individuals maximum willingness to pay for a QALY gained
  3. Marginal decreasing utility of treatment, eg the benefit varies by indication or by degree of severity
- Based on companies submissions or own TLV initiative

SWEDEN: guidelines for economic evaluation

General guidelines for economic evaluations from the Pharmaceutical Benefits Board (LFNAR 2003:2)

Decided on April 24, 2003. The Pharmaceutical Benefits Board has published the following general guidelines for economic evaluations submitted with applications for the inclusion of a medicine in the pharmaceutical reimbursement scheme, according to paragraph 15 (2002:160) of the law on pharmaceutical reimbursement.

1. Overview

These guidelines are aimed at companies intending to apply for the inclusion of a drug in the pharmaceutical reimbursement scheme and who, in connection with their application, enclose a health economic evaluation. For the Pharmaceutical Benefits Board the guidelines constitute a preferred approach to drawing up a health economic analysis. The majority of the points presented below can also be valuable in the planning and conducting of health economic evaluation studies with a view towards a pending application. The guidelines should not be interpreted as a manual rather as a support tool when drawing up applications and studies. In certain situations, there may be good reason to deviate from the guidelines on certain issues. When assessing an application, the Pharmaceutical Benefits Board will take account of the particular conditions that enabled an applicant to apply these guidelines.

2. Which costs and revenues should be included?

The health economic analysis should be done from a social economic perspective. Amongst other things, this means that all relevant costs and revenues for treatment and ill health, irrespective of the payee (county council, local authority, state, patient, relation) should be considered. The information must describe the situation in Sweden.

http://www.tlv.se/Upload/English/Guidelines-for-economic-evaluations-LFNAR-2003-2.pdf

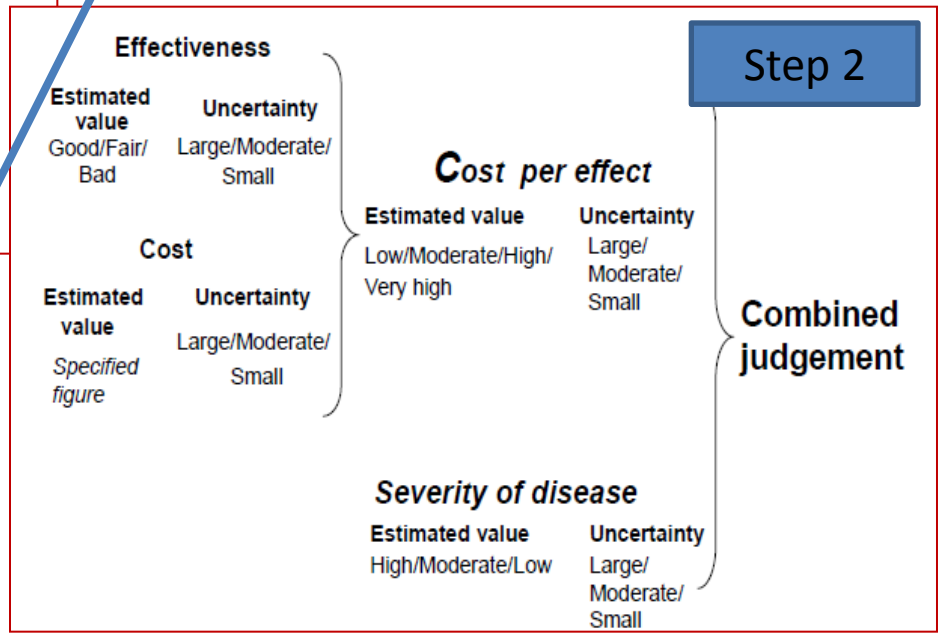
SWEDEN: the TLV set of criteria

- Cost-effectiveness: Cost compared to the effect
  - Cost
    - Drug costs
    - Physician visits
    - Hospital care
    - Lost production at work
    - Family care
  - Benefit
    - Longer life
    - Better quality of life
- Choice of comparator: To value the cost-effectiveness
  - The most relevant alternative treatment in Sweden
    - Another medicine
    - Another treatment
    - No treatment

Step 1

➔ Adjustement according severity of disease

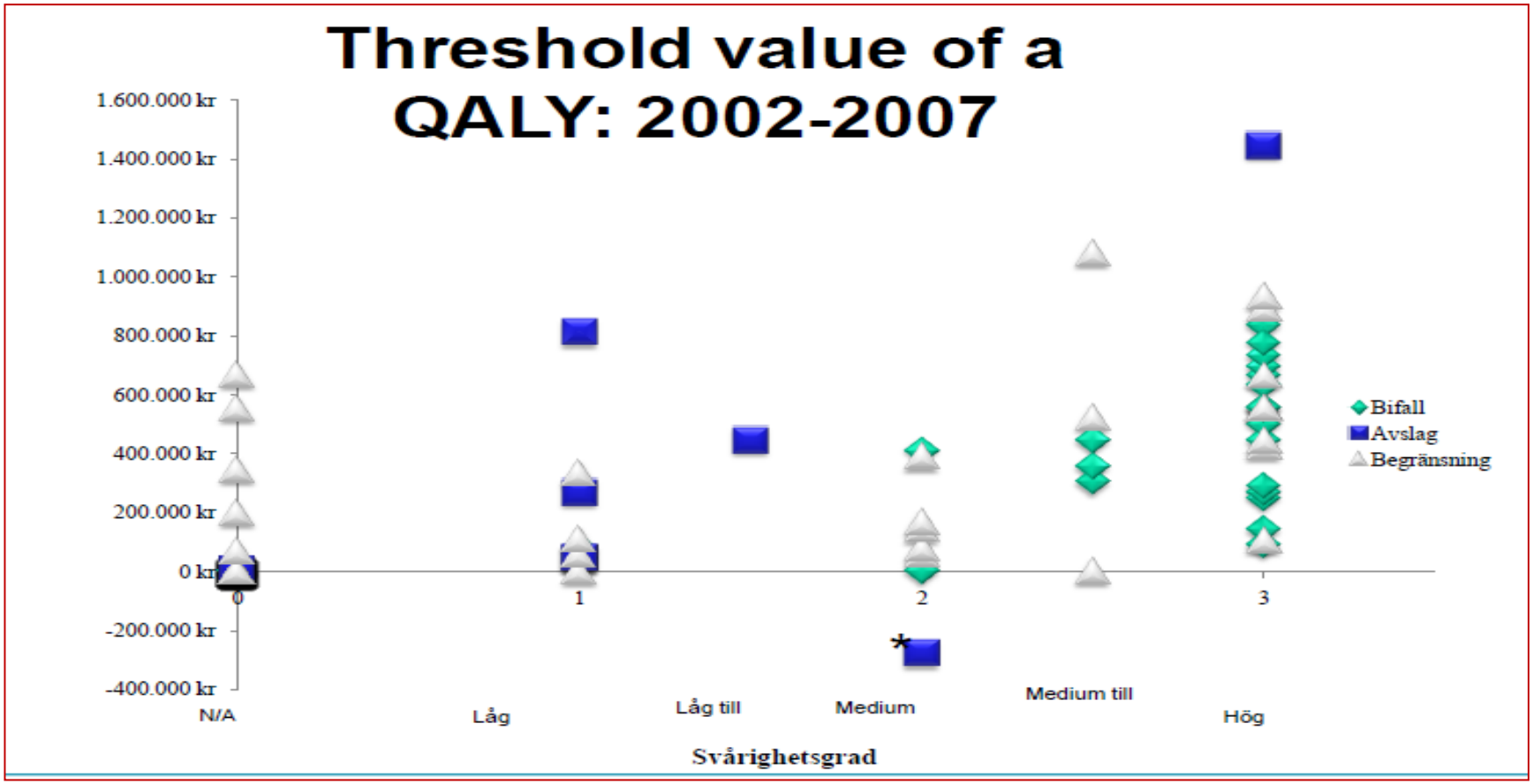
Step 2



Criteria:
- Equal value of all human beeings
- Need and solidarity
- Cost/effectiveness (Cost/QALY)

Source: TLV, July 2011

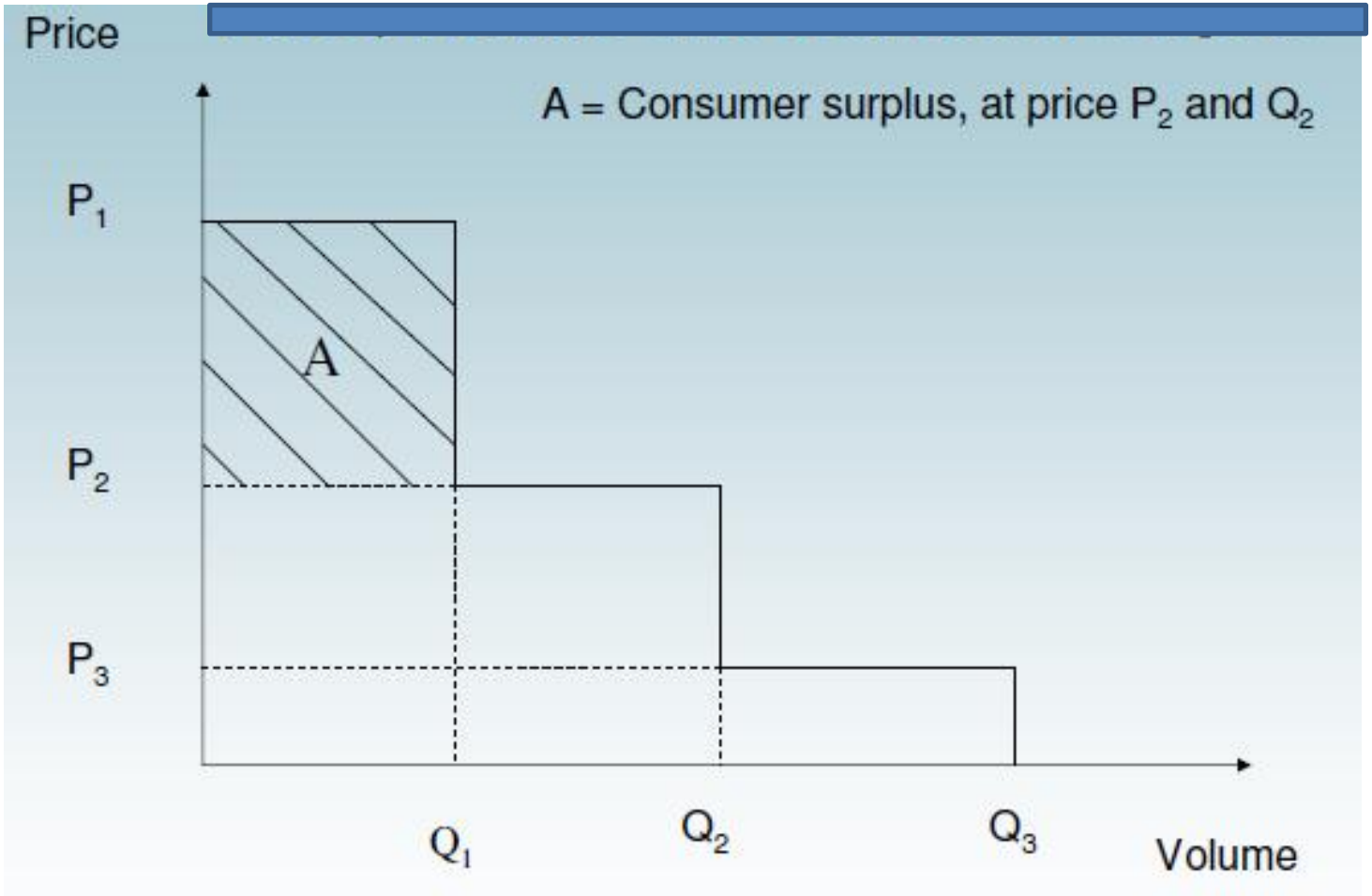
SWEDEN: Equity/need ajdusted reimbursement decisions



Source: TLV, July 2011

Bifall: ***Approved*** **-**
Avslag*: rejected*
Begränsning:***restricted***

SWEDEN Value Based Pricing : price, volume and consumer surplus



Source: Ulf Person – IHE at London School of Economics, 2011

Mise en perspective avec la France

- Pionnière dans la mise en œuvre de l'évaluation de l'efficacité relative ➔ maturité des évaluations
- Encore novice dans l'intégration de l'évaluation médico-économique dans les processus de décisions ➔ un « apprentissage » de toutes les parties concernées
- Des recommandations de l'HAS qui ont posé les choix fondamentaux
  - La perspective collective
  - l'horizon de temps et le critère de coût/Qaly pour l'évaluation des traitements chroniques
  - La souplesse du cadre méthodologique, l'exigence de la justification des choix
  - Une contextualisation incontournable

Mise en perspective avec la France

- Le rayonnement des évaluations françaises et de son expertise ?

- Assumer cette démarche dans les décisions publiques
  - Davantage de transparence dans les décisions
  - La préoccupation de l'équité : le « non choix » d'un seuil , par exemple
  - Des dimensions éthiques et sociales à prendre en compte

L'évaluation médico-économique est un outil d'aide à la décision, et seulement cela ….

MERCI DE VOTRE ATTENTION

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