

## The role of pharmacoeconomics in Pharmaceuticals Pricing Board decision-making

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## Pharmaceuticals Pricing Board

PHARMACEUTICALS PRICING BOARD,  
A SUBORDINATE OF MINISTRY OF SOCIAL AFFAIRS AND HEALTH  
Confirms reasonable wholesale price and reimbursement of medicinal  
products, clinical nutritional products and basic ointments

SECRETARIAT OF PPB  
Present the applications to the PPB

EXPERT GROUP OF PPB  
Prepares a statement regarding applications of special reimbursement and,  
when needed basic/restricted reimbursement to the PPB

## Pharmaceuticals Pricing Board

- Duties of PPB (Health Insurance Act, chapter 6).
  - Decides (if applied by MA holder) on the reimbursement status of medicinal products, clinical nutritional products and basic ointments and confirms their reasonable wholesale prices > products are reimbursed by Social Insurance Institute.
  - Decides on increase and termination of confirmed reasonable wholesale prices.

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## Decision-Making in PPB

- PPB legislation:
  1. Health Insurance Act (HIA), chapters 5-6 (1224/2004, amendment 885/2005).
  2. Government decree on the PPB (1356/2004, amendment 1110/2005).
  3. Decree by the Ministry of Social Affairs and Health on applications and appendices (1111/2005).

## Decision-Making in PPB

- A medicinal product is reimbursed if
  - it is intended to cure or alleviate a disease or its symptoms (basic reimbursement, 42 %)
  - special reimbursement can be further granted, if the product is used for the treatment of a severe and chronic disease (72 %) and has replacement or remedial effect (100 %)
  - reimbursement and a reasonable wholesale price has been confirmed by the PPB

## Decision-Making in PPB

- Confirming basic reimbursement
  - PPB must take into account the therapeutic value of the product
  - Should not be confirmed, if the product is for treatment of a temporary disease or disease with mild symptoms; if it has minor therapeutic value; if it is for other purposes than treating a disease; or if it is a herbal, homeopathic or anthroposofic product

## Decision-Making in PPB

- Basic reimbursement can be restricted if there is significant therapeutic value and:
  - the product is very expensive and indispensable for a severe disease; or
  - extensive use would cause unreasonable costs in relation to benefits

## Decision-Making in PPB

- A reasonable wholesale price:
  - The maximum price that the product can be sold to pharmacies
  - The MA holder can freely set prices for products without reimbursement

## Decision-Making in PPB

- When confirming reasonable wholesale price, PPB must consider:
  - Costs and benefits for the patient and health care and social services
  - Costs and benefits of other available alternatives

## Decision-Making in PPB

- Prices of comparable products in Finland
- Prices in other EEA countries
- Manufacture and R&D costs of the product
- Funds available for reimbursements

## Decision-Making in PPB

- Conditions for special reimbursement
  - First basic reimbursement for two years
  - Can be granted earlier than that if sufficient data on therapeutic value, indispensability, replacement of remedial effect and necessity

## Decision-Making in PPB

- When confirming special reimbursement, PPB must consider:
  - Type of disease
  - Necessity and cost-effectiveness
  - Proven therapeutic value
  - Funds available for special reimbursement
- Decision can be restricted (e.G. Severity)

## Decision-Making in PPB

- The decision of the PPB must be reached within 180 days
- The decision of the PPB may be appealed to the supreme administrative court

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## Health economic evaluations in decision-making

- Costs and benefits is one of the things that PPB must consider, when confirming reimbursement and reasonable wholesale prices
- There are also several other issues to consider
- A pharmacoeconomic evaluation is required for applications of new active substance

## Health economic evaluations in decision-making

- The pharmacoeconomic evaluation is prepared by the applicant and is evaluated for usefulness in the PPB
- Not many pharmacoeconomic evaluations have been of good quality

## Health economic evaluations in decision-making

- All pharmacoeconomic evaluations submitted during 2005 were systematically evaluated by the PPB and SII
- 22 PE:s
  - 11 cost-minimisation analyses
  - 7 cost-utility analyses
  - 4 cost-effectiveness analyses

## Health economic evaluations in decision-making

- Quality of the evaluations (or usability in decision-making) was poor
  - 14 cannot be used in decision-making
  - 8 can cautiously be used in decision-making
  - 0 can be used in decision-making as such

## Health economic evaluations in decision-making

- Problems
  - Assumptions poorly justified in the clinical studies; e.g. change in health state, relative effectiveness, effect on quality of life
  - Difficulties in confirming the results, e.g. missing references or “black boxes”

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## Health economic evaluations in decision-making

- Still, 70 % of the applications were approved!
- Why? PE:s are not the only issue to be considered by the PPB
- A good PE does not guarantee approval and a poor PE doesn't always lead to rejection

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## Some recent examples

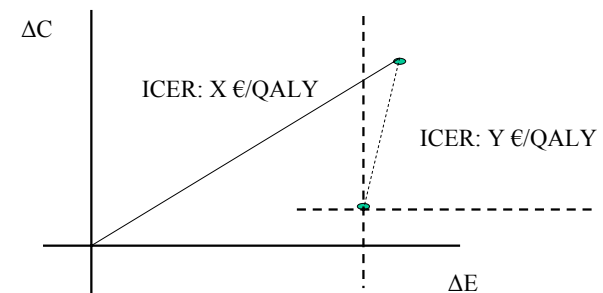
- Flaws: E.g. a life-time risk for an event is presented as an annual risk -> major effect on ICER (from cost-saving to X €/QALY)
- Comparative trial exists, meta-analysis used
- Application for primary treatment, but PE for secondary treatment
- Wrong comparator

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## Some recent examples



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PHARMACEUTICALS PRICING BOARD  
Finland

**Thank You!**

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