



TLV

TANDVÅRDS- OCH

LÄKEMEDELSFÖRMÅNSVERKET

Combining Cost-effectiveness and Severity of Disease Data for the Decision-making Process.

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The Swedish System in Brief

TLV :

- Is an independent agency under the social ministry.
- Although the agency is responsible also for dental interventions and deciding the pharmacy trade margins, this presentation will focus primarily on the duties concerned with pricing and reimbursement of pharmaceuticals.
- Makes the actual decisions on price and reimbursement.
- The decisions are made by an expert board. (12 persons, a lawyer as chairman , physicians, health economists and laymen.)
- An executive office prepares all the cases and gives it's recommendation for decision to the board.
- Is financed by the state and not through application fees from the drug companies or the pharmacies.

General Conditions

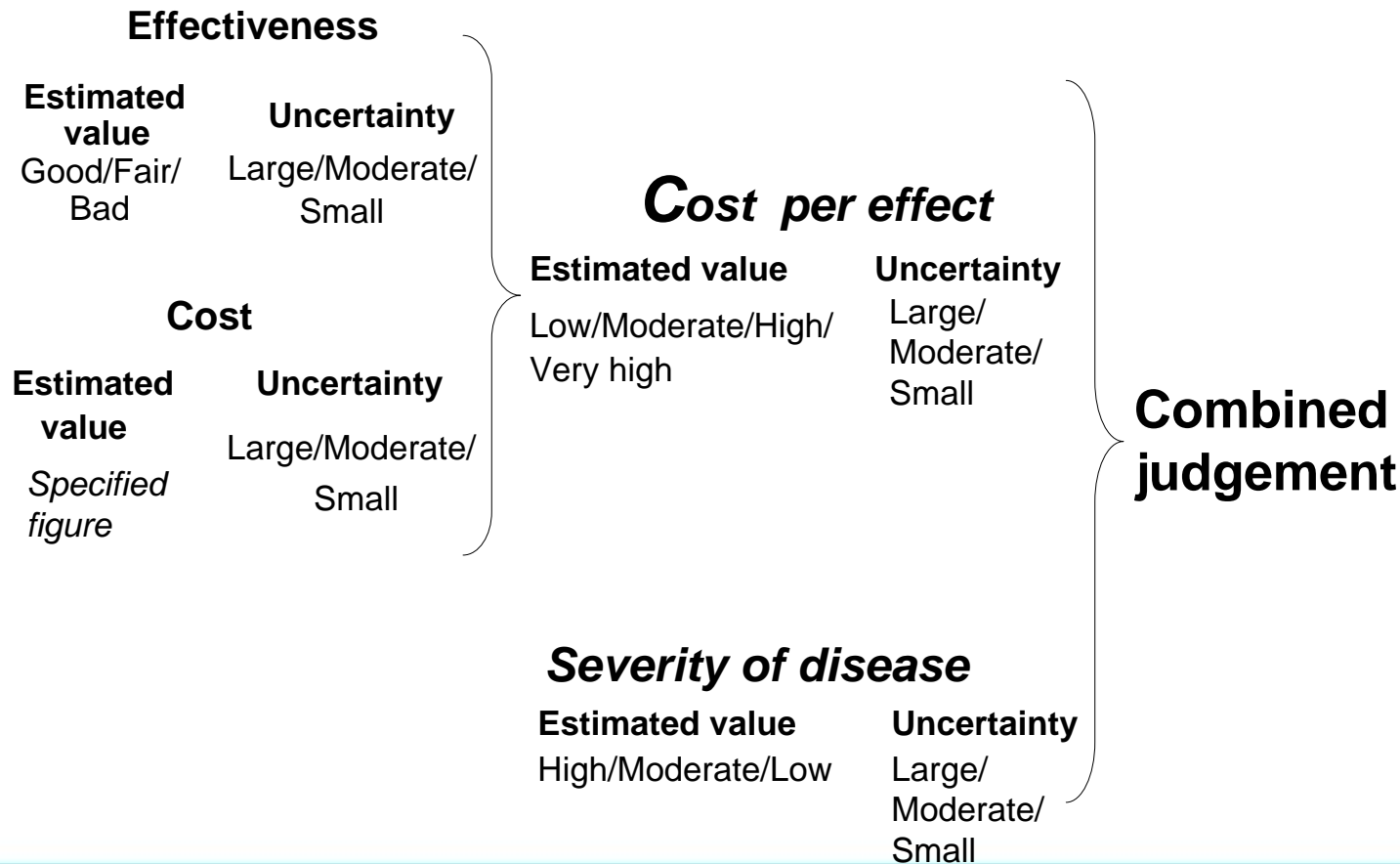
- The purpose of TLV's work is to make sure that we get as much health as possible for every tax payer's Swedish krona (SEK) we spend on drugs.
- New drugs and medical devices are assessed after a submission from the pharmaceutical companies.
- Old drugs are assessed during the review of the entire list of medicines eligible for reimbursement.
- The system is "value for money" based.
- We have no budgetary limits for our decision making and are not responsible for any drug budget.

Decision-making Criteria

All decisions are based on three criteria:

1. the principle of equal human value (respect for the equal human value of all people)
 2. the principle of need and solidarity (those in greatest need take precedence) and
 3. the cost-effectiveness principle (where we take a societal perspective).
- Of the two latter no one take precedence over the other.

Combining cost effectiveness and severity of disease



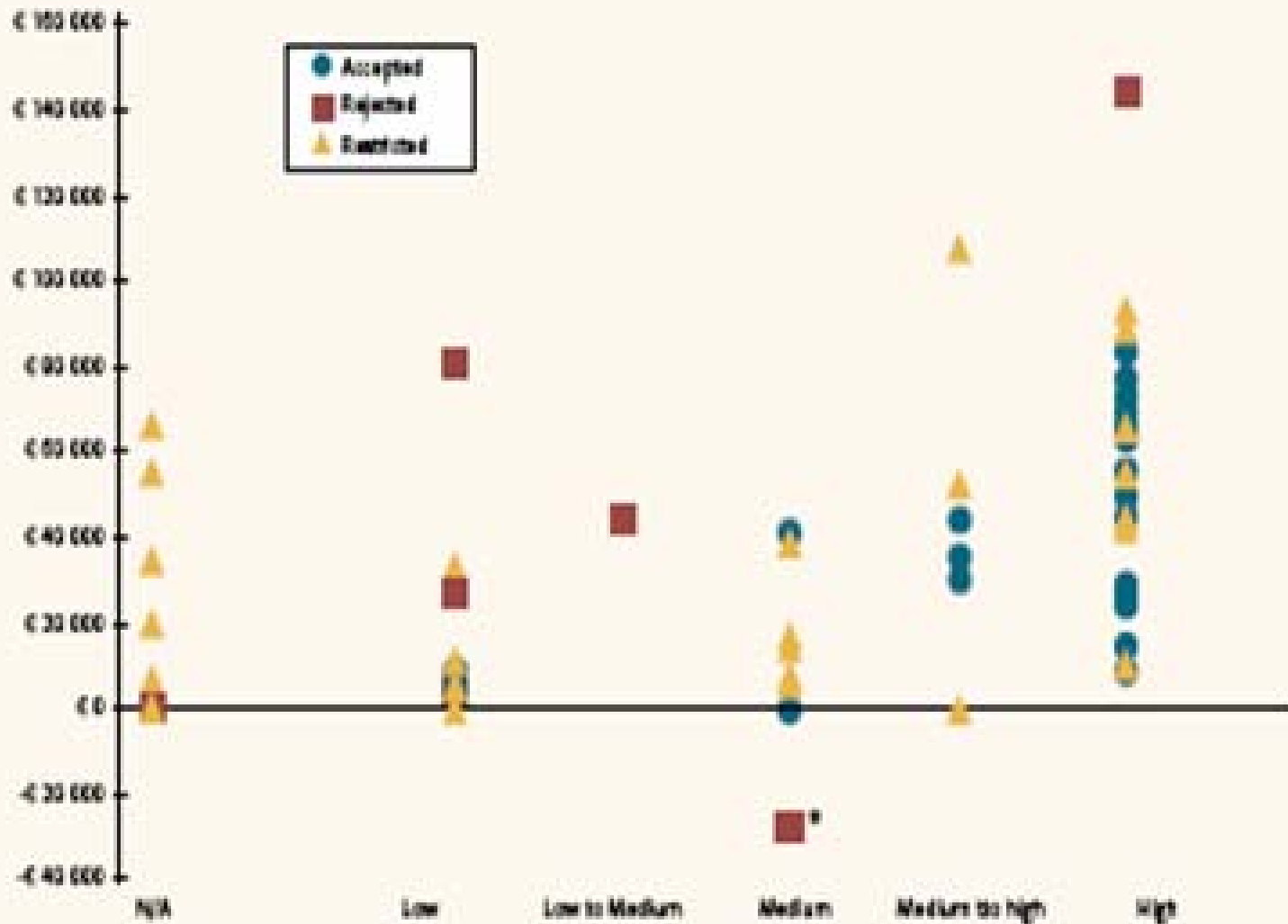
Different Decision-Types

TLV can make decisions of different types:

1. General reimbursement, the drug is reimbursed for all its indications.
2. Restricted reimbursement, the drug is only reimbursed for a limited part of the registered use (indications).
3. Rejected reimbursement, the drug is not included in the national reimbursement system. However, the drug can be sold without reimbursement, direct to the health care providers (county councils) for in-patient care and to patients for OTC-use, if permitted.

Decisions can be conditional, normally demanding the companies to come in with additional data.

The reimbursement system is product based and the number of restricted decisions shall be limited.



* Lower effect and lower cost than the comparator. Thus a saving per QALY lost.

Some recent decisions of interest

The TLV has decided that:

- From September 1st 2008 only patients that have tried but not tolerated an ACEi can have reimbursement on an ARB (sartan).
- From June 1st 2009 Lipitor and Crestor are not be reimbursed in their lowest dosage form (10 mg and 5 mg). Higher dosage forms are reimbursed but only if the patient has tried but not tolerated generic simvastatin.
- In October 2008 the TLV decided not to reimburse Tyverb for the treatment of breast cancer. The cost per QALY was too high and the uncertainties too large, even though the severity of disease is undoubtedly very high.

Changes in the pharmacy system

- On July 1st 2009 the Swedish system with a state owned monopoly on pharmacies will be deregulated. (OTC drugs following November 1st.)
- One goal of the deregulation is to increase the number of pharmacies.
- These extra pharmacies are expected to increase costs.
- The value for money based system for pricing and reimbursement of pharmaceuticals remains.
- However, money are to be saved on the supplier side:
 - Price cuts with 65 % on branded drugs when the patent expires and generic competition occurs.
 - Increased control of the generic substitution system.
 - More efficient competition on generics.

Thank you for your attention!



For more information:

www.tlv.se