

## The HTA Developments in the Central and Eastern European Region: Lock, Stock & Barrel in Challenging Times

Recent Developments in the Process of Updating the National List of Health Services in Israel

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## The Israeli Healthcare System

- A semi-public system, dominated by the Ministry of Health (and the Ministry of Finance) and the country's four health plans (HMOs)
- The National Health Insurance Law (NHIL) enacted in 1995 has made health insurance both compulsory and universal
- The NHIL stipulates a National List of Health Services (NLHS) which all residents are entitled to from their health plans (A positive list)

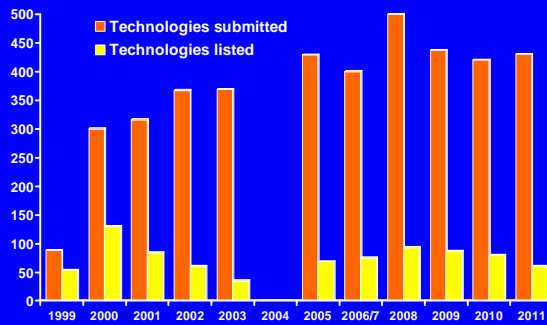
## The Process of Updating the NLHS

- The NLHS has been updated annually since 1998
- Every year, as part of the annual budgeting process, the government determines the budget that will be available to fund new technologies to be added to the NLHS
- Submission of dossiers according to guidelines published by the Ministry of Health

## The Process of Updating the NLHS

- Rapid screening and assessment of the proposed technologies
- Comprehensive evaluation and ranking of technologies
- Discussions and recommendations made by the Public National Advisory Committee (PNAC)
- Government approval, legislation and allocation of funds to health plans

## The Process of Updating the NLHS



## Recent Developments

- New guidelines for submission of economic evaluations
- Risk-sharing agreement applied for the first time

## Submission Guidelines

מדינת ישראל  
STATE OF ISRAEL  
Ministry of Health  
Pharmaceutical Administration  
משרד הבריאות  
אגף הרקוחות

**Guidelines for the submission of a request to include a pharmaceutical product in the national list of health services**  
The National Health Insurance Law, 1994  
Date: January 2010 | Guideline no. 53 version no: 8 | Page 1

### 1. General instructions for submission of a request to include a pharmaceutical product in the health services "basket":

- 1.1 A request to include a pharmaceutical product in the national list of health services ("basket") will include a comprehensive data file which will be submitted to the Pharmacoeconomics and Pharmacoepidemiology Department at the Pharmaceutical Administration of the Ministry of Health, according to the guidelines detailed herewith.

## Submission Guidelines

- Clinical and epidemiological data
  - Clinical/pharmacological profile
  - Pharmacoepidemiological data
  - The new treatment equilibrium
  - Supporting clinical information
- Economic evaluation

## Submission Guidelines

- Submission of economic evaluations has been previously required
  - Submission was not mandatory
  - Detailed submission guidelines did not exist
  - Technology sponsors were not required to submit the actual model (e.g., Excel, Data TreeAge)
- As of 2010, sponsors of expensive technologies (>\$30,000 per patient per year) are required to submit results of a cost-effectiveness analysis

## Requirements for Economic Evaluations

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Appendix D

**Instructions for performing an economic assessment**

The economic evaluation of medical technologies includes comparative analysis between alternatives in terms of costs and outcomes, and seeks to provide an objective and systematic method to improve the prioritizing process among decision-makers.

## Requirements for Economic Evaluations

- Detailed guidelines for submission of economic evaluations published in January 2010
- A training session presenting the guidelines was held in February 2010
- Deadline for submissions- April 15, 2010
- Submissions reviewed by the MOH and the Israeli Center for Technology Assessment in Health Care

## Use of Economic Evaluations

- A total of 22 economic evaluations were submitted
  - 17 drugs (including 4 orphan drugs)
  - 5 medical devices
- Only 10 of the submissions were mandatory (>\$30,000 per patient per year)

## Use of Economic Evaluations

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- Summary reports of each economic evaluation were submitted to members of the PNAC
- Nine technologies were presented at PNAC sessions close to the end of the deliberations
- No evidence that cost-effectiveness analyses have been considered in the decision-making process

## Lessons

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- It is unrealistic to perform and present economic evaluations for all submitted technologies
- Priority should be given to technologies with a high budget impact (rather than a high cost per patient)
- Economic evaluations should be presented to PNAC members earlier in the decision-making process

## Budget Impact Projections

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- A sub-committee of representatives from the MOF, MOH and the four health plans provides the PNAC with the anticipated budget impact of each technology considered
  - Product of the annual treatment costs per patient and the projected number of patients in need of the technology
- Projections consider rates of market growth and the proportions at which the new drug will replace an intervention already included in the NLHS for the same indication

## Risk-Sharing Agreements

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- Performance-based risk-sharing schemes
  - Less relevant in Israel
- Financial-based risk-sharing schemes
  - The aim is to reduce budget impact uncertainty
  - Relevant when there is a considerable uncertainty about the size of the population that will benefit from the technology
  - The allocated budget may be insufficient for covering the cost of the drug

## Risk-Sharing Agreements

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- Risk-sharing agreement regarding the drug sapropterin dihydrochloride (Kuvan®, Merck-Serono) indicated for PKU patients
  - Suggested by the Ministry of Health
  - Based on expert opinions, the maximum number of eligible patients was set at 49
  - Merck-Serono agreed to bear the extra cost of treatment if the actual use will exceed the expected quantity required normally for 49 patients
  - This pilot agreement will be valid for three years and will be then re-assessed

## Risk-Sharing Agreements

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- The Ministry of Health and health plans officials, as well as technology sponsors became more supportive towards exploring the feasibility of risk-sharing agreements
- The feasibility of a double-sided risk-sharing agreement is currently explored as part of an academic study
- It is unclear whether other risk-sharing agreements will be introduced in the near future

**Thank you!**