Pharmaceutical	Funding Requested For	Patient Population
Paliperidone palmitate depot injection	Schizophrenia	1,000-10,000
Paliperidone tablets	Schizophrenia second-line to risperidone or quetiapine	1,000-10,000
Palivizumab	Prevention of respiratory syncytial virus (RSV) infection in high risk infants	10,000-50,000
Paracetamol 500mg with codeine 30mg	Pain	50,000+
Paediatric oral feed 1 kcal/ml in 100ml Ready to Feed bottle (Infatrini)	Infants with increased nutritional requirements	1,000-10,000
Pegylated liposomal doxorubicin	Advanced epithelial ovarian cancer in women who have failed a first-line platinum-based chemotherapy	100-1000
Pemetrexed disodium	Non Small Cell Lung Cancer (NSCLC)	<100
Pipobroman	Polycythaemia and essential thrombocythaemia	<100
PKU Gel	Phenylketonuria (PKU)	<100
Potassium citrate	Recurrent calcium oxalate urolithiasis	100-1000
Pramipexole	Parkinson's disease	1,000-10,000
Prasugrel	Acute Coronary Syndrome (ACS) with Percutaneous Coronary Intervention (PCI)	1,000-10,000
Protein drink - PKU cooler 10mg,15mg, 20mg	Phenylketonuria (PKU)	<100
Protein drink MSUD	Maple Syrup Urine Disease	<100
Quetiapine extended-release tablets	Schizophrenia and bipolar disorder	1,000-10,000
Raloxifene	Osteoporosis - first line	10,000-50,000
Raloxifene	Osteoporosis in patients intolerant to bisphosphonates	1,000-10,000
Ranibizumab	Wet age-related macular degeneration	1,000-10,000
Riluzole	Amyotrophic lateral sclerosis	100-1000
Risedronate	Osteoporosis - first line	10,000-50,000
Risedronate	Paget's disease	1,000-10,000
Rituximab	Chronic Lymphocytic Leukaemia (CLL) - first line	<100
Rituximab	Large cell lymphoma pts who have relapsed following prior non rituximab therapy	<100
Rituximab	Relapsed Chronic Lymphocytic Leukaemia - previously treated with rituximab	<100
Rituximab	Relapsed Chronic Lymphocytic Leukaemia - rituximab naïve	<100

Pharmaceutical	Funding Requested For	Patient Population
Rituximab	Indolent Non-Hodgkins Lymphoma (NHL) - retreatment	100-1000
Rituximab	Large cell lymphoma - patients who have relapsed following prior rituximab therapy	<100
Rivaroxaban	Prevention of venous thrombosis following orthopaedic surgery	1,000-10,000
Rivastigmine capsules	Alzheimer's disease (Dementia)	10,000-50,000
Rivastigmine patches	Alzheimer's disease (Dementia)	1,000-10,000
Rosuvastatin	Hypercholesterolemia - third-line statin therapy	1,000-10,000
Sertraline	Depression	10,000-50,000
Sibutramine	Obesity	50,000+
Sildenafil	Pulmonary arterial hypertension (PAH) secondary to other lung disease	100-1000
Sildenafil	Post-Fontan Repair	<100
Sildenafil	Pulmonary arterial hypertension (PAH) secondary to congenital diaphragmatic hernia (CDH)	<100
Sildenafil	Pulmonary Arterial Hypertension (PAH) secondary to chronic lung disease (CLD)	<100
Sitagliptin	Type 2 diabetes	10,000-50,000
Sitagliptin and Metformin	Type 2 diabetes	10,000-50,000
Sorafenib	Hepatocelluar carcinoma	100-1000
Sorafenib	Renal Cell Carcinoma	<100
Strontium ranelate	Osteoporosis - second line following bisphosphonates	1,000-10,000
Sunitinib	Renal cell carcinoma	<100
Sunitinib	Gastrointestinal Stromal Tumour (GIST)	<100
Tamsulosin	Benign prostatic hyperplasia (BPH) in patients intolerant to alpha-blockers	1,000-10,000
Telmisartan	Hypertension	50,000+
Temozolomide	Anaplastic astrocytoma	<100
Temozolomide	Glioblastoma multiforme	<100
Tenofovir	Hepatitis B - Post liver transplant	<100
Tenofovir, emtricitabine	HIV infection	1,000-10,000
Tenofovir, emtricitabine, efavirenz	HIV infection	1,000-10,000
Teriparatide	Osteoporosis - second-line following bisphosphonates	1,000-10,000
Testosterone undecanoate injection	Testosterone deficiency	100-1000
Thalidomide	Multiple myeloma, first line for stem cell transplant ineligible	100-1000

Pharmaceutical	Funding Requested For	Patient Population
Thalidomide	Multiple myeloma, Stem cell transplant eligible	100-1000
Tolterodine and other formulations of oxybutynin (long acting and transdermal)	Overactive bladder	50,000+
Trastuzumab	Breast cancer - metastatic retreatment	<100
Travaprost and timolol	Glaucoma	1,000-10,000
Triamcinolone hexacetonide	Intra-articular injection	10,000-50,000
TYR Cooler, tyrosine and phenylalanine free protein substitute	Tyrosinaemia	<100
Varenicline	Nicotine addiction	1,000-10,000
Vildagliptin	Type 2 diabetes	10,000-50,000
Vinorelbine (oral)	Non-Small Cell Lung Cancer (NSCLC)	<100
Vitamin D	Vitamin D deficiency	10,000-50,000
Vitamin D and Calcium	Vitamin D deficiency and osteoporosis	10,000-50,000
Zoledronic acid	Osteoporosis - first line	10,000-50,000
Zoledronic acid	Paget's disease	1,000-10,000
Zoledronic acid	Osteoporosis - second line following bisphosphonates	1,000-10,000
Zolmitriptan	Acute migraine	10,000-50,000

2. ハンガリー

GYEMSZI (National Institute for Quality- and Organizational Development in Healthcare and Medicine)

[A. Healthcare system]

A-1. Overview of the healthcare system in your country

A-1.1. Financial resources for public medical service coverage are based

■ Primarily on social health insurance fees, collected through tax offices
❑ Primarily on taxes
❑ On something else (please specify:)

・ほとんど全ての国民が公的保険かあるいは税(年金生活者や失業者など支払い能力の欠如した人々など)によりカバーされている
・National Health Insurance Fund (OEP)が 7 カ所の地域 regional health fund をサポートしている。.
・患者はGP(general practitioners)を自由に選べ変更も可能である。
・GPs は(a) 人頭払い(capitation), (b) 固定費(operation costs など), (c) 補助的支払い(場所など) (d) 出来高により支払われる。
・患者は病院あるいは polyclinic のいくつかの専門医 (眼科医、産婦人科医、皮膚科医等)に紹介状無しで受診することも可能である。.
・入院医療は主に公立病院によって提供される。
・入院の支払いは DRG システムに基づく。.
・保険料率は賃金の約 7%。

A-1.2. What is the role of private insurance companies?

❑ All individuals (or the majority) are covered by public healthcare system and few people use private insurance.
❑ All individuals (or the majority) are covered by the public healthcare system, but private insurance companies are often employed to decrease co-payment costs.
❑ Some individuals are covered only by the public healthcare system, while some are covered only by private insurance.
■ Other (please specify): All individuals (or the majority) are covered by the public

healthcare system, but private insurance companies are often employed to finance a better or faster private in- or outpatient care for the patient

・民間保険の割合は少ない。

A-1.3. Medical fees paid by patients *(please specify if the system is more complicated or has some exceptions)*:

[(i) clinic/ (ii) hospital]

❑ Employ a co-payment system, for which the payment rates is __% for elderly and __% for all others
❑ Employ a deductible system, for which the amount is __ for elderly and __ for all others
■ Are basically non-existent (free of charge)

A-2. Overview of drug pricing in your country

A-2.1. In your pricing system *(Please specify if the system is more complicated or has some exceptions),*

[(i) Prescription only medicine/ (ii) Hospital only medicine/ (iii) Generics]

❑ Pharmaceutical companies set drug prices
❑ A governmental organization sets most drug prices.
❑ Another third-party organization (please specify:) sets drug prices.

・医薬品価格は企業により自由に設定できるが、革新的な医薬品はヨーロッパの最低価格であるときに償還対象となる。National Health Insurance Fund Association (OEP)はより低い価格となるよう交渉する可能性もある。
・リスク共有メカニズム (paybacks, financial or therapeutic risk-sharing) もしばしば用いられる。

A-2.1. Method of drug pricing

Please elaborate on the details of the drug pricing system in your country.
(e.g., How drug prices are determined, referencing countries…)

[Prescription only medicine]/ [Hospital only medicine]

・革新的医薬品の価格はヨーロッパの最低価格を超えない。(France, Ireland, Germany, Spain, Portugal, Italy, Greece, Poland, Check Republic, Slovenia, Slovakia, Belgium, Austria, one additional country).

・ATC-4 のレベルに基づき参照価格が導入されている。

・病院用医薬品も同様の仕組みで償還価格が設定される。また、病院は入札により購入する。

・個々のリスク共有メカニズムにより、契約量を超えて販売された額の払い戻しを受ける(price-volume agreements)などの仕組みがある。

A-2.3. Drug fees paid by patients *(Please specify if the system is more complicated or has some exceptions)*

[(i) Prescription only medicine/ (ii) Hospital only medicine/ (iii) Generics]

■ Employ a special reimbursement rules for people with low income.

❑ Employ a deductible system for which the deductible is __ for elderly and __ for all others.

❑ Are free of charge

1) Fully reimbursed drugs (including cancer, diabetes, multiple sclerosis, depression etc.): 一パックあたり HUF 300

2) Indication dependent drugs (treatment of almost 50 chronic conditions such as epilepsy, asthma and rheumatoid arthritis): 90、70%、あるいは 50%

3) Normative reimbursement: (including antibiotics, antidiabetics, antihypertensive drugs, NSAIDS, etc.) 80%、55% あるいは 25%.

・2007 年より該当する場合は、償還額に上限が定められるようになった。(慢性疾患の場合は、一月あたり HUF12,000、急性疾患の場合は一月あたり HUF6,000).

・償還価格が導入されているので、償還価格との差は患者負担となる。

・病院用医薬品については DRG に含まれるため自己負担は発生しない。

[B. HTA Organization]

B-1. When was the HTA organization or department established?

2004年

B-2. Objective and history of the organization

・Please list the objectives and the background history for the establishment of the HTA organization or department.

- 償還の可否に関する意思決定をサポートするための独立した研究機関である。
-

・ Please describe the business content of your organization or the HTA organization or department.

- 医薬品と医療機器に関する医療技術評価を行う。
- National Insurance Fund やMinistry of Health に対してHTA に関する助言を行う。
- EUnetHTA への参加

B-3. The organization is

■ Governmental department or agency for HTA
❑ Governmental department or agency for drug approval (e.g. FDA, EMEA)
❑ A national research institute
❑ Insurer
❑ Other (Please specify:)

B-4. Budget

B-4.1. Annual budget

How much are the annual budgets for the entire HTA organization or department and for the division of economic evaluation?

B-4.2. Funding sources

■ The funding comes from the government and/or others?
・Does funding come from pharmaceutical companies (or industry groups)?
・Do pharmaceutical companies pay for a review process?

B-5. Staff

B-5.1. Number of staff

· How many people work for your HTA organization or department?

- 15人 (physicians, economists. engineer, statistician)
-

· What percentage of the staff is administrative?

- 1人
-

· How many people are involved in economic evaluation or health technology assessment?

- 14人

B-5.2. Breakdown of the non-administrative staff

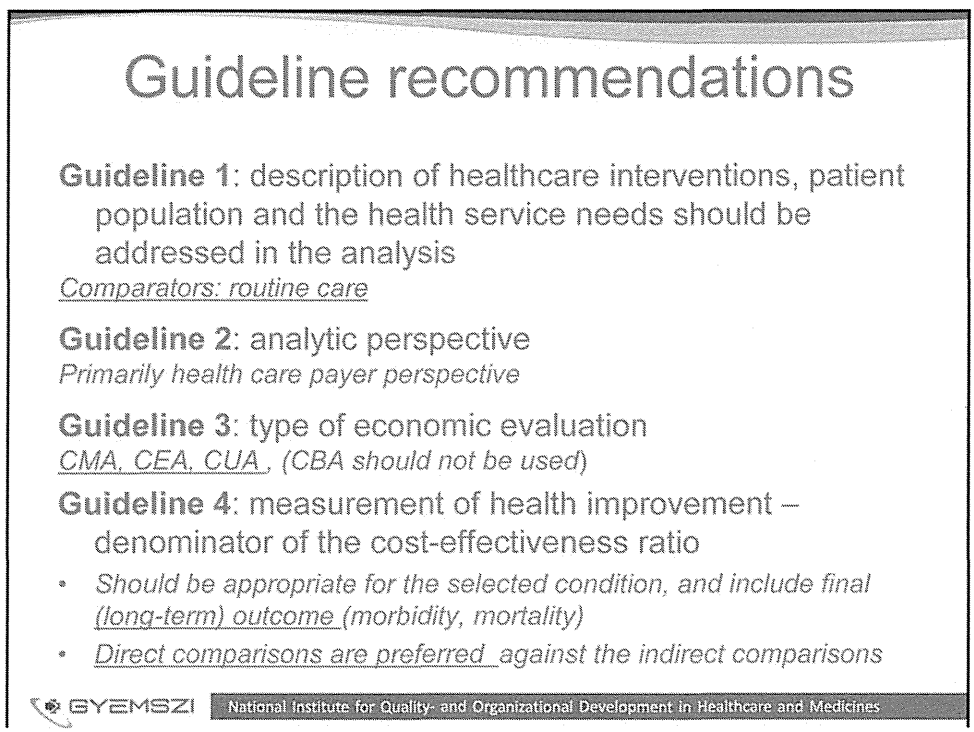
· How many non-administrative staff members *(e.g., health economists, biostatisticians, epidemiologists, etc.)* work for your HTA organization or department?

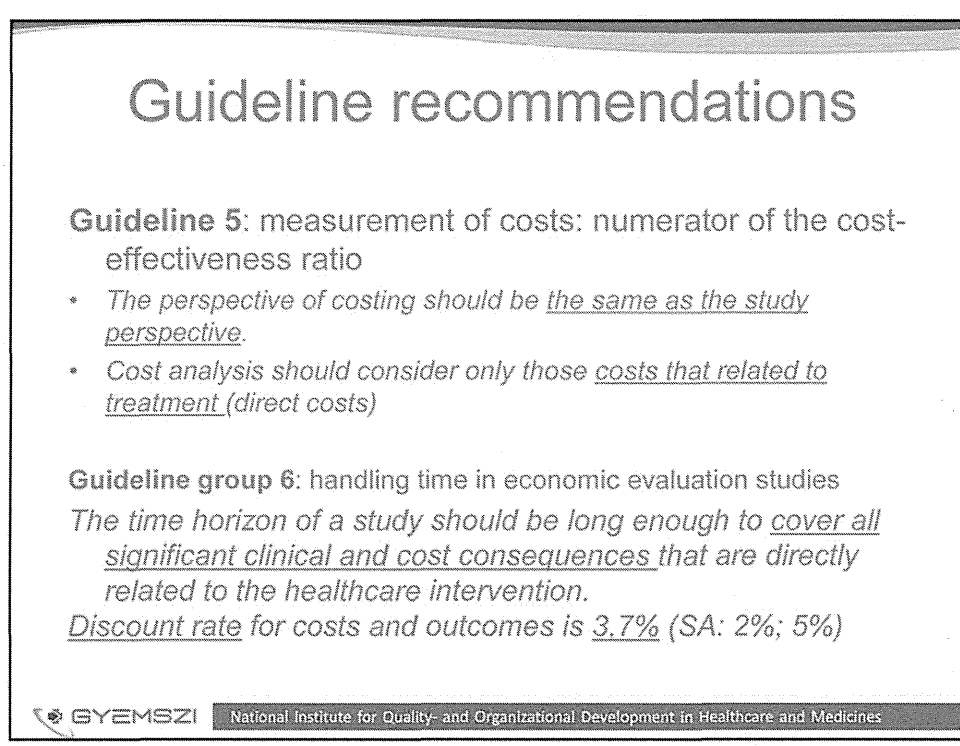
- 14

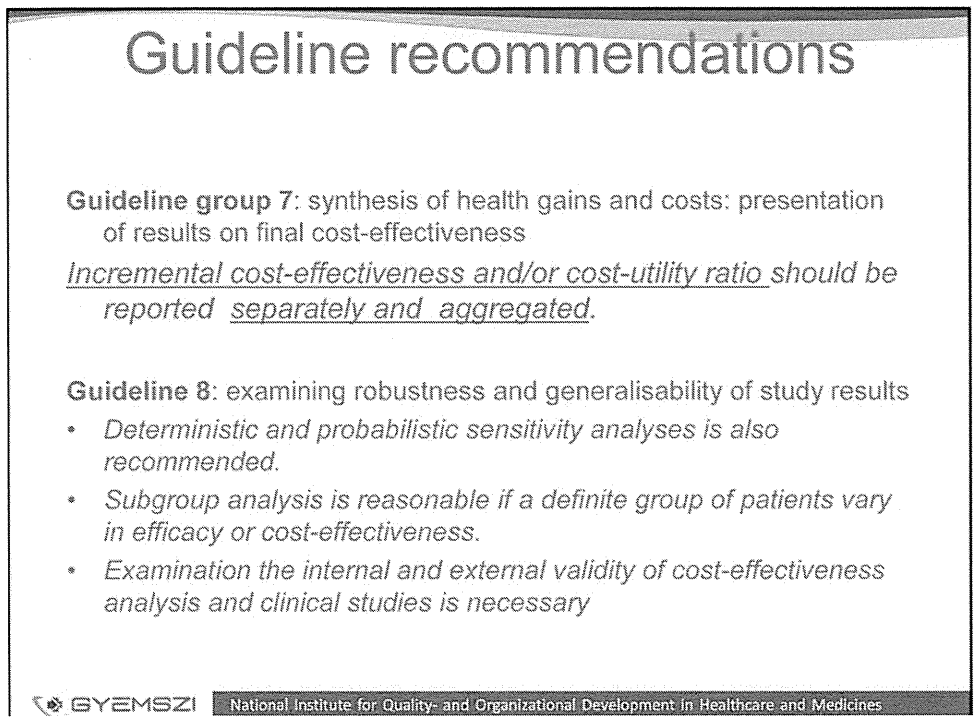
[C. Method of economic evaluation/HTA]

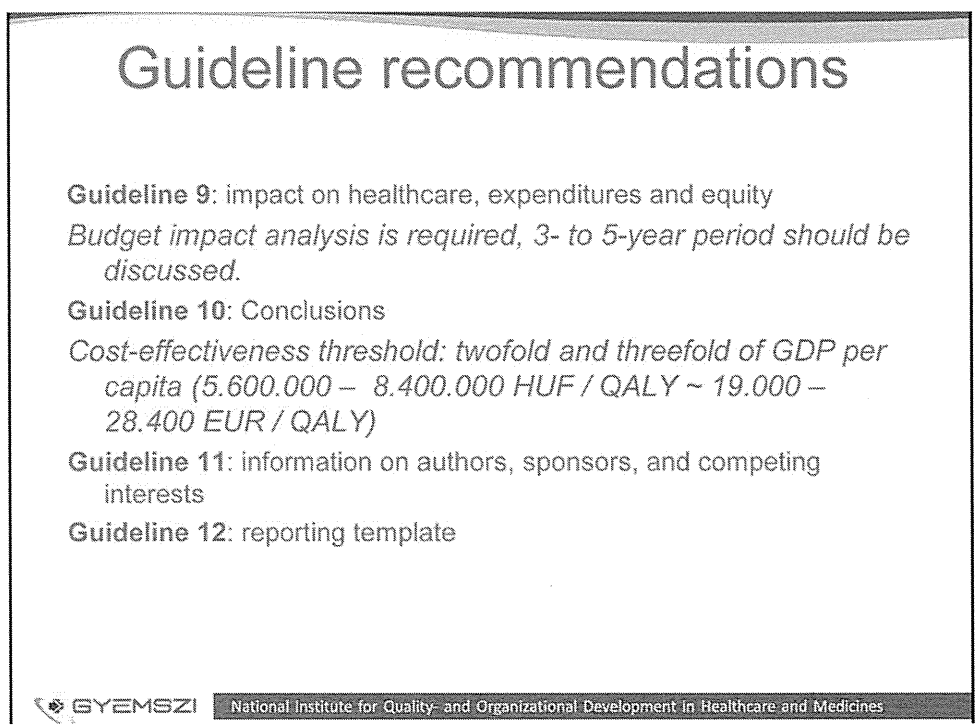
C-1. Recommended methodology or guidelines for economic evaluation

・Hungarian pharmacoeconomic guidelines が存在する。（例）割引率は 3.7%。









C-2. Methods of economic evaluation or HTA

C-2.1. Time of evaluation

❑ Before the new drug approval (NDA)

❑ Between the NDA and reimbursement

■ After it is marketed

C-2.2. Healthcare technology targeted by the economic evaluation

·Are all technologies assessed by the economic evaluation?

- Yes
-

·If not all technologies are targeted, who determines the targeted technologies, and how?

·Which technologies are targeted?

- 医薬品
- 医療機器
- 手技等

C-2.3. Evaluation process

C-2.3.1. Process

·Please explain the process of evaluation.

・ 臨床的・経済的エビデンスの妥当性
・ 相対的な有効性
・ ICER (cost/QALY)
・ 予算への影響

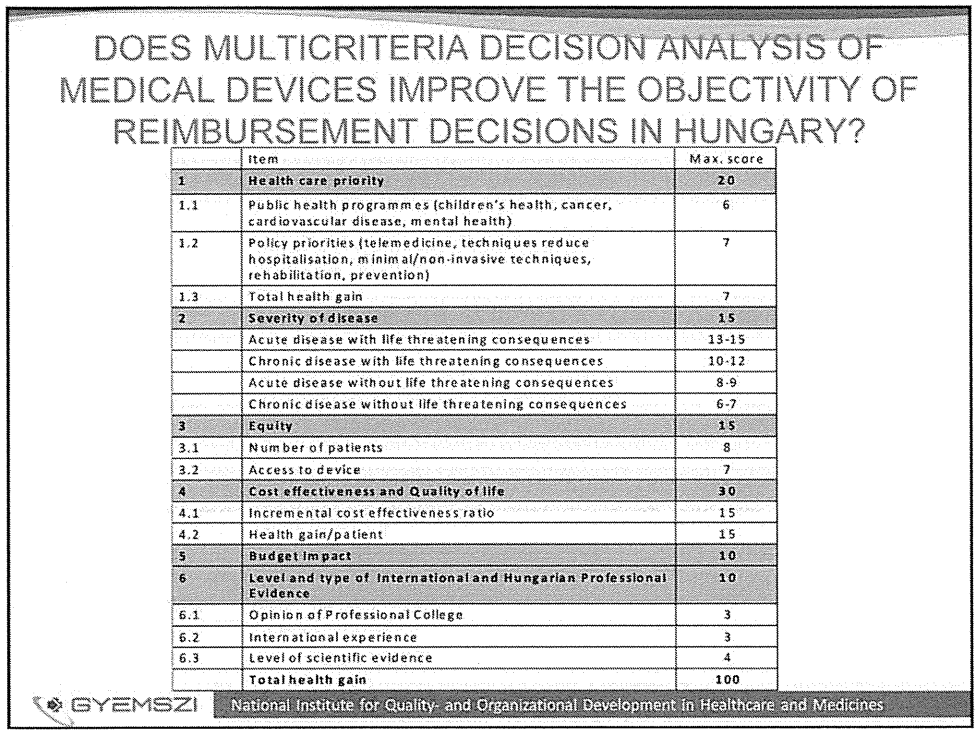
が検討される。

·医薬品については経済評価のチェックリストが存在する(別添)。

·医療機器については、MCDA(Multiple criteria decision analysis)という手法によるスコアリングを使用している。これは、

・ Health care priority
・ Severity of disease
・ Equity
・ Cost-effectiveness and quality of life
・ Budget impact
・ Level and type of international and hungarian professional evidence

の6つのドメインからなり、合計点が100点の評価尺度である。



DOES MULTICRITERIA DECISION ANALYSIS OF MEDICAL DEVICES IMPROVE THE OBJECTIVITY OF REIMBURSEMENT DECISIONS IN HUNGARY?

	Item	Max. score
1	**Health care priority**	**20**
1.1	Public health programmes (children's health, cancer, cardiovascular disease, mental health)	6
1.2	Policy priorities (telemedicine, techniques reduce hospitalisation, minimal/non-invasive techniques, rehabilitation, prevention)	7
1.3	Total health gain	7
2	**Severity of disease**	**15**
	Acute disease with life threatening consequences	13-15
	Chronic disease with life threatening consequences	10-12
	Acute disease without life threatening consequences	8-9
	Chronic disease without life threatening consequences	6-7
3	**Equity**	**15**
3.1	Number of patients	8
3.2	Access to device	7
4	**Cost effectiveness and Quality of life**	**30**
4.1	Incremental cost effectiveness ratio	15
4.2	Health gain/patient	15
5	**Budget impact**	**10**
6	**Level and type of International and Hungarian Professional Evidence**	**10**
6.1	Opinion of Professional College	3
6.2	International experience	3
6.3	Level of scientific evidence	4
	Total health gain	**100**

C-2.3.2. Economic evaluation analysts

・Who performs the economic evaluations? *(e.g., manufacturers, third-parties, academic groups, etc.)*

製造業者が提出する。

C-2.3.3. Reviewers of the economic evaluation

・Who reviews the submitted economic evaluations? *(e.g., members of the organization, academic groups, etc.)*

HTA 組織でレビューする。

C-2.3.4. Involvement by external researchers (from universities and research institutes)

・Are academic research groups involved in the evaluation process?

・If yes, how are they involved?

・How much academic research groups are involved in the organization, not individual process?

アカデミックルグループの活用はない。

C-2.3.5. Involvement of citizens or patient groups

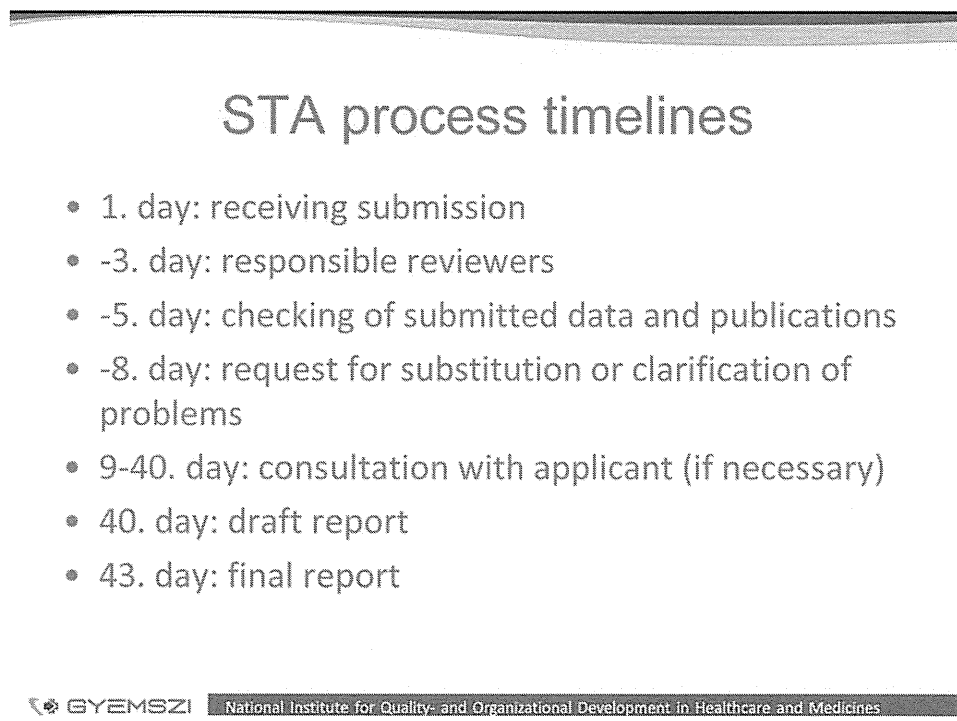
・Are citizens or patient groups involved in the evaluation process?
・If yes, how are they involved?

市民や患者が参加する直接のプロセスなどはない。

C-2.4. Evaluation period

・On average, how long does it take to perform one economic evaluation or HTA?

43 日



C-3. Threshold

・Do you have referable thresholds used in your economic evaluations?
・If yes, what are the approximate values of these?
・If no, how does your evaluation determine whether a healthcare technology is cost-effective or not?

200-300% GDP/QALY が使用される。.

C-4. Completed evaluation

C-4.1. Number of completed evaluations

・What are the total and annual counts for completed evaluations?

・If possible, please list the URL or the results of the evaluation.

70-80 pharmaceuticals/year

2-4 medical devices/year

60-80 medical devices intended for patient use

HTA レポートは公表されていない。

[D. The role of the evaluation in decision-making]

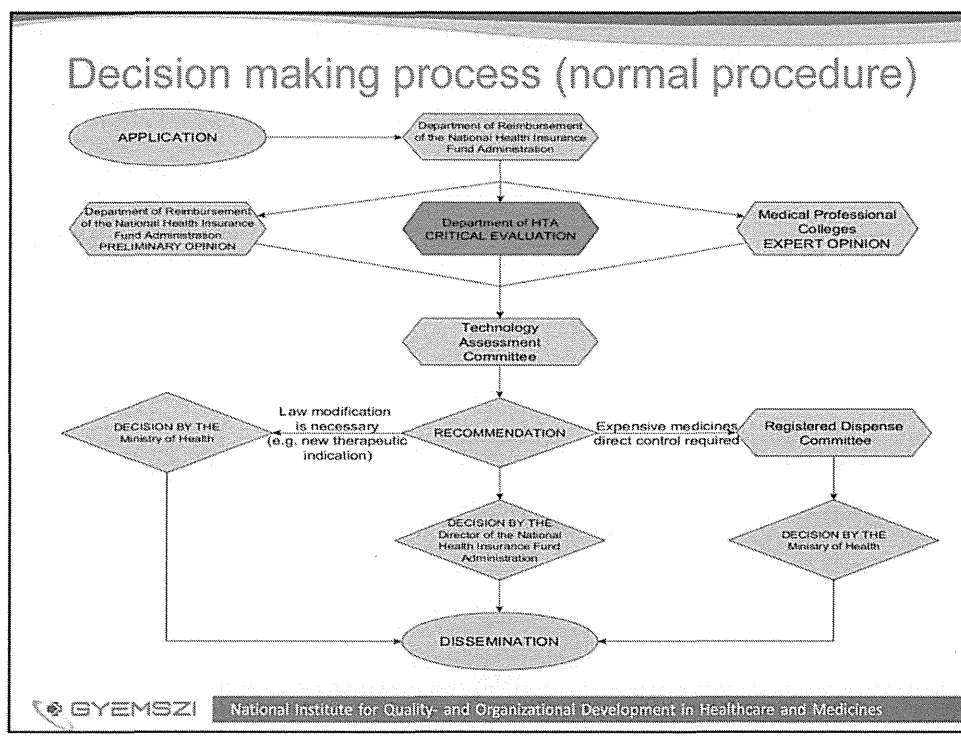
D-1. Application of evaluation to decision-making

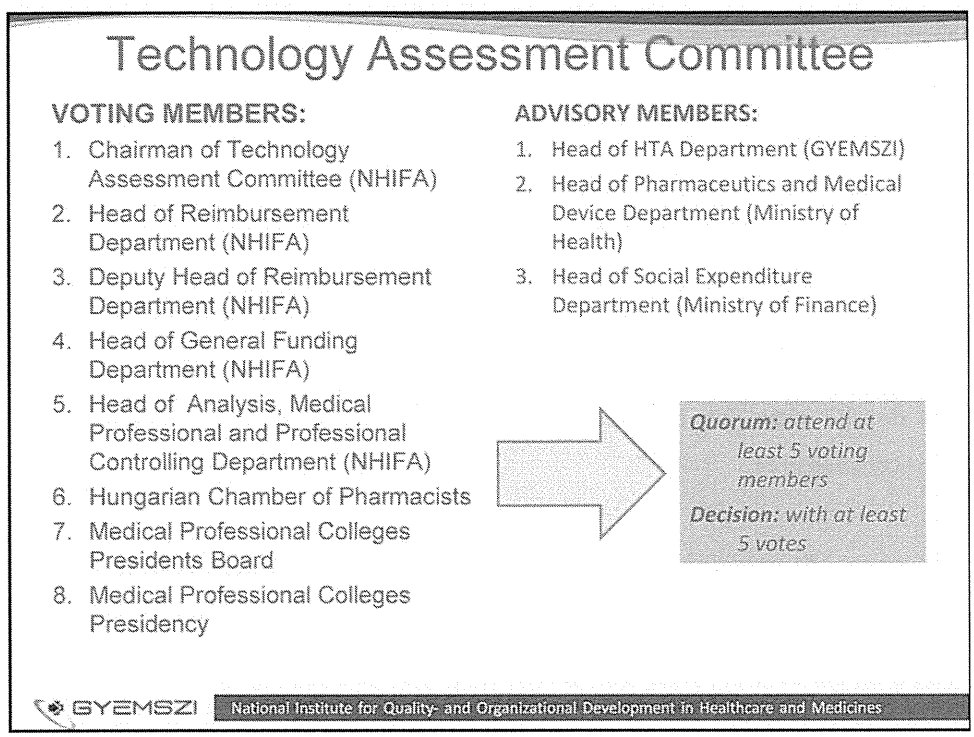
・How are the economic evaluations or HTA utilized? *(e.g., reimbursement, pricing, etc.)*
・How do those making decisions utilize the evaluation results? *(e.g., mandatory, optional, etc.)*

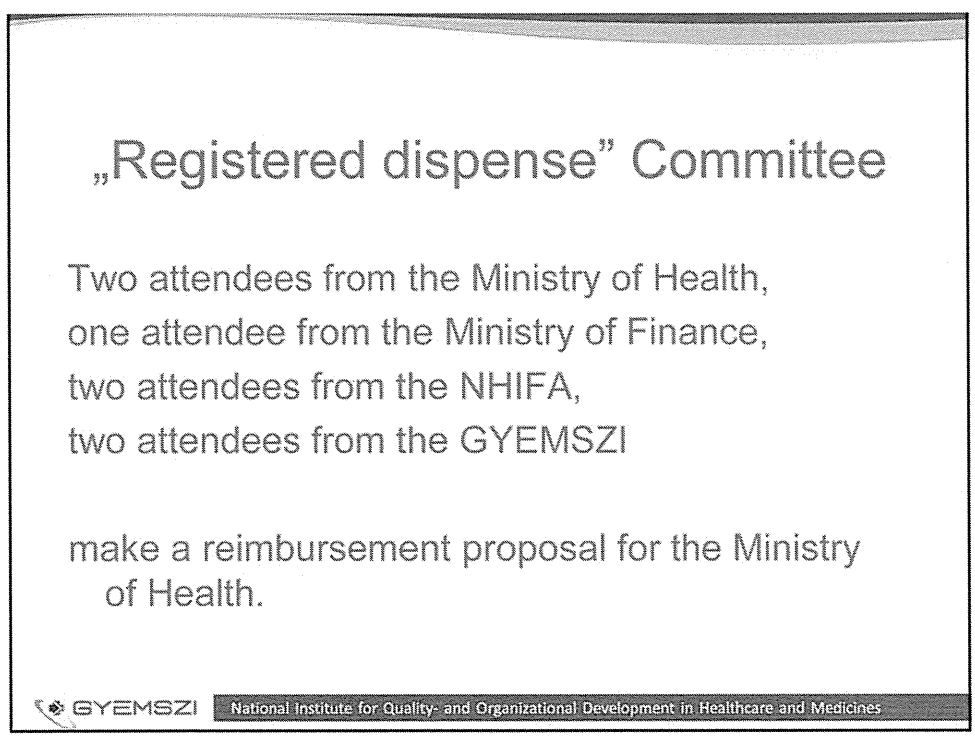
償還の可否を検討している。

D-2. Decision-making based on evaluation results

・Please describe the decision-making process as it employs the evaluation results.







D-3. Positive/negative results of the evaluation

· How are positive and negative evaluations handled? How do these results influence which processes, and in what way?

D-4. Feedback (in particular, negative feedback) about your organization from citizens/patient groups

・How do citizens or patient groups respond to decisions made based on economic evaluations or HTAs (in particular, negative assessments)?

D-5. Example of an evaluation and decision-making

・Please elaborate on the evaluation and decision-making process, using the example of sunitinib (®Sutent) for renal cell cancer.
・Please do the same for long-acting insulin (insulin glargin (®Lantus) and/or insulin detemir (®Levemir)).

(Please note: We commonly inquire about sunitinib and long-acting insulin and compare the answers from many organizations. If neither sunitinib nor long-acting insulin is utilized, please skip this question.)

Completion guide: "Yes" answers indicate the correct methodology in the questionnaire. Not every question will be relevant for all economic evaluations. If a "yes" answer cannot be justified for a relevant question, the answer should be "no". Explanations should be provided in the fourth column. Sub-questions in brackets also prompt explanations.

Question	Answer		Explanation
1. Economic Evaluation Checklist Questions			
1.1. Filter Questions			
Did the evaluation present a well defined question?	yes [ ]	no [ ]	(If yes, please rephrase the question.)
Did the evaluation give a comprehensive description of the competing alternatives?	yes [ ]	no [ ]	(If yes, please name the compared technologies.)
1.2. Research Question (relevance, comparator, financing protocol)			
Is the selection of the comparator justified, considering the target indication, patient group, disease severity, therapeutic stage and the requested reimbursement category?	yes [ ]	no [ ]	(If yes, please clarify all details.)
Does the economic evaluation adequately cover the full spectrum of indication submitted in the reimbursement application?	yes [ ]	no [ ]	
1.3. Health Benefit			
1.3.1. Source of Scientific Evidence			
Does the evaluation provide thorough evidence that the analyzed health technology is effective?	yes [ ]	no [ ]	
Does the evaluation provide thorough evidence that the comparator health technology is effective?	yes [ ]	no [ ]	
Was the search strategy for evidence supporting the effectiveness adequate and justifiable?	yes [ ]	no [ ]	(If yes, please indicate the methodology of literature review.)

Were the search strategy and origin of quality of life or utility data presented?	yes [ ]	no [ ]	not relevant [ ]	
Were the references for health benefits indicated and attached (including data on file)?	yes [ ]	no [ ]		
If there is direct comparative trial, is the economic evaluation based on its results? (i.e. were results from direct comparison ignored in favour indirect comparison because the indirect comparions is more favorable?)	yes [ ]	no [ ]	not relevant [ ]	
Can we exclude that only favourable studies for the new health technology were taken into consideration?	yes [ ]	no [ ]		
1.3.2. Evaluation of Relative Effectiveness in Case of Indirect Comparison				
If indirect comparison was used, were the following assumptions of relative effectiveness calculation explained in detail?	yes [ ]	no [ ]	not relevant [ ]	
In the studies used as basis of indirect comparison calculations...				
Was the methodology of the literature review to select the studies for the indirect comparison justified? (i.e. did they select even the less favourable studies?)	yes [ ]	no [ ]	not relevant [ ]	
Was the indirect comparison based on comparative studies and did those studies include the same comparator?	yes [ ]	no [ ]	not relevant [ ]	
Was the design of the selected studies similar, including the primary and secondary endpoints?	yes [ ]	no [ ]	not relevant [ ]	(If not, please justify why the selected studies are acceptable and indicate the methodology of adjustment.)

Was the time horizon of the studies comparable? (i.e. did the assessment of the effectiveness – e.g. risk reduction – take place at the same time horizon?)	yes [ ]	no [ ]	not relevant [ ]	(If not, please justify why the selected studies are acceptable and indicate the methodology of adjustment.)
Were the patient populations in the selected studies similar? (e.g. demographics, disease stage, and geographic location)	yes [ ]	no [ ]	not relevant [ ]	(If not, please justify why the selected studies are acceptable and indicate the methodology of adjustment.)
Was the effectiveness measured in the same appropriate units in the selected studies?	yes [ ]	no [ ]	not relevant [ ]	
Were the absolute risk reduction (ARR) and relative risk reduction (RRR) also presented in each of the selected studies?	yes [ ]	no [ ]	not relevant [ ]	
Were the comparator groups at similar risk in the selected studies? (i.e., in the case of equivalent RRRs was ARR also the same?)	yes [ ]	no [ ]	not relevant [ ]	(If not, please justify why the selected studies are acceptable and indicate the methodology of adjustment.)
Were all aspects of health benefit taken into consideration in the indirect comparison, including safety? (i.e. not only favourable aspects)	yes [ ]	no [ ]	not relevant [ ]	
1.3.3. Magnitude of Health Benefit				
Was every relevant and significant outcome and adverse event considered in the study when assessing health benefits?	yes [ ]	no [ ]	(If not, please indicate the justification)	
Do clinical trial data support the superior efficacy or improved side effect profile of the new health technology versus the	yes [ ]	no [ ]	not relevant [ ]	