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HOW TO AID THE DECISION-MAKER?

Improving on health technology assessment

A matter of perspective

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- CEE overview
- (How) does it work in Poland?
- Same struggle different solutions – examples from the West
- Ways to go forward

HTA and its impact on the reimbursement decision

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* For countries without the price data the average has been modelled based on results of similar countries

QUESTIONNAIRE	Bulgaria	Croatia	Czech Republic	Estonia	Hungary	Latvia	Lithuania	Poland	Romania	Russia	Serbia	Slovakia	Slovenia	Turkey	Ukraine
Average relation of price of an orphan drug to the lowest price of this drug in the CEE	111%	121%	102%	128%	119%*	109%	111%	118%	108%	102%*	126%	140%	126%	132%	102%*
Formal deadline to decision? [days]	90	90	165	180	180	180	180	180	180	67	365	180	270	180-360	not specified
Real time from submission to decision	1-2 years	0.5-1 year	below 0.5 year	above 2 years	0.5-2 years	above 2 years	above 2 years	0.5-1 year	0.5-1 year	0.5-1 year	1-2 years	0.5-1 year	0.5-1 year	1-2 years	1-2 years
Analytic effort to initiate the decision making process	simple HTA (no systematic review)	simple BIA (with expert opinion, optional modelling and CE)	complicated HTA with systematic review	complicated HTA with systematic review	simple BIA / simple HTA (no systematic review)	simple HTA (no systematic review)	simple BIA + est. DALY/QALY	complicated HTA with systematic review	simple HTA (no systematic review)	complicated HTA with systematic review (with direct and indirect costs)	simple HTA with expert opinion (BIA with full cost effectiveness modelling and with expert opinion)	complicated HTA with systematic review	simple BIA (NICE, COCHRANE, ANY OTHER data on pharmacoeconomics should be submitted, if available)	HTA is being required. Based on product and the therapy, some complicated / additional data may also be required.	simple HTA (no systematic review)

The Polish Way – reimbursement procedure

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- Application-based
  - Submission by a MAH post marketing authorisation
  - Reserved for pharmaceuticals, medical devices and foodstuffs for particular nutritional uses
- Decision taken by the Minister of Health
  - Agency for Health Technology Assessment and Tariff System
  - Economic Commission
- 180-day deadline

Agency for Health Technology Assessment and Tariff System

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- Stages
  - Formal check
  - Verification analysis
  - Position of the Transparency Council
  - Recommendation of the President
- Focused presenting on
  - Efficacy, effectiveness, safety, cost-benefit, cost-risk
  - Comparison to alternative treatment options
  - Foreign recommendations
  - Cost per QALY threshold

HTA requirements in Poland

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- 2011 Act on reimbursement
  - Analyses for products without reimbursed equivalent
    - Full set of classic HTA analyses
    - Rationalisation analysis
- 2012 Regulation of the Minister of Health on the minimum requirements for submitted analyses
- 2010 Agency Guidelines on HTA
  - Not a formally binding document

Decision-making in Poland

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- Vast improvement in efficiency of issuing reimbursement decisions after the introduction of the 2011 Act on reimbursement
  - Estimated time from a submission of application to a decision ~250 days (was up to several years in the past)
- Objections to transparency of the decision-taking
  - HTA process is siginificantly more transparent
- Limited number of newely introducted innovative reimbused therapies
  - Generated savings are used to cover other cost of other health services

Recommendations and decisions

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	May 2014 – Apr 2015 (12 months)	Mar 2014 – Feb 2015 (12 months)	Jan 2014 – Dec 2014 (12 months)
Transparency Council			
Positive position	75%	79%	84%
Negative position	**25%**	**21%**	**16%**
Agency's President			
Positive recommendation	77%	81%	87%
Negative recommendation	**23%**	**19%**	**13%**
Minister of Health			
Positive decision	46%	50%	56%
Likely negative decision	**54%**	**50%**	**44%**

Coherence between the Transparency Council and the President of the HTA Agency

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May 2014 – Apr 2015 (12 months)

	Positive recommendation of the Agency's President	Negative recommendation of the Agency's President
Positive position of the Council	**85**	1
Negative position of the Council	3	**25**

Mar 2014 – Feb 2015 (12 months)

	Positive recommendation of the Agency's President	Negative recommendation of the Agency's President
Positive position of the Council	**87**	0
Negative position of the Council	2	**21**

May 2014 – Apr 2015	Mar 2014 – Feb 2015	Jan 2014 – Dec 2014
0,904	**0,945**	**0,899**

Coherence between the President of the HTA Agency and the Minister of Health

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May 2014 – Apr 2015 (12 months)

	Positive decision	Likely negative decision
Positive recommendation of the Agency's President	**51**	46
Negative recommendation of the Agency's President	3	**17**

Mar 2014 – Feb 2015 (12 months)

	Positive decision	Likely negative decision
Positive recommendation of the Agency's President	**53**	46
Negative recommendation of the Agency's President	6	**14**

May 2014 – Apr 2015	Mar 2014 – Feb 2015	Jan 2014 – Dec 2014
0,284	**0,176**	**0,145**

But why?

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- Some reimbursement criteria are not considered by the President of the HTA Agency
  - Importance of the indication
  - Price competitiveness
  - Budget impact (public payer and beneficiaries)
  - Health priorities
- A pricing decision is taken based on a seperate set of criteria

Results

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- Predicitability
- Transparency

- Or their lack…

What is not considered a priority?

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- Cardiovascular diseases, malignant neoplasms, chronic respiratory diseases
- Injuries from accidents
- Mental disorders, bone diseases and joint disorders, infectious diseases
- Smoking, alcohol and drug abuse
- Obesity and diabetes
- Health care for mothers, newborns and children up to 3 years
- Long-term care and geriatric care

A single cost-effectiveness threshold (QALY)

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LASER ANALYTICA

Market access SENTINEL

If it's important to Market Access we find it!

Właściciel licencji: Norbert Wilk

Data wydania: 14.11.2014

TEMAT DNIA

Refundacja: AOTM opublikował informacje w sprawie obowiązującej od dnia 5 listopada 2014 r. wysokości progu opłacalności. Aktualnie wysokość progu kosztu uzyskania dodatkowego roku życia skorygowanego o jakość wynosi 119 577 zł (3 x 39 859 zł)

#AOTM #Próg opłacalności #PKB per capita

CZYTAJ WIĘCEJ stat.gov.pl www.rynekzdrowia.pl

WCZEŚNIEJ NA TEN TEMAT

2014-11-05 Refundacja: Na stronach GUS opublikowano Obwieszczenie Prezesa GUS w sprawie szacunków PKB za okres 2010-2012 (PKB = 39 859 PLN/per capita). W związku z powyższym wzrośnie próg opłacalności w analizach ekonomicznych (119 577 PLN/QALY)

INFORMACJE Z KRAJU

Refundacja: 17 listopada odbędzie się 40 posiedzenie Rady Przejrzystości AOTM

NICE approach

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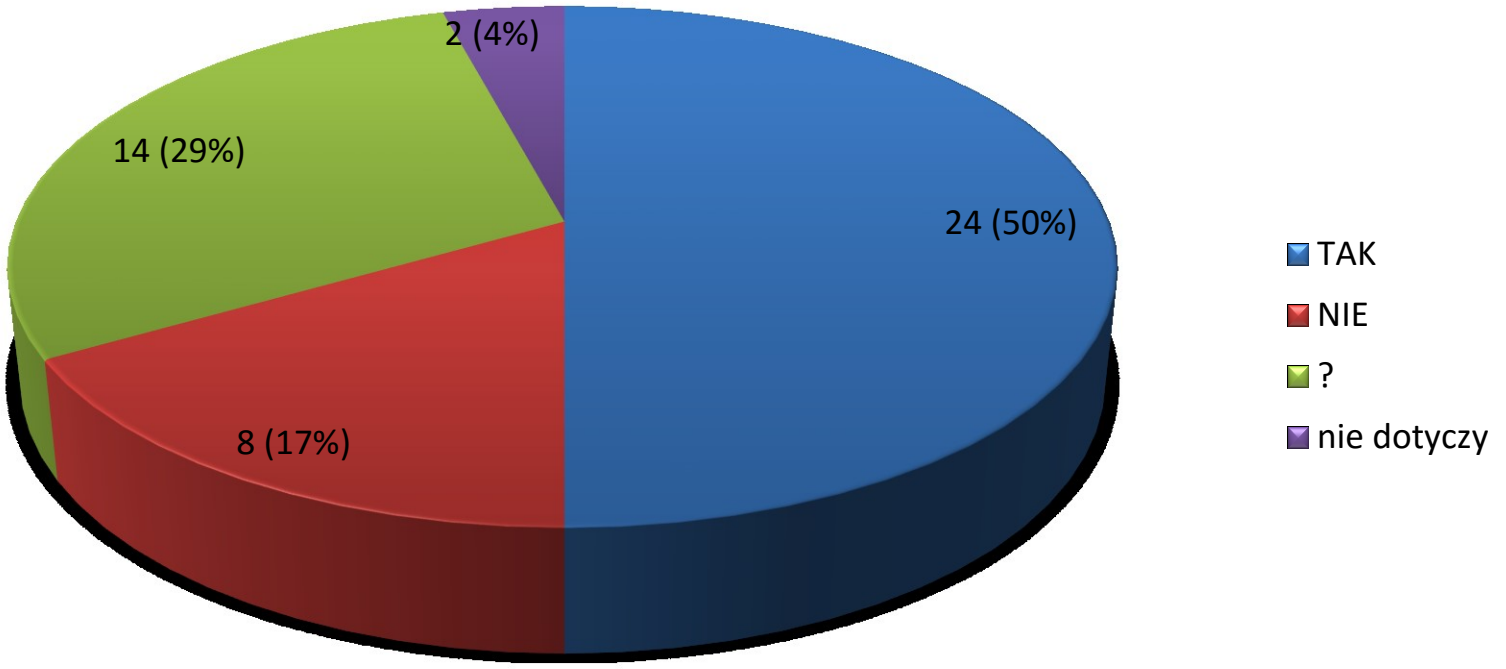
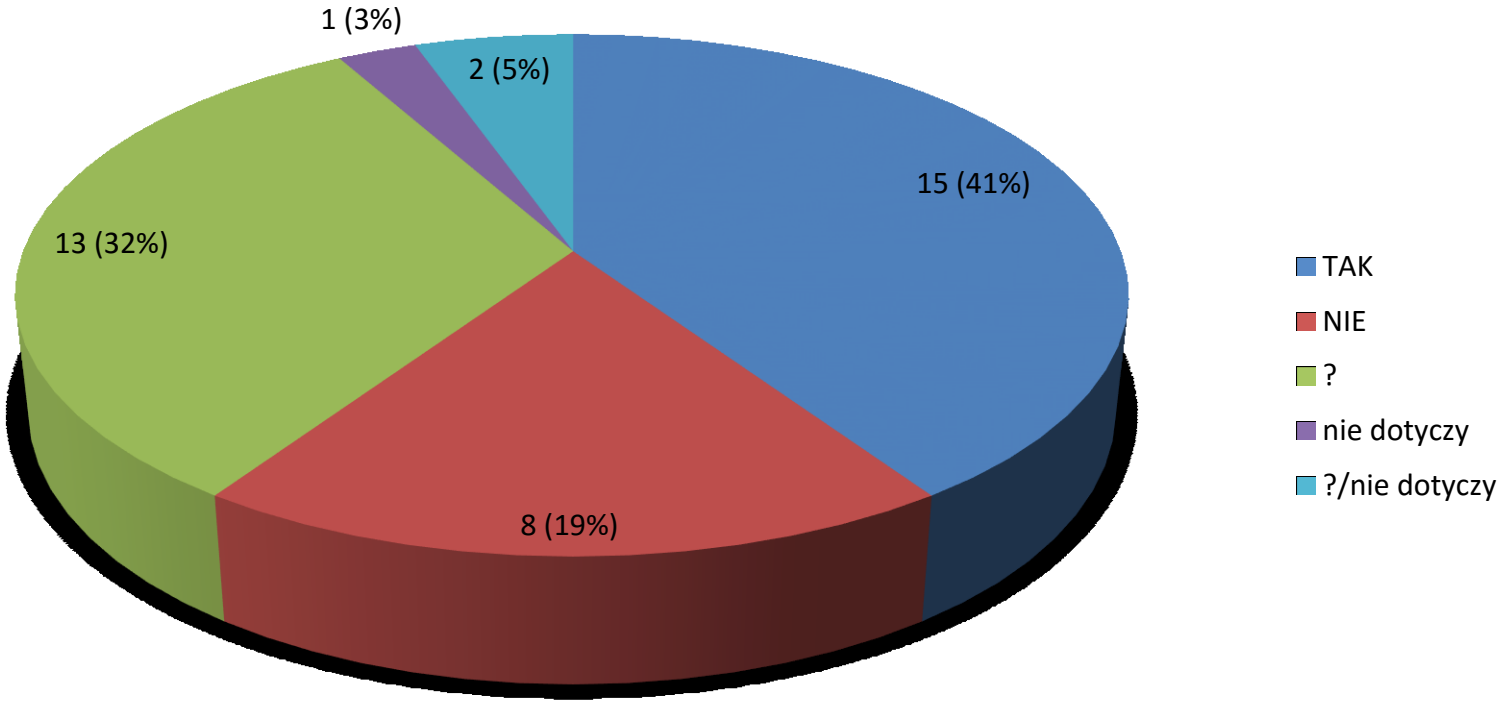
- Below a most plausible ICER of £20,000/QALY, judgements about the acceptability of a technology as an effective use of NHS resources are based primarily on the cost-effectiveness estimate
- Above a most plausible ICER of £20,000/QALY, judgements about the acceptability of the technology as an effective use of NHS resources are more likely to make more explicit reference to factors including:
  - the degree of uncertainty surrounding the calculation of ICERs
  - the innovative nature of the technology
  - the particular features of the condition and population receiving the technology
  - where appropriate, the wider societal costs and benefits.
- Above an ICER of £30,000/QALY, the case for supporting the technology on these factors has to be increasingly strong. The reasoning of the Committee's decision will be explained, with reference to the factors that have been taken into account

Oncologic drugs meeting the threshold



Positive decision in the case of drugs not meeting the threshold



Ongoing struggle – France

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- Changes in the medical benefit (SMR) and improvement of the medical benefit (ASMR) system
- SMR (reimbursement status and reimbursement rate) based on
  - Efficacy, effectiveness and safety
  - Position of the medicine in the therapeutic strategy and the existence or absence of therapeutic alternatives
  - **Severity of the disease**
  - Type of treatment: preventive, curative or symptomatic
  - **Public Health Impact**
- Plan to focus on relative efficacy od new drugs
  - Relative Therapeutic Index (ITR)

Ongoing struggle – United Kingdom

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- Value-based pricing not accepted under the 2014 PPRS
  - Payback scheme introducted (over GBP 12bn)
- Value-based assessment
  - Need to reflect the differential value of treatments for the most serious conditions, encompass the differential valuation of treatments designed to extend life at the end of life
  - Aiming at incorporating burden of illness and wider societal benefits (proportional and absolute QALY shortfall)
    - Instead of end-of-life treatment protocol
  - Should allow for better coverage of innovative treatment
- NICE's Guide to the Methods of Technology Appraisal
  - NICE proposal rejected after consultation
  - No changes for now

Ongoing struggle – United Kingdom

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- Cancer Drug Fund
  - Financing of pharmaceuticals under a simplified assessment scheme and on individual basis
  - Used for pharmaceuticals not approved by NICE and not available under NHS in England
  - GBP 340m per year
  - Scoring for PFS/OS, QoL, toxicity and unmet need
  - Prioritisation based on score and price

Evidence necessary

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8 Strength of Evidence

Criteria	Grade	Recorded Grade
Two or more good quality Phase III Randomised Controlled Trials, both published	A	
One good quality Phase III Randomised Controlled Trial, published	B	
Comparative Phase II trial, published	C	
Non-Comparative Phase II, published	D	
Unpublished data (in abstract form only)[1]	U1	
Unpublished data (in abstract form only)[2]	U2	[ ]

[1]Appropriate methodology for the treatment setting, presented at an international meeting

[2]Methodology inappropriate for treatment setting and/or not presented at international meeting

Quality of Life

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2	Quality of life		
	Criteria	**Score**	**Recorded Score**
	Published evidence of significant improvement in overall Quality of Life (QOL), using a validated tool.	2	
	Measurable evidence of significant improvement in relevant aspect(s) of QOL using a validated tool or evidence of lack of deterioration in overall QOL using a validated tool or clear evidence of major improvement in QOL without validated tool (e.g. clinically significant reduction in blood transfusion)	1	
	No QOL data collected in the trial or QOL data not analysed	0	
	Measurable evidence of significant deterioration in relevant aspect(s) of QOL using a validated tool or clear evidence of major deterioration in QOL without a validated tool (e.g. clinically significant increase in incidence of febrile neutropenia)	Minus 1	
	Published evidence of significant deterioration in overall QOL using a validated tool.	Minus 2	

Where to?

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- An algorithm similar to the one used in the UK Cancer Drug Fund was recently proposed in Poland by the Polish Clinical Oncology Society and Polish Oncology Society
  - Final score should indicate products with added value derserving financing from public funds
  - Scoring based on PFS, OS, QoL, safety profile comparison, cost/QALY, relative cost/efficacy, evidence quality, unmet need

Evaluation

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- No changes to the HTA requirements in Poland were made since the introduction of the new law
  - No changes to HTA guidelines since 2010
- Arcana Institute was requested by the Ministry of Health to valide the financing algorithm for oncologic drugs
  - The idea of a scoring system seems reasonable as it can be fine-tuned to reflect the perceived value of all the components in the decision-making process allowing for greater transparency of the decisions
  - The system has to be checked for gameability and adequate robustness

HTA and values

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- HTA analyses should be focused on supporting the key criteria for making the reimbursement decisions
  - HTA requirements should reflect the decision problem
- Prorities of different countries may vary significantly (budget impact, innovativeness, clinical benefits)
  - No one size fit all solution
  - Results of the reimbursement procedure need to reflect local values to be publically acceptable

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Still looking for answers

Thank you