HTA CONFERENCE

Value Driven Healthcare and Shared Decision Making

Budgets, Negotiations and the Assessment of the Agreements' Outcomes

Athanassios Vozikis

Associate Professor,
Director of the Laboratory of Economics and Health Management, University of Piraeus, Department of Economics

lahHEM
University of Piraeus

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Δομή Παρουσίασης

1. From Authorization to Reimbursement
2. Types of Budgets and Shadow prices
3. Negotiations, Scenarios and Outcomes' Assessment
4. Potential Solutions

Από την Αδειοδότηση στην Αποζημίωση: Τα 3 Α

Αδειοδότηση (authorization)

- ***Clinical Effectiveness***
  (safety and efficacy, quality)

ΕΜΑ → Ε.Ο.Φ.

Αποδοχή (adoption)

- ***Cost-Effectiveness***

HTA

Αποζημίωση (reimbursement)

- ***Affordability***

N.C.

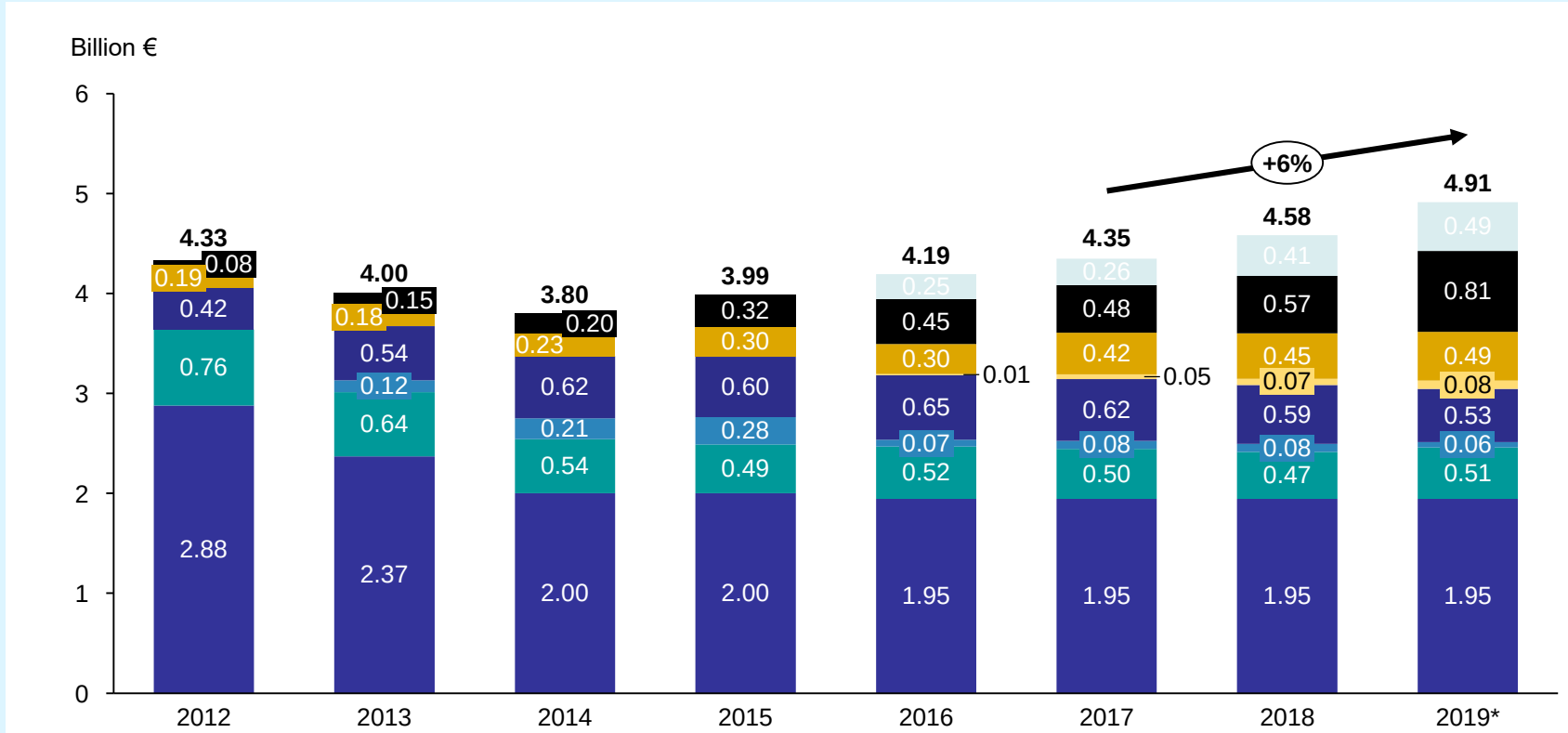
Ερώτημα:

Κλινικά αποτελεσματικά **ΝΑΙ**,
Οικονομικά αποδοτικά **ΝΑΙ**,
αντέχουμε όμως να τα αποζημιώσουμε;

Για την Ελλάδα απαιτείται ~5bn€ ετήσια φαρμακευτική δαπάνη με ετήσιο ρυθμό αύξησης +6% προκειμένου να καλυφθούν οι ανάγκες του πληθυσμού της

Pharmaceutical budget distribution evolution – 2012-2019

Pharmaceutical budget distribution evolution – 2012-2019



Comments

- Note 1: Figures do not include the non-reimbursed market (i.e. drugs purchased by patients out of pocket)
- *2019 figures - forecast

Legend

- In-patient clawback
- Out-patient clawback
- Out-patient rebate
- In-patient rebate
- Patient contribution
- EOPYY public expenditure (1A)
- In-patient public expenditure
- Out-patient public expenditure

Source: The pharmaceutical Market in Greece Facts & Figures 2017, ΣfEE

Μέτρα «συγκράτησης» της δαπάνης τα τελευταία χρόνια (πέρα από τη μείωση των τιμών)

1 Health Technology Assessment
- Independent government commission assesses comparative therapeutic value of new drug

2 Maximum Allowable Price
- Agency determines maximum price consistent with HTA
- New products enter five-year contract with no price increase and capped sales volume
- Manufacturers pay rebates if total sales volume exceeds contract

3 Negotiated Prices
- Agency negotiates confidential discounts of 10% to 30% off maximum allowed price
- Hospitals negotiate additional discounts from manufacturers when competing products exist

4 Price Decreases over Time
- Agency usually decreases prices after five years
- High-priced drugs in each class lowered over time toward lowest-price drugs in class

5 Annual Spending Cap
- Parliament sets budget for total drug spending growth
- All manufacturers pay back share of revenue if total spending exceeds the target

2012
- Outpatient : Fixed for inclusion in Rx list + scaled volume rebate
- Inpatient : Fixed on invoices
- Closed Budget on outpatient state spending
- Allocation based on Msh

2013
- Outpatient Budget Reduction

2014
- Outpatient : Change of Scaled rebate / 50-50 copay / ATC5 rebate / New active substance
- Inpatient : Scaled rebate + New active substance
- Outpatient Budget reduction

2015

2016
- Outpatient Budget reduction
- Closed Budget on inpatient state spending

2017
- Inpatient & Outpatient : Polynomial Rebates & 25% entry fee
- Inpatient Budget reduction
- Clawback Allocation based on Msh & Gsh

2018
- Inpatient Budget reduction

2019

Πως ορίζουμε το επίπεδο “ωριμότητας” ενός συστήματος υγείας, σχετικά με το P&R;

Four Types of Budgets

No budget

(means that there is no constraint on health expenditure. The price of a new drug is not relevant to the new drug adoption decision in this context)

An unconstrained budget

(is one that is expanded to accommodate any purchase that has an ICER at or below the maxWTP, where this maxWTP is defined by the social decision maker as in the endogenous budget)

A constrained budget

(can be expanded by a trigger such as the decision to finance a new drug, but there is a foregone benefit to the expansion to finance a drug; other health and non-health programmes or investments could instead have been expanded or implemented)

A fixed budget

(cannot be expanded and any additional purchases can be funded only if an existing activity is displaced)

Scenarios of Economic Context

Characteristic	Scenario 1	Scenario 2	Scenario 3	Scenario 4
Adopting a new drug	Yes	Yes	Yes	Yes
Budget	Expandable	Fixed	Fixed	Fixed
How is additional cost of the drug financed?	Expanding budget	Displacing programmes	Displacing programmes	Displacing programmes
Price distortions?	Only new drug	new drug (+ old drugs)	new drug (+ old drugs)	new drug (+ old drugs)
Is current budget efficient?	Economically efficient	**Economically efficient**	**Allocatively inefficient**	**Technically inefficient**
Is displacement optimal? (least cost-effective drugs displaced)	Not applicable	Optimal or suboptimal	Optimal or suboptimal	Optimal or suboptimal

What price???
Let' talk about *Shadow Prices*

Τιμές χωρών αναφοράς	Χονδρική Τιμή (ΧΤ)	Τιμή Παραγωγού (ΤΠ)	Νοσοκομειακή Τιμή (ΝΤ)	Νοσοκομειακή Τιμή -5%	Νοσοκομειακή Τιμή -5% - Rebate	Λιανική Τιμή	Ασφαλιστική Τιμή	Τιμή Αποζημίωσης

In the strictest sense

"the price given to a good or service which has no market price"

In Health Economics

"refers to the shadow price of the budget constraint or to the valuation of an input for which there is a supply but no market price"

In this case Reimburses must use PEA ≠ CEA (IPER instead of ICER)

The strategy of reimbursement comprises the actions of adoption and financing.

The health shadow price, is the IPER of the health effects gained by the target patients as a consequence of the strategy of reimbursing the new drug with clinical innovation and additional financial cost such that the funder is indifferent between the strategy of reimbursement and the best alternative strategy available to the funder using the same financial resources.

Reimbursement in a fixed budget involves

adoption + displacement + financing

Health Shadow Price and IPER

Health Shadow Price is the lowest ICER at which the health budget holder could use the funds required to finance the incremental cost of the new drug to purchase QALYs from some other source.

If a new drug's incremental price-effectiveness ratio (IPER) is above the health shadow price, the best alternative strategy to new drug reimbursement will result in more health benefits to the population, for the same financial cost

A decision making exercise

The Negotiation Committee says that it will proceed with negotiations for four drugs: SOC, Drug A, Drug B (and Drug C from 2020 and on) that are consider to be prevalent in your PCT.

You are asked to advise on how to fit the reimbursement in the budget while maximising the number of premature QUALYs.

The Ministry of Health hints that the fixed budget is set to €8 million for 2020.

You ask HTA experts, who tell you (after a systematic review and from the value dossiers of the drugs) that the QUALYs gained for each drug (SOC, A, B or C) would be as the following table 1 & 2, while the number of patients on treatment are estimated to be 8,000.

What would you first advise?

2019

Intervention	QALYs	ΔQALYs	Cost	Δcost	Cost/QALY	ICER	Patients	Cost / patient /year	QALYs / patient /year
(SOC)	100.00	100.00	1,300,000.00 €	1,300,000.00 €	13,000.00 €	-	4,000.00	325.00 €	0.025
Drug A	300.00	200.00	3,200,000.00 €	1,900,000.00 €	10,666.67 €	9,500.00 €	2,500.00	1,280.00 €	0.120
Drug B	400.00	300.00	11,000,000.00 €	9,700,000.00 €	27,500.00 €	32,333.33 €	1,500.00	7,333.33 €	0.267
	800.00		15,500,000.00 €		17,055.56 €		8,000.00	1,937.50 €	

fixed budget 2019 10,000,000 €

Clawback 2019 5,500,000 €

Ranking = Cost / patient /year

Scenario (2020 Starting with the entrance of a new drug - Druc C - After the Assessment of the HTA Committee)

Intervention	QALYs	ΔQALYs	Cost	Δcost	Cost/QALY	ICER	Patients	Cost / patient /year	QALYs / patient /year
(SOC)	95.00	95.00	1,235,000.00 €	1,235,000.00 €	13,000.00 €	-	3,800.00	325.00 €	0.025
Drug A	276.00	176.00	2,944,000.00 €	1,709,000.00 €	10,666.67 €	9,710.23 €	2,300.00	1,280.00 €	0.120
Drug B	293.33	193.33	8,066,663.00 €	6,831,663.00 €	27,499.99 €	35,336.19 €	1,100.00	7,333.33 €	0.267
Drug C	500.00	400.00	9,600,000.00 €	8,365,000.00 €	19,200.00 €	20,912.50 €	800.00	12,000.00 €	0.625
	1,164.33		21,845,663.00 €		17,591.66 €		8,000.00	2,730.71 €	

fixed budget 2020 8,000,000 €

Clawback 2020 13,845,663 €

Ranking = Cost / patient /year

2020 First Round of Negotiations (Scenario 1)

Intervention	QALYs	ΔQALYs	Cost	Δcost	Cost/QALY	IPER	Patients	Offer-Cost / patient /year	QALYs / patient /year	Priority setting
(SOC)	100.00	100.00	1,040,000.00 €	1,040,000.00 €	10,400.00 €	-	4,000.00	260.00 €	0.025	1
Drug A	312.00	212.00	2,860,000.00 €	1,560,000.00 €	9,166.67 €	7,358.49 €	2,600.00	1,100.00 €	0.120	2
Drug B	373.33	273.33	7,280,000.00 €	5,980,000.00 €	19,500.00 €	21,878.05 €	1,400.00	5,200.00 €	0.267	3
Drug C	937.50	837.50	14,400,000.00 €	13,100,000.00 €	15,360.00 €	15,641.79 €	1,500.00	9,600.00 €	0.625	X
	785.33		11,180,000.00 €		13,022.22 €		8,000.00	1,397.50 €		

fixed budget 2020 8,000,000 €

Clawback 2020 3,180,000 €

Ranking = Cost / patient /year

2020 Second Round of Negotiations

Intervention	QALYs	ΔQALYs	Cost	Δcost	Cost/QALY	IPER	Patients	Offer-Cost / patient /year	QALYs / patient /year	Priority setting
(SOC)	125.00	125.00	1,100,000.00 €	1,100,000.00 €	8,800.00 €	-	5,000.00	220.00 €	0.025	1
Drug A	360.00	260.00	2,970,000.00 €	1,670,000.00 €	8,250.00 €	6,423.08 €	3,000.00	990.00 €	0.120	2
Drug B	1,066.67	966.67	19,200,000.00 €	17,900,000.00 €	18,000.00 €	18,517.24 €	4,000.00	4,800.00 €	0.267	X
Drug C	1,875.00	1,775.00	23,400,000.00 €	22,100,000.00 €	12,480.00 €	12,450.70 €	3,000.00	7,800.00 €	0.625	X
	485.00		4,070,000.00 €		8,525.00 €		8,000.00	508.75 €		

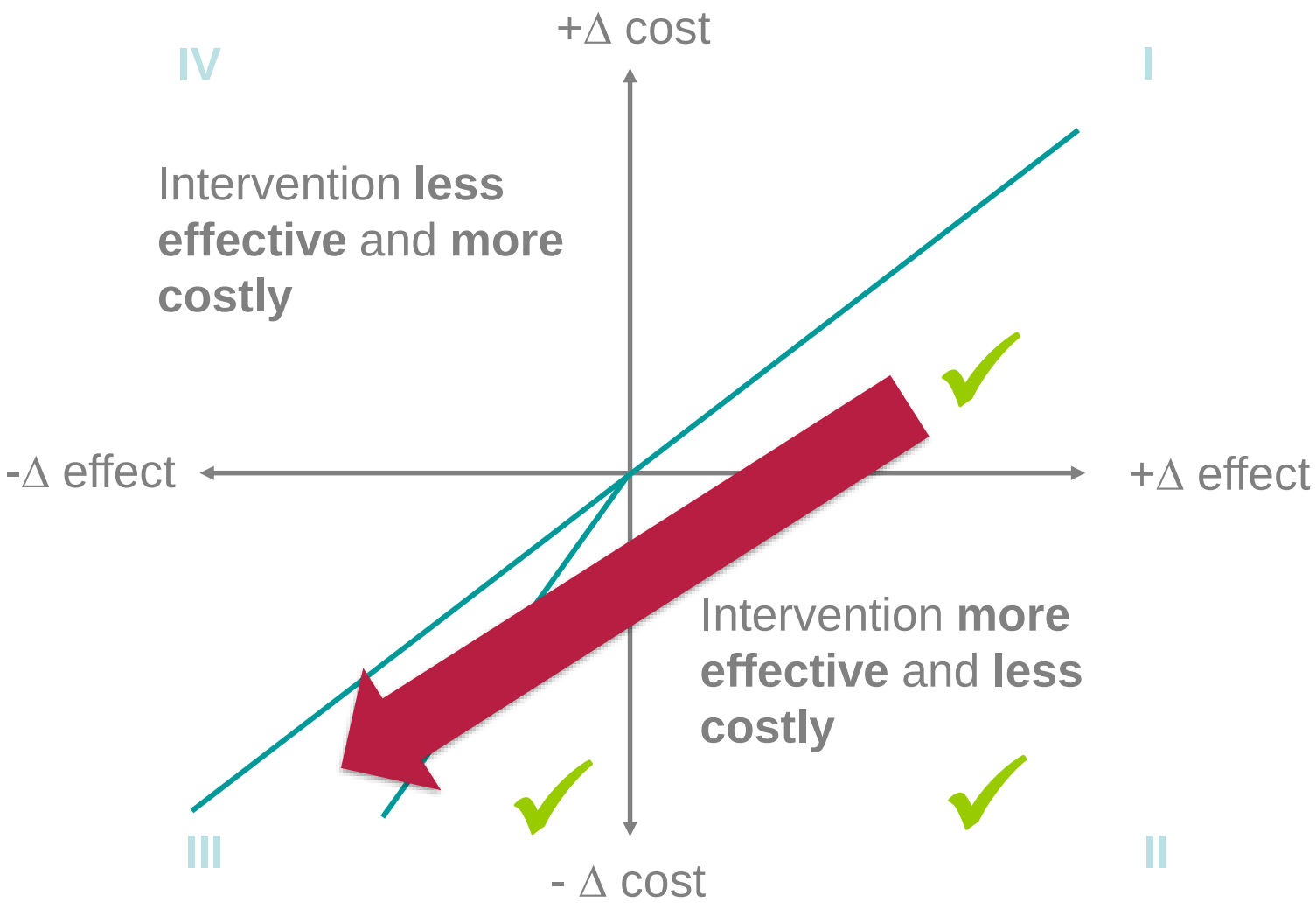
fixed budget 2020 8,000,000 €

Clawback 2020 0 €

Ranking = ???

The cost effectiveness plane

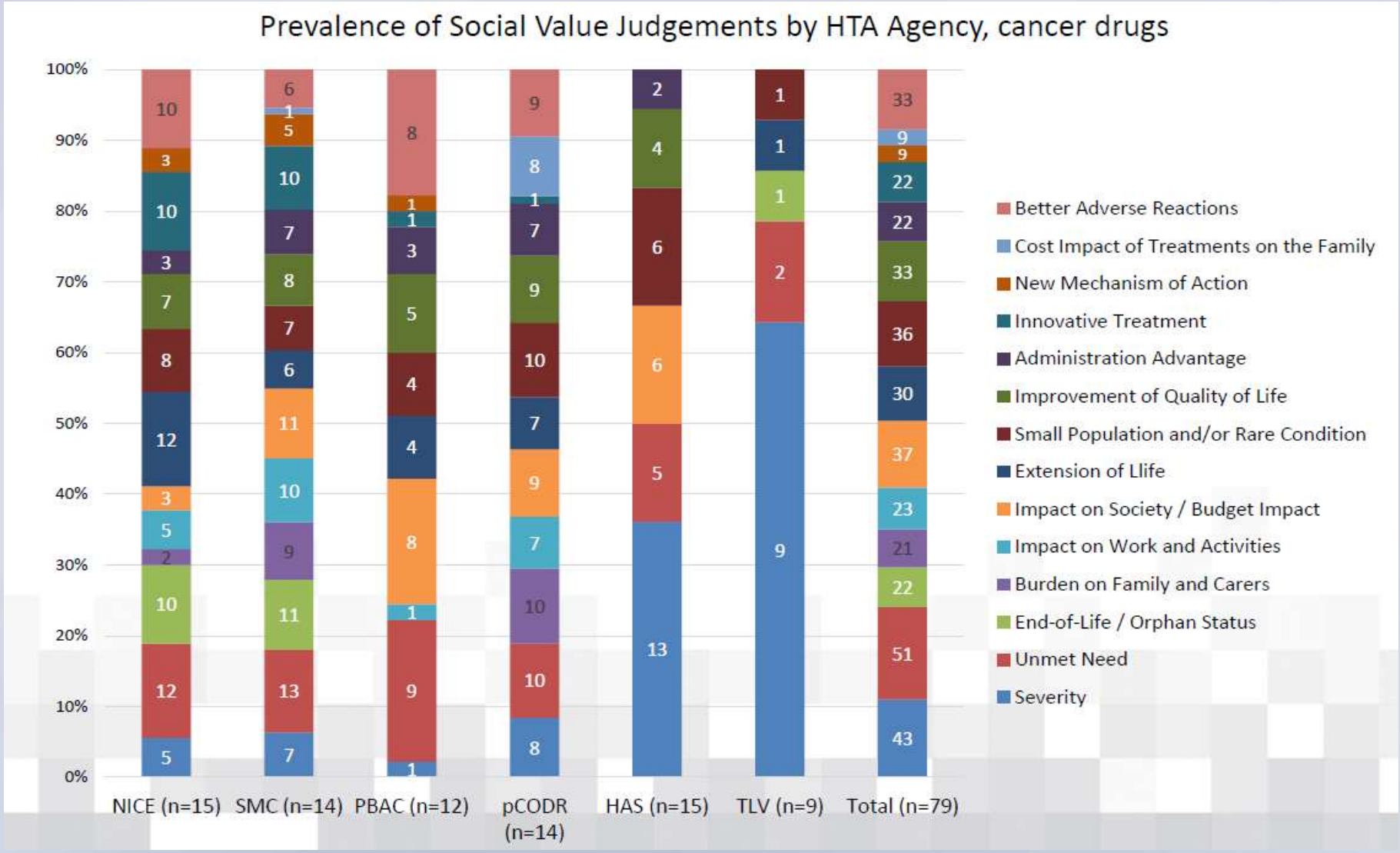
Difference in effect and cost of an option relative to its comparator



Mechanisms to manage affordability

1. Discounts and revenue caps
2. Targeting the highest value patient groups
3. Managed entry agreements
4. Pay-for-performance
5. Annualisation
6. Credit market solutions
7. And more….
8. Combination of the above

Ενσωμάτωση Διαστάσεων «Αξίας» από HTA & Negotiation Organizations



Source: Angelis and Kanavos, *Social Science & Medicine* 2017

Επαρκής χρηματοδότηση Σ.Υ. (Ευρεία κατανεμητική αποδοτικότητα)

Κατανεμητική αποδοτικότητα (των κλειστών προϋπολογισμών των Θ.Κ.)

Ιεράρχηση επιλογών

Κλινικός έλεγχος

Κλινικά Πρωτόκολλα

Συνταγογραφικά πρωτόκολα

Εκτοπισμός, Αντικατάσταση

Μητρώα Ασθενών

Αύξηση ποσοστού διείσδυσης γενοσήμων

Απλούστευση πλαισίου διαξαγωγής κλινικών μελετών

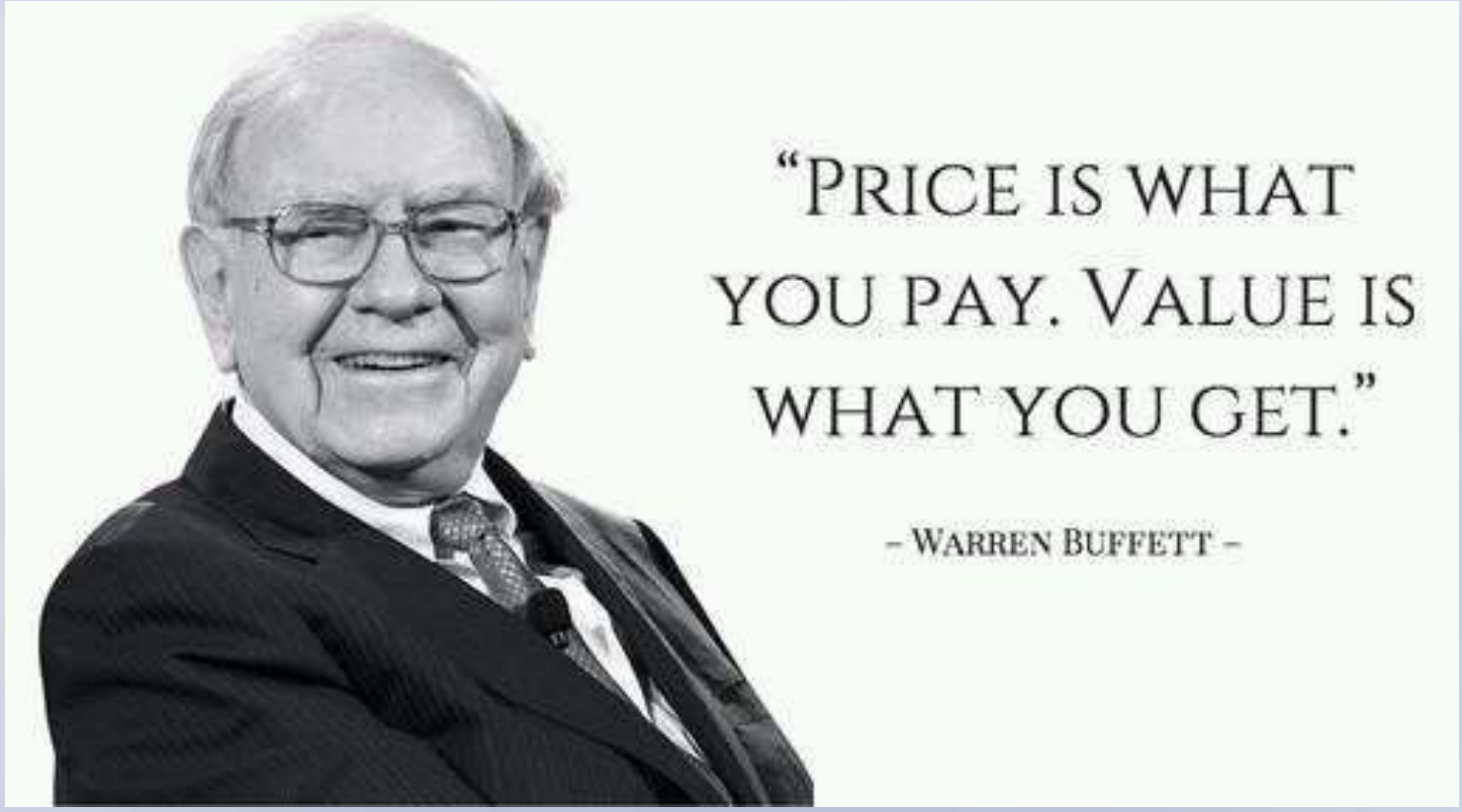
……..

"If your country lowers prices, we will not have the resources to invest in innovation and there will be no more new drugs in the future"

The claim by the pharmaceutical industry, that the demand to significantly lower prices for new drugs today will make the population worse off, is appropriately characterised as a threat. This claim could be credible or quite not.

In **NEGOTIATIONS**, the key to winning the new drug reimbursement game is for the regulator to know how to respond to this Threat.

However, the stake is to achieve the **HIGHEST VALUE ALTERNATIVE** (Joint) Adoption & Financing


"PRICE IS WHAT YOU PAY. VALUE IS WHAT YOU GET."
– WARREN BUFFETT –