Best Practices (do's and don't's) for effective HTA

Athens, 22nd January 2018

JUNTA DE ANDALUCIA
Escuela Andaluza de Salud Pública
CONSEJERÍA DE SALUD
WHO Collaborating Centre on Integrated Health Services based on Primary Care

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AdvanceHTA

Rethinking the future of Health Technology Assessment

Health Technology Assessment Toolbox for Emerging Settings

Best Practices and Recommendations

SEVENTH FRAMEWORK PROGRAMME
European Commission
JUNTA DE ANDALUCIA Escuela Andaluza de Salud Pública CONSEJERÍA DE SALUD
Pan American Health Organization
World Health Organization Americas
LSE

Agenda

- Setting the scene about HTA in Europe
- Why to use HTA?
- Best practices about HTA based on European experiences.
- Do’s and Don’t’s in HTA.
- Q&A - Debate

Institutions and advisory bodies responsible for HTA activities in selected EU countries, 2009

1. Denmark	• Reimbursement Committee/Danish Centre for Evaluation and Health Technology Assessment/ *Center for Evaluering og Medicinsk Teknologivurdering* (DACEHTA/CEMTV)
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Source: The authors from various sources; adapted and enhanced from Velasco-Garrido and Busse 2005; Zetner et al. 2005.
Note: [1] These are not an exhaustive list of the agencies available in the country.

Fuente: http://ec.europa.eu/enterprise/sectors/healthcare/competitiveness/pricing-reimbursement/national-systems/index_en.htm

Table 4.2.1: Criteria for assessment

Criteria	AT[4]	BE	CH	DE	FI	FR	NL	NO	SE	UK
Therapeutic benefit	X	X	X	X	X	X	X	X	X	X
Patient benefit	X	X	X	X	X	X	X	X	X	X
Cost-effectiveness	X	X			X		X	X	X	X
Budget impact		X			X	X	X	X		X
Pharmaceutical/innovative characteristics	X	X				X	X			X
Availability of therapeutic alternatives	X						X		X	X
Equity considerations								X	X	X
Public health impact						X				
R&D					X					

Source: Adapted from Zentner et al. (2005) and case studies.

Table 4.2.3 : Clinical and economic indicators used across 6 agencies to reach decisions on value of new treatments, 2010

	Clinical evidence	*Economic evaluation*			*Safety information*
HTA	**Preferred trial data**	**Preferred economic model**	**Preferred ICER units**	**Budget impact considered**	**Emphasis on adverse effects**
NICE	All available evidence including: Phase III RCT (head to head where available); Phase II, Clinical and patient expert opinion	CUA	QALY	Yes	Some
HAS	Phase III RCT, pharmacovigilence information, observational studies	n/a	n/a	No	Strong
TLV	Trial data used rarely specified in pubic documentation	CMA (CEA, CUA, CA)	QALY	No	Weak
SMC	Phase III RCT	CUA (CEA, CMA, DES)	QALY, LYG	Yes	Some

Source: The authors from the literature.

Why to use HTA?

"Legal" reason

SIXTY-SEVENTH WORLD HEALTH ASSEMBLY — WHA67.23

Agenda item 15.7 — 24 May 2014

Health intervention and technology assessment in support of universal health coverage

Recognizing the importance of strengthened national capacity, regional and international networking, and collaboration on health intervention and technology assessment to promote evidence-based health policy,

1. URGES Member States:[1]

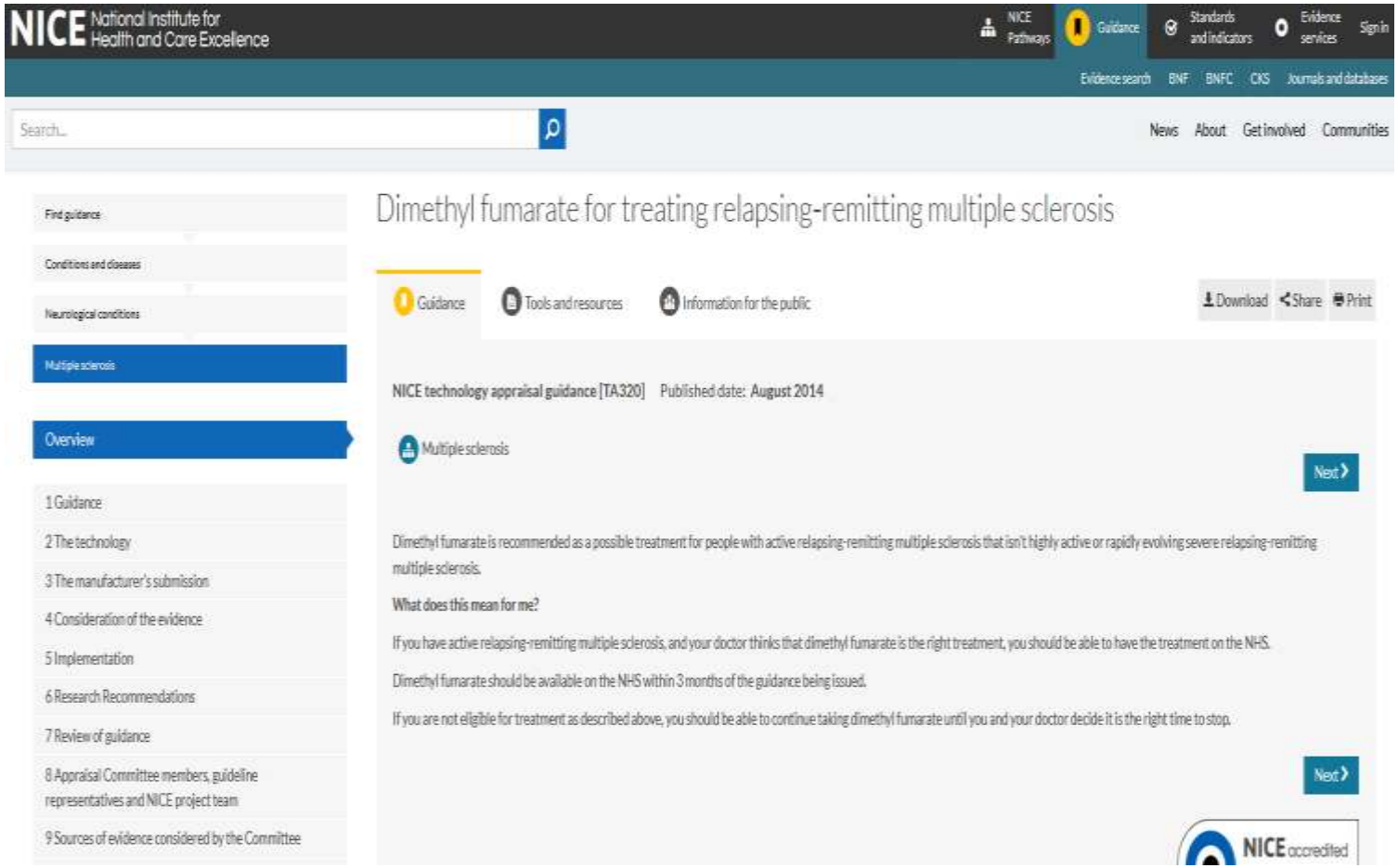
(1) to consider establishing national systems of health intervention and technology assessment, encouraging the systematic utilization of independent health intervention and technology assessment in support of universal health coverage to inform policy decisions, including priority-setting, selection, procurement supply system management and use of health interventions and/or technologies, as well as the formulation of sustainable financing benefit packages, medicines, benefits management including pharmaceutical formularies, clinical practice guidelines and protocols for public health programmes;

(2) to strengthen the link between health technology assessment and regulation and management, as appropriate;

(3) to consider, in addition to the use of established and widely agreed methods, developing, as appropriate, national methodological and process guidelines and monitoring systems for health intervention and technology assessment in order to ensure the transparency, quality and policy relevance of related assessments and research;

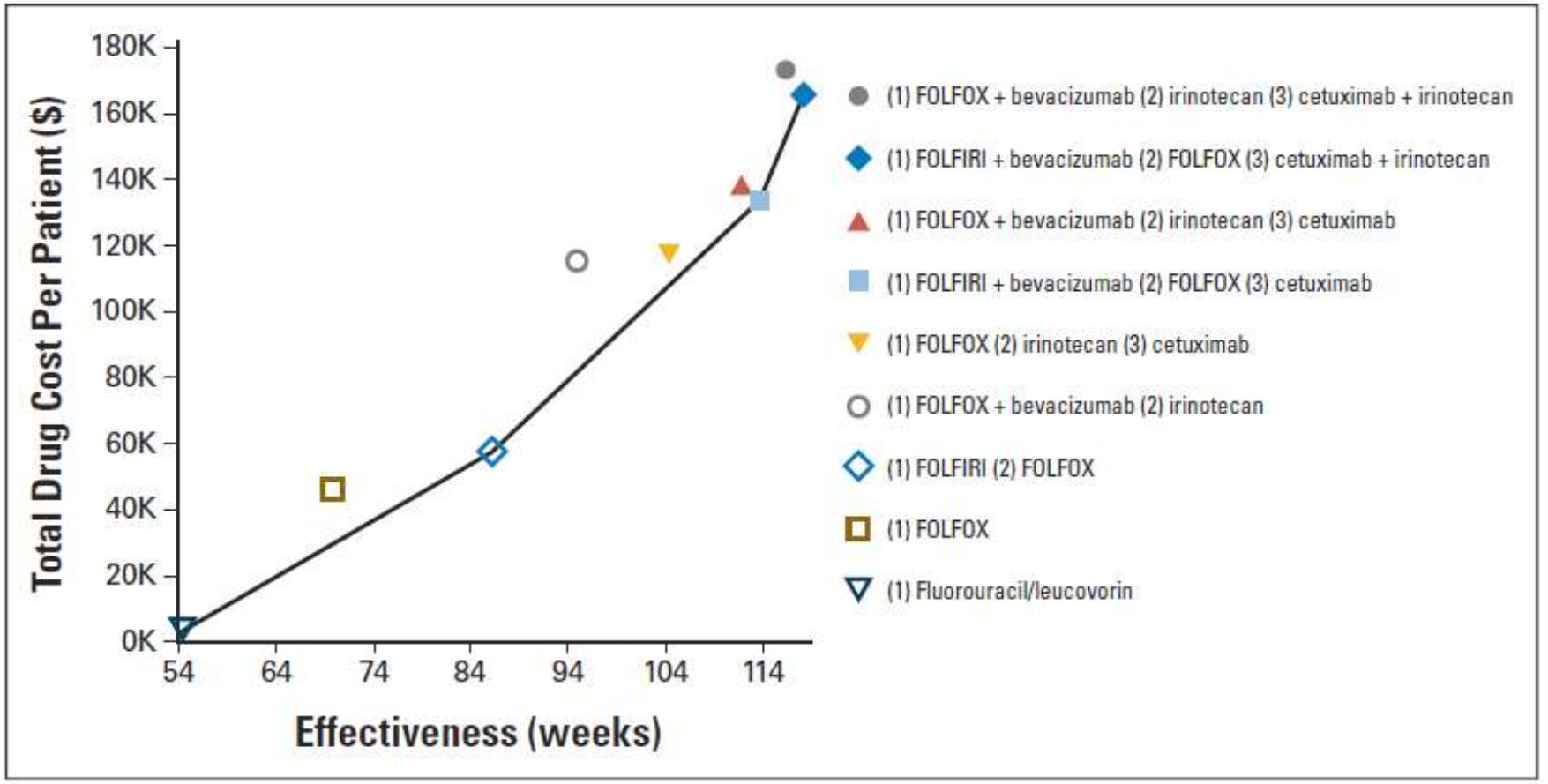
What can we gain by using HTA?

Transparency?



What can we gain by using HTA?

EFICIENCY



FROM ASSESSMENT TO MONEY

Assessment of value

1

- HTA report
- Therapeutic report.
- Economic evaluation (QALYs, ICER, etc) with different Perspectives (social, payer, …)
- …

Decision making

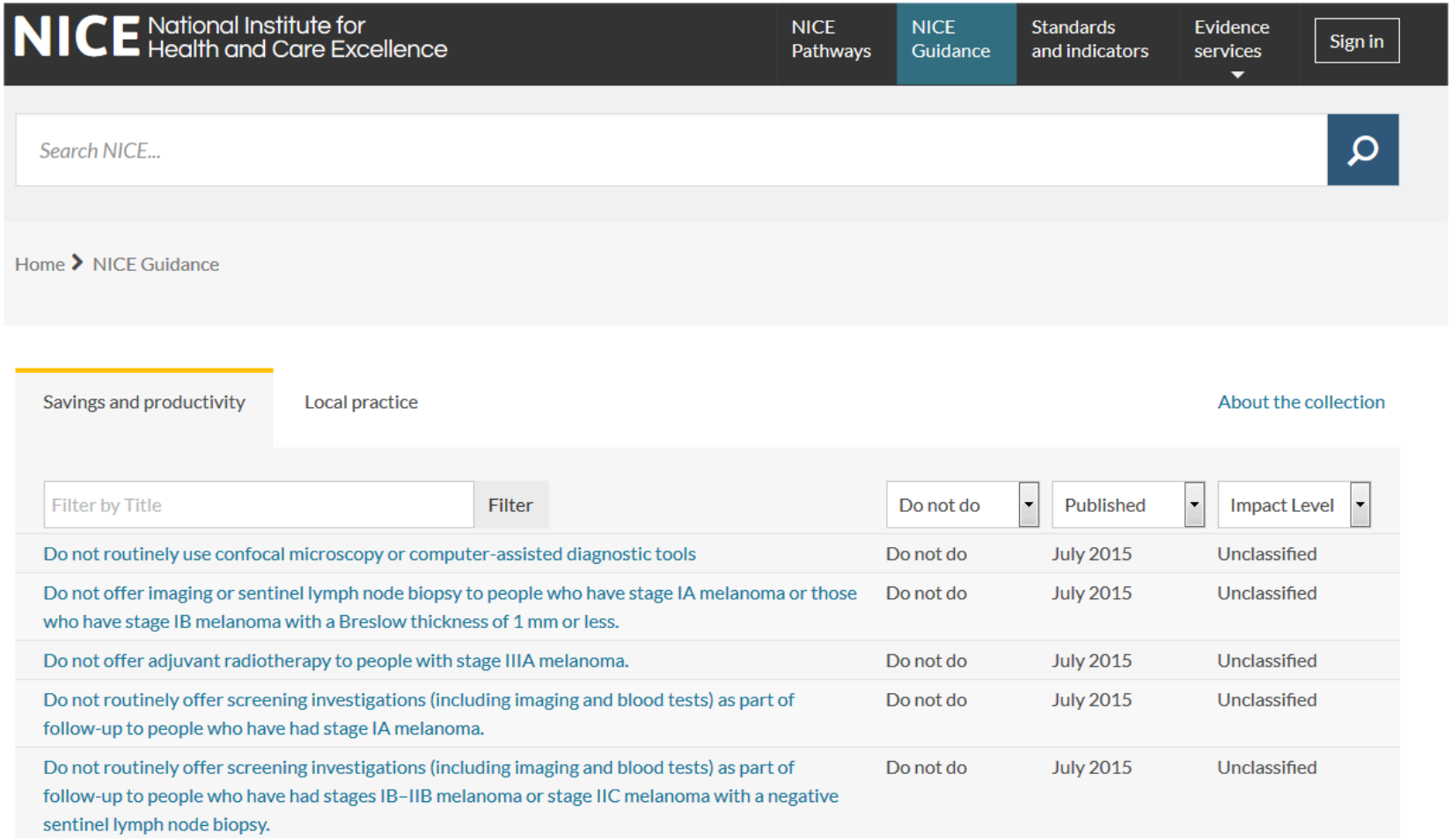
2

- **Price**
- **Reimbursement level**
- **Utilisation rules**
- **Timing uptake**

Expenditure/ Revenue

3

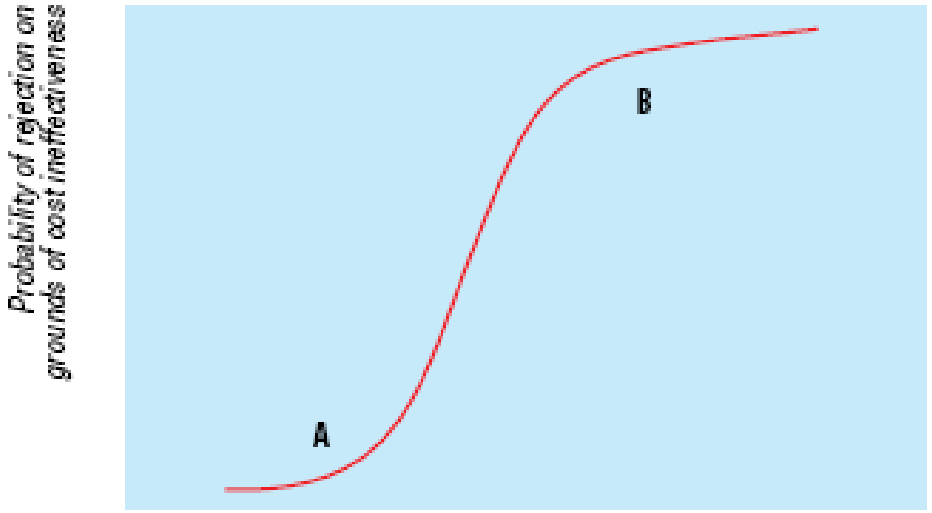
NOT ONLY HTA for Pricing and Reimbursement, but also GUIDELINES



National Institute for Clinical Excellence and its value judgments

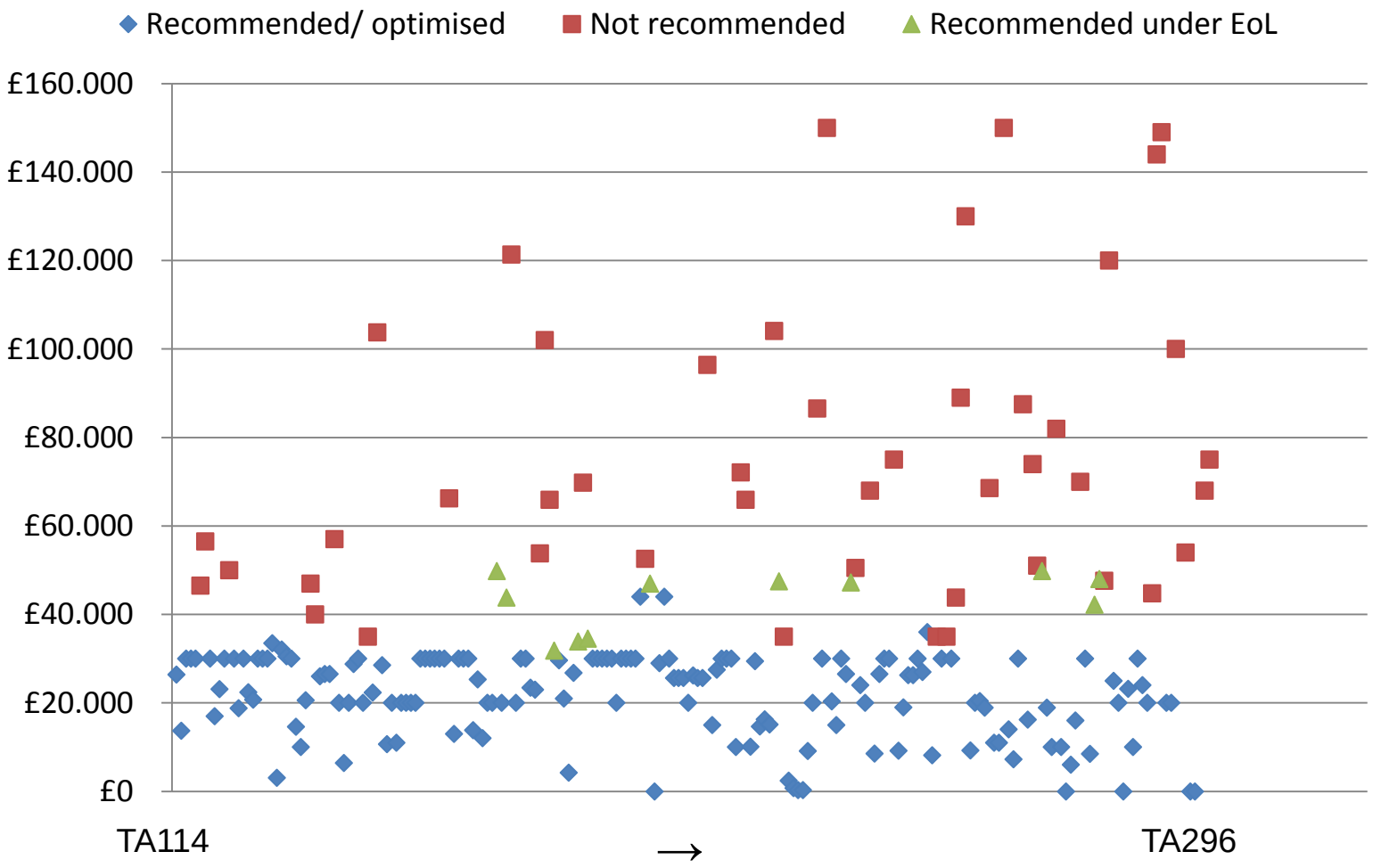
BMJ VOLUME 329 24 JULY 2004 bmj.com

Michael D Rawlins, Anthony J Culyer



Relation between likelihood of a technology being considered as cost ineffective plotted against the log of the incremental cost effectiveness ratio

Most credible ICER for technologies appraised by NICE 2007 – Sept 2013



Fuente: Dr. Freiberg. NICE International

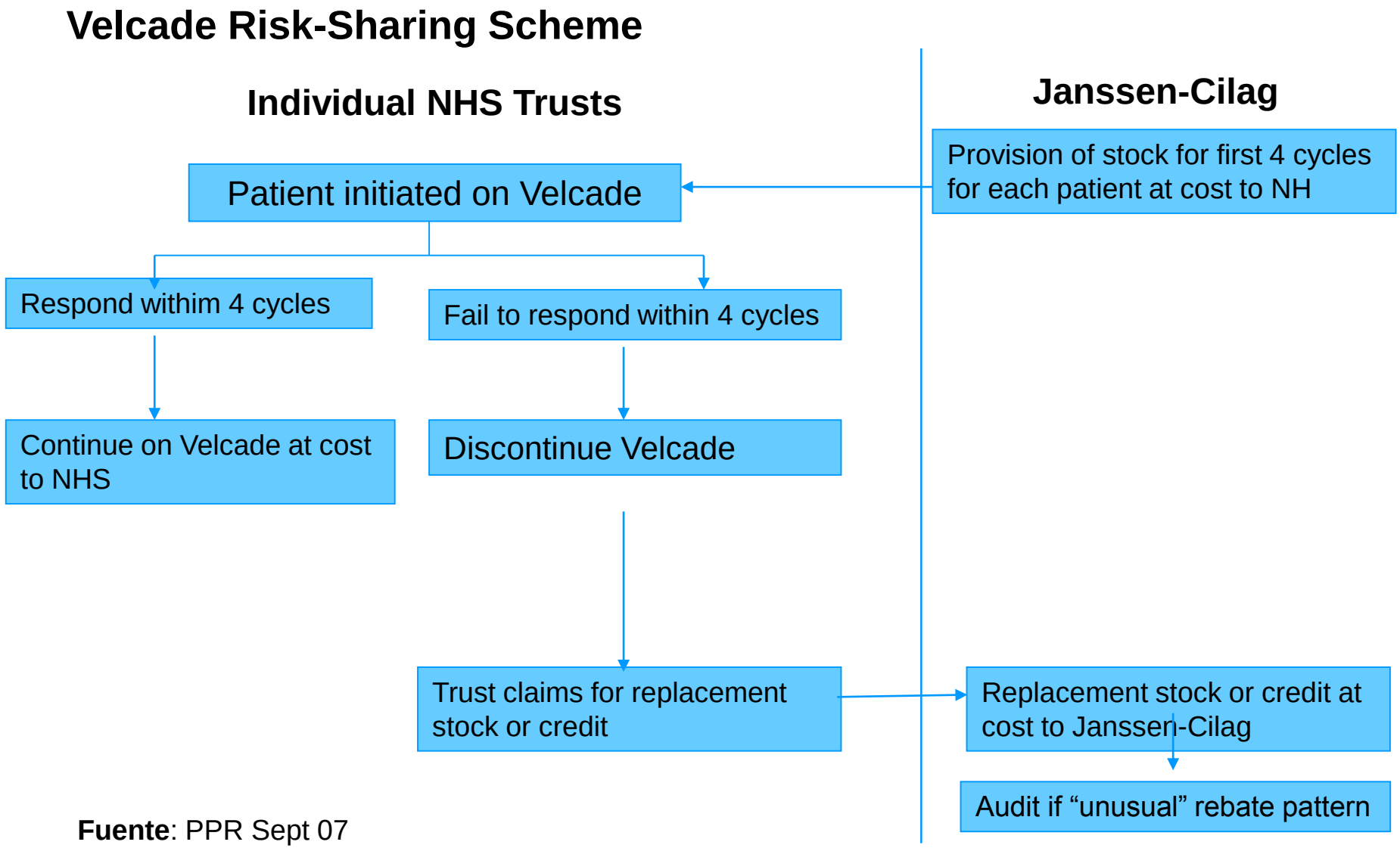
Table 1. Economic evaluation in the HTA process.

Country*	Is an economic evaluation required for the decision-making process?	How often an economic evaluation is explicitly considered in the decision-making process?	Are there explicit 'thresholds' for cost-effectiveness? If not, what other approaches are used to decide whether an intervention is potentially cost-effective?	What is the perspective normally used of the economic evaluation?
BU	Yes	Always	No	Third-party payer
CR	NO. Only BIA	NEVER	No	No answer
CZ	Yes	ALWAYS	NO(3xGDP per QALY is used as reference)	Third-party payer
EE	Yes	Always	NO. (1-3 GDP per capita is used as reference)	Third-party payer
GR	Not Yet.	Rarely	Not applicable	Not definded yet
HU	Yes	Always	Yes	Third-party payer
LT	No answer	No answer	No answer	No answer
LV	Yes	Always	The ICER for an additionally obtained year of life or progression-free year of life shall not exceed the ICER of pharmaceuticals already included in the Positive list.	Third-party payer
PL	Yes	Always (for reimbursement submissions)	3x GDP per capita for ICUR/QALY or ICER/LYG	National Health Fund (public payer) perspective and joint perspective of payer and patient
RU	Yes	Frequently	No	Public Sector
SI	No	rarely	Yes	Third-party payer
SK	It is mandatory based on the law 363/2011.	Always	Threshold 1 is 24 x average monthly salary € / QALY; Threshold 2 is 35 x average monthly salary € / QALY	Third-party payer

BU: Bulgaria; CR: Croatia; CZ: Czech Republic; EE: Estonia; GR: Greece; HU: Hungary; LT: Lithuania; LV: Latvia; PL: Poland; RS: Republic of Serbia; RU: Russia; SI: Slovenia; SK: Slovakia; BIA: budget impact analysis; QALY: Quality adjusted life year; ICER: incremental cost effectiveness allocation; ICUR: incremental cost utility ratio. * No respond was obtained from Republic of Serbia

García-Mochón L, Espín Balbino J, et al. HTA and decision-making processes in Central, Eastern and South Eastern Europe: Results from a survey. Health Policy. 2017. pii: S0168-8510(17)30085-4.

A YES means YES; a NO means “Pershaps”



Fuente: PPR Sept 07

EMINET

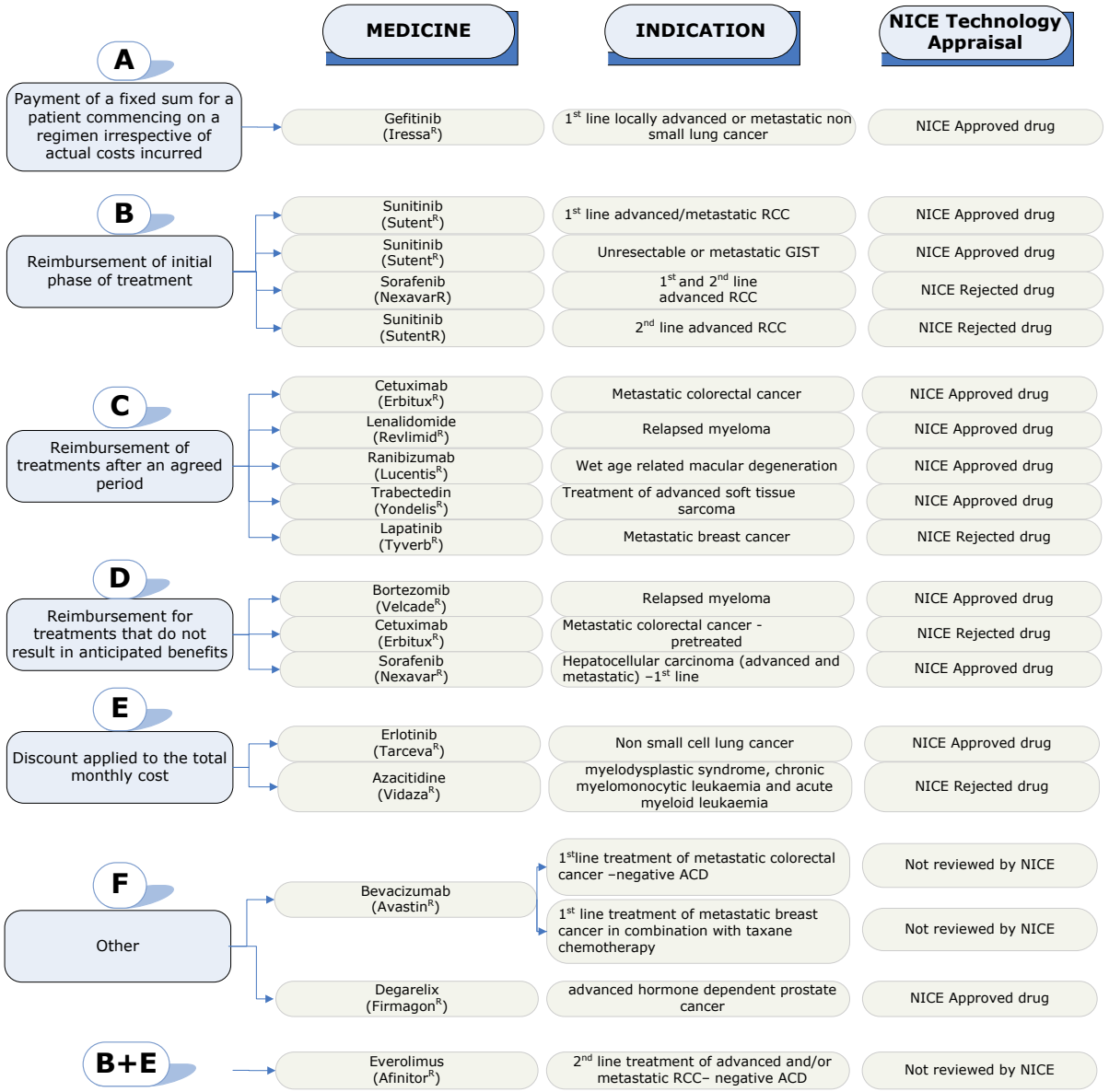
Experiences and Impact of European Risk-Sharing Schemes Focusing on Oncology Medicines

Jaime Espin, Joan Rovira and Leticia Garcia

Andalusian School of Public Health

JANUARY 2011

Escuela Andaluza de Salud Pública
CONSEJERÍA DE SALUD



Link: http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/risksharing_oncology_012011_en.pdf

AN IMPORTANT IMPLICATION

Has NICE been nice to cancer?

EUROPEAN JOURNAL OF CANCER 42 (2006) 2881–2886

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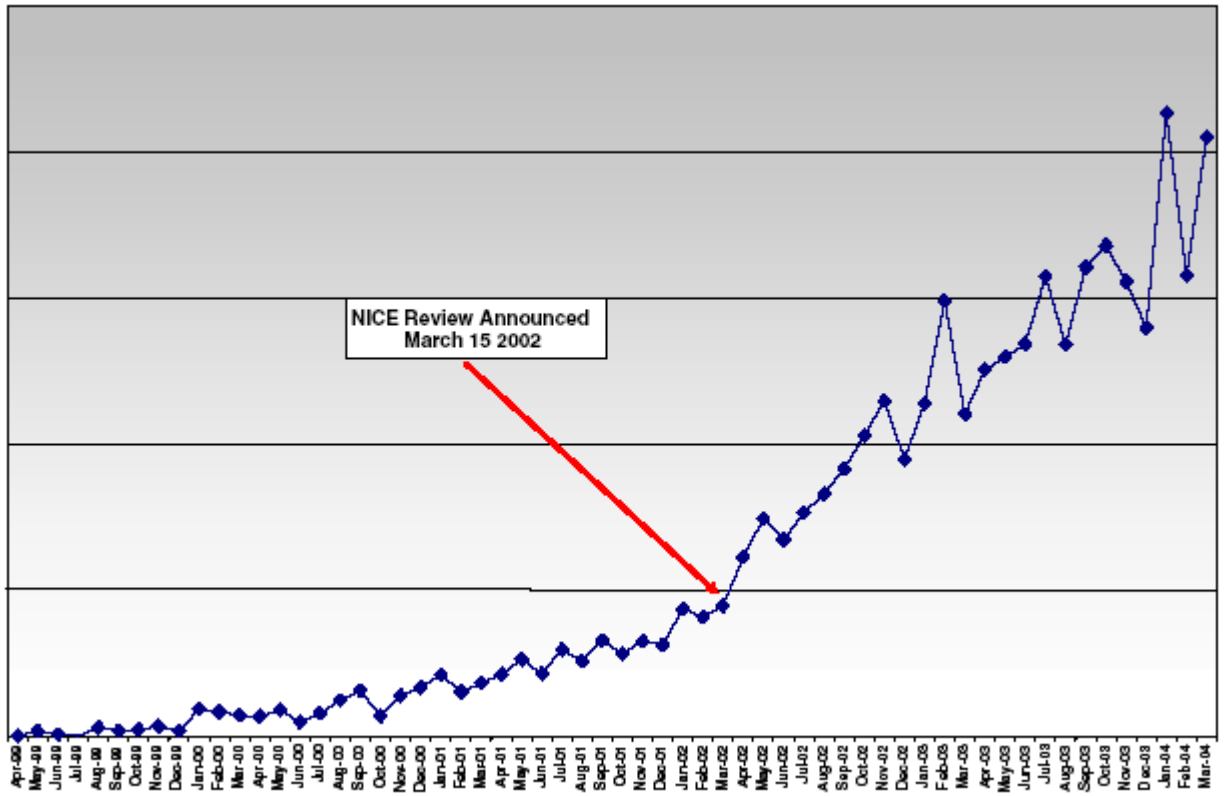
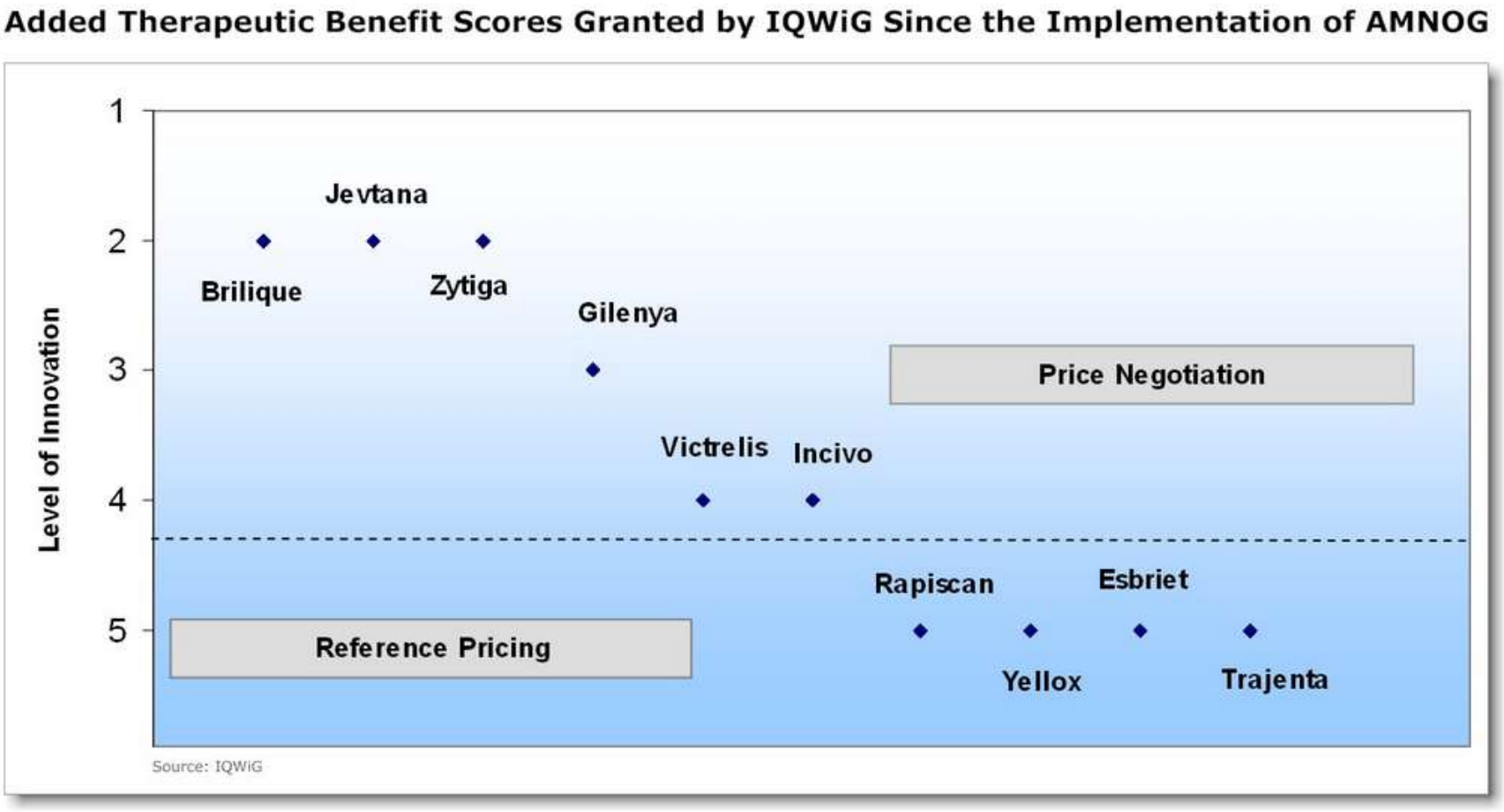


Fig. 1 – Monthly sales of trastuzumab from UK launch.

COST EFFECTIVENESS v. THERAPEUTIC BENEFIT



Fuente: http://healthcare.blogs.ihs.com/2012/02/02/amnog-german-health-reform-pharma-market-access-2012/

Resultados de las negociaciones de precios en los dos primeros años de la normativa AMNOG

Marca comercial	Principio activo	Precio de venta en euros	Beneficio	Descuento en euros	Descuento en porcentaje
Brilique®	Ticagrelor	99	Significativo	13	19
Zytiga®	Abirateron	4.400	Significativo	1.144	26
Benlysta®	Belimumab	742	Significativo	244	38
Yervoy®	Ipilimumab	4.250	Significativo	950	22
Jevtana®	Cabazitaxel	4.395	Discreto	912	21
Gilenya®	Fingolimod	1.850	Discreto	550	30
Vyndaqel	Tafamidis	15.239	Discreto	2.438	15
Edurant®	Rilpivirin	358	Discreto	65	18
Yellox®	Bromfenac	8	Sin beneficio terapéutico añadido	6	77
Rapiscan®	Regadenoson	70	Sin beneficio terapéutico añadido	27	39
Victrelis®	Boceprevir	3.200	No cuantificable	680	21
Incivo®	Telaprevir	9.921	No cuantificable	1.910	19
Halaven®	Erebulin	2.400	Menor que el comparador	384	16

Fuente: International Law Office.

COORDINATION!!!!!!

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CLEAR CRITERIAS

Assessment of Clinical / Therapeutic Benefit

Actual Benefit (AB);

Severity of disorder

+ Clinical effectiveness

+ Impact on public health

Major

Important

Moderate

Low

Insufficient

Improvement in Actual Benefit

Added Value compared to existing treatments (IAB)

I Major

II Important

III Moderate

IV Minor

V No Improvement

Assessor: Transparency Committee / High Authority for Health (HAS) /

Table 4. Key limitations faced by institutions that perform HTA in CESEE and the Americas

	Countries	
	Central, Eastern and South Eastern Europe	Region of the Americas
Main limitations	1st Lack of funding	1st Skills training 1st Lack of institutional support
	2nd Insufficient human resource allocation	2nd Lack of funding

Source: Mapping report 2015 (2)

Do's and Don't's (I)

- HTA is not only pricing and reimbursement; also for defining health priorities, setting guidelines (do not do)…
- A explicit cost effectiveness **threshold** is NO mandatory; clear rules and transparency in the process, YES.
- Training and capacity building is the first step
- Misalignment of HTA with decision making needs

Do's and Don't's (II)

- Clarifying the roles and responsibilities of the different stakeholders
- Financial resources and specific funding (considering HTA as investment and not as cost).
- HTA body independence.
- HTA can play a difference roles: Advisory (NICE); Regulatory (TLV) or Coordination
- HTA is not only CE studies but also MCDA…
- HTA is not for introducing new HTA, also for **disinvestment**

Thank you very much for your attention.

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