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Overview of the Japanese HTA reform towards pharmacoeconomic requirements in 2016

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Japan

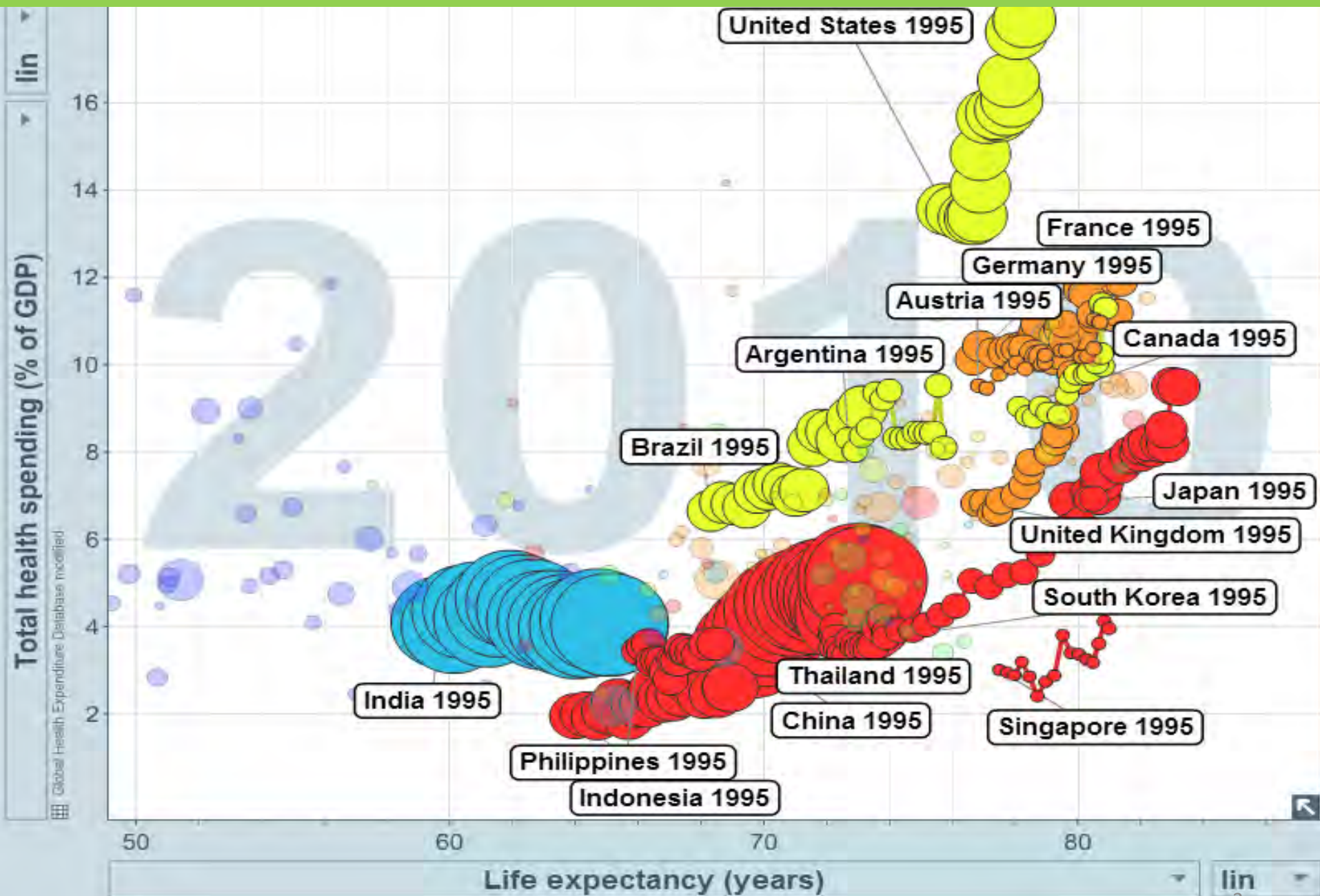
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Factors affecting health care

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- Biology
- Environment
- Life style
- Health care organization
- Medical care
- Medical expenditure

Health Expenditure & Life Expectancy: evolution during 1995 - 2010 in selected countries



Size of the circle indicates total population. The figure was achieved from Gapminder World: <http://www.gapminder.org/>

Health Insurance System in Japan

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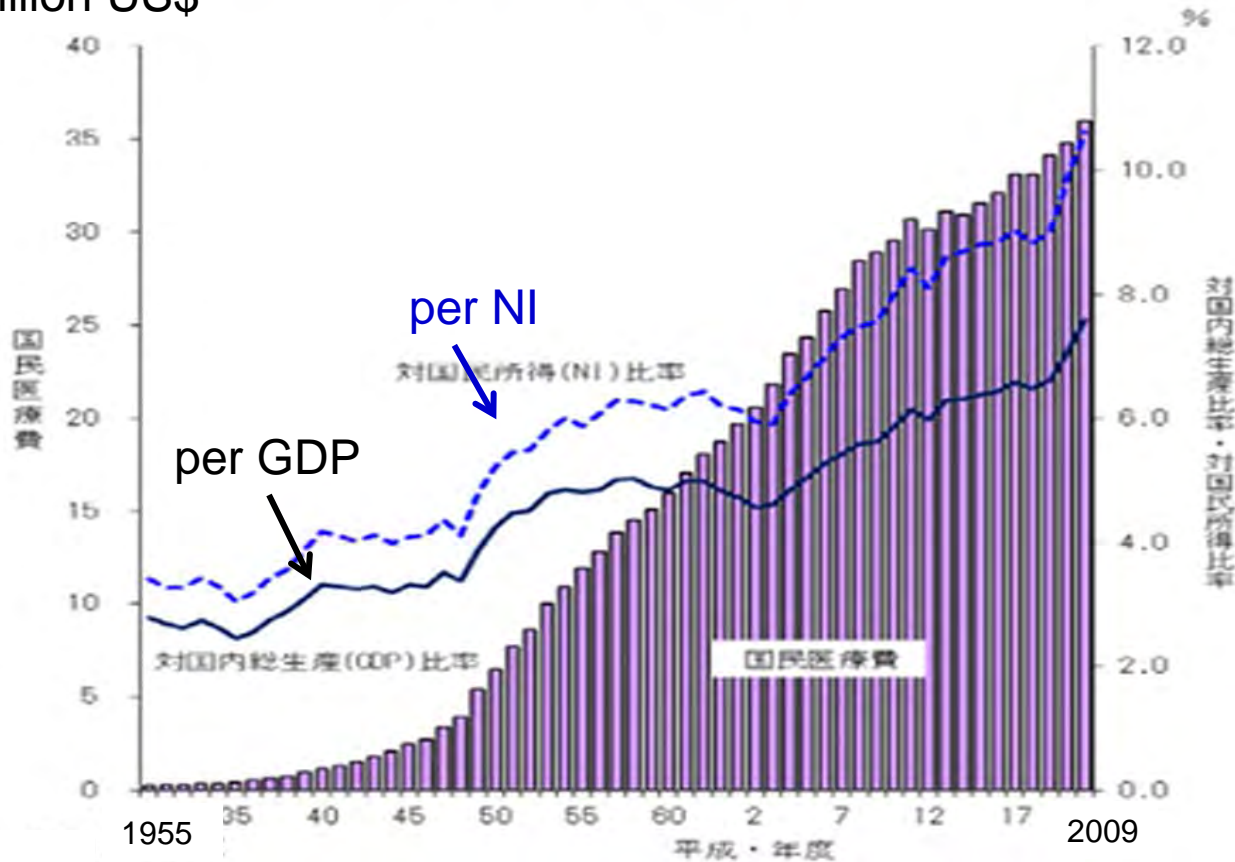
- Universal coverage of health insurance for all, established by MLHW in 1961
 - Government issues a Health Insurance Card for anyone as ID
 - All healthcare used to be free for any card-holder
 - ▣ More than 5000 insurers:
 - Employees' Health Insurance (EHI) 60%
 - National Health Insurance for non-employees (NHI) 40%
- Free-to-choose access to any hospital
- Fee-for-Service (FFS) (out-Pts) and flat payment (in-Pts) with co-payment of 30%
- Fees: biennially revised by MHLW

Growing Health Care Costs in Japan 1995-2009

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Total Health Expenditures

10 Billion US\$



Total Health Expenditures as a Share of national income

Financial Problems

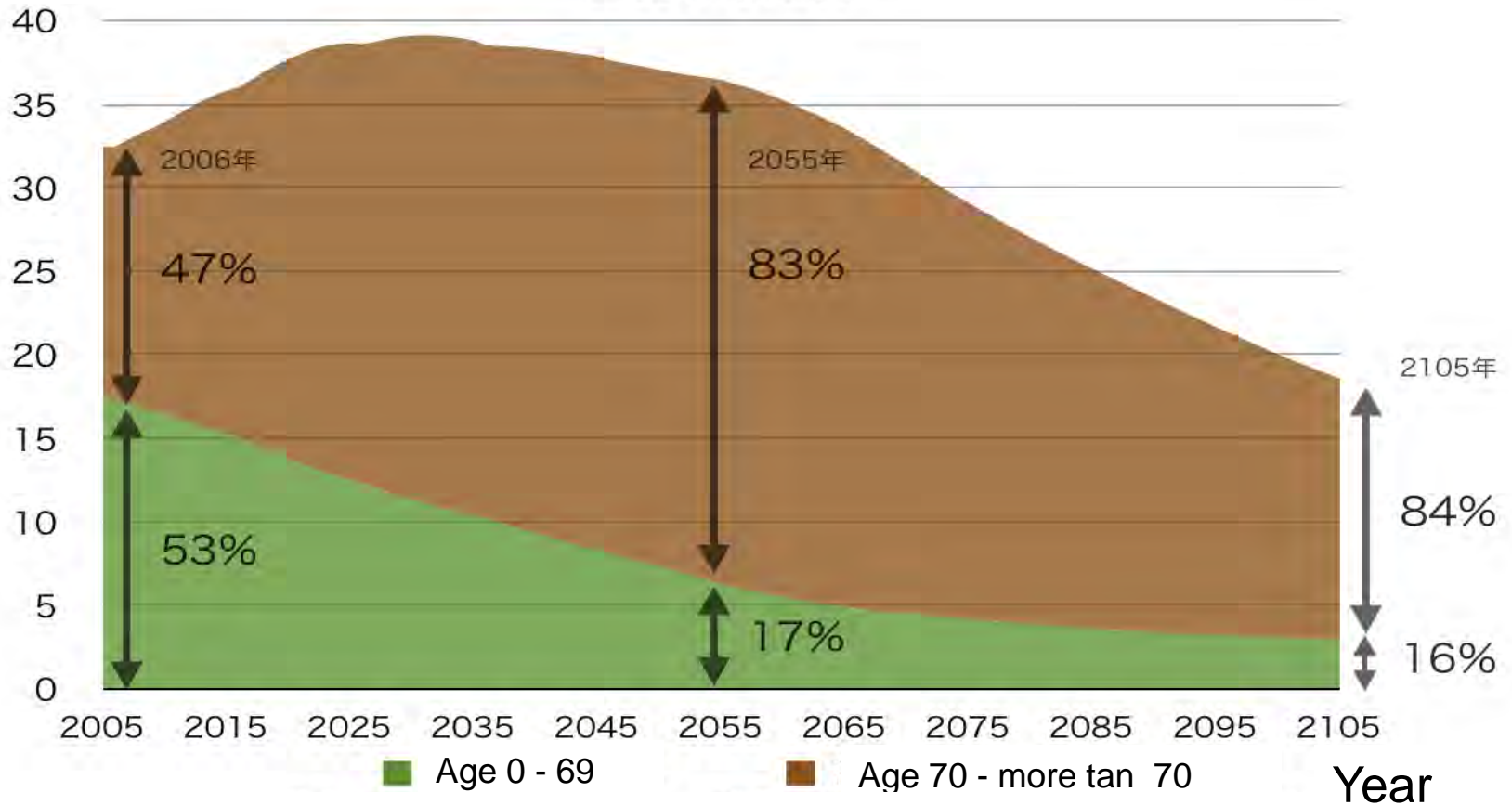
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- Complicated systems without reasonable control against increasing Total Health Expenditure:
 - around JPY1T(USD10B) per year.
- The aging society: The more high-risk elderly people go into NHI, a group of the insured financially weak
- The population shift: more elderly, less children.
- Inappropriate care in excess induced by FFS.
- Financial crisis: national debt, government budget deficit, strong Yen, burden caused by the Tsunami Disaster in March 2011
- Revenue depending on the economy:
 - deficits of premiums revenue compensated by taxes

Projection of expected growth for elderly costs

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10 Billion US\$

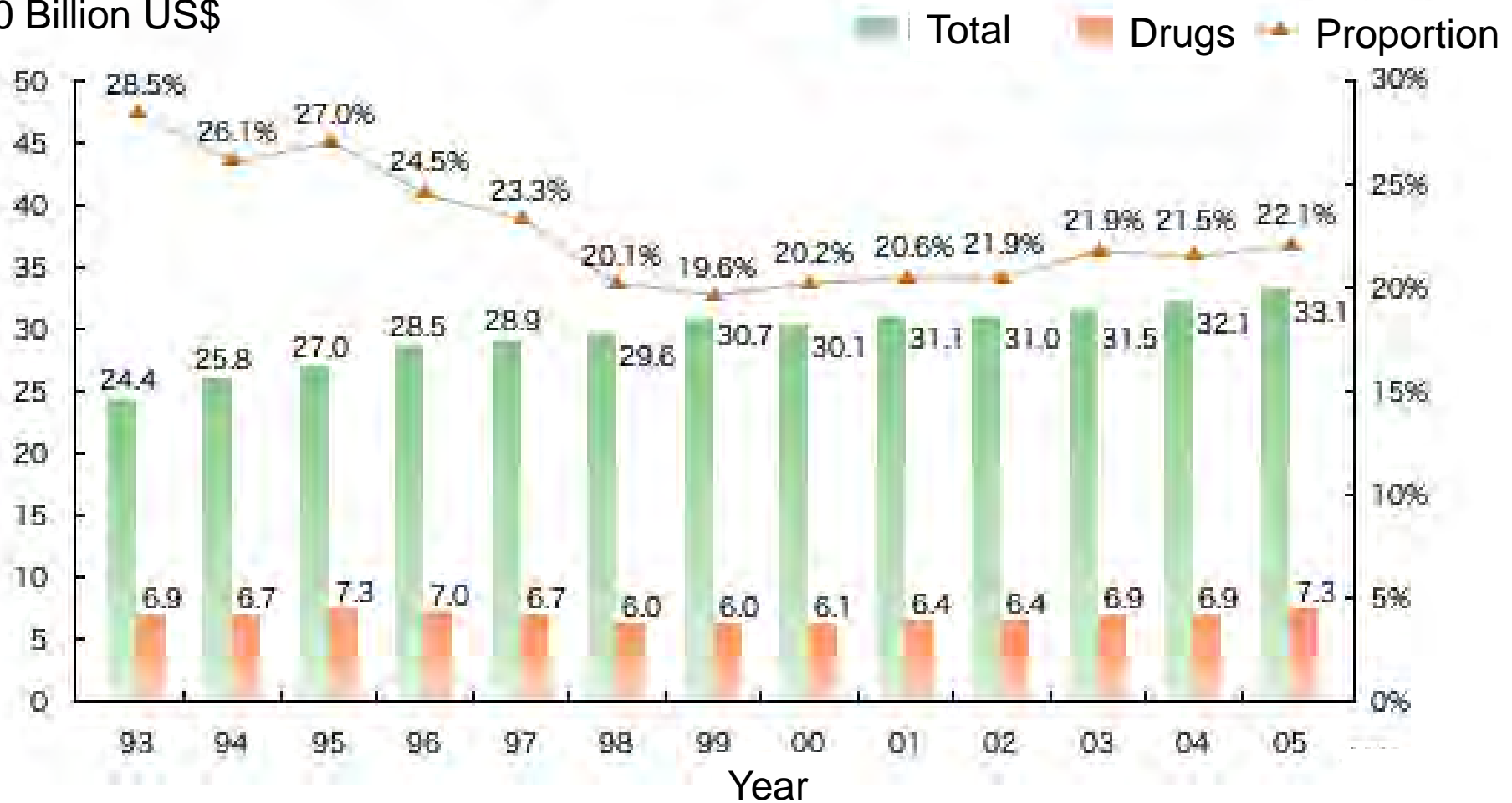


Pharmaceuticals, % total expenditure on health

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Reference: MHLW

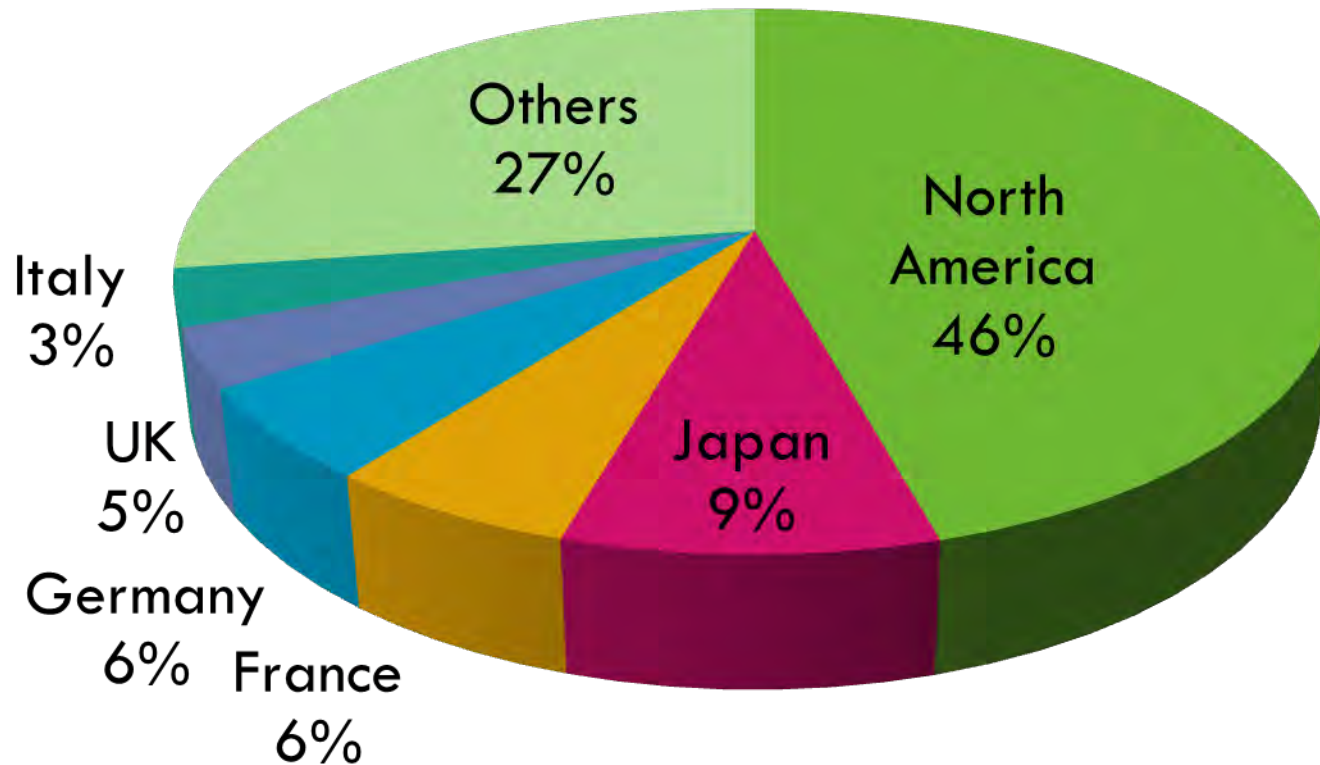
10 Billion US\$



Pharmaceutical Market Share in the World

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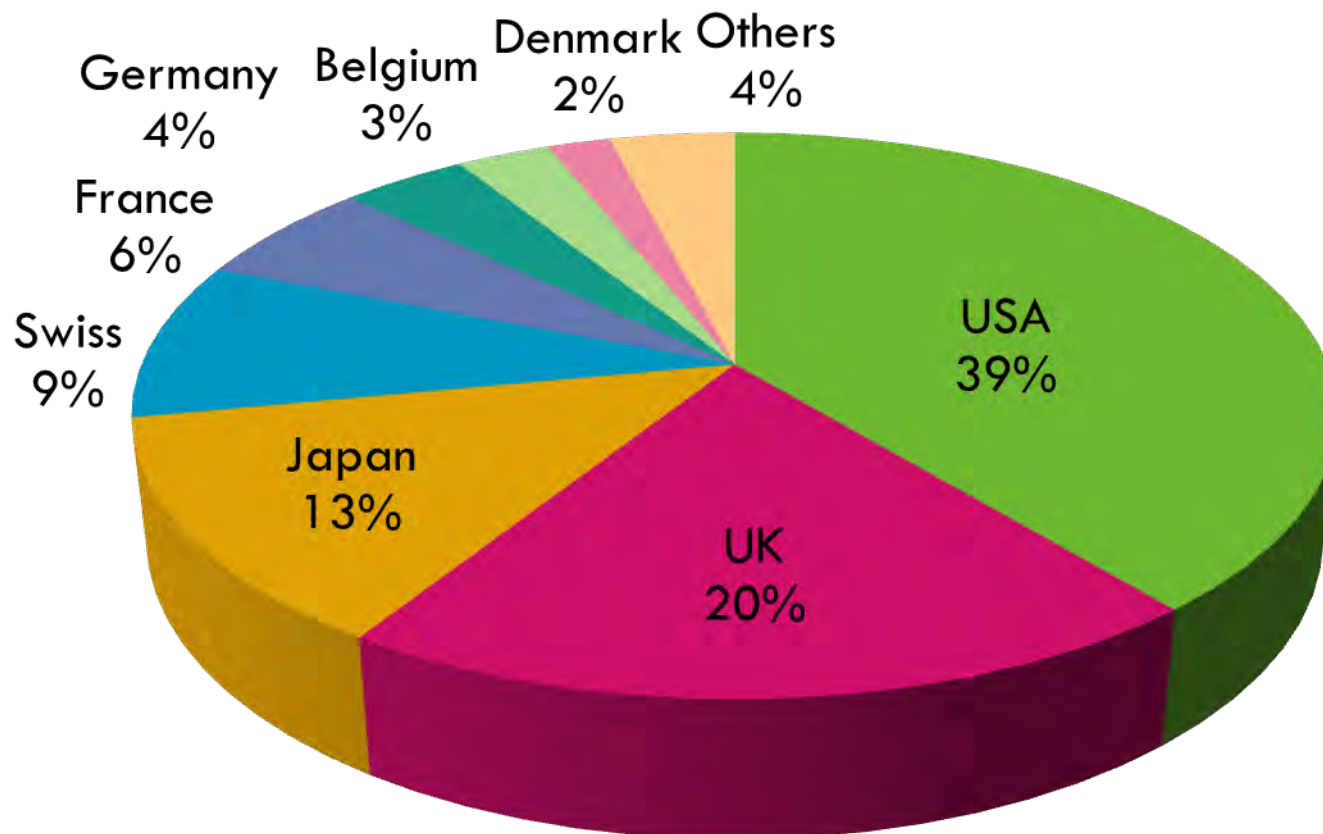
6,674 Billion US\$, 2007



Ranking of Countries by Drug Development, 2007

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The top 100 drugs by sales in the world were made by:



Paradigm shift in healthcare

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Experience-based Healthcare



Evidence-based Healthcare

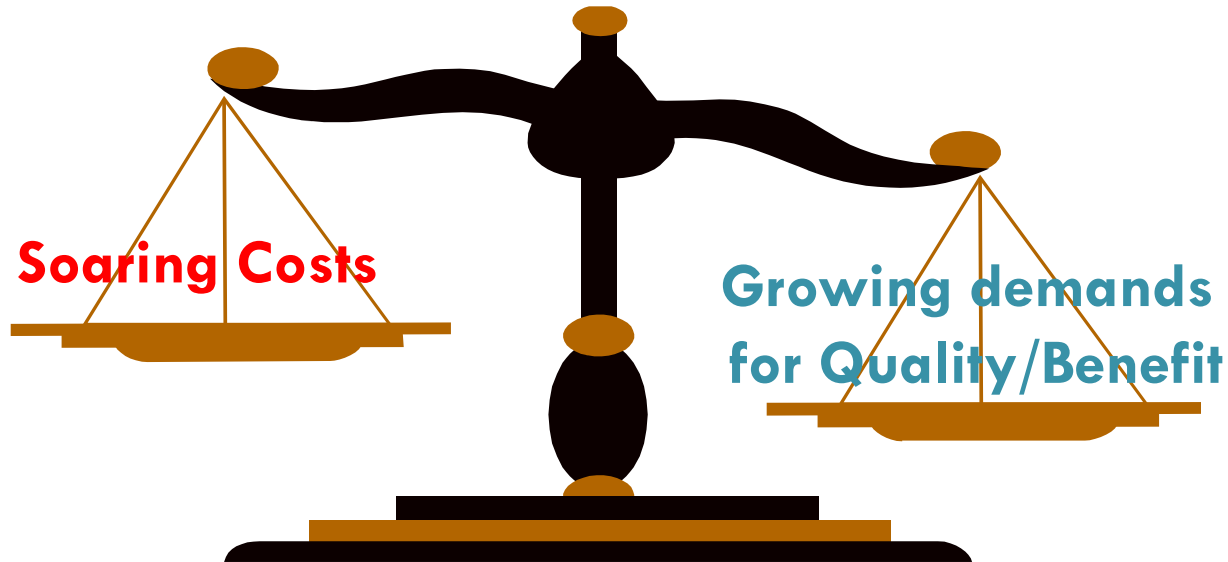
RCT

Value-based Healthcare

CEA-RCT

Globally faced dilemma in public policy

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- HTA as a key concept
 - ▣ Value-based pricing / reimbursement
 - ▣ Value-based policy making / marketing

Fundamental solution

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How to assess the health technology ?

Value-based ?

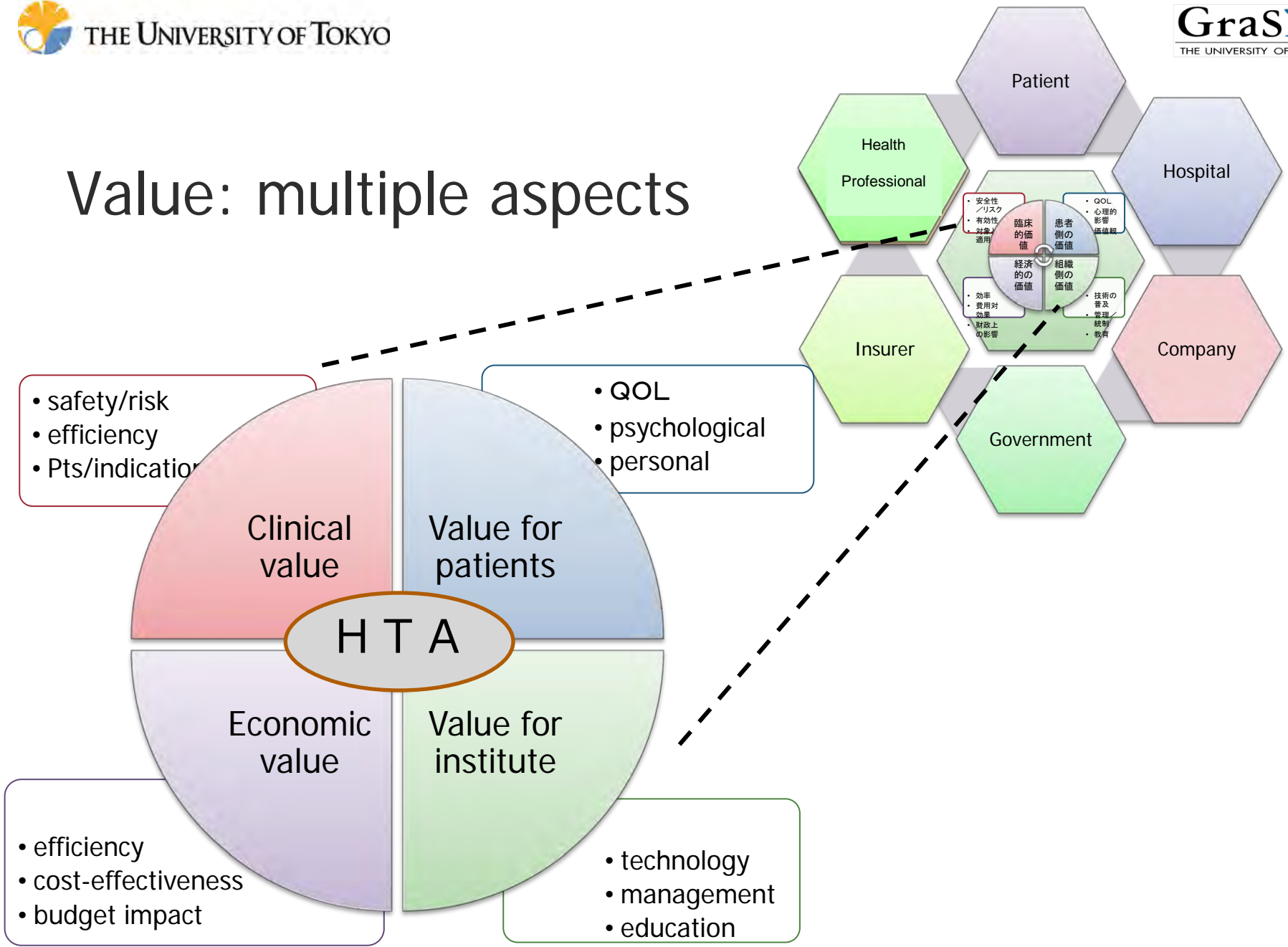


HTA, definition

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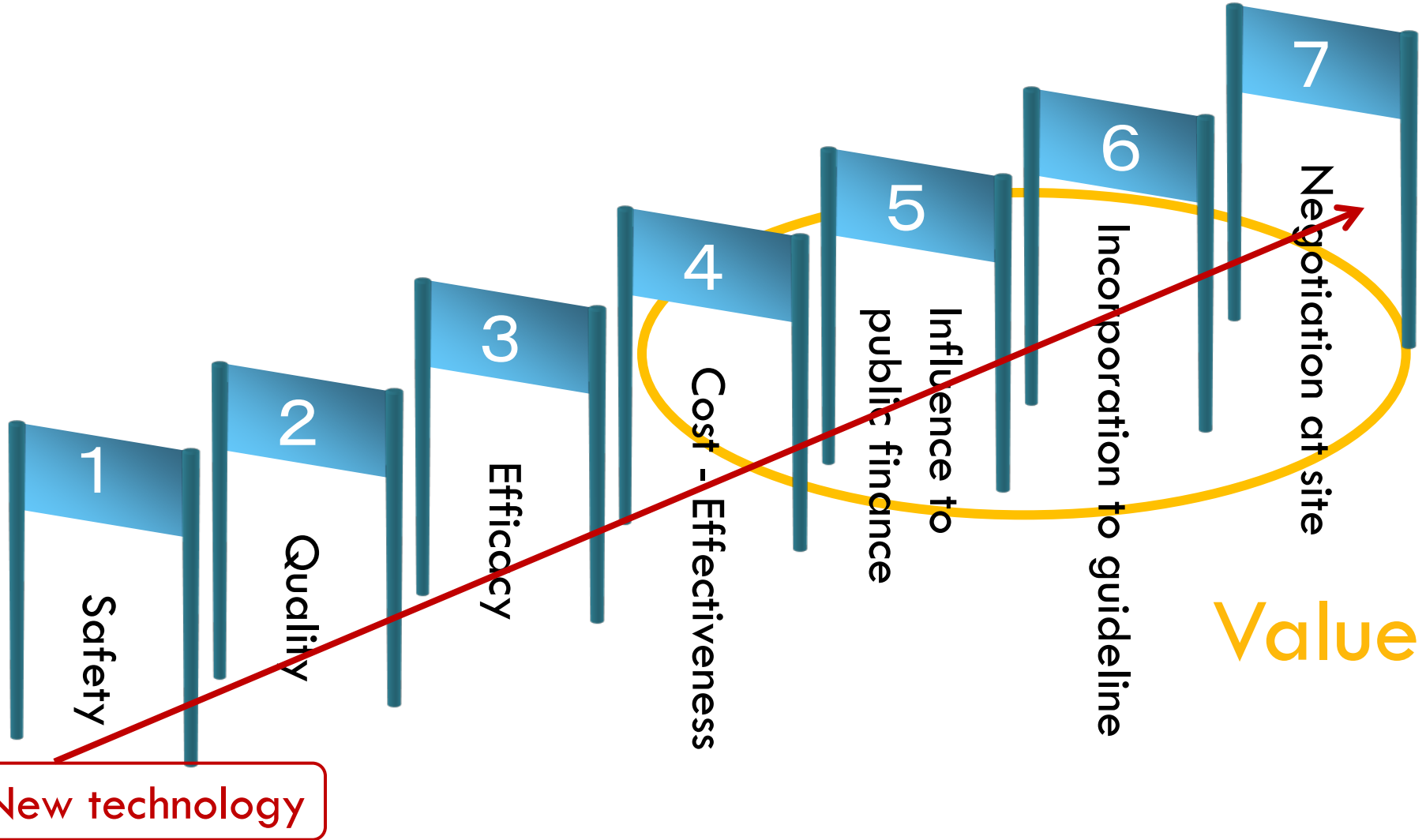
- Multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner.
- Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value.

Value: multiple aspects



7 Hurdles: from approval to market access

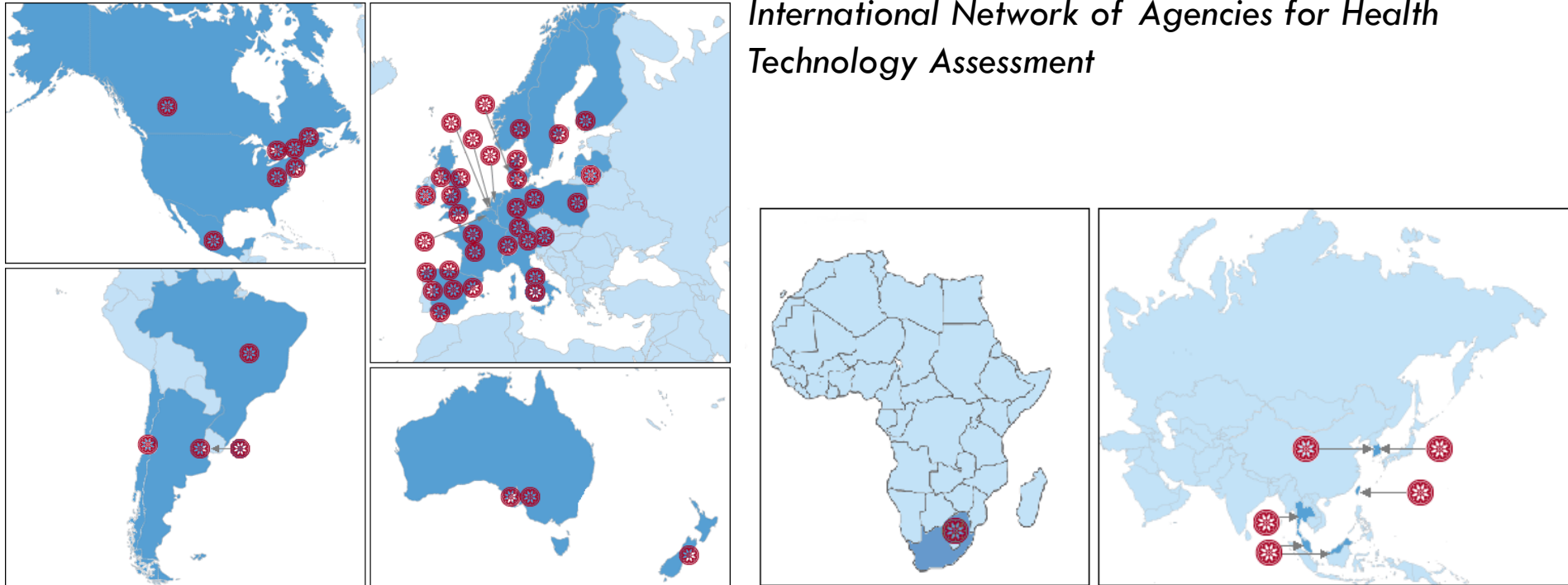
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HTA Agencies / INAHTA

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International Network of Agencies for Health Technology Assessment



INAHTA was established in 1993 and has now grown to 53 member agencies from 29 countries. The Network stretches from North and Latin America to Europe, Asia, and Australasia.

National Institute for Health and Care Excellence

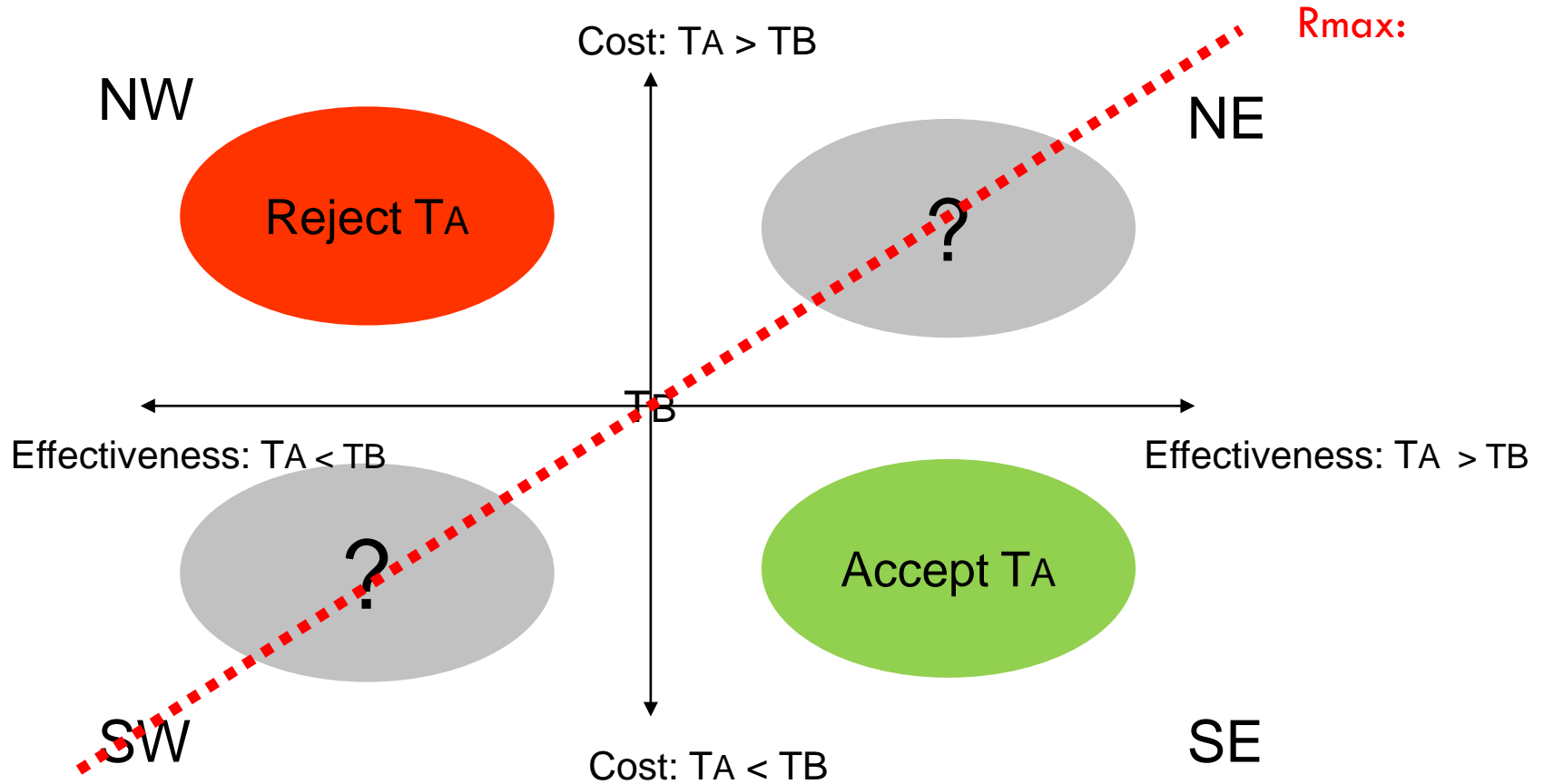
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- Established in 1999 as the UK National Institute for Clinical Excellence (NICE) in London by Tony Blair.
- Famous phrase
 - "NICE is not nice."
 - "NICE is good for business."



Cost-Effectiveness Plane

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Decision rule: accept the area under the line R_{max} , reject one over it.

Objection to NICE

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- “Arrogant, illogical and totally out of touch, NICE must be scrapped ...it's killing too many people”
(Daily Mail, August 12, 2008)
- “Alzheimer's protesters gathered outside the High Court at the start of the hearing, which is due to last four days”
(Telegraph, June 25, 2007)



HTA Position in Asian Countries

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- Rapidly changing: *Regulatory stage*
 - ▣ Korea (HIRA)
 - ▣ Thailand (HITAP)
 - ▣ Taiwan (HTA Division, CDE)
- Moderately changing: *Intermediate stage*
 - ▣ China, Japan, Singapore, Malaysia, Philippines
- Gradually changing: *Developing stage*
 - ▣ India, Pakistan

HTA requirements in Asia: at a glance

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	Approval	Reimbursement	Price
Japan	No (recommended)	No	No (but value appreciation by premium price)
Taiwan	No	Yes (review by HTA Division)	No (Negotiation by Government Rules)
ROK	No	Yes (mandatory submission & review listed drugs by HIRA)	No (Negotiation by Price-Volume, expected sales amounts, etc)
Thailand	No	Yes (revision of NLED by HITAP)	No (Negotiation for MPC, Compulsory Licensing)

Recent sounds in government

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- Official HTA discussion and implementation
 - MHLW: Central Social Insurance Medical Council
(Chu-i-kyo)
 - Apr 20, 2011 Plenary Session Dr. Morita newly elected as the chairman
 - May 23, 2012 Chu-i-kyo: Special Committee on Cost-Effectiveness Evaluation, 1st meeting
 - Dec, 2013 provisional draft of HTA towards 2016

Provisional draft suggests ...

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Agenda	The Point at Issue	Suggested Direction
Cost	scope	Direct cost (medical only)
Effectiveness	outcome index: QALY or otherwise?	▪ not automatically apply QALY. Further discussing how to combine different set of outcomes
Application	pricing or coverage? Both?	No consensus yet

Quasi-VBP in Japan

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- ▣ Quasi-VBP is a feature of Japanese-style HTA.
- ▣ Pricing mechanism reflecting value for money in an experience-based manner.
- ▣ Adding a premium to the control price
- ▣ Premium rate is subjectively determined, taking clinical benefit into account
- ▣ also considers a price-volume impact to the national budget in two-year horizon.

Suggestions for HTA and market access in Asia

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- Health economic studies will play more roles than ever.
 - *Don't miss boarding a boat*
- Customized approach to local HTA agency
- More value-based approach to reimbursement / pricing for payers and industry (*risk-sharing, performance-based agreement, Japanese quasi-VBP, etc.*)
- Fill the gap between opportunity and reality
- More evidence-based approach to decision makers / professionals in hospital – CE first and HTA next?
- Priorities in Asia: training, DB/Registry, and guidelines

Conclusion

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Health economics is ...
not just an academic discipline,
but a life style
for all.

Thank you very much for your interest in Asia.

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Danke schön.
ありがとうございました。