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Multi-Criteria Decision Analysis (MCDA) in interchangeability.

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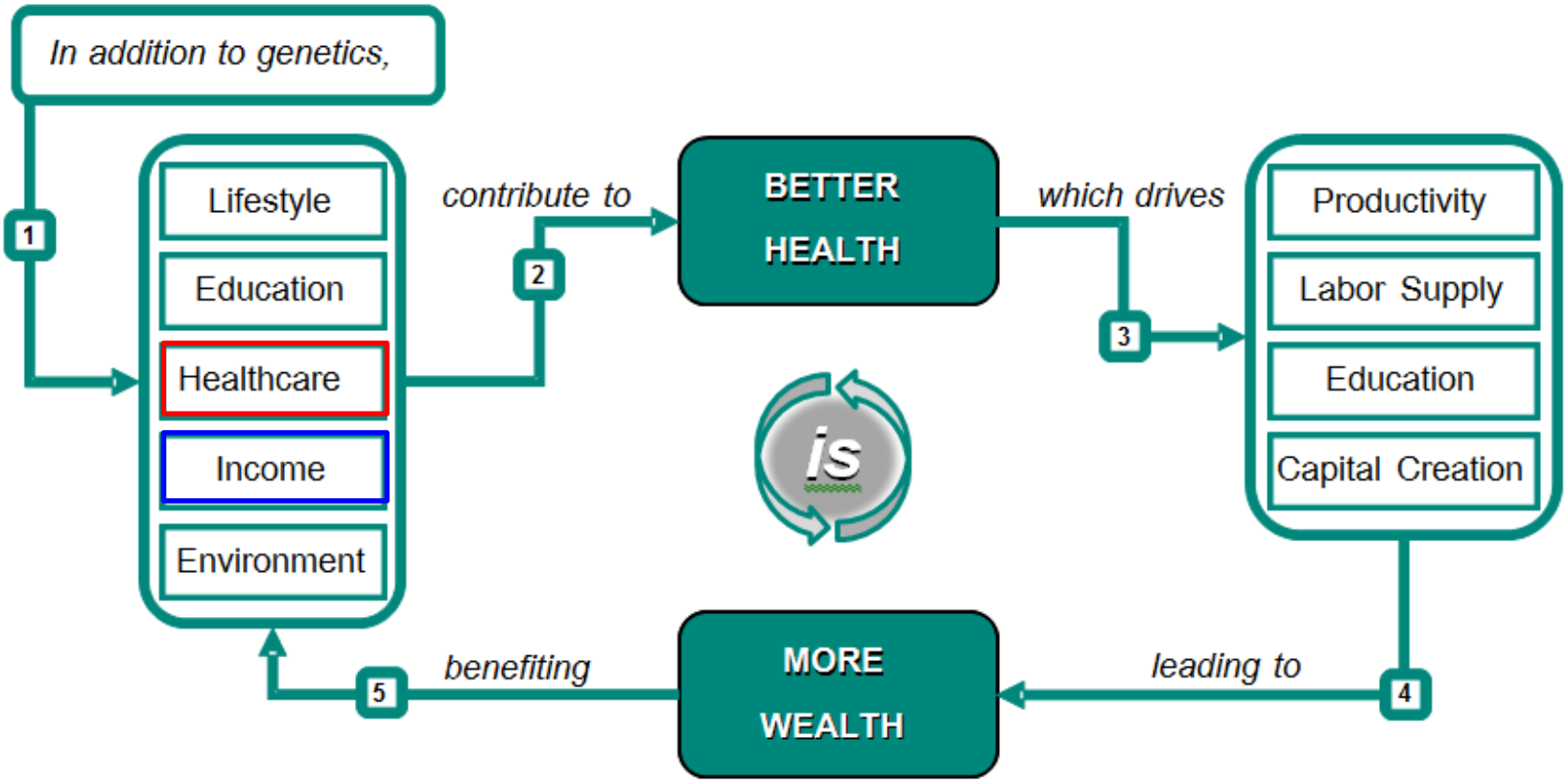
Health Spending Contributes to Economic and Social Development in multiple ways

Health spending is a crucial investment to promote economic growth



Source: The contribution of health to the economy in the European Union", Suhrcke, McKee for the European Commission, DG Sanco (2005)

WHO European Ministerial Conference on Health Systems: "Health Systems, Health and Wealth" Tallinn, Estonia, 25–27 June 2008

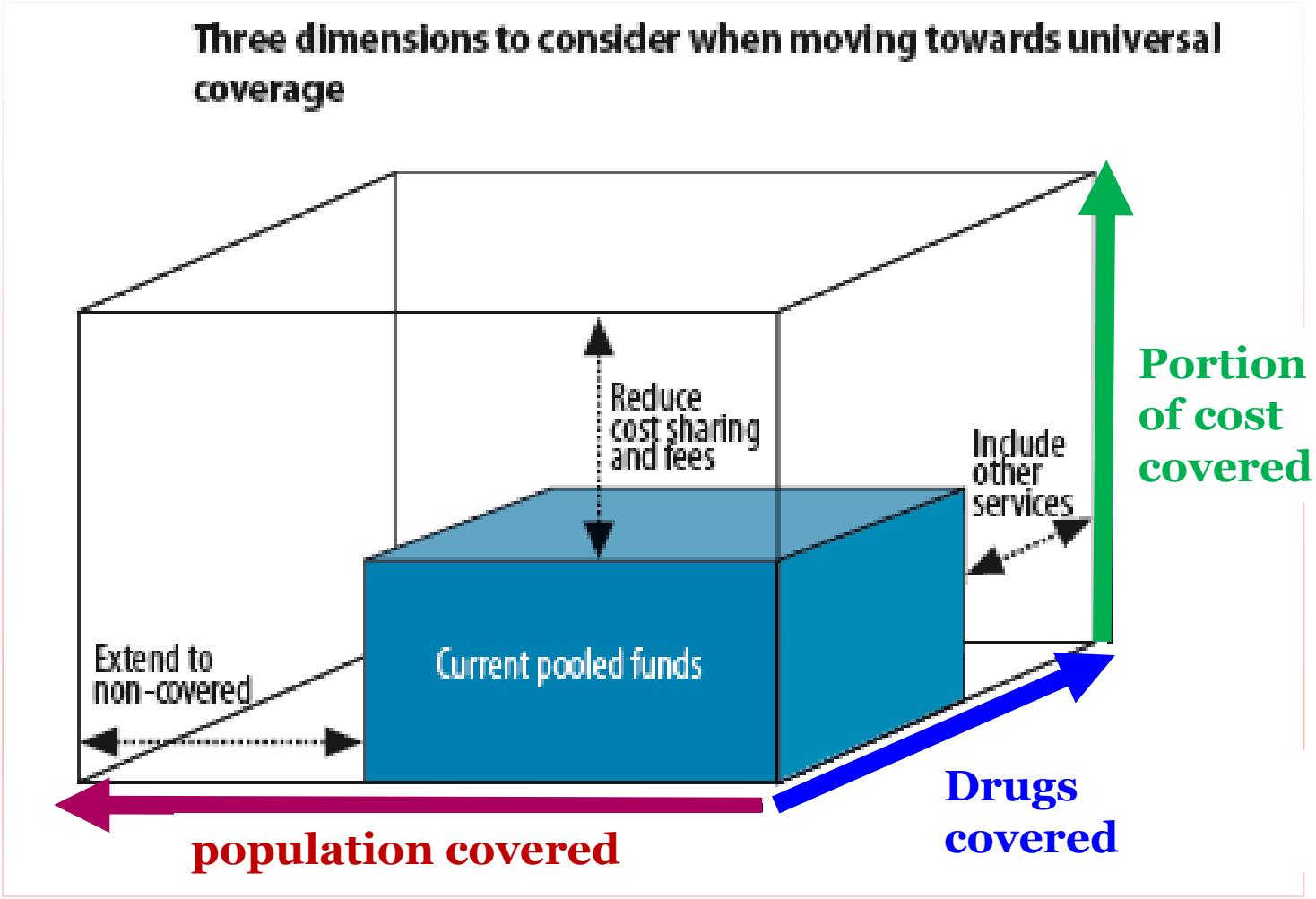
Better health contributes to Economic growth

The economic costs of ill health in the European Region

Table 1. Monetary value of life expectancy gains in selected European countries, 1970–2003

Country (1)	Monetary value		
	Life expectancy gains (PPP$) (6)	Gains per life year gained (PPP$) (7)	(7) as % of 2003 GDP per capita (8)
Austria	87 986	9 875	33
Finland	74 037	8 899	32
France	54 741	8 409	30
Greece	29 085	5 692	29
Ireland	95 450	12 676	34
Netherlands	45 426	8 925	30
Norway	64 398	11 624	31
Spain	45 312	6 567	29
Sweden	42 705	7 708	29
Switzerland	69 794	9 220	30
Turkey	37 796	2 598	38
United Kingdom	55 106	8 478	31

Coverage Expansion Will Enroll More Patients, Provide Better Benefit and Reduce Patients' Self-pay



Source: WHO - World Health Organization

Efficiency also important

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Toward a Broader Concept of Value: Identifying and Defining Elements for an Expanded Cost-Effectiveness Analysis

Louis P. Garrison Jr., PhD[1,], Sachin Kamal-Bahl, PhD[2], Adrian Towse, MA, MPhil[3]*

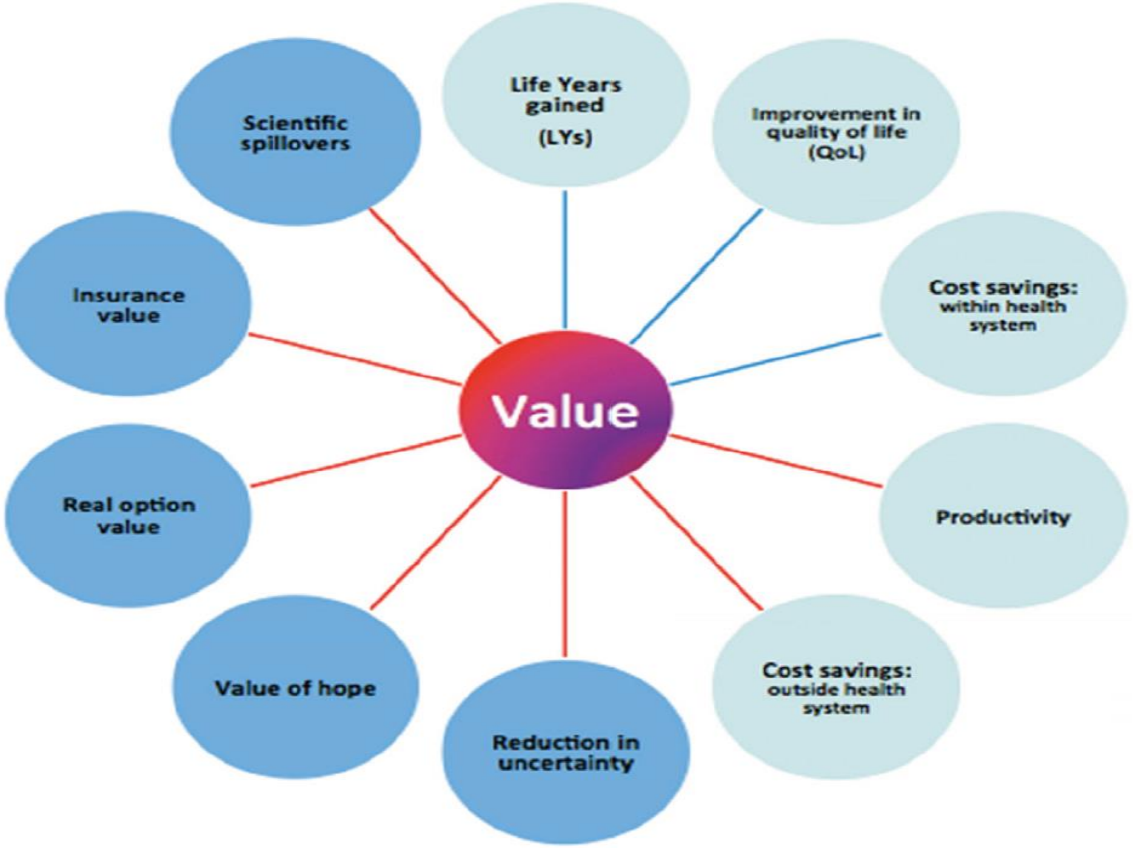
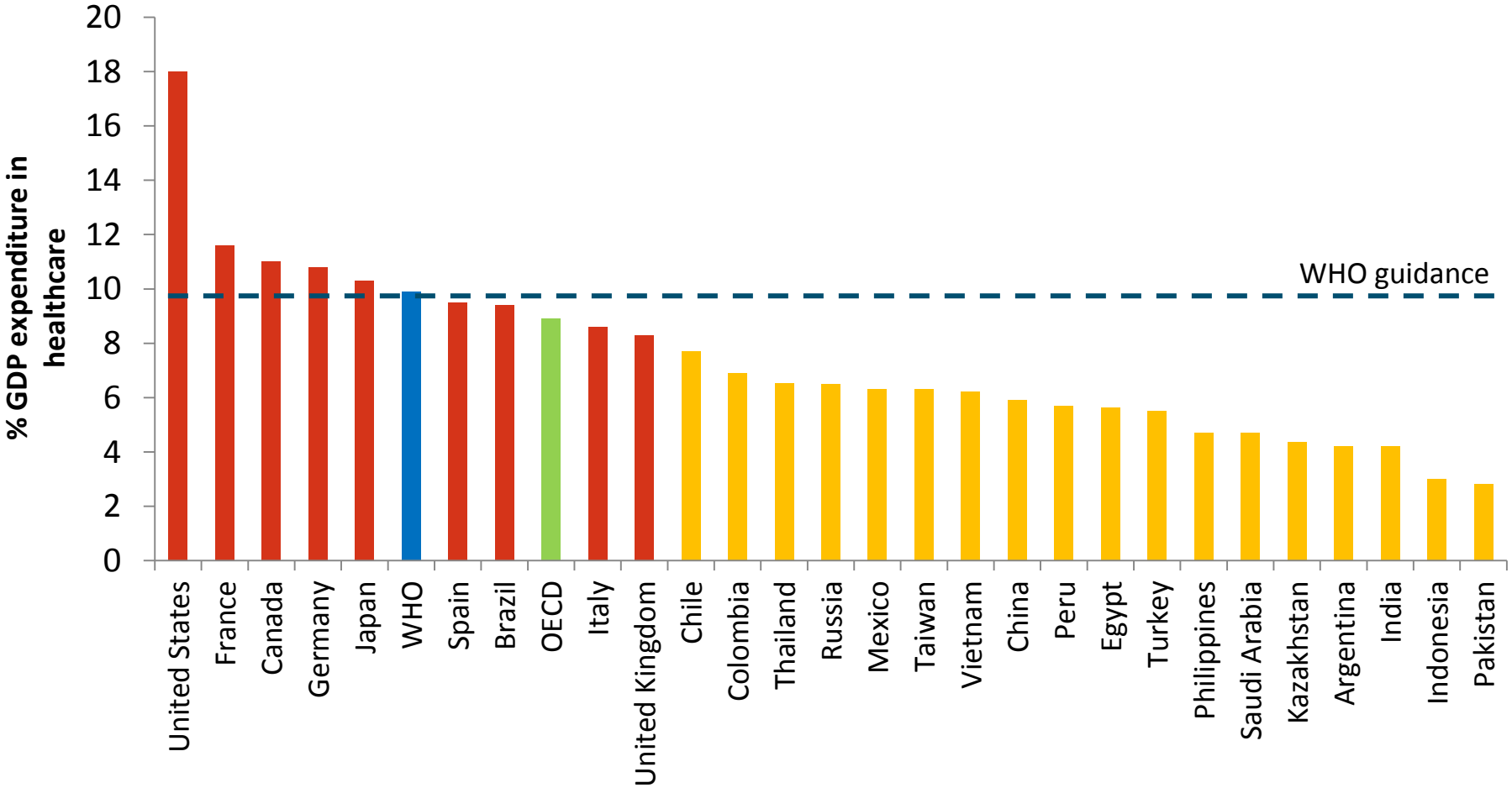


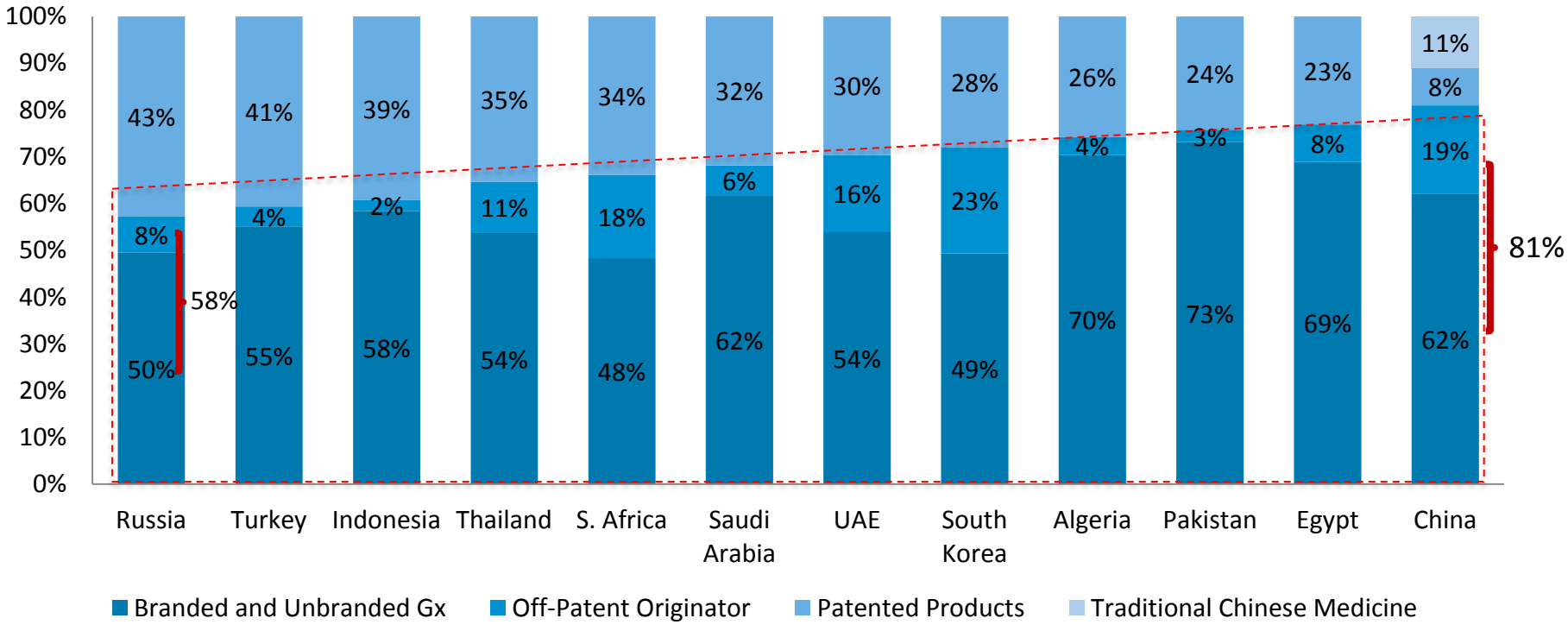
Fig. 1 – Elements of Value.

Currently, Emerging Markets are Moving into Coverage Expansion, However % GDP Spend on Healthcare Below WHO Guidance



Source: http://www.who.int/gho/health_financing/total_expenditure/en/ accessed 4 Nov 2016

OPP (Off-Patent Pharmaceuticals) Play a Critical Role



- Off-Patent Pharmaceuticals (OPP) comprise of:
  - Off-patent originators
  - Branded generics
  - International Non-proprietary Name (INN) generics
- Majority patients are treated with OPP (~60-80%)

Source: IMS MIDAS, MAT 2015

OPP key essentials are PE & BE, however many emerging markets have not yet reached both level

Country	Generic definition	In line with int'l standard	Required GMP meet WHO standard (manuf. sites)	GMP standard implemented	New registration require BE (local prod.)	Mandate BE for in-market local products	In-vitro test performed in routine quality check (local products)
Russia	Yes	Yes	Yes (2018)	Partially	Yes	Partially[1]	No
China	Yes	No	Yes	Partially	Yes	Partially [2]	Random
Vietnam	Yes	No	Yes	Partially	No (till 2025)	Partially[3]	Random[4]
Indonesia	Yes	No	Yes	Partially	Partially[5]	Partially[5]	No
Philippines	Yes	Yes	Yes	Partially	Yes	Partially[6]	No
Pakistan	Yes	No	Yes	Partially	No	No	No
Egypt	Yes	No	Yes	Partially	Yes	No	No
Algeria	Yes	No	Yes	Partially	Yes	No	No
India[7]	Yes	Yes	Yes	Partially	Yes	No	Partially
Chile[7]	Yes	Yes	Yes	Partially	Yes	Partially[6]	Partially
Peru[7]	Yes	Yes	Yes	Partially	No	No	Partially
Saudi Arabia	Yes	Yes	Yes	Partially	Yes	Yes	Yes
South Africa	Yes	Yes	Yes	Partially	Yes	Yes	Yes
Colombia[7]	Yes	Yes	Yes	Yes	Partially	No	Partially
Argentina[7]	Yes	Yes	Yes	Yes	Yes	Yes	Partially

Note: : 1. Products >20 years exempted; 2. Start in 2016, 280 Molecules by 2018; 3: required for 12 molecules; 4. blacklist if identified; 5. Required for 90 molecules and Extended Release; 6. at product renewal; 7. Global initial mapping

**PE: Pharmaceuticals Equivalence; BE: Bio-Equivalence; GMP: Good Manufacturing Practices; WHO: World Health Organization*

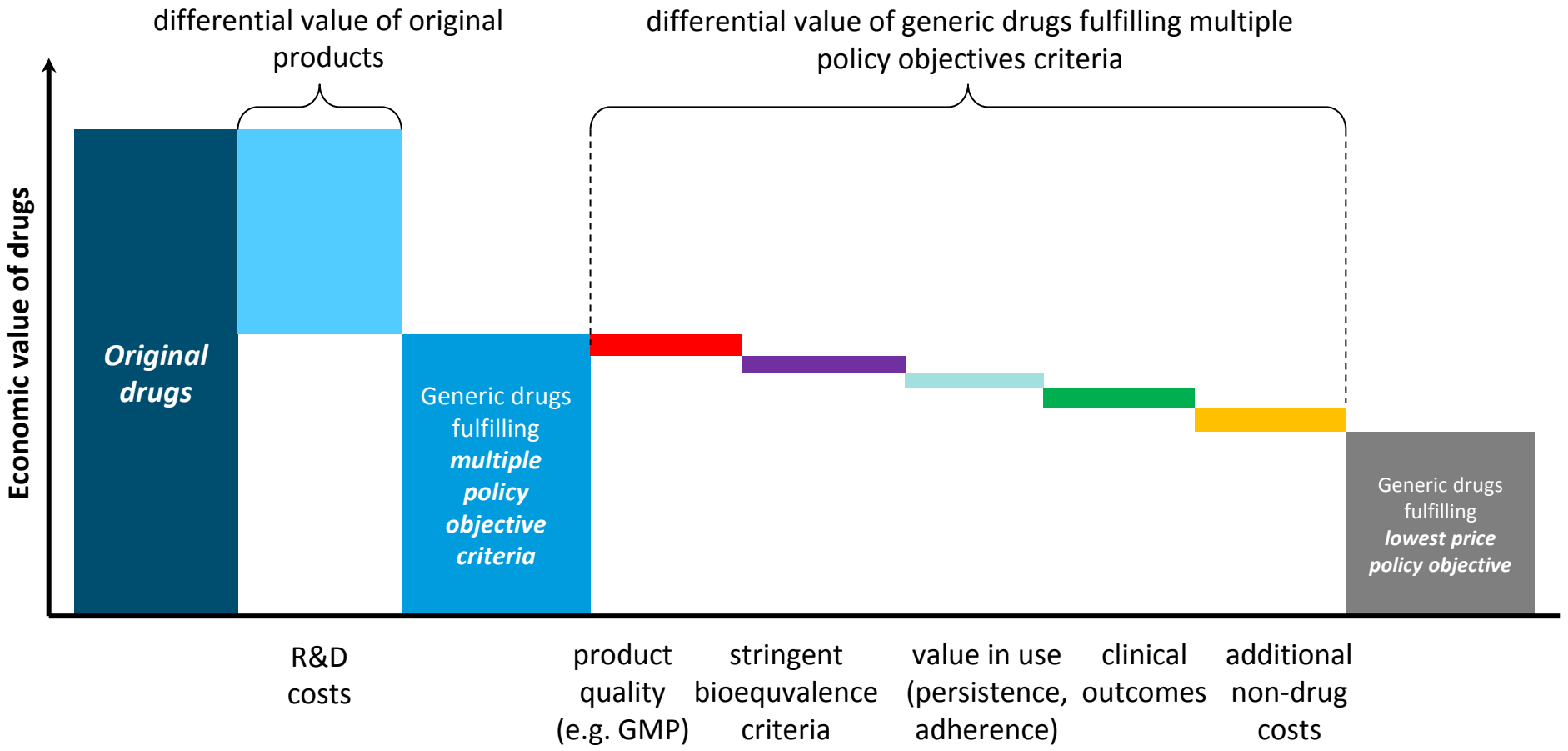
Source: Alfonso et al, Journal of applied HE in health policy making, 2015 updated with local BA/BE regulations on June 2016

Manufacturing standards are different; EU-GMP or PIC/S with WHO-GMP and local-GMP

	EU GMP & PIC/S	WHO - GMP	Local GMP (example EM)
Objective	• To ensure continuous monitoring of the manufacturing process, Risk identification and mitigation. • Post Market Surveillance.	• One time exercise to certify the manufacturer . • First steps in term of GMP.	• One time exercise to certify the manufacturer . • First steps in term of GMP.
Certification requirements	Very similar requirements for certification in terms of quality assurance, production, inspection process, materials and documentation.		
Re-certification & monitoring	On-going interaction with regulators and manufacturers to ensure compliance and constant improvement (risk identification and solutions).	• Manufacturer has to request re-certification. No requirement to recertify. • On Going Monitoring varies depending on local authorities.	• Manufacturer has to request re-certification. • Requirement to recertify varies by country • On Going Monitoring varies depending on local authorities.
Criteria	Criteria allows for manufacturer to pro-actively identify GMP risks and provide solutions to ensure a high quality standard is maintained.	Strict criteria on what needs to be achieved but does not ensure highest quality is maintained.	Strict criteria on what needs to be achieved but does not ensure highest quality is maintained.
Other	EU-GMP does have jurisdiction over member countries and hence can enforce penalties.	WHO has no jurisdiction and hence cannot enforce certification.	Local jurisdiction

Source: WHO GMP (2011) and European Commission GMP (2013)

OPP Are Not The Same, They Offer Differential Value To The Public Health System: Need value based approach to capture benefits



Source: Kaló Z et al. Value in Health, 2015

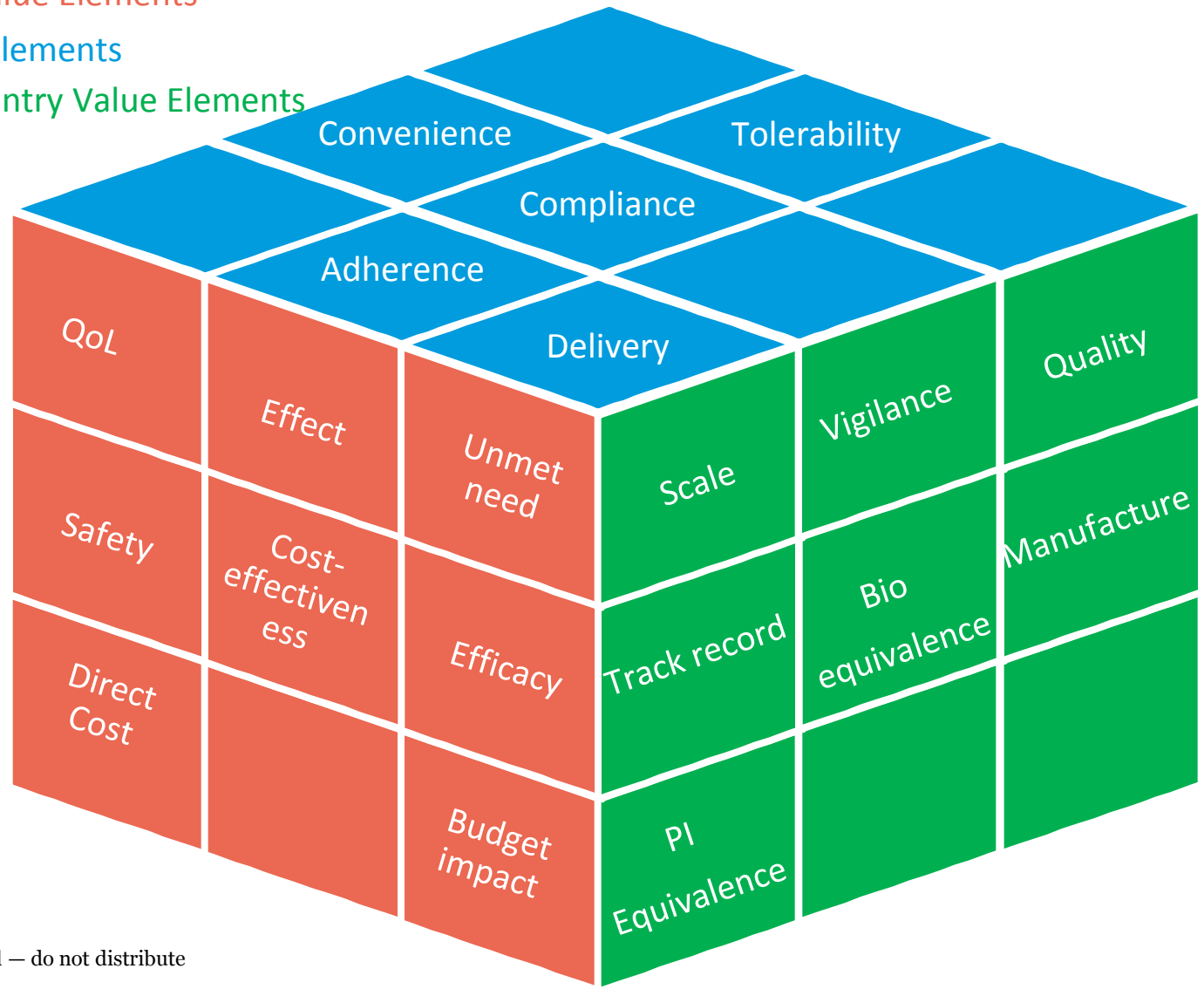
*OPP: Off-Patent Pharmaceuticals; GMP: Good Manufacturing Practice

Value assessment must consider a broad array of metrics

= Traditional Value Elements

= Other Value Elements

= Emerging Country Value Elements



MCDA to measure value

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Using Multicriteria Approaches to Assess the Value of Health Care

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ABSTRACT

Practitioners of cost-utility analysis know that their models omit several important factors that often affect real-world decisions about health care options. Furthermore, cost-utility analyses typically reflect only single perspectives (e.g., individual, business, and societal), further limiting the value for those with different perspectives (patients, providers, payers, producers, and planners—the 5Ps). We discuss how models based on multicriteria analyses, which look at problems from many perspectives, can fill this void. Each of the 5Ps can use multicriteria analyses in different ways to aid their decisions. Each perspective may lead to different value measures and outcomes, whereas no single-metric approach (such as cost-utility analysis) can satisfy all these stakeholders. All stakeholders have unique ways to measure value, even if assessing the same health intervention. We illustrate the benefits of this approach by comparing the value of five different hypothetical treatment choices for five hypothetical patients with cancer, each with different preference structures. Nine attributes describe each treatment option. We add a brief discussion regarding the use of these approaches in group-based decisions. We urge that methods to value health interventions embrace the multicriteria approaches that we discuss, because these approaches 1) increase transparency about the decision process, 2) allow flight simulator-type evaluation of alternative interventions before actual investment or deployment, 3) help focus efforts to improve data in an efficient manner, 4) at least in some cases help facilitate decision convergence among stakeholders with differing perspectives, and 5) help avoid potential cognitive errors known to impair intuitive judgments.

Keywords: multicriteria analysis, priority setting, systems analysis, value modeling.

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ISPOR TASK FORCE REPORT

Multiple Criteria Decision Analysis for Health Care Decision Making—An Introduction: Report 1 of the ISPOR MCDA Emerging Good Practices Task Force

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Multi-criteria/simple scoring definition and measurement

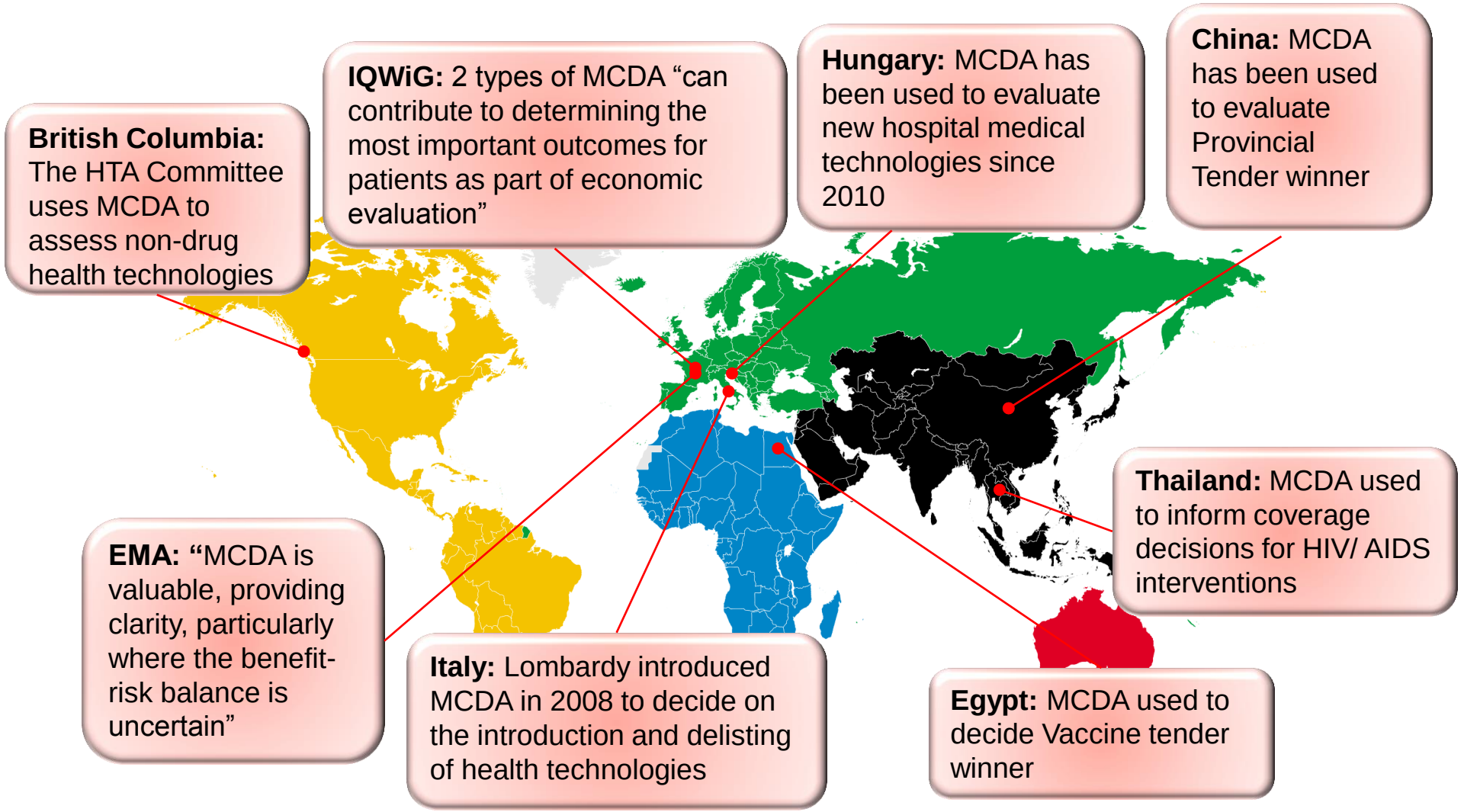
A set of methods and approaches to aid decision-making, where decisions are based on more than one criterion, which make explicit the impact on the decision of all the criteria applied and the relative importance attached to them.

→ As generally understood, multiple criteria/simple scoring

- Comprises **a broad set of methodological approaches**, stemming from operations research.
- **Decomposes complex decision problems**, where there are many factors to be taken into account ('multiple criteria') by using a set of **relevant criteria**
- Provides a way of **structuring decisions**, and aims to help the decision-maker be clear about what criteria are relevant and the relative importance of each in their decisions.
- Facilitate **transparent and consistent decisions**

Source: Thokala, et.al. 2016

How is MCDA being used in health care?



Source: Kalo, MCDA Workshop, Jakarta, 2017

MCDA for OPP - Initial Resonance at Int'l Platforms

ISPOR Milan 2015

- 53 participants across 15 EM countries
- MCDA criteria defined and validated

HTAi Japan 2016

- 50 public health and health economist experts
- Positive feedbacks from WHO and patients community groups

ISPOR Singapore 2016

- 63 participants across 12 countries
- 7 potential real-life application presented, additional 16 ideas generated form the workshop

HTAi: Health Technology Assessment International; ISPOR: International Society of Pharmacoeconomics and Outcome Reseach; MCDA: Multi Criteria Decision Analysis

Value-based MCDA for Off-Patent Pharma

- Adapt MCDA Simple Scoring to reflect HCS development status & priorites
- Involve key stakeholder in defining criteria and scoring to achieve policy acceptance and long-term sustainability
- Applicable for drug decision making (pricing, reimbursement, formulary listing, drug purchasing, interchangeability)
- The criteria are further grouped and specified as below

Product	Manufacturer	Service	Cost Effectiveness
• *Equivalence with the reference (original) product*	• *Quality assurance*	• *Pharmacovigilance*	• *Real world clinical or economic outcomes*
• *Patient benefit via pharmaceutical technology*	• *Macroeconomic benefit*	• *Added value service related to the product*	• *Pharmaceutical acquisition costs*
	• *Reliability of drug supply*		

Source: Brixner, et al. 2017, Value in Health Regional Issue

Real-life Example 1: China MCDA Simple-Scoring Applied in Beijing Tenders

Category	Evaluation Item	Scoring	Weight (%)
Manufacturer Size (50)	1、Quality Assurance (GMP)	3	3.0
	2、Company Rankings in China (per MIIT)	10	10.0
	3、Annual Turnover (revenue V.A.T)	15	15.0
	4、Innovation (as recognized in China)	12	12.0
	5、Local investment and contribution	5	5.0
	6、Corporate Brand (Subjective scores)	5	5.0
Product Quality (50)	7、Quality Specification	5	5.0
	8、Differential Pricing (per NDRC)	10	10.0
	9、Product line/formulation quality control(GMP)	5	5.0
	10、Tender winning record	10	10.0
	11、API Quality Control (GMP)	2	2.0
	12、Output Ranking (per MIIT)	10	10.0
	13、Electronic Monitoring	3	3.0
	14、Product Reputation (Subjective scores)	5	5.0
Additional Point (10)	15、Bad Records of Quality (Negative)	-10	
Total		100	100

Subjective Scores will be determined by KOLs

Real-life Example 2: Egypt MCDA Applied in Vaccine Tenders

No	Criteria	Score
1	Prequalification (WHO, EMA, FDA, TGA, MHLW) [1=3, 2=6, 3=9, >3= 12]	12
2	Country of origin is one of reference country	12
3	Registered in 3 reference country [each country=3]	9
4	History of previous delivery within the last 5 yrs [1 year=2, 2years=4, 3years=6, 4 years=8, >5 years=10]	10
5	Compliance with all technical aspects in previous delivery [50 to <60%=3, 60 to <80%=5, >80%=8]	8
6	Timeliness in previous delivery [similar % as above = 3 , 7 , 11]	11
7	Length of Shelf-life	6
8	# of doses/vial (single dose/vial preferred)	10
9	Vaccine is composed of best strain available	10
10	No change in vaccine physical appearance (become unusable) in previous delivery	8
11	Availability of Vaccine Vial Monitor (heat sensor)	4
	Total	100

*MCDA: Multiple Criteria Decision Analysis

Conclusions

- Investing in health care and pharmaceuticals in good value for money for society
- Under financial limitations is important to maximise value for money
- Whilst money spend is easy to measure, the quantification of value differs depending on the setting
- In emerging economies the majority of pharmaceuticals belong in the off patent space
- In the OPP space the drug decision must be considered and quantified on the basis of differential value (i.e. PE, BE, GMP, Clinical outcomes) amongst others
- MCDA can easily reflect multiple dimensions and hence can prove to be a very useful tool for OPP decision making in such settings