VALUE BASED DECISION MAKING IN EMERGING MARKETS: MCDA FOR OFF-PATENT PHARMACEUTICALS

Educational Symposium – ISPOR Asia - Tokyo, Sep 11, 2018

Moderators: **Anke-Peggy Holtorf**, Health Outcomes Strategies / Switzerland

Panelists: **Diana Brixner**, Univ. of Utah / USA
Nikolaos Maniadakis, National School of Public Health / Greece
Zoltán KALÓ, Syreon Research Institute, Hungary
Kalman Wijaya, Abbott Products Operations AG / Switzerland

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Agenda

» Opening	AP Holtorf
» Policy environment in for Off-Patent pharmaceuticals in Emerging Markets	AP Holtorf (for N. Maniadakis)
» Using a MCDA simple scoring approach for Off-Patent Pharmaceuticals in Emerging Markets	Z Kaló
» Experiences from Indonesia, Vietnam, Kazakhstan, Kuwait, and Thailand	K Wijaya
» Implementation process & Evidence Framework	D Brixner
» Panel-Audience Discussion	

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Gaps in Off-Patent Pharmaceutical (OPP) Decision Making

Pharmaceutical Policy Environment in Emerging Markets

Prof. Nikolaos Maniadakis, BSc, MSc, PhD, FESC
Chair, Department of Health Care Services Administration
Alternate Dean, National School of Public Health, Athens, Greece
Presented by AP Holtorf

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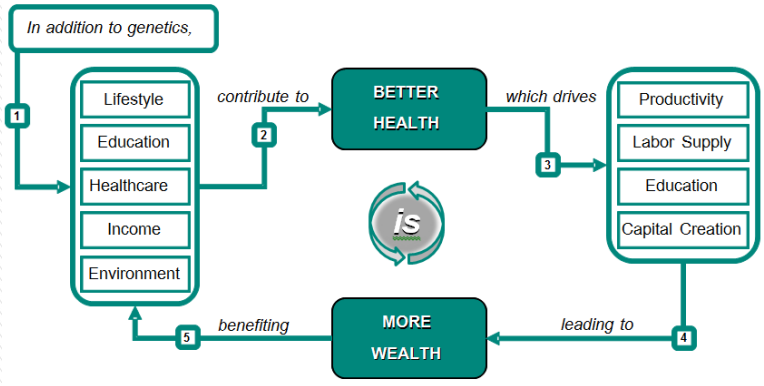
Investing in Health is the Foundation for Economic Growth

Healthcare Spending Contributes to Economic and Social Development in Multiple Ways



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

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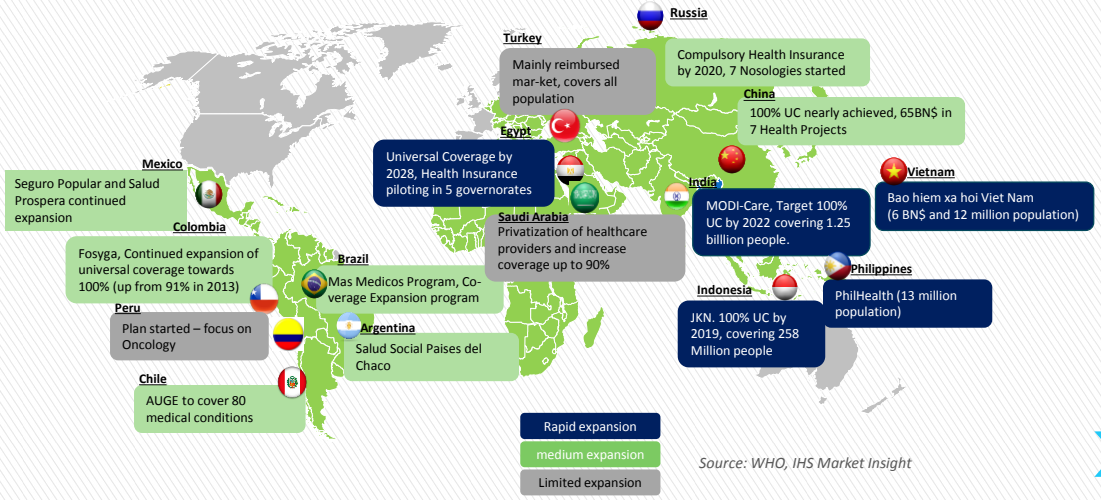
Emerging Markets are Moving towards Coverage Expansion



Source: WHO, IHS Market Insight

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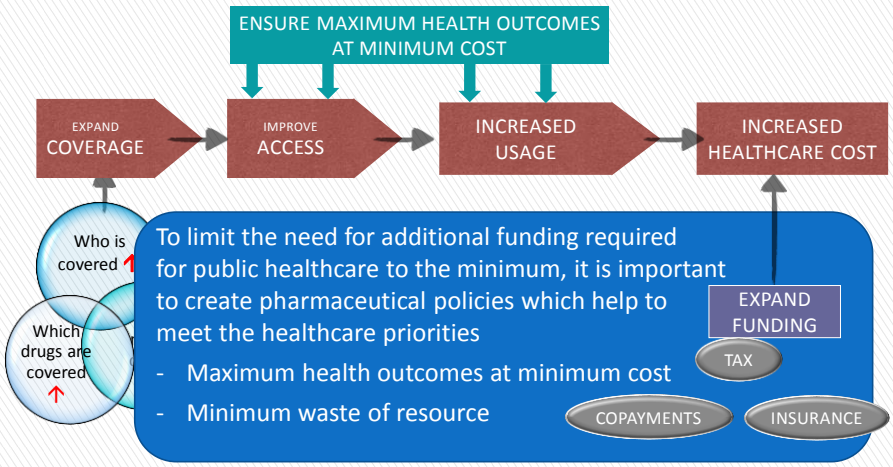
Improving Access by Expanding Coverage Means Increasing Cost



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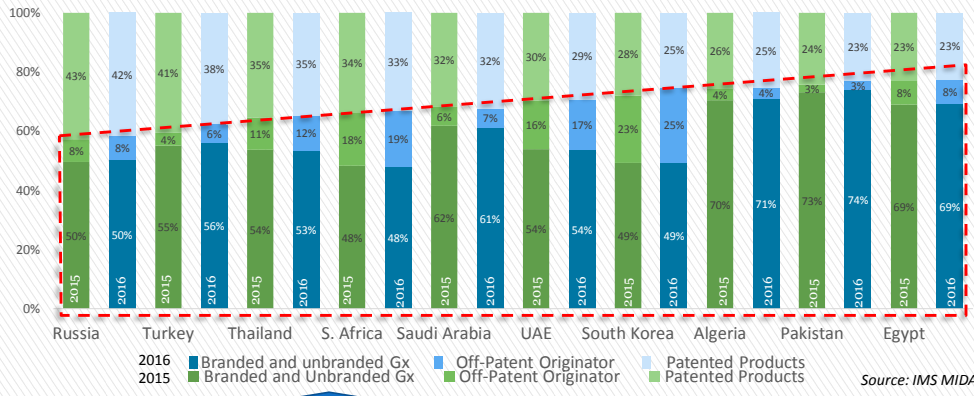
OPP (Off-Patent Pharmaceuticals) Play a Critical Role: The Majority of Patients are Treated with OPP (~60-80%)



Source: IMS MIDAS, MAT 2015 & 2016

First-line therapy for most common diseases
High impact on health for patients

Off-Patent Pharmaceuticals (OPP) comprising:
- Off-patent originators
- Branded generics
- International Non-proprietary Name (INN) generics

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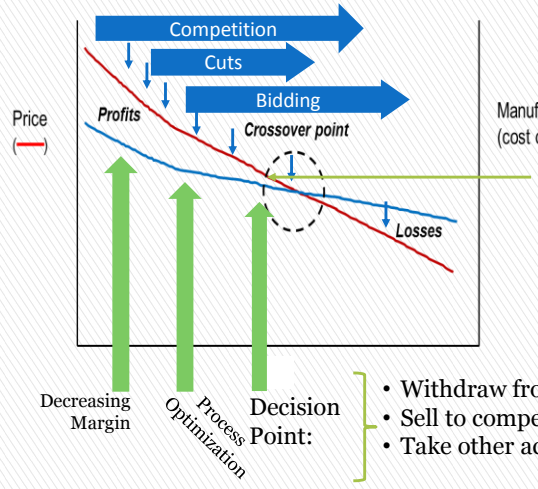
Lowest Price Decision Making May Cause Issues for Drug Availability and Access



No further efficiency possible without compromising on supply or health outcomes

- Withdraw from market?
- Sell to competitor: Consolidation?
- Take other action ?

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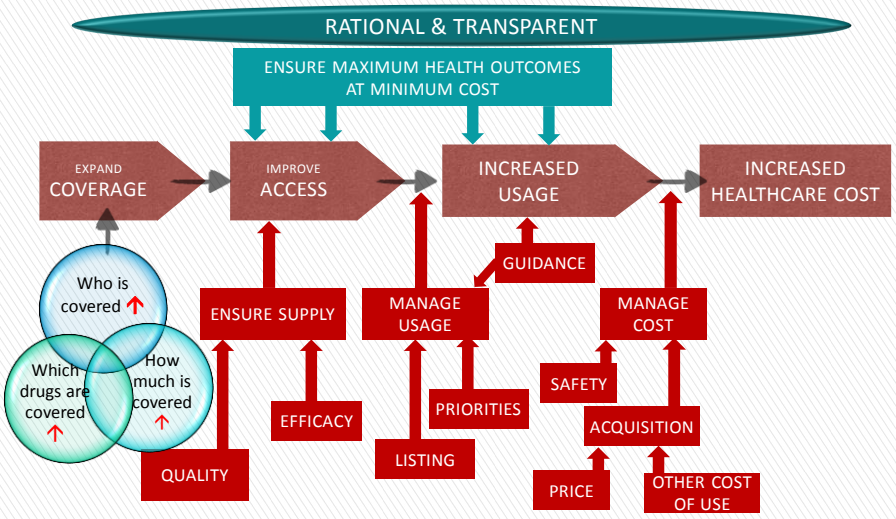
Good Off-Patent Pharmaceutical Policies Can Ensure Maximum Health Outcomes at Minimum Cost



OPP = Off-Patent Pharmaceuticals

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Rational and Comprehensive Decision Making is Important to All Stakeholders

Policy makers and payers	•Policy makers can **reach their health policy objectives** by defining the right **targets and benchmarks** •Payers can set targets to achieve both, **long- and short term performance**
Patients	•Reliance on National Healthcare policy makers as agents for **patients' health and patients healthcare rights (access)** •**Transparency** of targets and policies improves **equity and comprehension**
Healthcare professionals (physicians, pharmacists)	•**Focus on their core tasks** and competencies instead dealing with negative impact of short term priorities
Manufacturers	•**Transparency** helps to meet policy expectations •Rewards for meeting benchmarks improves **competitive fairness**

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Development of a Multiple Criteria Decision Analysis Tool

A Multiple Criteria Simple Scoring Approach for OPP's in Emerging Markets

Prof. Zoltan Kaló
Eötvös Loránd University (ELTE)
Syreon Research Institute, Budapest, Hungary

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Many Factors Contribute to the Success of OPP* Policies

How can these factors be considered when making decisions for Off-Patent Products?

Value consideration along all stages

ENSURE SUPPLY
MANAGE USAGE
MANAGE COST
EDUCATION
SAFETY
GUIDANCE
EFFICACY
PRIORITIES
ACQUISITION
QUALITY
LISTING
PRICE
OTHER COST OF USE

*OPP = Off-Patent pharmaceuticals

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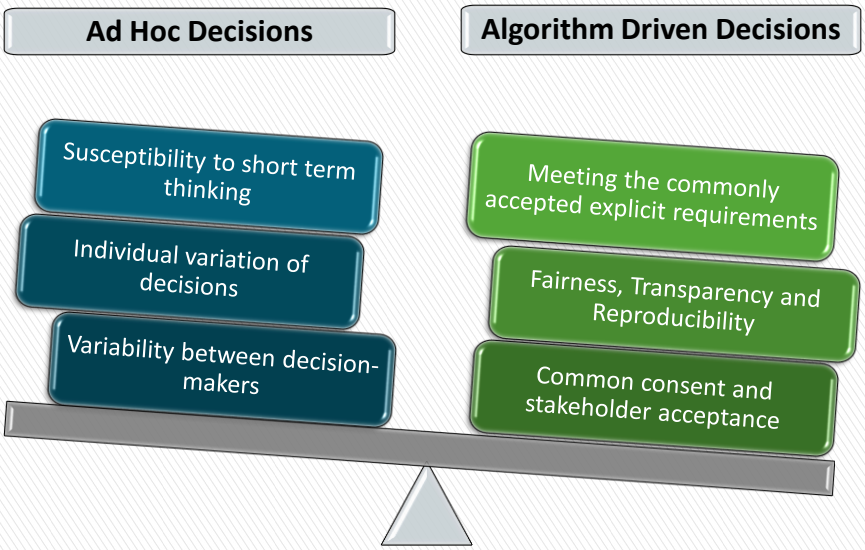
Using a Consistent and Validated Set of Criteria to Make More Effective Decisions



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What is MCDA and How it Can be Beneficial for OPP Decision Making in Emerging Markets?

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. *Source: Thokala, et.al. 2016*

Improvement of decision consistency and transparency

- Standardized explicit decision-making algorithm
- Decisions can be replicated consistently over time
- Decisions mechanisms are public and transparent

Adaptability

- Criteria for decisions can be adjusted based on current national healthcare status and priority

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Why MCDA for OPP in Emerging Markets?

Background:

1. **Limited resources (capacity and time) in developing countries for in-depth HTA analysis**
2. **Increasing transparency measurement across drug decision making process in developing countries**
3. **Fast and simple process for OPP is required**

Objectives:

1. Develop a Simple Multiple Criteria Decision Process and Tools, adaptable to developing countries' local healthcare requirements and priorities in decisions related to Off-Patent Pharmaceuticals*
2. Support the use of the process and tool by creating a range of easy-to-adopt open-source templates, which can be easily adapted to the decision setting in developing countries

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Development of MCDA for OPPs: Key Considerations

1. The MCDA system

1. Selection of criteria
2. Scoring function of each criterion
3. Weighting of each criterion

2. MCDA Application Mode

1. Rule vs. Tool
2. Single or repeated use

3. MCDA Framework

Recommended for Emerging Markets

1. "Non-scientific" MCDA
2. MCDA system developed by expert group with ongoing validation (revealed preferences)
3. Research based MCDA (stated preferences)

OPPs: Off-Patent Pharmaceuticals

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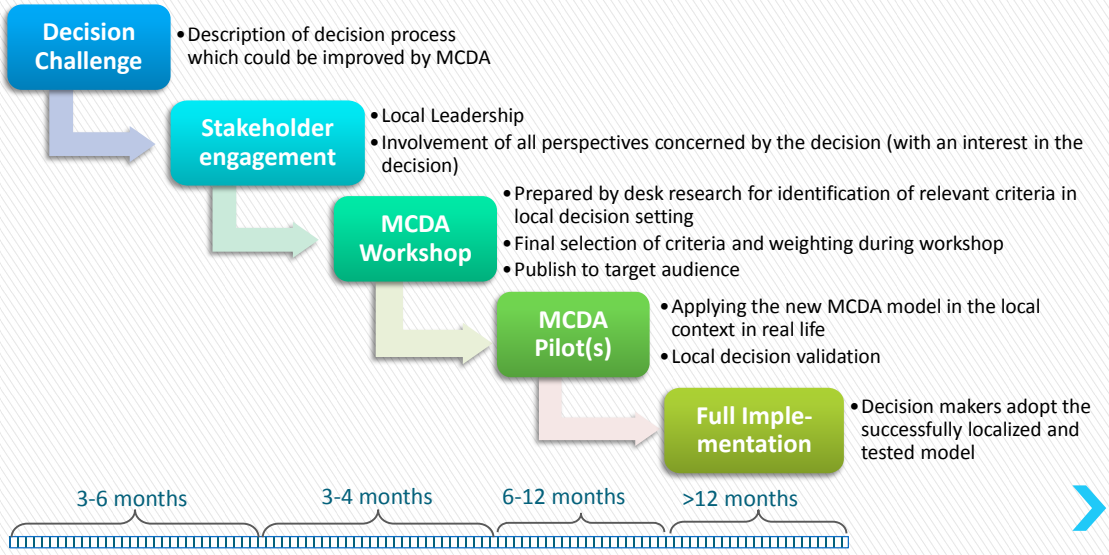
Stepwise Approach for Value Based Decision Making in the Emerging Market Context



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Conclusions

- MCDA can be applied across a broad range of decisions in healthcare
- Use of MCDA can help to improve decision consistency, transparency, and adaptability to an evolving healthcare system
- MCDA is an practicable tool for prioritizing investments in public health
- There are established methods which can be applied in the local context to develop an MCDA process

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Case Presentations

Experiences from Indonesia, Vietnam, Kazakhstan, Kuwait and Thailand

Kalman Wijaya, BSc, Pharm, Dipl. HE & Health Policy, MBA
Global Market Access and Policy Sr. Manager
Abbott Established Pharmaceuticals, Allschwil, Switzerland

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5 Real-life Multiple Stakeholder Policy Workshops Realized

Indonesia, March 2017 - Application: Drug Procurement
- Participants: MoH, MoF, National Tender Agency, local FDA, Social Security, Pharma assoc.
- Collaboration with University Gajah Mada

Kazakhstan, June 2017 - Application: SK-Ph Drug Procurement
- Participants: MoH, National Tender Agency, local FDA.
- Collaboration with Nazarbayev University

Vietnam, July 2017 - Application: Drug procurement
- Participants: MoH, National Tender Agency, local FDA, Social Security, Pharma assoc.
- Collaboration with IQGx and EuroCham

Kuwait, March 2018 - Application area: Drug procurement
- Participants: MoH, National Tender Agency, local FDA, Social Security
- Collaboration with Kuwait Pharmacists Association

Thailand, June 2018 – Application Area: Tender for public purchasing
- Participants: MoH, Hospital Tender, Regulatory, Academic
- under Patronage of the Thai Pharmaceutical Association

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MCDA Initiative in Indonesia

A 2-day consensus workshop was organized through Medical Faculty UGM (*Universitas Gajah Mada*) with participation of key local stakeholders in the national procurement of Off-Patent Pharmaceuticals.

Objectives

1. To develop, test and fine-tune a multi-criteria decision analysis framework using MCDA Simple Scoring, designed to facilitate the decision making in the national procurement of OPPs in Indonesia.

Outcomes:

1. Ready to use MCDA tool to support procurement of OPP
2. 7 criteria were selected for OPP in the eCatalogue tender
3. Manuscript publication at international journal (on going)

Stakeholders

Institution	Count	%
BPOM – Local FDA	4	20%
LKPP – National Public Procurement Agency	1	5%
Ministry of Health	7	35%
National Social Security Council	1	5%
Hospital association	1	5%
National formulary committee	4	20%
Pharma manufacturer association	2	10%
Total	**20**	**100%**

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MCDA initiative in Kazakhstan

A 1-day consensus workshop was organized with participation of key local stakeholders involved in the public procurement of Off-Patent Pharmaceuticals.

Objectives

1. Identify a number of criteria which are relevant in the Kazakh procurement process of Off-Patent Pharmaceuticals
2. Perform a ranking and weighting of the criteria
3. Develop scoring functions of each criterion
4. Validate and fine-tune the MCDA framework based on reference cases.

Outcomes:

1. 9 Criteria were selected, weighted and scored for tender system
2. Whitepaper publication

Stakeholders

Institution	Count	%
Republic Center of Health Development	18	45
Academia	10	25
SK-Pharmacia	3	7.5
National Center of Drug Expertise	3	7.5
Industry associations	3	7.5
Other MoH	2	5
Global Experts	1	2.5
Total	**40**	**100%**

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MCDA initiative in Vietnam

- Policy area: tender (the upcoming drug tender circular)
- Key stakeholders: MoH- Drug department, MoH-National Drug Procurement Centre, Vietnam's Association of Health Economics
- Country's workshop: July 13, 2017 in Hanoi
- Workshop overview:
  - + Market Trends and Challenges for Vietnam Healthcare Sector in the upcoming years,
  - + The Importance of Off-Patent Pharmaceuticals (OPP) in Vietnam Healthcare,
  - + Updates on Tender Process,
  - + Multi-Criteria Decision Analysis (MCDA) Methodology for Off-Patent Pharmaceuticals (OPP),
  - + Best practice from other countries in key drug decision making area

» Workshop outcomes: Consensus white paper on potential application of MCDA in drug procurement and formulary listing

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MCDA Initiative in Kuwait

Policy Area: Purchasing Decisions (e.g. Tender)

- Key stakeholders: MoH- Drug department, MoH-National Drug Procurement Centre, Vietnam's Association of Health Economics
- Country workshop: March 13/14, 2018 in Kuwait City
- Workshop overview:
  - Market Trends and Challenges for Kuwait,
  - The growing importance of OPPs,
  - MCDA Methodology
  - Interactive adaptation for a Kuwait tender decision
  - Action plan
- Workshop outcomes:
  - 9 criteria were selected, weighted and scored
  - Consensus white paper
  - Manuscript for publication

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MCDA Initiative in Thailand

A 1-day consensus workshop was organized under Patronage of the Thai Pharmaceutical Association with participation of key local stakeholders in the public (hospital) procurement of Off-Patent Pharmaceuticals.

Objectives

1. To define a set of consensus criteria for multi-criteria decision analysis which can be broadly applied for tender decisions across hospitals
2. Improve transparency, consistency, and documentation of tender decisions

Outcomes:

1. Ready to use MCDA tool (9 criteria) to support procurement of OPP in the hospital setting
2. Five hospitals volunteered for piloting
3. Publication in process

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The Workshops in Five Different Countries Contributed to the Iterative Process Improvement

Process

- Localization Process
- Engagement Process
- Workshop Format

Methodology

- Reduction of Base Criteria from 22 to 9
- Selection and Weighting of Criteria
  Smart and Swing Methodology
- Definition of Criteria
- Measurement of Criteria
- Excel Model Template

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Technical Guidance Published

Taylor & Francis

Expert Review of Pharmacoeconomics & Outcomes Research

ISSN: 1473-7167 (Print) 1744-8379 (Online) Journal homepage: http://www.tandfonline.com/loi/ierp20

Guidance toward the implementation of multicriteria decision analysis framework in developing countries

András Inotai, Huong Thanh Nguyen, Budi Hidayat, Talgat Nurgozhin, Pham Huy Tuan Kiet, Jonathan D. Campbell, Bertalan Németh, Nikos Maniadakis, Diana Brixner, Kalman Wijaya & Zoltán Kaló

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To link to this article: https://doi.org/10.1080/14737167.2018.1508345

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Learnings, External Influencing Factor and Next Steps

Positive outcome:

» **High Rate of Acceptance** of the MCDA instrument

» **Stakeholders recognition** on:

>Potential for improved decision making

>Ease of process (with limited resources)

>Benefit of bridging multi-stakeholders view in transparent

External influencing factor:

» **Pharma-Political situations:** slows the process for piloting and implementation (e.g., Kazakhstan)

Next steps:

» Supporting Processes (Good Practice) for **Full Implementation**

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Realization in a Developing Country Environment

MCDA Implementation: Real-life Application in Emerging Markets

Prof. Diana Brixner, PhD, RPh, FAMCP

Executive Director, Pharmacotherapy Outcomes Research Center, Department of Pharmacotherapy, Univ. of Utah, Salt Lake City, USA

Immediate Past President Academy of Managed Care Pharmacy

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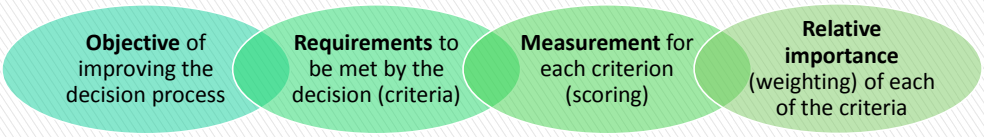
No One Solution Fits all in Emerging Markets – Each Phase of the MCDA May be Tailored

A standard MCDA development process can be applied to:

- **>Define the problem**
- **>Identify-stakeholders**
  (e.g., Policy makers, Academics, Budget holders, Patients, Providers, Insurances, manufacturer associations)
- **>Develop consensus among the stakeholders on:**



- >Agree on a **meaningful pilot** for validation
- >Confirm **additional steps required to implement MCDA** in the decision process

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Incorporating the Output of MCDA Process into Real-life Applications

Pilot phase validation, improvement and expansion with continued stakeholder consensus

Scientific dissemination of the process
- Presentations
- White Paper
- Manuscripts

Periodic review of MCDA tool to accommodate evolving policy

Full transparency of MCDA criteria to increase reliance on the process for policy decisions

Quality Assessment: Assure process is applied fairly and accurately across technologies, companies and disease areas

PRACTICALITY: Support the users in applying the Tool in their daily decision practice

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Enabling Transparent, Multi-Criteria-Based Decisions

The **Evidence Framework for Off-Patent Pharmaceutical Review** (EFOR) provides value-based criteria for health authorities in emerging markets to support transparent choices (pricing, reimbursement, formulary listing, drug procurement)

Supporting Payer and Manufacturer Insight on MCDA for OPP in Emerging Markets

Facilitate the Use of the Decision Model in Practice

- Minimize the effort of evidence collection
- Maximize the standardization
- Maximize the transparency to all stakeholders

EFOR: Evidence Framework for Off-Patent Pharmaceutical Review

The EFOR "Base Case" Defines 9 Criteria and Provides a Simple Scoring Scale for Each Criterion

» Nine high-priority evaluation criteria in 4 categories (Product, Manufacturer, Service, and Value Assessment)

» The template has an open source format, which allows health authorities to adapt criteria, weighting, and scoring to their specific country's healthcare priorities because

Product Category	Manufacturer Category	Service Category	Value Assessment Category
Equivalence with the Reference (Original) Product	Quality Assurance	Pharmacovigilance	Pharmaceutical Acquisition Costs
Pharmaceutical Technology	Supply Track Record	Value-Added Service Related to the Product	Real World Patient Outcomes and Costs
	Macroeconomic Benefit (Local Investment)		

Source: Brixner D, Maniadakis N, Kaló Z, Kim K, Wijaya K. An Evidence Framework for Off-Patent Pharmaceutical Review (EFOR) for Health Technology Assessment in Emerging Markets. Value in Health Regional Issues. 2018;15

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The EFOR Submission Dossier for Manufacturers

1.0 Executive Summary
- Summary Template
- Self Scoring

2.0 Product Description
- 2.1 Disease Description, Incidence, and Prevalence
- 2.2 Product Description and Place in Therapy
- 2.3 Current Treatment Options

3.0 Evidence: Product Criteria
- 3.1 Equivalence with the Reference (Original) Product
- 3.2 Pharmaceutical Technology

4.0 Evidence: Manufacturer Criteria
- 4.1 Quality Assurance
- 4.2 Supply Track Record
- 4.3 Macroeconomic Benefit (Local Investment)

5.0 Evidence: Service Criteria
- 5.1 Pharmacovigilance
- 5.2 Value-Added Service Related to the Product

6.0 Evidence: Value Assessment Criteria
- 6.1 Pharmaceutical Acquisition Costs
- 6.2 Real World Patient Outcomes and Costs

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The Scoring Scale Allows for Consistent Assessment and Comparison of OPPs

» Scoring

3.1 Equivalence with the Reference (Original) Product
- » No data on pharmaceutical equivalence (exclusion criterion)
- » Bioequivalence proven based on local criteria
- » *Bioequivalence proven based on European EMA or US FDA criteria*
- » Pharmaceutical equivalence
- » Therapeutic equivalence proven in clinical trial
- » Improvement in efficacy and/or safety based on clinical trial data

4.3 Macroeconomic Benefit (Local Investment)
- » The manufacturer has no local investment in the country
- » The manufacturer has minor local investment in the country
- » The manufacturer has moderate local investment in the country
- » *The manufacturer has significant local investment in the country*

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Conclusion

- With a focused set of MCDA criteria, a structured submission template such as EFOR can be readily understood and adapted for implementation in any market.
- The EFOR improves communication between manufacturers, healthcare providers and health authorities.
- A consistent list of criteria will help to establish reliable decision-making, accountability, and transparency within the market.
- Better decision-making will improve the quality of health-care for a country's population in balance with the need for affordability.
- The EFOR format will be available as an open source dossier template to allow Health authorities to adapt the EFOR criteria for their market.

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Moderators: **Anke-Peggy Holtorf**, Health Outcomes Strategies / Switzerland

Panel Discussion

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