DEVELOPMENT OF MULTIPLE CRITERIA DECISION ANALYSIS FRAMEWORK FOR OFF-PATENT PHARMACEUTICALS DECISION MAKING IN VIETNAM

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Introduction

Off-patent pharmaceuticals (OPP), which include off-patent originators, branded generics, and International Non-proprietary Name (INN) generics, have a critical role in maximizing the efficiency of the public healthcare system through improved accessibility of patients to affordable medical therapies. In Vietnam, the majority of patients are treated by OPP (more than 80%) [1], therefore, a value-based methodology, that considers both improved outcomes and affordability, for patients treated by OPP can significantly contribute to the efficient use of scarce health care resources [2].

Vietnam plans to achieve public health insurance access for 90% of the population by 2020. The new pharma law, which was effective in January 2017 is intended to drive better patient access and quality improvement in Vietnam. One of the important components of the patient access process is the Drug Purchasing (tender) procedure which is intended to support the National Reimbursement Drug List procurement. This tender process in Vietnam has been performed using a categorization approach which differentiates between quality standards of OPPs. Within each category, tender evaluation is mainly based on price (70-80%) and other criteria (20-30%) [3][4]. However, deliberate consideration of the critical parameters in the current methodology can be improved, such as Pharmaceutical Equivalence (PE), Bio-Equivalence (BE), competency of manufacturing of suppliers, supply reliability and local investment as well as guidance to ensure these criteria are evaluated in the provincial and hospital tender process.

This interest in a more objective process to consider the priority and weight of the criteria for categorization motivated the consideration of value-based Multiple Criteria Decision Analysis (MCDA) in the drug procurement process. MCDA is a method aimed to support decision makers in evaluating alternatives, while considering multiple and sometimes conflicting criteria. Each criterion has a weight reflecting its relative importance within the decision context. The subject of the evaluation is scored according to performance within each criterion. The aggregated scores for each criterion is multiplied by the relative weight resulting in a composite score. The scores of the alternative options are then compared. MCDA has been used widely to inform decision making in healthcare, including benefit-risk assessment of medicines and shared decision making between patients and physicians [7,8]. The application of MCDA in off-patent drug decision-making has now been considered in China and Egypt [1,2]. Furthermore, research has been conducted by the International Outcomes Research Board (IORB), representing policy and health economic experts from emerging and developed markets from around the world, to identify 22 criteria to evaluate OPP in drug decision making.

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(pricing, reimbursement, formulary listing and drug procurement) [2]. These 22 criteria were further reviewed for potential overlap or double counting which resulted in 9 final criteria as value-based MCDA for OPPs drug decision making. MCDA is a highly recommended methodology for drug decision making for Emerging Markets, specifically for countries which have not yet implemented consistent standards for generic product evaluation (such as PE and BE) to address medicine access, quality and affordability. [2]

**Methods**

On July 13th, 2017, a workshop on the application of MCDA in Vietnam was organized by the Ministry of Health, the International Quality Generics Group (IQGx) and EuroCham. The workshop consisted of introduction of the concept and sharing of international best practice of using MCDA for OPP reimbursement decisions. Furthermore, the potential application area and action plan for MCDA in Vietnam was also discussed with key 20 invited stakeholders involved in the healthcare decision making (pricing, reimbursement, formulary listing and drug procurement) of OPPs for Vietnam. Customized pre-reading material was developed and circulated among participants prior to the workshop.

**Results**

Participants of the workshop consisted of 19 key stakeholders from the Ministry of Health (18) which consists of the Drug Administration of Vietnam (DAV), the Health Economics Association, the National Centralized Drug Procurement Center, the Finance and Planning Department, the Medical Service Administration Department, the Health Insurance Department and Vietnam Social Security (1).

An initial set of MCDA criteria was presented and discussed among all stakeholders. This was followed by a presentation of how the process is conducted. Further discussion involved who the appropriate representatives would be from which organizations to conduct the actual criteria selection, weight and scoring for reimbursement decisions.

**Table 1. Initial MCDA, Definition and Performance Categories (Outcome)**

<table>
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<tr>
<th>Name of criterion</th>
<th>Intended definition</th>
<th>Performance categories</th>
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| Equivalence with the reference (original) product | to capture evidence on health outcomes from pharmaceutical-, bioequivalence- and clinical trials (efficacy data from controlled clinical settings) | - No data on pharmaceutical equivalence  
- Pharmaceutical equivalence  
- Interchangeability defined based on local criteria  
- Bioequivalence proven based on local criteria  
- Bioequivalence proven based on European EMA or US FDA criteria  
- Therapeutic equivalence proven in clinical trial  
- Improvement in efficacy and/or safety based on clinical trial data |
<table>
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<tr>
<th>Category</th>
<th>Real world clinical or economic outcomes such as adherence or non-drug costs</th>
<th>Product stability and drug formulation</th>
<th>Quality assurance</th>
<th>Macroeconomic benefit</th>
<th>Reliability of drug supply (history and future guarantee)</th>
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<td>to capture evidence on health outcomes (effectiveness) and costs from real-world data</td>
<td>to capture evidence on stability and drug formulation</td>
<td>to capture evidence on manufacturing- and product quality-, and standardisation</td>
<td>to capture wider economic benefits of selecting the medicine (e.g. tax, investment, employment etc.)</td>
<td>to capture the stability and reliability of drug supply (history and future guarantee)</td>
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<td>- No real world data on equal a) tolerability, b) adherence and persistence, c) non-drug cost</td>
<td>- No data on product expiry or stability</td>
<td>- Limited information on quality assurance</td>
<td>- The manufacturer has no local investment in the country</td>
<td>- Major and multiple problems in the last 5 yrs</td>
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<td>- International real world data on either equal a) tolerability, b) adherence and persistence, c) non-drug cost</td>
<td>- Data on non-inferior product expiry or stability in local environment</td>
<td>- Local/non GMP quality assurance only for active product ingredient</td>
<td>- The manufacturer has minor local investment in the country</td>
<td>- Minor and fairly frequent problems in the last 5 yrs</td>
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<td>- Local real world data on either equal a) tolerability, b) adherence and persistence, c) non-drug cost</td>
<td>- Data on improved product expiry</td>
<td>- Local/non GMP quality assurance for the entire manufacturing process</td>
<td>- The manufacturer has moderate local investment in the country</td>
<td>- Single precedence of supply problems in the last 5 yrs</td>
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<td>- International real world data on improvement in a) tolerability, b) adherence and persistence, c) non-drug cost</td>
<td>- Data on improved product stability in local environment</td>
<td>- WHO GMP certification</td>
<td>- The manufacturer has significant local investment in the country</td>
<td>- No precedence of supply problems in the last 5 yrs</td>
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<tr>
<td></td>
<td>- Local real world data on improvement in a) tolerability, b) adherence and persistence, c) non-drug cost</td>
<td>- Data on improved product expiry and stability in local environment</td>
<td>- EU or PIC/s GMP</td>
<td>- Manufacturer is financially capable and willing to guarantee supply</td>
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Discussion

Participants from multiple affiliations confirmed the importance of adopting this MCDA methodology in drug decision making in Vietnam, especially for the drug procurement (tender) process. The relevance of the MCDA methodology implementation was highlighted to improve the tendering process by reflecting on current issues and to improve consistent access of quality medicines across the nation. Participants also suggested an improvement in the clarity of requirements of submitting dossiers from manufacturer to tender authorities with regard to the OPP reimbursement process. The development of a framework (including but not limited to tender committee selection, criteria selection, weighting and scoring) was considered important in improving tender practice. Such a framework is currently in development and called the Emerging Market Framework Off-Patent Pharmaceutical Review (EFOR). Once the process of criteria selection, weighting and scoring has been completed in Vietnam the EFOR will be customized for manufacturers submitted tenders for this country.

Conclusion and Recommendation

Following the discussion among representatives during the Conference, the MCDA framework is strongly recommended for adoption to support Vietnam Drug Decision Making, especially in the Drug Procurement (tender) process. Committee member finalization, criteria selection, criteria weighting and criteria scoring for tender decisions were proposed as the next step followed by a customized framework for manufacturers to present their products for consideration.

References


3. Vietnam Pharma Law 2017

4. Degree 63/2014/ND-CP guiding the Tender Law

5. Thokala P. *Multiple criteria decision analysis for health technology assessment*. Sheffield, UK: School of Health and Related Research, University of Sheffield, 2011.

