

A Multi-Criteria Decision Analysis (MCDA) Tool for Purchasing Off-Patent Oncology Drugs in Egypt

Baher Elezbawy¹, Ahmad Fasseeh^{1,2}, Amal Sedrak³, Randa Eldessouki⁴, Mary Gamal³, Mariam Eldebeiky³, Hanaa Amer⁵, Shimaa Akeel³, Ahmad Morsy⁶, Amira Amin⁷, Amr Shafik⁵, Sherif Abaza⁸, Zoltán Kaló^{9,10}

1. Syreon Middle East, Alexandria, Egypt
2. Eötvös Loránd University, Budapest, Hungary
3. The Egyptian Authority for Unified Procurement, Medical Supply, and The Management of Medical Technology (UPA), Cairo, Egypt
4. Fayoum University, Fayoum, Egypt
5. Ain Shams University, Cairo, Egypt

6. Presidential Program for Women's Health, Ministry of Health and Population (MoHP), Cairo Egypt
7. Egyptian Pharmaceutical Vigilance Center, Egyptian Drug Authority (EDA), Cairo, Egypt
8. Syreon Middle East, Cairo, Egypt
9. Semmelweis University, Budapest, Hungary
10. Syreon Research Institute, Budapest, Hungary

INTRODUCTION

There are significant differences in the fundamental attributes of healthcare alternatives, therefore selecting the best alternative is a hard decision and could be subjective. Considering that Egypt is aiming to achieve universal health care by year 2030, multi-criteria decision analysis can be used as an evidence-based decision-making tool to evaluate and rank off-patent pharmaceuticals in an objective way.

OBJECTIVE

To develop an MCDA tool to be used by the Egyptian Authority for Unified Procurement (UPA) for tendering among off-patent oncology drugs.

METHODS

An initial list of criteria was curated through a literature review followed by local expert interviews. Later a workshop hosting diversified stakeholders representing different governmental bodies was conducted to rank the criteria and weigh them according to their relative importance. Furthermore, the scoring functions of each criterion were voted on. The tool was then tested in local settings to assess its performance and was adjusted accordingly.

RESULTS

Criteria

The initial list included 13 criteria. After discussion with the experts, the criteria were narrowed down to seven non-price criteria. Each criterion had a score from 0% to 100% based on participants’ consensus. Final criteria and their scores are presented in Table 1.

Table 1 List of criteria with scoring functions

Criteria name	Possible scoring elements	Score (%)
Use in reference countries	Pharmaceutical has an FDA or EMA certificate	100%
	Pharmaceutical is used in any of the reference countries	70%
	Pharmaceutical is not used in any reference country and doesn't have FDA or EMA certificate	20%
	Pharmaceutical is not marketed in its country of origin	EXCLUSION
Equivalence with the reference product	Bioequivalence is proven through clinical trials or real-world evidence	100%
	Intravenous dosage form OR Bioequivalence proven through FDA or EMA	80%
	Local bioequivalence certificate (Only for non-IV dosage forms)	50%
	Pharmaceutical equivalence certificate only	20%
Manufacturing quality	WHO or PIC/s GMP certificate for both API and final product	100%
	WHO or PIC/s GMP certificate for API or final product and the other certificate from another source	70%
	GMP certificate for both API and final product from another source than WHO or PIC/s	40%
	No GMP certificates	EXCLUSION
Pharmacovigilance	A percent of pharmacovigilance measures fulfillment to be provided for each product based on the pharmacovigilance unit report	(0%-100%)
Supply reliability	No supply reliability issues during the previous 2 years	100%
	Supplier has 75% or more reliable supplies during the previous 2 years	80%
	Supplier has 50% - <75% reliable supplies during the previous 2 years	60%
	Supplier has 25% - <50% reliable supplies during the previous 2 years	30%
	No previous supply	20%
	Less than 25% supply reliability during the previous 2 years	EXCLUSION
Previous use in local settings	Pharmaceutical is in the local market for 5 or more years, and has won 4 or more governmental tenders during the last 3 years	100%
	Pharmaceutical is in the local market for less than 5 years, and has won 4 or more governmental tenders during the last 3 years	80%
	Pharmaceutical is in the local market for 5 or more years, and has won less than 4 governmental tenders during the last 3 years	60%
	Pharmaceutical is in the local market for less than 5 years, and has won less than 4 governmental tenders during the last 3 years	20%
	Pharmaceutical is in the local market for less than 3 years, and has not won any governmental tender during the last 3 years	0%
Macroeconomic benefit	The company has full manufacturing in Egypt	100%
	The company has only a packaging factory in Egypt	70%
	The company has no factory in Egypt	30%

Ranking

The final seven non-price criteria were ranked according to their importance based on the average votes as follows 1) use in reference countries, 2) equivalence with the reference product, 3) manufacturing quality, 4) pharmacovigilance services, 5) supply reliability, 6) previous use in local settings, 7) macro-economic benefit.

Weights

After ranking the criteria, a weight was given for each criterion based on participants votes in which “use in reference country had the highest weight of 23.49% and the criterion with the least weight was “macro-economic benefit” accounting for 8.67%. (Table 2)

Table 2 Criteria weights

#	Criteria	Weight
1	Use in reference countries	23.49 %
2	Equivalence with the reference product	18.79 %
3	Manufacturing quality	15.53 %
4	Pharmacovigilance services	12.94 %
5	Supply reliability	10.78 %
6	Previous use in local settings	9.80 %
7	Macro-economic benefit	8.67 %

Threshold

To ensure the quality of the product, a threshold was set in which any product having a score less than the threshold is excluded. It was set to be 60 points based on the voting however, after testing the MCDA tool in local settings it was modified to be 65 points.

Price criterion

The price criterion was not added to the MCDA tool to conform to the current tendering process. It was added as a separate step after using the MCDA tool and providing an overall score for each pharmaceutical. The financial committee then chooses the option which provides the lowest price per point.

Pharmacovigilance

The pharmacovigilance unit in the Egyptian Drug Authority (EDA) will provide a fulfillment score for each comparator to be incorporated in the MCDA tool. Sixty percent of the score is based on the pharmacovigilance system responsible for the product, and 40% of the score is related to the product itself.

Final tool

After testing the MCDA tool in the local settings and implementing the final modifications, the tool was developed in its final format. The final MCDA tool is a Microsoft Excel form that has a dropdown list for different scoring elements of pharmaceuticals. It automatically calculates the score for each pharmaceutical based on the inputs provided and compares performance using numbers and figures.

CONCLUSION

The tool is capable of comparing off-patent oncology drugs with the same active constituent by considering several criteria, with objective scoring functions. It provides a technical score for each comparator, then in the financial phase of the tender, the cost per point is evaluated. The one that provides the cheapest price per point is selected. The developed MCDA tool puts the highest emphasis on product quality, and considerable weight on post-marketing surveillance, and consistency in supply.

References:

Thokala, P., Devlin, N., Marsh, K., Baltussen, R., Boysen, M., Kalo, Z., ... & Ijzerman, M. (2016). Multiple criteria decision analysis for health care decision making—an introduction: report 1 of the ISPOR MCDA Emerging Good Practices Task Force. *Value in health, 19*(1), 1-13.

Brixner, D., Maniadakis, N., Kaló, Z., Hu, S., Shen, J., & Wijaya, K. (2017). Applying multi-criteria decision analysis (MCDA) simple scoring as an evidence-based HTA methodology for evaluating off-patent pharmaceuticals (OPPs) in emerging markets. *Value in health regional issues, 13*, 1-6.

Inotai, A., Brixner, D., Maniadakis, N., Dwiprahasto, I., Kristin, E., Prabowo, A., ... & Kalo, Z. (2018). Development of multi-criteria decision analysis (MCDA) framework for off-patent pharmaceuticals—an application on improving tender decision making in Indonesia. *BMC health services research, 18*(1), 1-12.

Le Tuan, P., Kiet, P. H. T., Brixner, D., & Ngo, V. H. Development Of Multiple Criteria Decision Analysis Framework For Off-Patent Pharmaceuticals Decision Making In Vietnam.