

National Drug Formulary of the Ministry of Health in Saudi Arabia

Yousef Ahmed Alomi,  The Former General Manager of General Administration of Pharmaceutical Care, The Former Head, National Clinical pharmacy and pharmacy practice, The Former Head, Pharmacy R and D Administration, Ministry of Health, Riyadh, SAUDI ARABIA.

Saeed Jamaan Alghamdi, General Administration of Pharmaceutical Care, Ministry of Health, Riyadh, SAUDI ARABIA.

Radi Abdullah Alattyh, General Administration of Pharmaceutical Care, Ministry of Health, Riyadh, SAUDI ARABIA.

Correspondence:

Dr. Yousef Ahmed Alomi,
The Past General Manager of General Administration of Pharmaceutical Care, The Past Head, National Clinical Pharmacy and Pharmacy Practice, The Past Head, Pharmacy R and D Administration, Ministry of Health, Riyadh, SAUDI ARABIA.

Phone no: +966504417712
E-mail: yalomi@gmail.com

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ABSTRACT

Objective: To explore the Ministry of Health drug formulary system at the Ministry of Health foundations in the Kingdom of Saudi Arabia. **Method:** It is description analysis of Ministry of Health drug formulary system at Ministry of hospitals and primary healthcare centers. It analysis illustrated within the Pharmacy strategic plan 2012-2020. The analysis process used. The modified pharmacy business model system and Project Management Procedure. **Results:** Ministry of Health drug formulary system established with clear vision, mission and goals. The project had human or economic and other resources described in the review. To assure the continuity of the system; the risk management was used and described. Besides, the monitoring and controlling of the system as illustrated. The closing stage with convention to operation project demonstrated in the Analysis. **Conclusion:** The Ministry of Health drug formulary system founded and it is considered as part of Pharmacy strategic planning and regulations. The Ministry of Health drug formulary has normal development accordingly at all Ministry of Health institutions in the Kingdom of Saudi Arabia.

Key word: Drug, Formulary, Ministry of Health, Saudi Arabia.

INTRODUCTION

According to the ASHP, drug formulary is defined as a list of the drugs that should be available in the hospital pharmacy 24/7.¹ There are several benefits of maintaining drug formulary at the hospital pharmacy.² Maintaining a drug formulary became mandatory by national and international accreditation standards.^{3,4} Several studies have reported on the process of addition or deletion of medications to a drug formulary.^{5,6} However, to the best of our knowledge, there are no studies describing the drug formulary of the Ministry of Health (MOH) in any country. Therefore, in this study, we aimed to explore the national drug formulary of MOH in the Kingdom of Saudi Arabia (KSA).

The MOH in the KSA published several editions on MOH drug formulary starting from the first edition in 1977 to the last edition in 2014 (Appendix 1).⁵ The drug formulary must include names of all medications, vaccines, chemical substances, dialysis solutions for hemodialysis or peritoneal dialysis, radiopharmaceuticals and insecticides. The MOH's drug formulary lists medications from more than 250 hospitals and 2500 PHCs. It also includes names of more than 1500 line items, which gets updated annually. The MOH has published two updated editions to date. MOH's drug formulary needs a formulary system to control the distribution of drugs to hospitals and PHCs. The system includes several things including a list of drugs especially designed for PHCs, with drug classification according to the level of PHC and prescribing privilege system. Moreover, it includes a list of drugs especially designed for the hospitals with the privilege of prescription based

on the specialties. Some medications are restricted for use in some hospitals such as nuclear medicine line radiopharmaceutical and dialysis solution for artificial kidney centers only with a particular privilege. The public health administration at MOH has the prescribing privilege for insecticide. In addition, the GAPC in collaboration with the medical department of the MOH designed some treatment protocols with first- and second-line treatment choices based on evidence-based medicine and pharmacoeconomic concept. In this study, the authors aimed to explore the Drug formulary at MOH hospitals Saudi Arabia.

MATERIALS AND METHODS

Method of Development of the Project

The drug formulary task force committee consists of expert people from the pharmacies of the MOH hospital, PHCs and the dental centers to set up a national drug formulary. The first author of this article headed the drug formulary committee; he conducted regular periodical meetings. The committee unitized and drove the pharmacy drug formulary of the GAPC and some development at non-MOH hospitals. Besides, the using the international business model, pharmacy guidelines, project management institution guidelines of a new project.⁷⁻¹⁰ The draft was sent to several reviewers of the RAPC. The draft was corrected and updated continuously. Then, the second draft was submitted to the re-

viewers again for their final comments and approval, which took around 2 months to complete the task. The General Administration of Pharmaceutical Care (GAPC) at the MOH sent the final document to all the hospitals for implementation. The drug formulary consisted of the following phases: the initial phase, planning phase, execution phase, monitoring and controlling phase.

Initial Phase

Assessment Needs

A drug formulary is one of the essential requirements of a hospital's pharmacy services. It is a list of drugs that should be available for patients 24/7. The national drug formulary at MOH should include all medications at the general administration of medical supply drug list for procurement and purchases. To prevent any misuse of medications, it is mandatory to place a request to add or delete medications from drug formulary. The central drug formulary needs to perform unified purchase of medications and get the best prices for medications. The number of drug information services were few and it was challenging to coordinate or established the hospital drug formulary.

SWOT Analysis

In this project, we performed a SWOT analysis. The strengths of this project were unified formulary for all MOH institutions, control of addition or deletion medications used in the healthcare institutions and prevent the additional cost of group purchasing. The weak points were a long time taken to add or delete medications and prevention of competition in medications. The opportunities for this project were the implementation of local and international accreditation standards and monitoring of cost management. The threats in this project will be privatized healthcare institutions and the removal of group purchases at MOH institutions.

Market Analysis

Most of the hospitals have drug formulary, including MOH and non-MOH hospitals and private hospitals. Few groups of hospitals have unified drug formulary, for instance, King Abdulaziz Medical City, Military some group non-MOH hospitals. The MOH drug formulary had the most significant number of the hospitals with unified drug formulary.

Planning Phase

The Scope of the Project

The scope of this project is the establishment of the MOH drug formulary, the method of addition and deletion medications and the future suggestions for New Saudi Vision 2030.

Vision, Missions, Goals

The vision of this project is to prepare the best and updated MOH drug formulary for all institutions in the KSA. The mission of this project is to provide the MOH drug formulary for hospital and PHCs in addition to specialized medical centers and medical cities. The goals of this project were to establish, update and implement a unified MOH drug formulary for the addition and deletion of medications to the MOH drug formulary.

Project Description

All pharmacists and healthcare providers should follow the policy in evaluating medications for inclusion in the formulary.

1. If any caregiver in the MOH hospital/PHC needs to add or delete any medication or nutrition support products, then he/she should fill the formulary addition drug request form.

2. The caregiver should utilize the formulary addition drug request form (Appendix 1) and complete the following information:

- Drug name
- Therapeutic class
- Dosage form and strength

- Clinical pharmacology and pharmacokinetics
 - FDA-approved indications
 - Non-FDA-approved indications
 - Adverse drug reactions
 - Drug InteractionsPotential errors
 - Rationale for addition
 - Literature review (cite major trials only), which includes pharmacoeconomic literature and summarized findings (if available).
 - Place in therapy: comparison of formulary agents including therapeutic advantages over drugs currently on the formulary/safety advantages/drugs that could be considered for deletion.
 - Comparative therapy
 - Indicate the estimated annual acquisition costs (savings) for this new drug by the program
 - Name, profession, address, phone number and signature.
3. The caregiver should obtain approval and signature from the hospital's PTC and from the regional pharmacy and therapeutic committee.
 4. The form should be sent to corporate PTC for final approval.
 5. If the drug approved is to be added to the MOH's drug formulary, then the medicine should be ranked based on the therapeutic category and its cost.

Plan Cost Management

The project needs financial support for the publication of the drug formulary. They need financial support for drug information resources during the process of addition or deletion of medications from the drug formulary. Moreover, the education and training courses for stakeholders and management team members require costs for awareness and to update policies and procedures.

Executing Phase

Management Team

The management team responsible for the follow-up of the MOH's drug formulary was drug information committee. The central committee designed through GAPC at MOH, the committee consisted of representatives from each region specialized in the drug information center. Another regional committee established for each region consisted of representatives from each hospital and group PHC. All committees had a monthly meeting to discuss several things related to the drug information center issues including the MOH drug formulary addition and deletion, prepare drug evaluation for regional PTC, any update regulation for MOH formulary.

Education and Training

On a regular basis, the education and training courses should be conducted for drug information pharmacists, for drug formulary team management. In addition, other awareness courses for healthcare staff of addition and deletion medications from MOH drug formulary.

Risk Management

There are six types of risks: budget risk, scope risk, personal risk, schedule risk, technical risk and quality risk. The project might experience most of the risks such as budget, personnel, schedule and quality risks. The budget risk is related to the unavailability of the budget for publication of the drug formulary. The project might be exposed to personal risks such as lack of qualified and specialized pharmacist. In addition, the MOH drug formulary members might not have received education and training related to the project or drug evaluation procedures. The project might experience scope risks due to the lack of training of members about MOH drug formulary scopes and functions or to expand the goals of training beyond the scope of the project. The project may be

exposed to schedule risks with the delay in publishing the drug formulary at the convenient timing or may not be published at all. The project may be quality risks due to a nonqualified pharmacist being available and training in the quality pharmacy tools to drug formulary documentation or measurement or monitoring tools. The project may be exposed to technical risks such as the unavailability of the electronic system of drug formulary with friendly use.

Monitoring and Controlling Phase

Project Quality Management

To follow the project for compliance of policies, procedures and improvements, the required outcomes, several Key Performance Indicators (KPIs) should be implemented. For instance, the number of additions or deletions of medications, number of revision drug formulary, assessment of drug evaluation policies and procedures and number of the memo of awareness of new medications.^{11,12}

The Closing of the Project

The drug formulary at MOH institution is a critical tool to control the cost of drugs and prevent misuse of medications in the KSA. The annual report of MOH drug formulary should be prepared. Education and training courses to healthcare providers should be conducted regularly about updating of new medications and drug regulation. Furthermore, a cost avoidance of control and prevention of drugs misuse should be implemented in the future. Annual celebration with involving members of the project can be planned.

ACKNOWLEDGMENT

None.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

ABBREVIATIONS

ASHP: American Society of Health-System Pharmacist; **KSA:** Kingdom of Saudi Arabia; **MOH:** Ministry of Health; **PTC:** Pharmacy and Therapeutic Committee; **RAPC:** Regional Administration of Pharmaceutical Care; **GAPC:** General Administration of Pharmaceutical Care.

ORCID ID

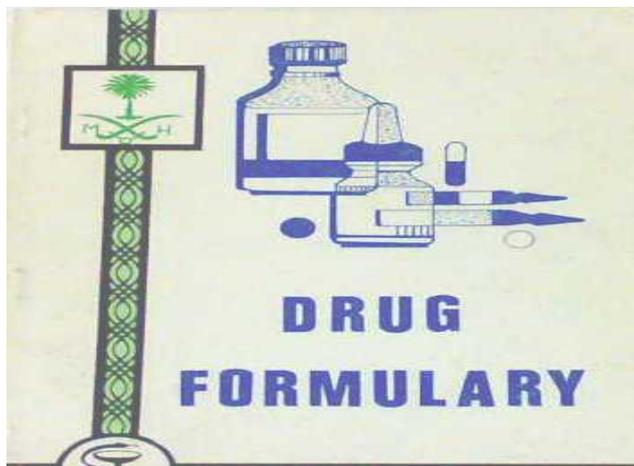
Yousef Ahmed Alomi  <https://orcid.org/0000-003-1381-628X>.

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Appendix 1

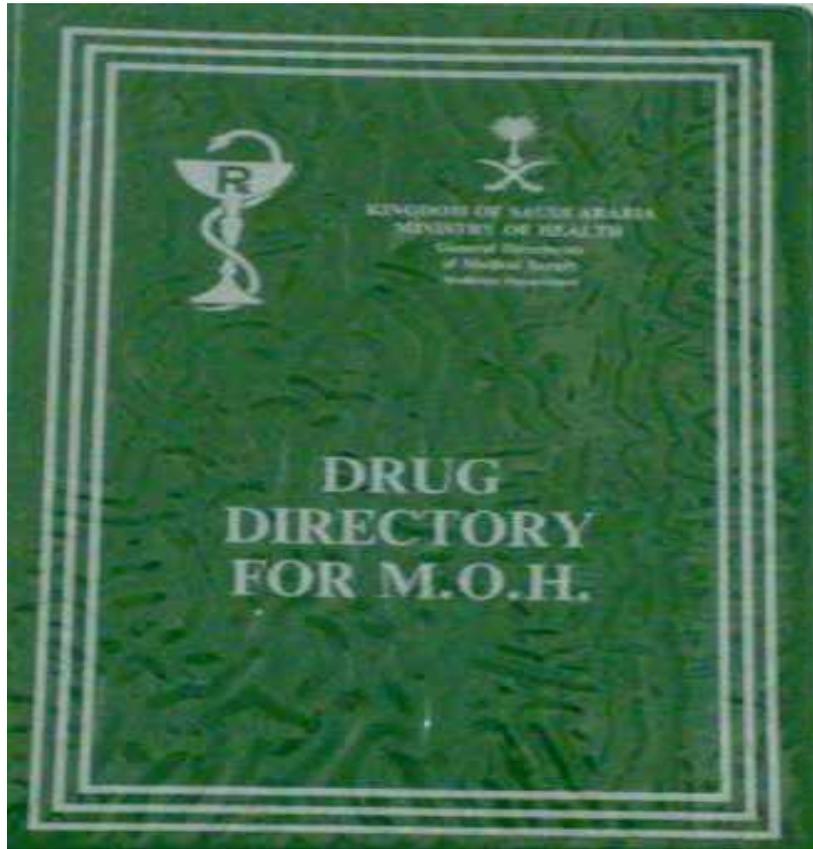
1st Edition in 1399H-1977M.



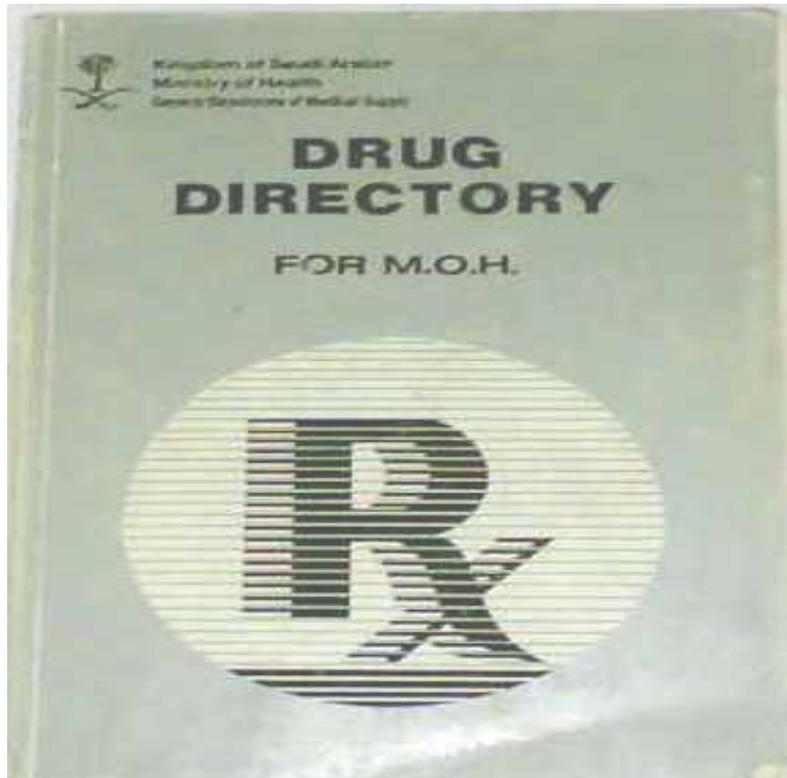
2nd Edition in 1401H-1980M.



3rd Edition in 1405H-1984M.



4th Edition in 1410H-1989M



FORMULARY ADDITION REQUEST FORM DRUG EVALUATION and ECONOMIC ANALYSIS

Important:

All information requested on this form must be filled out completely and referenced by published scientific articles or it will be returned to requesting health care professional. Pharmaceutical company promotional literature is not acceptable. No action will be taken on forms that are submitted incomplete.

- Full drug evaluation should be attached
- Drug Used evaluation should be attached once the requisition is for addition.

Requested by:

Drug Name:

Proprietary Name:

Therapeutic Classification:

Manufacturer:

Dosage Form:

Clinical Pharmacology and Pharmacokinetics:

FDA, (others) Approved Indications:

FDA, (others) Recommended dose and Approved Route of administration:

Adverse Effects:

Drug Interactions:

Potential for Error:

Include published medication safety literature

Rational for Addition / Change:

Literature Review (cite major trails only):

Include Pharmacoeconomic literature and summarize findings (if available).

Place in Therapy:

Comparison to formulary agents including: therapeutic advantages over drugs currently on formulary / safety advantages / drugs that could be considered for deletion.

Comparative Therapy:

Generic Name (Manufacturer)	Dose	Cost / Unit	Usage in Previous Year	Total Cost
<i>Requested Drug</i>				
<i>Comparator Drug # 1</i>				
<i>Comparator drug # 2</i>				

Hospital Pharmacy and Therapeutic Committee:

▪ رئيس قسم الصيدلية ▪ عضو اللجنة ▪ عضو اللجنة

▪ رئيس اللجنة

Regional Pharmacy and Therapeutic Committee:

▪ عضو اللجنة ▪ عضو اللجنة ▪ عضو اللجنة

▪ رئيس اللجنة

Corporate Pharmacy and Therapeutic Committee:

▪ عضو اللجنة ▪ عضو اللجنة ▪ عضو اللجنة ▪ عضو اللجنة

▪ رئيس اللجنة

Recommendations:

Conclusions:

Include budget impact or other cost savings such as lab costs, decreased stay in hospital, labor, if applicable.

(4)

Disclosures:

Include impact or other cost saving such as lab costs, decreased stay in hospital, labor, if applicable

Utility Rank (for Corporate P and T USE ONLY):

Therapeutic:

Rank = 1 if large randomized clinical trials demonstrate clear- cut therapeutic advantage (enhanced efficacy and / or reduced toxicity) over available modalities and use of drug will Lead to clinically significant improvement in patient mortality, morbidity or quality of life.

Rank= 2 if clinical studies indicate therapeutic advantage over available modalities but there Is questionable/ marginal improvement in patient outcome and /or efficacy advantage is somewhat offset by toxicity disadvantage.

Rank= 3 if no therapeutic advantage but secondary chrematistics confer some advantage e.g. dosage form, route/ frequency of administration, pharmacokinetics, convenience).

Cost:

Rank = A if addition of drug will significantly reduce direct cost to hospital

Rank = B if addition of drug will modestly reduce direct costs to hospital

Rank = C if addition of drug will have minimal direct cost impact (i.e., less than 20,000 per year)

Rank = D if addition of drug will modestly increase direct costs to hospital (i.e.,20,000 SR to 60,000 SR per year)

Rank = E if addition of drug will significantly increase direct cost to hospital (i.e., more than 60,000 SR per year)