Hashemite Kingdom of Jordan

Pharmacy and Therapeutics Committees in Jordan

(Recommended Policies to Improve Rational Use of Medicines)

2014

Designed By: JFDA\IT UNIT

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Preface

Irrational use of medicines is a global phenomenon that requires strenuous efforts to reduce the damage caused by this practice. Reports issued by the World Health Organization showed that about 50% of the medicines are improperly prescribed or procured or consumed. Irrational drug use occurs when there is over-prescribing, extravagant prescribing, incorrect prescribing, under-prescribing, and multiple prescribing.

The World Health Organization has recommended several strategies and interventions to promote more rational use of medicine which include: Establishing a mandated multi-disciplinary national body to coordinate medicine use policies; Use of Clinical treatment guidelines; Development and use of national essential medicines list; Establishment of drug and therapeutics committees in districts and hospitals; Inclusion of problem-based pharmacotherapy training in undergraduate curricula; Continuing in-service medical education as a licensure requirement; Use of independent information on medicines; Public education about medicines; Avoidance of perverse financial incentives; Use of appropriate and enforced regulation and Sufficient government expenditure to ensure availability of medicines and staff.

Medicines are an important part of health care in Jordan. Statistics announced by the High Health Council in 2013 has shown that Jordan health expenditure accounted for 7.7% of the GDP and 27% of this spending was on medicines, of which 45% of this spending occurs in the public sector. This has become imperative for everyone to work on finding the necessary legislation for the rational use of drugs, which would achieve a balance between scarce resources on the one hand and the provision of high quality health care on the other.

The steering committee for the Medicine Transparency Alliance (MeTA) has formed technical committee from all relevant sectors to review and update policies for the rational use of medicines; the committee reviewed the policies and regulations for the committees responsible for rational use of medicines in Jordan and developed recommendation on the formation, functions and responsibilities of the pharmacy and therapeutic committees and recommendations on the mechanisms of addition and deletion of medicines to Rational Drug List (RDL) based on the following principles:

- Transparent mechanisms should be followed to the inclusion of medicines within their own lists.
- Efficacy and safety studies in addition to the cost are the basis for the development of essential medicine list

- Complementary cooperation of all health sectors in this national effort will support the implementation of rational medicine use policies.

The work of this committee is summarized in the following:

- Assessment of the pharmacy and therapeutics committees in terms of functions, composition, duties and responsibilities of each committee.
- Reconsideration of the criteria for addition and deletion of medicines from rational drug list.
- Classification of medicines (Unrestricted, Restricted, Authorized) and the need for detailed instructions based on scientific evidences.

On behalf of the Ministry of Health and Jordan Food and Drug Administration, it is my pleasure to endorse this document and the recommended policies to improve rational use of medicines. In addition, I express the Jordanian government's commitment to the Medicine Transparency Alliance phase II in Jordan to improve access to quality medicines for all people in Jordan.

Dr. Ali Hyasat

Minister of Health

Head of JFDA Board of directors

Contents

Members of the Rational Drug Policy Committee

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Dr. Basim Zoubi/ Prince Hamza Hospital

Dr. Raghad Hadidi/ High Health Council

Dr. Taiseer Malkawi / King Abdullah University Hospital

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Dr. Mahmoud Bataineh/ Director General of Joint Procurement Department

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Introduction

Jordan, like all countries, is faced with a difficult problem; how to provide equitable, evidence-based and cost-effective health care within the capacity of a country's ability to pay. Health expenditure accounted for 7.7% of the GDP and 27% of this spending was on medicines, of which 45% of this spending occurs in the public sector. Because of this, rational use of medicines in health care become a pressing issue as Jordan has the challenge of balancing its scarce resources on one hand and providing equitable quality healthcare to its growing population on the other.

Different studies[1],[2],[3] conducted in Jordan emphasized that the problem with rational use of medicines , these problems include poor organization and management of health services at all levels; weakness of the health information system and lack of access to an update unbiased information on the currently used drugs; poor communication between health professional & patient; promotional activities of pharmaceutical industries; over prescribing of antimicrobials; self-medication by the public of prescription drugs, including inappropriate use of antibiotics; poor compliance; lack of patient education about illnesses & drugs; inadequate training & education of medical graduates in good prescribing practice; lack of continuing medical education for doctors & pharmacists, and lack of standard treatment guidelines.

The rational use of medicine strategy in Jordan is highly fragmented. According to legislation, the Rational Drug Use Department within the JFDA is the coordinating entity for activities surrounding the rational use of medicine, including the development of standard treatment guidelines and the updating of the Jordan Rational Drug List and Jordan National Drug Formulary. The rational drug use policy is not fully implemented.

Core strategies to improve medicine use

Several choices exist for interventions to change medicine use practices. These approaches can be characterized as educational, managerial, economic, or regulatory. Whichever approach is used, intervention should focus on specific problem behaviors and should target prescribers, dispensers, facilities, or the public, depending on where the assessment shows the problem lie. A single intervention rarely results in sustainable changes, so a combined strategy is preferred.

[1]Jordan health sector reform project, deliverable 9: A STUDY OF JORDANIAN PRESCRIBING PRACTICE, October 2004

[2]Otoom S, Batieha A, Hadidi H, Al-Saudi K. Evaluation of drug use in Jordan using WHO prescribing indicators. Eastern Mediterranean Health Journal 2002; 8: Nos 4/5

[3]Al-Bakri et al, Community consumption of antibacterial drugs within the Jordanian population: sources, patterns and appropriateness. International Journal of Antimicrobial Agents 26 (2005) 389–395

The core strategies to promote more rational use of medicine:

1. Establishing mandated multi-disciplinary national body to coordinate medicine use policies :

Ensuring rational use will require many activities which will need coordination among many stakeholders. Therefore, a national body is necessary to coordinate policy and strategies at national level, in both the public and private sectors. This should involve government, health professions, academia, pharmaceutical industry, CSOs, consumer groups and national regulatory authority. MeTA Council is a good example of this type of national body, and rational drug use department can facilitate the activities of this national body.

2. Implementing procedures for developing, using, and revising STGs

STGs are systematically developed to help prescribers to make decisions about appropriate treatments for specific clinical conditions.

3. Implementing procedures for developing and revising an essential medicines list (or hospital formulary) based on efficacy, safety, quality, cost and cost-effectiveness.

An essential medicines list makes pharmaceutical management easier at all levels: procurement, storage, and distribution are easier with fewer items, and prescribing and dispensing are easier for professionals.

4. Establishing pharmacy and therapeutics committee in hospitals with defined responsibilities for monitoring and promoting rational drug use .

The committee is responsible for ensuring the safe and effective use of medicines in the facility. The committee should operate independently, and members should represent all the major medical specialties and the administration. The primary tasks of the committee are to develop and revise institutional STGs (based on national guidelines) and to maintain an institutional essential drug list or formulary.

5. Using problem-based training in pharmacotherapy based on national STGs in undergraduate curricula.

The quality of basic pharmacotherapy training for undergraduate medical and paramedical students can significantly influence future prescribing habits. Training is most successful when it is problem based, concentrates on common conditions, takes into account student's level of knowledge, and is targeted to their future prescribing requirements.

6. Continuing in-service medical education as a licensure requirement and targeted educational programs by professional societies, universities, and the government to offer independent, unbiased continuing medical education courses.

7. Developing a strategic approach to improve prescribing in the private sector through regulation and collaborations with professional associations.

A range of strategies should be considered to improve rational medicine use, including licensing regulations with appropriate enforcement, accreditation and continuing education through professionals associations, and financial incentives.

8. Monitoring, supervision, and using group processes to promote rational medicine use .

Effective forms of supervision include prescription audit and feedback, peer review, and group processes of self-identifying medicine use problems and solutions

9. Training pharmacist to offer useful advice to consumers and to establish the consumer's level of understanding of their medication including how to take it and what would happen if they don't taking into account the consumer's literacy and their medication regime.

10. Encouraging involvement of consumer organizations, and devoting government resources to public education about medicines.

Governments have a responsibility to ensure the quality of information about medicines available to consumers. Regulation of consumer advertising and promotion by pharmaceutical companies, as well as public education activities led by consumer organizations, may influence medicine use by the public.

11. Appropriate and enforced regulation

The following are some of the regulatory measure to support rational drug use:

-Registration of medicines to ensure that only safe efficacious medicines of good quality are available in the market;

-Limiting prescription of medicines by level of prescriber; this includes limiting certain medicines to being available only with a prescription and not available over-the-counter;

-Setting educational standards for health professionals and developing and enforcing codes of conduct; this requires the cooperation of the professional societies and universities;

-Licensing of health professionals – doctors, nurses, paramedics – to ensure that all practitioners have the necessary competence with regard to diagnosis, prescribing and dispensing;

-Licensing of medicine outlets – retail shops, wholesalers to ensure that all supply outlets maintain the necessary stocking and dispensing standards;

-Monitoring and regulating medicine promotion to ensure that it is ethical and unbiased. All promotional claims should be reliable, accurate, truthful, informative, balanced, and up-to-date.

1. Hospital Pharmacy and Therapeutics Committees (HPTC)

1.1 Goal:

The goal of a HPTC is to ensure that patients are provided with the best possible cost-effective and quality of care through rational and cost-effective drug use through collaborative drug management involving all health workers use of medicines, addressing drug-related problems in the hospital and Improving health and economic outcomes of hospital care, particularly those related to drug use.

1.2 Domain:

1. Ministry of Health hospitals and Prince Hamzah Hospital.
2. Royal Medical Services hospitals
3. Jordan University Hospital
4. King Abdullah University Hospital
5. King Hussein Cancer Center
6. Any hospital followed by the public sector

1.3 Members and composition of the HPTC committee

The hospital pharmacy and therapeutics committee shall be formed in each hospital in the Ministry of Health and Royal Medical Services by the decision of the hospital director and headed by qualified and experienced internal medicine specialist with acclaimed professional skill, integrity and responsibility. The committee secretary will usually be the pharmacist. The hospital director appoints the other committee members with reference to their positions and responsibilities and they should have defined terms of reference. In most hospitals, the membership includes:

1. Surgeon
2. Gynecologist
3. Pediatrician
4. Head of pharmacy department
5. Clinical pharmacist or doctor of pharmacy,
6. Head of nursing department
7. Head of quality unit
8. Internist
9. Chairman of the infection control committee.

- Hospital pharmacy and therapeutics committee at university hospitals and the King Hussein Cancer Center are the Central Committee of pharmacy and therapeutics.
- Committee shall elect a vice-president at its first meeting from among its members and the committee secretary will be the head of pharmacy department.
- Members (1, 2, 3, and 5) are assigned for a period of two years, renewable once only.

- Committee member is replaced in the event of his absence, including more than 50 % of the meetings during the year or the absence of three consecutive meetings without excuse.
- Taking into account the nature and size of the hospital and staff available in it, the committee may call any of the staff in the hospital to take his opinion in any of the things without having the right to vote.

1.4 Duties and Responsibilities of HPTC

1. To formulate policies and protocols relating to pharmaceuticals and treatments and follow-up implementation these policies.
2. Regular assessment of supply, procurement, storage, prescription, dispensing and use of medicines and propose solutions to the related problems to ensure safety and patient satisfaction.
3. Do periodic and regular review of prescriptions and identify prescribing patterns to ensure compliance with the approved guidelines in this regard.
4. To review reports relating to the medicine-use problems like: medication errors, side effects and manufacturing defects and propose appropriate solutions to avoid or reduce them and report adverse drug reaction to JFDA.
5. To disseminate pharmaceutical information to health care providers and patients and their families.
6. To study requests to add any drug to the rational drug list and make recommendation based on scientific evidence.
7. To follow-up to decisions issued by the Central Committee to ensure the implementation of these decisions.
8. Follow-up to the commitment of all health service providers in the medical sector on the use of National Drug Formulary and refer to it as a national scientific reference on the uses of medicines.
9. Follow-up commitment to the application of national standard treatment guidelines and to provide the Central Committee with any comments or recommendations.

1.5 Function and operation of the HPTC

1. The Committee shall meet at least once a month or when needed and shall elect a vice-president at its first meeting.
2. The meeting considered legal in the presence of at least half of the members +1, including the president or vice president.
3. Committee shall take its decisions by a majority of the members, and in the case of equal number of votes the vote of the chair of the session will be considered.
4. The recommendations and decisions of the Commission should be demonstrated by the signature of those who attended the meeting.
5. The Committee can liaise with other hospital committee and can invite any health professional to seek his opinion
6. The decisions taken by the committee should be documented and circulated to all hospital staff through the hospital's director.

7. The Committee shall submit its recommendations and proposals that require a measure of decision-makers through the director of the hospital to the Central Pharmacy and therapeutics committee.
8. Committee members should abide the professional scientific and objective work with the utmost transparency, impartiality and integrity to achieve the public interest and justice.
9. Committee members should sign a declaration of interests form to disclose conflicts of interest and impartiality (Annex 1), and acknowledge the confidentiality of the meetings form (Annex 2).

1.6 Duties and Responsibilities of the HPTC secretary

1. Coordination with the Chairman of the Committee or his deputy to determine the date of the meeting and topics that will be discussed.
2. Preparation of the meeting invitation and the agenda and the minutes of the previous meeting and sending the agenda of the meeting at least a week prior to the date of the meeting.
3. Preparation of all the attachments that committee needs in its meetings and provide copies to all members at least a week prior to the date of the meeting.
4. Ensure the readiness of the site of the meeting to ensure the smooth running of the meeting.
5. Present evidence and scientific facts on the subject of search.
6. Preparation and presentation of the addition and deletion applications after confirming the completion of the documents.
7. Codification of the recommendations and decisions of the Commission and signed by those who attended the meeting during the session.
8. Preparation of minutes of meeting.
9. Dissemination of decisions issued by the Committee through the director of the hospital and follow up the implementation of the recommendations.
10. Sending the recommendations and proposals that require action through the director of the hospital to the Central Pharmacy and therapeutics committee.
11. Dissemination of the decisions of the Central Pharmacy and therapeutics committee and follow-up the implementation of the decisions.
12. Preparation of quarterly reports of the achievements of the Committee.

2. The Central Pharmacy and Therapeutics Committee (CPTC)

2.1 Goal:

Promote rational use of medicines and the application of the concept of good pharmaceutical practice and address drug - related problems within the hospital / affiliated hospitals.

2.2 Domain:

1. Ministry of Health hospitals
2. Royal Medical Services hospitals
3. Jordan University Hospital
4. King Abdullah University Hospital
5. King Hussein Cancer Center

* Hospital pharmacy and therapeutics committee at university hospitals and the King Hussein Cancer Center are the Central Committee of pharmacy and therapeutics.

2.3 Members and composition of the CPTC

A. the Central Pharmacy and Therapeutics Committee in the Ministry of Health shall be formed by a decision of the Minister of Health. Headed by the Secretary General and include the following members:

1. Director of the hospital directorate.
2. Director of Internal specialization.
3. Director of surgery specialization.
4. Director of Gynecology and Obstetrics specialization.
5. Director of pediatric specialization.
6. Consultant in Health Economy / Pharmacoeconomics.
7. Director of Clinical Pharmacy Directorate.
8. Director of Procurement and Supply Directorate.
9. Director of health insurance.
10. Clinical pharmacist from the Clinical Pharmacy Directorate / secretary of the committee.

B. The Central Pharmacy and Therapeutics Committee in the Royal Medical Services shall be formed by a decision of the Director General of the Royal Medical Services. Headed by the Director General of the Royal Medical Services or his representative and include the following members:

1. Chairman of the Internal Medicine Department.
2. Chairman of the surgery Department.

3. Chairman of the Obstetrics and Gynecology Department.
4. Chairman of the pediatric department.
5. Consultant in Health Economy / Pharmacoeconomics.
6. Director of pharmacy and medicine.
7. Director of Medical supply.
8. Chairman of the Procurement Division.
9. Clinical pharmacist from pharmacy and medicine Directorate / secretary of the Commission.

C. The Central Pharmacy and Therapeutics Committee in the University Hospitals shall be formed by a decision of the Director General of the hospital. Headed by the Medical Director or the director of Internal Medicine Department and include the following members:

1. Chairman of the Internal Medicine Department/ Internist.
2. Chairman of general surgery Department.
3. Chairman of special surgery Department
4. Chairman of the Obstetrics and Gynecology Department.
5. Chairman of pediatric department.
6. Director of Pharmacy Department.
7. Director of Tenders Department or Director Medicines.
8. Clinical pharmacist.
9. A representative of Nursing Department.
10. Pharmacist / Quality Coordinator in the Department of Pharmacy.

2.4 Duties and responsibilities of the CPTC

1. To develop drug policies in the institution and to ensure consistency with the national drug policy.
2. Monitor the implementation of good pharmaceutical practice and activate the concept of pharmaceutical care and adoption of standard policies and procedures relating to pharmaceuticals and treatments and develop programs and mechanisms those achieve the scientific and economic feasibility of the use of therapeutics.
3. Prepare and approve lists of medicines and update drug formulary in the organization.
4. Adoption of the medicines classification.
5. Monitor the implementation of the policies of the rational use of medicines in order to ensure the safety and effectiveness of therapeutics used
6. To study, discuss, approve, implement and disseminate policies and mechanisms of action sent by hospital committees.
7. To study the recommendations and requests sent from pharmacy and therapeutics committees in hospitals for adding and deleting medicines in the rational drug list and take the appropriate decisions.
8. To develop policies to rationalize medicines in terms of prescription and dispensing.

9. Develop policies and mechanisms to ensure the availability of special treatments and life-saving medicines.
10. To investigate the problems related to the use and supply of medicines including the side effects of medicines and the medical errors, and to develop appropriate arrangements to prevent or minimize the occurrence.
11. Develop appropriate mechanisms to sustain the revision and updating of the Jordan National Drug Formulary.
12. Follow-up commitment to the application of national standard treatment guidelines.
13. Review and evaluation mechanisms and methods used to procure unavailable medications.

2.5 Function and operation of the CPTC

1. The Committee shall meet at least once a month or when needed. Committee shall elect a vice-president at its first meeting from among its members and the committee secretary will be a pharmacist.
2. The meeting considered legal in the presence of at least half of the members +1, including the president or vice president.
3. Committee shall take its decisions by a majority of the attending members (half of the members of the Committee +1), and in the case of equal number of votes the vote of the chair of the session will be considered.
4. The Committee can invite any health professional to seek his opinion when needed, is not entitled to vote on the resolutions.
5. The decisions of the Committee should be documented and circulated to all staff in the organization, and the committee is responsible for assuring the implementation of their decisions.
6. The members of the committee should abide the professional scientific and objective work with the utmost transparency, impartiality and integrity to achieve the public interest and justice.
7. Committee members should sign a declaration of interests form to disclose conflicts of interest and impartiality (Annex 1), and acknowledge the confidentiality of the meetings form (Annex 2).

2.6 Duties and Responsibilities of the CPTC secretary

1. Coordination with the Chairman of the Committee or his deputy to determine the date of the meeting and topics that will be discussed.
2. Preparation of the meeting invitation and the agenda and the minutes of the previous meeting and sending the agenda of the meeting at least a week prior to the date of the meeting.
3. Preparation of all the attachments that committee needs in its meetings and provide copies to all members at least a week prior to the date of the meeting.
4. Ensure the readiness of the site of the meeting to ensure the smooth running of the meeting.

5. Present evidence and scientific facts on the subject of search.
6. Preparation and presentation of the addition and deletion applications after confirming the completion of the documents.
7. Codification of the recommendations and decisions of the Commission and signed by those who attended the meeting during the session
8. Preparation of minutes of meeting
9. Dissemination of decisions issued by the Committee through the Director General of the organization and follow up the implementation of the recommendations.
10. Prepare semi-annual reports of committee achievements.

3. Jordan National Drug Formulary (JNDF) Technical Committees

3.1 Goal

The Technical committees (18) are responsible for revising and updating the Jordan Rational Drug List and Jordan National Drug Formulary.

3.2 Domain:

1. Ministry of Health
2. Royal Medical Services hospitals
3. Jordan University Hospital
4. King Abdullah University Hospital
5. King Hussein Cancer Center
6. Jordan Food and Drug Administration
7. Joint Procurement Department

3.3Members and composition of the JNDF Technical Committees

The members of these committees are nominated by their respective public sector agencies and officially appointed by the Minister of Health. They are experts in all medical and pharmaceutical fields (to the extent possible).

Each technical committee has 7-9 members, representing different clinical specialties and includes a chief of department or a senior physician, and at least three pharmacists. The chief of department or the senior physician represents different medical specialties from MOH, Royal Medical Services, the Jordan University Hospital, King Abdullah Hospital. Thus, the technical committees collectively possess expertise and professional knowledge in different medical specialties, clinical practice, standards development, drug use in clinical practice, and prescribing information (see Annex 3).

Each committee has an elected chairperson and a secretary (pharmacist) from among its members. These 18 Technical committees are:

1. Gastro-intestinal system and nutrition.
2. Cardiovascular system
3. Respiratory system
4. Psychiatrics
5. Central nervous system
6. Infections
7. Endocrine system
8. Obstetrics and gynecology
9. Immunomodulators, kidney diseases and genitourinary drugs
10. antineoplastic
11. blood diseases and blood product
12. Musculoskeletal drugs
13. Eye
14. Ear, nose and throat
15. Dermatological drugs
16. Vaccines, immunoglobulins, antitodes and antivenoms
17. Anaesthesia and intravenous fluids
18. Diagnostics

- The formation of committees (Annex 3), technical committees shall invited by the Department of the rational drug use in the Food and Drug Administration during the month of receiving the request to study any requests to add , delete, or specify the use of medication in the rational drug list.
- Each committee shall elect a physician chairman of the technical committee and his deputy in the first meeting, and select a pharmacist to be rapporteur of the committee.
- The duration of membership in the Committee is three years, renewable once.
- Committee member is replaced in the event of not attending the 50 % of the total meetings or absent three consecutive meetings without excuse.

3.4 Duties and responsibilities of the JNDF Technical Committees

1. Evaluation of the medicines requests for additions and deletions to the rational drug list within the form adopted for this purpose (Annex 4) and make appropriate recommendations with justifications.
2. Review, combine, and update the existing JRDL and JNDF on the national level.
3. Provide appropriate recommendation for the classification of medicines in the rational drug list.

4. Studying pharmacovigilance reports from the Food and Drug Administration and the latest periodic safety update reports of the product (PSUR) and taken it into account when considering requests for additions or deletions medicines from the rational drug list.

3 5.Function and operation of the JNDF Technical Committees

The Committee shall meet at least every two months or when needed through invitation from the rational drug use departments at JFDA and after coordination with the Chairman of the Committee, and shall elect a vice-president at its first meeting.

The meeting considered legal in the presence of at least half of the members +1, including the president or vice president.

Committee shall take its decisions by a majority of the members (half of the present members +1), and in the case of equal number of votes the vote of the chair of the session will be considered.

Committee can ask the applicants or the rational drug use department to provide her with additional documents or information it deems necessary.

The recommendations and decisions of the Commission should be demonstrated by the signature of those who attended the meeting, and those who have reservation to this decision should write the justifications.

The decisions taken by the committee should be submitted within one week to the rational drug use department for completion of the necessary procedures.

Committee members should abide the professional scientific and objective work with the utmost transparency, impartiality and integrity to achieve the public interest and justice .

Committee members should sign a COI form to disclose conflicts of interest and impartiality (Annex 1), and acknowledge the confidentiality of the meetings form (Annex 2).

3.6 Duties and Responsibilities of the secretary of JNDF Technical Committees

1. Coordination with the Chairman of the Committee or his deputy to determine the date of the meeting and topics that will be discussed.
2. Preparation of the meeting invitation and the agenda and the minutes of the previous meeting and sending the agenda of the meeting at least a week prior to the date of the meeting.
3. Preparation of all the attachments that committee needs in its meetings and provide copies to all members at least a week prior to the date of the meeting.
4. Present evidence and scientific facts on the subject of search.
5. Preparation and presentation of the addition and deletion applications after confirming the completion of the documents.
6. Codification of the recommendations and decisions of the Commission and signed by those who attended the meeting during the session

7. Preparation of minutes of meeting
8. Dissemination of recommendations issued to the national pharmacy and therapeutics committee.
9. Preparation of annual reports of committee achievements.

4. National Pharmacy and Therapeutics Committee (NPTC)

4.1 Goal

The goal of the NPTC is to ensure that patients are provided with the best possible cost-effective and quality of care through determining what medicine will be available, at what cost, and how they will be used.

4 2.Domain:

1. Ministry of Health
2. Royal Medical Services hospitals
3. Jordan University Hospital
4. King Abdullah University Hospital
5. King Hussein Cancer Center
6. Jordan Food and Drug Administration
7. Joint Procurement Department

4.2 Members and composition of the NPTC

The National Pharmacy and Therapeutics Committee shall be formed by the decision of the Minister of Health and headed by qualified and experienced internist with acclaimed professional skill, integrity and responsibility and headed by the Director General of the Jordan Food and Drug Administration and the membership includes- :

1. Head of Internal medicine department /Jordan University Hospital
2. Head of Internal medicine department / King Abdullah University Hospital.
3. Head of Internal medicine department / Ministry of Health.
4. Head of Internal medicine department / Royal Medical Services.
5. President of Obstetrics and Gynecology Department / Ministry of Health.
6. Head of surgery department / Ministry of Health.
7. Head of Pediatric department / Ministry of Health.
8. Head of anesthesia department/ Ministry of Health.
9. Head of Antineoplastic department / Ministry of Health.
10. Director of Procurement and Supply Directorate / Ministry of Health.
11. Director of pharmacy and medicine / Royal Medical Services.

12. Director of the Department of Pharmacy / Jordan University Hospital.
13. Head of Pharmacy / King Abdullah University Hospital.
14. Director of the Drug Directorate / Jordan Food and Drug Administration.
15. Head of Pharmacy / King Hussein Cancer Center.
16. Pharmacist in the Joint Procurement Department with experience of not less than two years in the department.
17. An expert in the Pharmacoeconomics, named by the Minister of Health.
18. Head of the Rational Drug Use department/ Jordan Food and Drug Administration.

4.4 Duties and responsibilities of the NPTC

1. Take the appropriate decision on the recommendations of the technical committees regarding deletion and addition or determine the use of any medication in the rational drug list.

2. Study the causes of the failure of providing medications in the public sector and make recommendations to the Steering Committee of rational Drug Use (JNDF Advisory Board).

3. Evaluate the economic feasibility (cost-effectiveness) for the use of medicines in the rational drug list through the experts in the Pharmacoeconomics.

4.5 Function and operation of the NPTC

1. The Committee shall meet at least three times a year or when needed. Committee shall elect a vice-president at its first meeting from among its members and the committee secretary will be the head of rational drug use department.
2. The meeting considered legal in the presence of at least half of the members +1, including the president or vice president.
3. Committee shall take its decisions by a majority of the attending members (of two thirds of the audience)
4. The Committee can invite any health professional to seek his opinion when needed, is not entitled to vote on the resolutions.
5. The decisions of the Committee should be documented and signed during the session.
6. Any representative from each of the (Association of Importers of medicines, the owners of Drugstores Association, the Jordanian Association of Pharmaceuticals Manufacturers) can attend the meetings of the National Committee for listening purposes only.
7. The members of the committee should abide the professional scientific and objective work with the utmost transparency, impartiality and integrity to achieve the public interest and justice.
8. Committee members should sign a COI form to disclose conflicts of interest and impartiality (Annex 1), and acknowledge the confidentiality of the meetings form (Annex 2).

9. The secretary of NPTC shall inform the applicant in writing of the decision within one week from the date of meeting. The applicants has the right to appeal within three weeks from the date of notification, if there is no objection then the Committee decision shall be final and duly circulated.
10. Prepare and submit annual reports on the work of Committee to the steering committee of rational drug use (JNDF Advisory Board).

4.6 Duties and Responsibilities of the NPTC secretary

1. Coordination with the Chairman of the Committee or his deputy to determine the date of the meeting and topics that will be discussed.
2. Preparation of the meeting invitation and the agenda and the minutes of the previous meeting and sending the agenda of the meeting at least a week prior to the date of the meeting.
3. Preparation of all the attachments that committee needs in its meetings and provide copies to all members at least a week prior to the date of the meeting.
4. Ensure the readiness of the site of the meeting to ensure the smooth running of the meeting.
5. Present evidence and scientific facts on the subject of search.
6. Preparation and presentation of the addition and deletion applications after confirming the completion of the documents.
7. Codification of the recommendations and decisions of the Commission and signed by those who attended the meeting during the session
8. Preparation of minutes of meeting
9. Dissemination of decisions issued by the Committee to the concerned authorities and through the website of the Rational Drug Use Department.
10. Prepare annual reports of committee achievements and publish it on the website of the Food and Drug Administration / Rational Drug Use Department.

5. Appeal Committee for studying objections

5.1 Members and composition of the appeal committee

The National Committee forms from of its members, a small committee to study the objections and as follows:

1. Head of Internal medicine department /Jordan University Hospital
2. Head of Internal medicine department / King Abdullah University Hospital.
3. Head of Internal medicine department / Ministry of Health.
4. Head of Internal medicine department / Royal Medical Services.
5. Chairman of the technical committee interest with the subject.

6. Head of the Rational Drug Use department/ Jordan Food and Drug Administration.

5.2 Duties and responsibilities of the appeal committee

1. Study objections to the decisions of the National Committee to add or delete Medicine to Rational Drug List.
2. Make recommendations to the National Commission for pharmaceuticals and treatments after studying the objections.

5.3 Function and operation of the appeal committee

1. The Committee shall meet at least two weeks of receiving the objection to it. Committee shall elect a president at its first meeting from among its members and the committee secretary will be the head of rational drug use department.
2. The meeting considered legal in the presence of at least four members including the president.
3. Committee shall take its decisions by unanimously or by a majority of the attending members.
4. The Committee can invite any health professional to seek his opinion when needed, is not entitled to vote on the resolutions.
5. The decisions of the Committee should be documented and signed during the session.
6. Committee members should sign a COI form to disclose conflicts of interest and impartiality (Annex 1), and acknowledge the confidentiality of the meetings form (Annex 2).

5.4 Duties and Responsibilities of the NPTC secretary

1. Coordination with the Chairman of the Committee to determine the date of the meeting and topics that will be discussed.
2. Preparation of the meeting invitation and the agenda and the minutes of the previous meeting and sending the agenda of the meeting at least a week prior to the date of the meeting. And dissemination of decisions issued by the Committee to the concerned authorities and through the website of the Rational Drug Use Department.
3. Preparation of all the attachments that committee needs in its meetings and provide copies to all members at least a week prior to the date of the meeting.
4. Present evidence and scientific facts on the subject of search.
5. Codification of the recommendations and decisions of the Commission and signed by those who attended the meeting during the session.
6. Preparation of minutes of meeting.

6. Steering Committee for Rational Drug Use

6.1 Members and composition of RDU Steering Committee

The Minister of Health is the chairman, and members are:

1. Secretaries General of the MOH.
2. Secretaries General of the High Health Council.
3. Director General of Royal Medical Services,
4. Director General of Jordan University Hospital.
5. Director General of Prince Hamzeh Hospital.
6. Director General of King Abdullah Hospital.
7. Director General of Jordan Food and Drug Administration,
8. Director General of Joint Procurement Directorate.
9. Director General of the National Center for Diabetes and Endocrinology and Genetics.
10. Director General of the King Hussein Cancer Center.
11. President of Jordan Pharmacy Association.
12. President of Jordan Medical Association
13. A representative of one of the associations of civil society appointed by the Minister of Health.

6.2 Duties and Responsibilities of RDU Steering Committee

1. Adoption of policies and strategies for the rational use of medicines and implementation plans.
2. Study the recommendations of the National Pharmacy and Therapeutics Committee and take the necessary decisions about it.
3. Providing expert advice on the revision, updating, and production of the Rational Drug List (RDL), Jordan National Drug Formulary (JNDF), and Standard Treatment Guidelines (STG).
4. Reviewing the recommendations of the National Pharmacy and Therapeutics Committee to ensure the availability of treatments in the public health sector and to take the necessary decisions.

6.3 Function and operation of the RDU Steering Committee

1. The Committee shall meet at the request of the President at least once a year or when needed. Committee shall elect a president at its first meeting and the committee secretary is the Director General of Joint Procurement Directorate.
2. The meeting considered legal in the presence of at least half of the members of +1
3. Committee shall take its decisions by majority of the attending members.

6.4 Duties and Responsibilities of the Secretary of the RDU Steering Committee

1. Coordination with the Chairman of the Committee or his deputy to determine the date of the meeting and topics that will be discussed.
2. Preparation of the meeting invitation and the agenda and the minutes of the previous meeting and sending the agenda of the meeting at least a week prior to the date of the meeting.

7. Procedure of addition/ deletion of medicines in Rational Drug List

1. The physician fill in the attached form prepared for this purpose according to the following steps:
    a. Writing the generic and trade name of the medicine and the manufacturing company.
    b. Writing dosage form and concentration of the medicine.
    c. Determine the dose and estimated duration of treatment.

2. Determine the scientific and therapeutic justifications indicating the superiority of the requested medicine over the currently existing formulary medicine .
3. Attach the necessary data that show the cost of therapeutic treatment for the entire duration course of therapy.
4. Writing name, signature and date on the form by the applicant and attach all the studies and data referred to above.
5. Send the fill out form with the required documents and after being studied by a hospital pharmacy and therapeutics committee through the director of hospital to the central pharmacy and therapeutics committee.
6. The central pharmacy and therapeutics committee meets to discuss, study and making the right decision of accepting or rejecting the request within a maximum period of one month from the date of submission of the application.
7. In case of approving the addition of the requested medicine; the form is sent through the Chairman of the central pharmacy and therapeutics committee to the rational drug use department at the Food and Drug Administration with all the attachments.
8. The rational drug use department consults the Technical Committee with providing them with copies of the form and attachments.
9. The rational drug use department calls for the National Committee meeting and provides the members with copies of the form with the technical Committee's recommendation and all other attachments.
10. The final decision will be taken by the members of the National Committee including determining of dispensing category.
11. The decision of the National Committee will circular to all public institution through the Jordan Food and Drug Administration.

8. Appeal Procedure for the decision of addition/deletion of medicines in RDL

1. The applicant has the right to object to the decision of the National Committee within one month of the issuance of its decision and submit it to the Department of the rational use of the drug in the General Organization for Food and Drug Administration.
2. The head of rational drug use department/ Rapporteur of the appeal committee submit the objection to the appeal committee within two weeks from the date of receiving the objection.
3. The head of rational drug use department should invite the members of the Committee through its chairman to study objections within two weeks from the date of receiving of the Committee for the objection.
4. The head of rational drug use department should submit the recommendations of the committee to the National Committee three business days from the date of issuance of the recommendations.
5. The head of rational drug use department should invite the members of the National Committee through its chairman to study the recommendations of the Appeal
6. Committee within two weeks from the date of receiving the recommendations and decision of the National Committee shall be final and disseminate to the concerned authorities and through the website of the Rational Drug Use Department

Annex (1) Disclosure of conflicts of interest Form

DECLARATION OF INTERESTS FOR EXPERTS

Title of meeting or work to be performed, including description of subject-matter, substance (compounds and organisms), technology or process to be considered ：

_____

Public health considerations have a primary importance in all technical work. Measures need to be taken to ensure that the best possible assessment of scientific evidence is achieved in an independent atmosphere free of either direct or indirect pressures. Thus, to assure the technical integrity and impartiality of work, it is necessary to avoid situations in which financial or other interests might affect the outcome of that work.

Each expert is therefore asked to declare any interests that could constitute a real, potential or apparent conflict of interest, with respect to his/her involvement in the meeting or work, between (1) commercial entities and the participant personally, and (2) commercial entities and the administrative unit with which the participant has an employment relationship. "Commercial entity" refers to any company, association (e.g., trade association), organization or any other entity of any nature whatsoever, with commercial interests. Nevertheless, declaration of such an interest would not necessarily be considered a reason to disqualify an expert.

What is a conflict of interest ？

Conflict of interest means that the expert or his/her partner ("partner" includes a spouse or other person with whom s/he has a similar close personal relationship), or the administrative unit with which the expert has an employment relationship, has a financial or other interest that could unduly influence the expert's position with respect to the subject-matter being considered. An apparent conflict of interest exists when an interest would not necessarily influence the expert but could result in the expert's objectivity being questioned by others. A potential conflict of interest exists with an interest which any reasonable person could be uncertain whether or not should be reported.

Different types of financial or other interests, whether personal or with the administrative unit with which the expert has an employment relationship, can be envisaged and the

following list, which is not exhaustive, is provided for your guidance. For example, the following types of situations should be declared:

1. A current proprietary interest in a substance, technology or process (e.g. ownership of a patent), to be considered in - or otherwise related to the subject-matter of - the meeting or work;
2. A current financial interest, e.g. shares or bonds, in a commercial entity with an interest in the subject-matter of the meeting or work (except share holdings through general mutual funds or similar arrangements where the expert has no control over the selection of shares;
3. An employment, consultancy, directorship, or other position during the past two years, whether or not paid, in any commercial entity which has an interest in the subject-matter of the meeting/work, or an ongoing negotiation concerning prospective employment or other association with such commercial entity;
4. Performance of any paid work or research during the past two years commissioned by a commercial entity with interests in the subject-matter of the meetings or work;
5. payment or other support covering a period within the past two years, or an expectation of support for the future, from a commercial entity with an interest in the subject-matter of the meetings or work, even if it does not convey any benefit to the expert personally but which benefits his/her position or administrative unit, e.g. a grant or fellowship or other payment, e.g. for the purpose of financing a post or consultancy.

With respect to the above, an interest in a competing substance, technology or process, or an interest in or association with, work for or support by a commercial entity having a direct competitive interest must similarly be disclosed.

How to complete this Declaration: Please complete this Declaration and submit it to the Secretariat. Any financial or other interests that could constitute a real, potential or apparent conflict of interest should be declared (1) with respect to yourself or partner, as well as (2) with respect to the administrative unit with which you have an employment relationship. Only the name of the commercial entity and the nature of the interest are required to be disclosed, no amounts need to be specified (though they may be, if you consider this information to be relevant to assessing the interest). With respect to items 1 and 2 in the list above, the interest should only be declared if it is current. With respect to items 3, 4 and 5, any interest during the past 4 years should be declared. If the interest is no longer current, please state the year when it ceased. With respect to item 5, the interest ceases when a financed post or fellowship is no longer occupied, or when support for an activity ceases.

Assessment and outcome: The information submitted by you will be used to assess whether the declared interests constitute an appreciable real, potential or apparent conflict of interest. Such conflict of interest will, depending on the situation, result in (i) you being asked not to take part in the portion of the discussion or work affecting that interest, (ii) being asked not to take part in the meeting or work altogether, or (iii) if deemed by the public institution to be appropriate to the particular circumstances, and with your agreement, you taking part in the meeting or work and your interest being publicly disclosed.

Information disclosed on this Form may be made available to persons outside of public institution only when the objectivity of the meeting or work has been questioned such that the Director-General considers disclosure to be in the best interests of the Organization, and then only after consultation with you .

Declaration: Have you or your partner any financial or other interest in the subject-matter of the meeting or work in which you will be involved, which may be considered as constituting a real, potential or apparent conflict of interest?

Yes: ☐ No: ☐ if yes, please give details in the box below.

Do you have, or have you had during the past 4 years, an employment or other professional relationship with any entity directly involved in the production, manufacture, distribution or sale of medicines or any medical products, or directly representing the interests of any such entity? Yes: ☐ No: ☐ if yes, please give details.

Type of interest, e.g. patent, shares, employment, association, payment (including details on any compound, work, etc...)

Name of commercial entity

Belongs to you, partner or unit?

Current interest? (or year ceased)

Is there anything else that could affect your objectivity or independence in the meeting or work, or the perception by others of your objectivity and independence?

_____

_____

I hereby declare that the disclosed information is correct and that no other situation of real, potential or apparent conflict of interest is known to me. I undertake to inform you of any change in these circumstances, including if an issue arises during the course of the meeting or work itself.

Signature …… Date…….

Name …….. Institution……..

Annex (2): Acknowledging the confidentiality of meetings Form

Model acknowledge the confidentiality of meetings

I.....

Member of the Committee..... .....

I pledge to maintain the confidentiality of what is being circulated and the decisions taken in the meetings of this committee.

Accordingly fells

……..

Annex (3): Technical committee members

1. Gastro-intestinal system and nutrition	
Gastroenterologist Pediatrician specialized in gastrointestinal system (number 1) Physician Nutrition Specialist (if available)	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital
Pharmacist	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital, Jordan Procurement Department
2. Cardiovascular system	
Cardiologist cardiothoracic surgeon(if available)	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital
	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital, Jordan Procurement Department
3. Respiratory system	
Pulmonologist Immunologist (number 1)	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital
Pharmacist	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital, Jordan Procurement Department
4. Psychiatrics	
Psychiatrist	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital
Pharmacist	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah

	University Hospital, Jordan Procurement Department
5. Central nervous system	
Neurologist	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital
Pharmacist	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital, Jordan Procurement Department
6. Infections	
Infectious disease specialist or internal medicine doctor. Family medicine doctor	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital
Pharmacist	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital, Jordan Procurement Department
7. Endocrine system	
Endocrinologist Pediatrician specialized in endocrinology	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital
Pharmacist	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital, Jordan Procurement Department
8. Obstetrics and Gynecology	
Obstetrician / Gynecologist	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital
Pharmacist	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital, Jordan Procurement Department

9. Immunomodulators, Kidney diseases and Genitourinary drugs	
Nephrologist Urologist Immunologist (number 1)	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital
Pharmacist	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital, Jordan Procurement Department
10. Antineoplastic	
Medical oncologists	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital, King Hussein Cancer Centre
Pharmacist	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital, Jordan Procurement Department, King Hussein Cancer Centre
11. Blood diseases and blood product	
Hematologist & Blood disorder specialist	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital, King Hussein Cancer Centre
Pharmacist	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital, Jordan Procurement Department, King Hussein Cancer Centre
12. Musculoskeletal drugs	
Musculoskeletal Physicians , Rheumatologist Immunologist (number 1)	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital
Pharmacist	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital, Jordan Procurement Department
13. Eye	

ophthalmologist	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital
Pharmacist	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital, Jordan Procurement Department
14. Ear, nose and throat	
Otolaryngologist	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital
Pharmacist	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital, Jordan Procurement Department
15. Dermatological drugs	
Dermatologist	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital
Pharmacist	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital, Jordan Procurement Department
16. Vaccines, immunoglobulins, antitodes and antivenoms	
Pediatrician Emergency physician	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital
Pharmacist	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital, Jordan Procurement Department
17. Anaesthesia and intravenous fluids	
Anesthesiologist Pediatrician (number 1) Critical care/ Emergency physician (number 1)	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital

Pharmacist	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital, Jordan Procurement Department
18. Diagnostics	
Radiologist Nuclear Medicine Physician (number 2)	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital
Pharmacist	Ministry of Health , Royal Medical Services , Jordan University Hospital , King Abdullah University Hospital, Jordan Procurement Department

Annex (4) Jordan National Drug Formulary Addition / Deletion Request Form

Jordan National Drug Formulary Addition / Deletion Request Form

Addition ☐ Deletion ☐

All information requested on this form must be filled out completely and referenced by published scientific articles or textbooks. No action will be taken on forms that are submitted incomplete.

1	**Generic Name:**
2	**Dosage form(s) & Strength(s):**
3	**Therapeutic Class:**
4	**Approved indication by FDA, EMEA and JFDA:**
5	**Mechanism of action:**
6	**Dosage schedule & Estimated duration of therapy per indication:**
7	**List any therapeutically equivalent drugs in the (JNDF):**
8	**How is requested drug superior to the currently existing formulary drugs in terms of:** **Indication:** **Therapeutic efficacy:**

	Safety: **Administration of the drug:** **Patient Compliance:** **Monitoring:** **Availability in the market:** **Storage Conditions:**
9	**Economic Analysis:** **Drug cost for an entire course of therapy per indication** *** Cost effective studies to be provided if available** *** For chronic disease per month or per year**
10	**Trade Name(s) & Manufacturer(s):**
11	**Pack size of each strength:** **Public price per pack:**
12	**Should this drug be restricted to use by certain specialty of the medical staff? If so to whom and Why?**

13	**References attached:** **1-** **2-** **3-**
14	**Requested by physician** **full name(s):** **Hospital name:** **Specialty:** **Signature** **Date:**
15	**Head of Specialty Remarks** **Remarks:** **Full name:** **Signature:** **Date:**

Hospital Pharmacy and Therapeutics Committee
Hospital name:
Request Approved: **Yes** ☐ **Denied** ☐
Justification:
Prescribing category: **unrestricted** ☐ **restricted** ☐ **authority required** ☐
PTC members signatures: **Date:**

Central Pharmacy and Therapeutics Committee
Request: **Approved** **Yes** ☐ **Denied** ☐
Justification:
Prescribing category: **unrestricted** ☐ **restricted** ☐ **authority required** ☐
CPTC members signatures: **Date:**

JNDF Specialty Technical Committee
Request: **Approved** **Yes** ☐ **Denied** ☐
Justification:
Prescribing category: **unrestricted** ☐ **restricted** ☐ **authority required** ☐
Medicines that should be deleted:
TC members signatures: **Date:**

National Pharmacy and Therapeutics Committee
Request: **Approved** **Yes** ☐ **Denied** ☐
Justification:
Prescribing category: **unrestricted** ☐ **restricted** ☐ **authority required** ☐
Medicines that should be deleted:
NPTC members signatures: **Date:**

Annex (5): criteria and conditions to be followed in the selection of medicines in the Rational Drug list

A - Criteria:

1. The prevalence of particular diseases or medical procedures.
2. The degree of seriousness of the disease in terms of its effect on morbidity and mortality, and the speed of its spread.
3. The feasibility of the use of medication (Cost effectiveness) , taking into account:

• Choose the least expensive drug in the event of equal therapeutic efficacy based on scientific evidence (Evidence-Based)

• Choose the most expensive drug, which has better advantages that justify the additional cost.

• Choose the least expensive medication with the less advantages if the additional advantages does not justify the additional cost.

• Choose the least expensive medicine when there was no need for the additional benefits.

4. Fixed ratio combinations will only be selected if the following criteria are met:

• The clinical condition requires the use of more than one drug.

• The therapeutic effect of the combination is greater than the sum of the effects of each drug.

• The cost of the combination is less than the total cost of the individual products.

• Sufficient combination is less than the total cost of the individual products..

• Compliance is improved.

B - Conditions to be met when studying the addition or deletion of medicines:

The drug should be registered in the Jordan Food and Drug Administration to ensure the safety, effectiveness and quality of the medication with the exception if the drug has no substitute registered in Jordan and is registered in the U.S. Food and Drug Administration (USFDA) or European medicine Agency (EMEA) for a period of not less than three years.

Annex (6) Appeal Form to the decision of addition/ deletion of medicines in Rational Drug List

Jordan National Drug Formulary Addition / Deletion Appeal Form

1	**Generic Name:**
2	**Dosage form(s) & Strength(s):**
3	**Therapeutic Class:**
4	**Decision of the National Pharmacy and Therapeutic Committee**
5	**Trade Name(s) &Manufacturer(s):**
6	**How is requested drug superior to the currently existing formulary drugs in terms of:** **Indication:** **Therapeutic efficacy:** **Safety:** **Administration of the drug:** **Effect on Patient Compliance:** **Monitoring:** **Availability in the market:** **Storage Conditions:**

	Drug cost(Hospitalization)
7	**Reason for appealing**
8	**References attached:** **1-** **2-** **3-**
9	**Requested by physician** **full name(s):** **Hospital name:** **Specialty:** **Signature** **Date:**
10	**Head of Specialty Remarks** **Remarks:** **Full name:** **Signature:** **Date:**
11	**Appeal Committee Recommendation:**

	Justification **Members signatures** **Date:**
12	**National Pharmacy and Therapeutic Committee Final decision** **Justification** **Members signatures** **Date**

Annex (7) Flow Chart of Addition - deletion of medicines in RDL