Health Finance and Governance (HFG)

Report on Vaccines Procurement Legislation Review

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Introduction

The right of each individual to have the highest attainable standard of physical and mental health is a universal human right. The right to health first emerged as a social right in the World Health Organization (WHO) Constitution, the Universal Declaration of Human Rights, and the International Covenant on Economic, Social, and Cultural Rights (ICESCR). The WHO Action Program on Essential Drugs emerged as an extension of these documents that included principles on the accessibility, availability, appropriateness and assured quality of good as services of essential drugs[1].

Access to essential drugs comprises of complex systems ranging from identifying and tracking need, procuring drugs and vaccines, and managing the supply chain to ensure access and maintaining quality. These systems must operate in the most cost-efficient manner to promote financial sustainability and ensure accessibility. International best practices show that focusing on purchasing capacity and economies of scale for pharmaceuticals and vaccines is a critical factor in reducing spending.

Immunization programs are an extremely important and cost-effective investment in the health of the population, and have become the cornerstone of primary health care. These programs are a critical part of any modern health care system as they help in eliminating many communicable diseases, which consequently reduces the overall cost of health care. Securing funding for vaccines and immunization programs is a long-term investment that requires a stable and efficient approach to maintain sustainability[2].

This report addresses the legislative environment related to pharmaceutical procurement in the Jordanian public sector. It emphasizes on the factors that impact vaccine procurement, especially the engagement of international suppliers. This includes a review and analysis of factors affecting the registration process of drugs and agents, legislation on vaccines, intellectual property legislation and the impact of all these factors on the availability of drugs and vaccines at reasonable prices. In addition, the procurement process will be reviewed and evaluated in accordance with internationally agreed standards outlined in the UNCITRAL Model Law on Public Procurement,[3] issued by the United Nations Commission on International Trade Law. This will include focusing on those elements that affect objectivity, equity, participation, competition, integrity and transparency.

Some of the main points and recommendations that were included in the scope of work for this report include:

- Highlight the extent to which the legislative framework can be amended to simplify registration procedures of WHO-prequalified vaccines and to provide recommendations encouraging the entry of new or alternative suppliers to the Jordanian market.
- Permit negotiations on quotations before awarding, set institutional procedures for the use of information in negotiations (market intelligence) and adopt the international prices as a reference for the procurement process.
- Consider the partial prepayment for vaccines to encourage competition, enhance the purchasing power, meet the requirements of international vaccines providers and some international companies, and obtain prepayments discounts and any other advantages.
- Potential purchasing for more than one year as a required method.
- Prepare a budget for several years and forecasting for future quantities of vaccines.
- Establish an institutional cooperation mechanism between the entities concerned with vaccines procurement (MoH, JFDA, and JPD – replaced by Government Procurement Department).

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1 https://www.who.int/medicines/areas/human_rights/ar/

2 Immunization Financing Guide -2017- (p. 83) Legislative requirements to assist vaccines procurement from International Organizations. https://www.immunizationfinancing.org/

3 UNCITRAL website http://www.uncitral.org/uncitral/ar/uncitral_texts/procurement_infrastructure/2011Model.html

His Majesty King Abdullah II highlighted the danger when he said: **"When it comes to the health and drugs of Jordanians, there is no indulgence, and the current situation of drug prices is not correct, and the deficiency needs to be immediately addressed."**[4] It is the intent of this report to provide a review of the legislative system affecting vaccine procurement and provide a series of recommendations promoting reform and future cost savings.

Purpose of Report

This report aims at highlighting the legislation governing procurement, either directly or indirectly, the legal instruments that could be utilized within the framework of the international commitments, and outlining the multiple legal options. It will also provide the officials and policymakers with options that can be adopted to provide patients with essential vaccines and drugs at affordable prices that fall within their income levels.

This can be achieved by conducting a critical analysis of the legislative vacuum related to the vaccine procurement process and a review of legislations, laws, bylaws, instructions, policies and practices. This analysis will help in identifying best practices and recommendations that will reduce costs and reduce vaccine prices.

Methodology

In order to maintain an efficient and sustainable procurement system, it is important to identify the gaps in regulations, legislations and practices contributing to the problems or weaknesses. To achieve this, the following methodology was employed:

1- List the relevant legislation (of all levels) impacting the procurement of drugs and vaccines, and the relevant policies and practices.

Legislation is generally divided into three main sections:

- Legislation related to JFDA work, in addition to the legislation issued under the Drug and Pharmacy Law (this group governs the registration mechanism of drugs, agents, licensing conditions, drug pricing, drug examination, etc.).
- Legislation related to JPD work, in addition to samples of some general legislation related to tenders, which may benefit from the provisions relating to negotiation. For example, the procurement legislation gives the Central Bank the right to negotiate before awarding the tender. (This group governs procurement, tendering, awarding, objection, etc.)
- General legislation that may influence the procurement process, such as the Public Health Law, the Competition Law, the Commercial law (Chapter on Duties of Agents), and Patents Law.

The list also included the international treaties, public and private tendering conditions, and some relevant MoUs and JPD annual reports.

2- List the important points that should be considered

In this phase, relevant questions on specific points will be answered, including:

- Stakeholders and the level of coordination between them: The low level of coordination between stakeholders reduces efficiency and effectiveness and leads to improper elimination and lack of transparency and accountability.

[4] https://agwarnews.net/?p=43478

- Are there effective mechanisms for dispute settlement and referral to court? An impartial and effective judiciary system encourages more drugs and vaccines factories to register and submit for tenders in Jordan (examples of relevant precedents have been provided in this regard).
- Is it possible to purchase from international organizations and funding agencies? What are the obstacles to adopting this option?
- Registration procedures and requirements: Are they clear and excessive? Can they be reduced and simplified without affecting their viability? Are international registrations taken into consideration or not? Are there any limits on the number of agents in the Jordanian market, whether maximum and minimum? Are there different rules for different drugs? Is there a special treatment for vaccines as they are provided free of charge to all regardless of the financial capacity of individuals?
- Control on agents: Is there a regular control on agents' performance, for example using periodic reports? Are there profit limits? Are there margin requirements? Are there rules for submission to tenders by a certain percentage? Are there guidelines on the procedures taken when an agent fails to provide vaccines or drugs or refrains from submission to tenders? Is it appropriate to oblige agents that do not participate by providing the reasons for refraining from submission to tenders? (Related to drug security).
- Cases of drug security contained in legislation, including the cases in which direct import and bypassing the agent are allowed? Are they enough? Does this include unregistered drugs?
- The case of having one agent for several pharmaceutical factories: Are there rules addressing this case that ensures there is no conflict of interest?
- Is there a mechanism to receive complaints and report lack of drugs? Where are they submitted?
- Are there advantages and incentives to submit for tenders?
- Cooperation between the public and private sectors: Where does the private sector obtain drugs? Is it possible for new categories of the private sector to enter the joint procurement?
- Tendering procedures, negotiation, awarding, appeal, international contracting and its cases.
- Taxes: how are taxes and customs levied in this sector?
- Is there a provision obliging procurement through JPD?
- Mechanism for identification of vaccines and drugs to be purchased: Are the drug inventory and JPD linked? Is there certain data required to be available before invitation to tender? Who determines the required drug?
- Are data on vaccine and drug registrations required? Are alternatives identified in the absence of competition in the tender or in other cases? Are the target prices initially identified? Are there standards for assessment of prices and quality of tenders?
- How are excess drugs dealt with? Is rotation allowed between JPD members? Is sale permitted to parties that are not covered by joint procurement (the private sector under certain conditions)? Does JPD review the inventory? Is information in this regard shared?
- What is the extent of JPD authority to know the details of prices and purchase prices and is there a broker? Taking into account that the cost price is declared to other parties.

3- Identify the aspects that need to be addressed and the gaps in existing legislation, and the directives and requirements necessary to identify the required changes.
4- A document or analytical table has been prepared describing the key regulatory problems and gaps that need to be added or changed for each stakeholder (MoH, MoF, JPD, JFDA, MoIT) and recommendations on reform.
5- Present the document to the relevant authorities for discussion before approval of findings and issuance of the final report.

Third: Addressing new developments

It should be noted that while preparing this report, significant developments emerged that require addressing. The developments were as follows:

1- The emergence of a new government procurement bylaw that cancels the current joint procurement system. This modification was obtained from the Legislation and Opinion Bureau website and it was studied.
2- The Legal Committee of the Prime Ministry made amendments on the draft bylaw under which JPD was canceled and merged with the General Supplies Department under a new name (Government Procurement Department). Accordingly, it was necessary to make a comparison between the joint procurement bylaw and the new drafted government procurement bylaw as amended.
3- Make minor amendments at the request of the cabinet. The most important amendment before publication of the bylaw in the official gazette was fully enrolling the Armed Forces, Public Security and Security Services within the framework of government procurement. Except for defense supplies and emergency procurement.
4- Issue the new government procurement bylaw in its latest version and publish it in the official gazette.
5- A draft law amending the Drug and Pharmacy Law of 2019 is published on the Legislation and Opinion Bureau website. The Cabinet decided to approve a draft law amending the Drug and Pharmacy Law of 2019. It was stated that it was approved for the purposes of realizing drug security and permitting the import of unregistered drugs through tenders of official entities.[5]

This required conducting comparisons between the provisions of the joint procurement legislation, the new bylaw of government procurement, and the amendments of the draft by the Legal Committee. The possibility of not approving the bylaw was taken into consideration in order to benefit from the new provisions that are consistent with developing new procurement methods that will be included in the joint procurement bylaw. The same has been made with the proposed amendments to the Drug and Pharmacy Law, as the published amendments permit the import of unregistered drugs in commercial quantities.

Fourth: Meetings and collection of information

Several meetings were held with a number of stakeholders, including:

- The Pharmacists Association represented by its president (a member of the Higher Technical Committee). He pointed out a number of suggestions:

  - Identify segments of profit rates for participants in the process of selling or purchasing drugs.
  - Study the feasibility of pricing vaccines or determine the purchase prices before tendering.

5 http://alrai.com/article/10477462/%D9%85%D8%AD%D9%84%D9%8A%D8%A7%D8%AA/%D9%85%D8%AC%D9%84%D8%B3-%D8%A7%D9%84%D9%88%D8%B2%D8%B1%D8%A7%D8%A1-%D9%8A%D9%88%D8%A7%D9%81%D9%82-%D8%B9%D9%84%D9%89-%D9%86%D8%B8%D8%A7%D9%85-%D9%85%D8%B2%D8%A7%D9%88%D9%84%D8%A9-%D8%A7%D9%84%D9%85%D9%87%D9%86-%D8%A7%D9%84%D8%AA%D8%B9%D9%84%D9%8A%D9%85%D9%8A%D8%A9-%D9%84%D8%B3%D9%86%D8%A9-2019

- Mechanism for selection of drugs and vaccines entering the tender (the most expensive and newest despite availability of cheaper alternative), including vaccines.
- Reconsider imposition of taxes on drugs and medical supplies.
- Reconsider the currently approved pricing mechanism for drugs.

- JFDA to check and define the legislation. However, the technical matters were not discussed as they are not part of this report.

- The General Budget Department to collect information before holding discussions with stakeholders on financial matters, as well as studying the possibility and obstacles of allocating public funds.

- Several meetings with JPD were held and activities held by HFG were attended to discuss the main obstacles of procurement as per JPD's staff.

Fifth: Present the findings to the stakeholders and taking their notes and feedback

In order to ensure that the report provides the desired results, and to obtain the highest level of accuracy, this report will be presented to the stakeholders and will be discussed by specialists from different entities (technical committee members). The feedback will be taken into account before the approval of the final version of this report.

By examining the regulatory and supervisory framework that impacts on flexibility, sustainability and efficiency, several legislative issues have been identified that must be addressed. These include:

1. Lack of coordination between stakeholders.
2. Registration and eligibility requirements.
3. Lack of strategic planning approach for procurement processes.
4. Allocation of resources and procurement policies.
5. Lack of competition and benefiting from flexibilities in the international trade agreements and patent laws.
6. Lack of flexible procurement mechanisms permitting to meet the requirements of procurement from the international entities.

It will be difficult to achieve the objective of providing drugs at the lowest possible prices in Jordan and achieving drug security until these areas are tackled and legislation is drafted or amended in a strategically coordinated manner. This report identifies the key legislative issues and highlights the key principles contributing to sustainability and efficiency.

Components of Report:

Due to the complexity of the subject, the report was divided into three main components to provide a comprehensive approach.

- Component 1: Requirements of procurement from international entities and assessment of availability of the feasibility of those requirements in Jordanian legislation. This component is further divided into three elements including; regulatory provisions, financial provisions, and contractual issues.
- Component 2: Analysis of legislation correlated to patents, intellectual property, competition laws, drugs registration, and drug security.

- Component 3: Provisions of the government procurement system; Recommendations and instructions of the joint procurement system to explain the changes and their impact.

Component 1: Requirements of procurement from international entities concerned in vaccines

According to WHO, the objective of vaccines procurement is to **"obtain quality-assured products on a timely basis and at affordable prices in order to improve the performance of immunization programs".** Procurement of vaccines for national immunization programs should be driven by the same guiding principles governing all public sector procurement including openness and integrity based on clear requirements and well-defined procedures.

With regard to the Jordanian landscape, vaccines procurement significantly differs from the procurement of other health goods. First, safety and product quality regulations should be a top priority in procurement decisions as vaccines are administered to a healthy population to protect them from diseases and prevent catastrophic health conditions. Second, for the majority of vaccines, there is a limited number of suppliers which limits procurement options, and in some cases, this grants suppliers significant control over the market. Lastly, grace periods are prolonged ranging between 8 to 24 months, thus procurement decisions must be made in advance to avoid inventories and shortages. Ensuring continuity of supply and sustainable prices of vaccine can be deemed more important than other goods given the importance of long-term financial planning and avoidance of high costs of treatment.

The Development Institute[6] developed a recent report indicating the regulatory and legislative changes required to purchase vaccines through UNICEF, where countries can procure vaccines at lower prices through UNICEF. In certain cases, legislative and regulatory changes may be necessary before such countries can utilize these options. Vaccine prices are influenced by demand, trust in demand and payment, supply contract period, as well as product features and market competitiveness. Middle-income countries are able to access vaccines at prices similar to those paid by GAVI, in the cases when the purchase is conducted through UNICEF.

Assessment of vaccines requires specialized expertise to ensure high levels of effectiveness, safety, and quality. For example, select governments have the resources to verify that suppliers in other countries have met acceptable manufacturing standards. Accordingly, the WHO developed a pre-qualification system for vaccines to verify vaccines acceptability for purchase by UN agencies, thus all vaccines recommended by the WHO for routine immunization are provided by qualified suppliers.

When evaluating purchase options and considering procurement from UNICEF or the Revolving Fund, governments should take several factors into account:

- Legal restrictions: Some countries have laws or regulations restricting utilization of external agents in procurement or prohibit prepayment, which is a set requirement by UNICEF.
- Price: UNICEF and the Revolving Fund usually obtain competitive prices which are lower than the prices countries are quoted for the same products. UNICEF and the Revolving Fund charge a minor percentage of the value of the procurement services as an overhead charge.
- Control on payment terms: UNICEF prepayment requirements are an obstacle for some countries, although UNICEF provides short-term funding through the Vaccine Independence Initiative.

[6] Immunization Financing Guide -2017- (p. 83) Legislative requirements to assist vaccines procurement from International Organizations. https://www.immunizationfinancing.org/

- Development of ability to purchase: In some countries, procurement is considered a government function and should only be outsourced in exceptional circumstances. In such countries, external agents are just temporary means aiming at establishing the national procurement capacity as soon as possible.

Azerbaijan is an example of a country which utilized the option of purchasing from the UNICEF Supply Division. Azerbaijan has cooperated with the UNICEF Supply Division since 2014[7], where the Ministry of Health has purchased all vaccines included in Azerbaijan's national list through the UNICEF Supply Division. Government officials reported several advantages including:

- Best price: Vaccines prices were significantly lower than direct purchase.
- Guaranteed quality: All UNICEF-purchased vaccines are certified by WHO to ensure their quality.
- Continuous supplies: Health officials reported that there had been no supply or stock interruptions since starting to purchase through UNICEF.
- Transparency: The government considers the UNICEF Supply Division as a respected organization having clear procedures.
- Compliance with cold chain: Government trusts UNICEF requirements for compliance with cold-chain during delivery.
- Flexibility UNICEF requires a 10% protection payment to meet market fluctuations and exchange rates. In the event where such funds are not used, they can be reprogrammed or returned to the government. The Government of Azerbaijan requested reprogramming the funds to meet other national needs, such as purchase of vitamin A and additional quantities of the pneumococcal vaccine.

Vaccination (immunization) advocates consider legislation an extremely powerful tool to support sustainable immunization funding as it provides a legal commitment to immunization and an operational framework for immunization services. Accordingly, the table below reviewed the procurement requirements (from international organizations) and correlated to the Jordanian legislations, clarifying the required legislative issues and verified their inclusion in the Jordanian legislation:

[7] Immunization Financing Guide -2017- (p. 83) Legislative requirements to assist vaccines procurement from International Organizations. https://www.immunizationfinancing.org/

#	Issue	Solution Rationale	Legislative Status	Proposed Legislative Solutions	Priorities and responsible entities
	Compliance of Jordanian legislations with the requirements of purchase from UNICEF Supply Division	Prices obtained are much lower than the current prices approved by UNICEF as it collects its purchases for all countries and makes long-term contracts with manufacturers. The requirements are justified since payments are prepaid and is evaluated by the WHO. Other financials and policies will be reviewed later.	It will be addressed for each item separately.	It will be addressed for each item separately.	Priorities will be identified for each issue separately.
First: General Regulatory Provisions					
1	Multiplicity of legal provisions	Reducing the number of legislations helps with effective implementation.	Vaccination and governmental procurement rules are guided by several legislations.	Compiling the rules on obligatory and free vaccination, procurement and supply chain in one legislation	No priority now as this requires time. Responsible Entity: Cabinet and Parliament
2	Mandatory vaccination	Maintaining the health of individuals and children is the countries duty regardless of the cooperation of individuals	Public Health Law, as amended, No. 47 of 2008 Article 28: A. Parent of each child or guardian thereof shall refer to any of MOH health centers, MOH-approved vaccination center MOH-approved doctor to vaccinate the child with the vaccines included in the National Vaccination Program according to MOH instructions. The person who vaccinated the child shall issue a vaccination	No need for legislative intervention except for considering the possibility of compiling the rules relating to vaccination	N/A

			certificate that includes the name of the vaccine and the date. B. If required by public health conditions and in special cases, the Minister may decide to administer the necessary vaccinations to people of various age groups and may decide to re-vaccinate in repeated doses whenever necessary.		
3	Penalties	Normally, legislations should include penalties However, the current law and vaccination instructions do not include penalizing some of the cases that have been internationally monitored and included in the legislation, such as Model Vaccination Law in Latin America[8] for the following violations: 1. Hindering the vaccination activities provided in this document 2. Failing to comply with the guidelines and regulations 3. Receiving payment for the administration of vaccines included in the National Vaccination Scheme	Article 66: whoever violates any of the provisions of this law or the regulations issued shall be penalized by imprisonment from two months to one year, a fine not less than JOD 500 and not exceeding JOD 1000, or both penalties.	Such violations should be made available in the instructions and penalties should be listed based on Article 66.	Prioritized. Responsible entity: MOH minister or Cabinet

[8] Model Law sponsored by the Carso Health Institute, Sustainable Immunization Financing (SIF) Program Sabin Vaccine Institute - item 52, https://www.sabin.org/sites/sabin.org/files/latin_american_parliament_model_vaccination_law_2009.pdf

		4. Selling vaccines intended for vaccination campaigns conducted within the public health system 5. Issuing forged Vaccination Cards or Cards with false vaccination record			
4	Free of charge vaccination	According to international standards, vaccination should be free of charge since it protects individuals from diseases.	Article 28/C The Ministry shall provide vaccines and preventive serums for the protection of individuals and children Article 29 No fees or charges shall be collected for vaccines and preventive serums provided by the MOH centers Article 19 of the Health Insurance Regulations The Ministry shall provide the following free services: A. Vaccines and preventive serums should be given to prevent and treat communicable diseases.	No need for legislative intervention, as in the Public Health Law (accordance with Article 73), overrules any article that contradicts with it.	N/A
5	Vaccines selection mechanism	Vaccination legislation often includes an operational provision governing the national vaccination schedule. This provision usually identifies the process through which vaccines are introduced in and removed from the schedule, the authorized people to make decision, criteria for decision-making, people supervising decision-making, etc. These	Vaccination Instructions No. 1 of 2009 Article 2: The Ministry shall include vaccines in the National Vaccination Program that meet the international standards by a decision of the Minister upon the recommendation of the National Vaccination Technical Committee.	Instructions and a specialized committee addressing most of these requirements are available in Jordan. However, instructions should be developed to regulate the work of the Technical Vaccination Committee. It is preferable to do this in the same legislation	Prioritized. Responsible entity: MOH minister

		elements are essential for sending both routine vaccines and financial needs to the national vaccination programs. However, there is no clear work path for the National Vaccination Technical Committee. In addition, decisions related to newly introduced vaccines have long-term effects on immunization costs, logistics and service delivery. Selection of vaccine provision also affects cost and delivery. During decision making, policymakers should consider the burden of disease, vaccine safety and efficacy, cost effectiveness and affordability, operational feasibility and delivery requirements, and public perceptions and demand. * Independent technical committees, often called National Immunization Technical Advisory Groups (NITAGs), can help ensure transparency, credibility and evidence-based decisions when introducing a new vaccine. * A variety of tools are available to support countries in making decisions related to new vaccines and to enhance the decision-making processes. The PAHO	The Ministry shall provide the vaccines mentioned in Paragraph (A) above Article 3: Administration of vaccines identified in Article (2) above shall be mandatory and free in the Ministry for all children under age of 18 residing in the Kingdom regardless of the nationality of the child. Article 4: A. vaccination card shall be issued to each of the children mentioned above in Article (3), identifying the types of vaccines included in the national vaccination program, number of required doses and age of child taking the vaccine according to the prescribed doses. B. The health staff shall write down the date of vaccine administration to the child when visiting the vaccination place. C. This card shall be a basic document for the enrolment of children in kindergarten or school, and should be saved in the file of the children or students. Article 5:	relating to vaccination that includes vaccination instructions and selection as well as the criteria to select the members of the committee. In addition, Vaccination Guidelines prepared in cooperation with UNICEF and school instructions should be legally binding to ensure that those violating them are subject to disciplinary and legal liability. The set criteria should take into consideration newly introduced vaccines that are recommended by WHO and NITAGs	

		ProVac initiative is a model that supports decision-making.[9] The important considerations for adopting decisions are as follows: • Burden of disease and importance of public health • Vaccine effectiveness and safety • Delivery requirements and operational feasibility • Cost • Cost-effectiveness • Affordability • Acceptance and population demand	A. Vaccines shall be given in the following places: 1. MOH health centers and mobile clinics 2. MOH-approved vaccination centers (Royal Medical Services, University of Jordan Hospital, King Abdullah University Hospital, UNRWA) 3. Any centers approved by the Ministry in accordance with the provisions of Article 28/A of the Public Health Law 4. Clinics of licensed general practitioners and pediatricians B. The parties mentioned in Paragraph (A) above shall comply with the vaccination guidelines issued by the Ministry. Article 7: A. The approved parties shall not sell vaccines provided by the ministry for free and they shall provide the ministry with a monthly report on the number of children vaccinated through the Directorates of Health. B. Doctors referred to in Article 5/A/4 of these		

[9] Immunization Financing Guide -2017, p. 31, Item 4.

			instructions shall issue a vaccination card/ vaccination certificate indicating the information mentioned in Article 4/A of these instructions. C. The certificate or card issued by doctors referred to above in Paragraph (B) shall be approved for the purpose of child enrolment in kindergartens or schools after being certified by the concerned Directorate at the Ministry. Article 8: The Ministry supervises, controls and follows up on its vaccination centers and other approved centers to maintain the Cold Chain System (a system that ensures maintaining effectiveness of vaccines from manufacturing till administration). Article 9: The Ministry as needed, conducts vaccination campaigns for the targeted groups in line with international programs and the epidemiological situation in Jordan.		

			In addition, the Vaccination Guidelines[10] is available and was prepared in cooperation with UNICEF and taking into consideration the school instructions		
Second: Financial Provisions					
I	Financing	One of the most significant barriers to contracting with international entities is to guarantee maintaining a sustainable fund that covers regular distribution of medicine and medical equipment and consumables as stated in the National Medicine Policy. This includes taking the necessary measures to improve efficiency and reduce wasted resources. It was proposed to allocate budget by the government to enhance preventive measures. In addition, the Integrity Assessment in the Health Sector in Jordan[11] recommended to allocate a financial resource from the treasury or to establish a financing system for drugs where funds would be available before purchase procedures start.	There are no clear items for securing funds for purchasing and according to MOH budget of 2018, vaccines procurement amounted to approximately 20 million JD. As well, tax allocation requires legal detailing as in the following item.	One of the following options should be considered: - Allocate specific financial resources, such as taxes on drugs and pharmaceutical export in case they are not sustained - Price of drugs should be used to finance drug procurement - Issue financial obligation for payment from the Ministry of Finance to ensure payment of prices. Strategic solutions can be sought from a specialized budget and an independent entity to handle procurement process or issue a	Prioritized. Responsible entity: Ministry of Finance, and a strategic choice depending on the of Cabinet

10 http://www.moh.gov.jo/EchoBusV3.0/SystemAssets/communicable/MOH%20Vac%20ManualA.pdf

11 Integrity Assessment in the Health Sector in Jordan issued by UNDP in Arab States http://www.arabstates.undp.org/content/rbas/ar/home/library/Dem_Gov/Informal_sector_gov.html

		The generally accepted resources include budgetary allocations, taxes on health-harmful products such as sugar, cigarettes, and lottery, as well as local and international donations.		system similar to the trade account system.	
2	Resource allocation	As mentioned above, it is important to allocate resources to maintain. As for allocation, Article 113 of the Constitution states that: all tax revenues and other country revenues should be paid into the Treasury and shall be included in the country's budget unless otherwise stated in the law. Funds shall not be appropriated or spent for any reason except by law. According to the Civil Health Insurance Regulations, it is important to know that all MOH sales of drugs are given to the Civil Health Insurance Fund and are not used to purchase drugs. A tax was enforced on exported drugs that were exempt until 2018. noting that drug exports amounted to USD 468 million in 2016 and decreased to USD 352 million in 2018 according to JFDA Director. Procurement financing[12] is used using reliable mechanisms, such	The following are legislations in which imports are allocated: Article 11 of the Income Tax Law where specific percentages of the tax are allocated to the National Contribution Fund designated for the payment of public debt, including: A. 3% of the taxable income of banks and electricity distribution and generation companies. B. 7% of the taxable income of basic material mining companies. C. 4% of the taxable income of brokers, financial companies and persons practicing financial leasing activities. D. 2% of the taxable income of major telecommunications, insurance and reinsurance companies.	Funds should be allocated according to the above mentioned. Taking advantage of the experience of commercial account for wheat procurement issued under the Commercial Account Management System at the Ministry of Industry and Trade No. 67 of 2000. Article 3: Assets of the account shall consist of all movable and immovable property owned by the Ministry for the purpose of trading, storing and operating the designated facilities. In addition to the allocations appropriated in the general budget for facilities and capital projects of the account.	Prioritized. Responsible entity: Ministry of Finance and Ministry of Planning

[12] Enhancing Access to Medical Technology and Innovations -2012 – issued by WTO, WHO and ` - p. 162 http://www.who.int/phi/Trilateral_Study_Summary_arabic.pdf

		as decentralized accounts for drug procurement or renewable financing. In each case, the mechanism itself should also be adequately financed.	In addition to the Agricultural Risk Management Fund Law with amendments of No. 5 of 2009 where Article No.7 states that the financial resources of the Fund shall consist of: The allocated annual general budget should not be below 3 million JD. 10% of the fees collected for the product in the wholesale markets of vegetables and fruits shall be given to the public treasury and re-allocated to the treasury fund annually. B. Agricultural Risk Management Fund shall not be subjected to the provisions of the Financial Surpluses Law. As well as the health insurance regulations that allocates all drug and treatments price carried out in government hospitals for the Health Insurance Fund.	Article 10: The financial resources of the account shall consist of the following: A. Revenues from sale of basic materials and supplies B. Proceeds from the operation of the facilities of the account. C. Allocations in the general budget. D. Cash and donations provided to the Ministry that benefit the account. E. Any other returns. The account shall be audited on a commercial basis.	
3	Commitment to payment	It shall be addressed later.	It shall be addressed later.	It shall be addressed later.	It shall be addressed later.
4	Multi-year budget	Issuance of a multi-year budget is vital for long-term contracts and required for some strategic contracts	Article 4 of the Budget Law states that: "All figures and data related to years 2020 and 2021 contained in this law are indicative and	Budgets are issued annually and therefore the solution is to deliver products in the same financial year of	

			subject to amendment and updating based on future developments in the next year."	contracting, to seek obligation guarantee or learn from the commercial account experience	
5	Customs tariff	According to recommended global practices, cold chain equipment and components should be considered as part of the national vaccination strategy and granted customs exemptions	Customs Law No. 20 of 1998 and amendments. In the integrated tariff published on the customs website, pharmaceutical products are subject to zero customs tariffs, but subject to 4% sales tax.	Cold chain supplies should be exempted from customs	To be checked with the technical committee
6	Sales tax on drugs and vaccines	In accordance with the recommended practices, exemptions should be granted for essential drugs and vaccines in case of taxation. In Jordan, sales tax is enforced on drugs and vaccines, while veterinary vaccines and drugs are subject to 0% tax. In addition, exemption is granted to specific entities, including the army, King Hussein Cancer Center and Center for Cell Therapy at the University of Jordan. As well, Government enforces 16% tax on certain types of drops and drugs as they are considered medical consumables.	No provisions exempt public tender purchases from sales tax as they are not included in Articles 21 and 22 of the Sales Tax Law. Drugs and vaccines[13] are subject to a sales tax of 4%. Pharmaceutical products and drugs except (ambulance bags and pharmaceutical waste as well as the items included in Table (2) annexed to the Law). Noting that the drug tax enforced by the government by 4%, is charged on the final price after the adding of profits and costs. On the other hand, veterinary drugs, veterinary	One of the following options should considered: Exemption of drugs, especially vaccines from sales tax, or allocate such tax to support drug procurement, especially vaccines.	Prioritized. Responsible entity: The Cabinet

[13] Reduction of sales tax from 16% to 4% and amendments thereto of 2017, published on page 1142 of the Official Gazette No. 5442, dated 12/2/2017, issued in accordance with Article 22, Paragraph 3 of the General Sales Tax Law and amendments thereto No. 6 of 1994

		A recent example of discussion was the injection "HYALONE", which is administered in the knee joint. It was classified as a medical device that is not subject to pricing and after pricing by JFDA, it is now priced approximately 72 JD, rather than 410 JD previously. It was previously recommended to review the tax on drugs and to cancel the tax but the government did not agree.	vaccines, laboratory reagents, medical consumables and cancer treatment equipment for King Hussein Cancer Center, as well as drugs, laboratory reagents, medical consumables and equipment for the use of Cell Therapy Center at the University of Jordan are subject to 0% tax, contrary to human vaccines.		
7	Sales tax on supply chain and vaccine-related materials	According to the recommended global practices, the equipment and components of cold chain devices should be considered as part of the national vaccination strategy and therefore they should be granted customs and tax exemptions. For example, Article 47 of the Latin American Model Law stipulates that acquisition and maintenance of equipment and supplies for the cold chain should be exempted from payment of taxes and fees.	No provisions on exemption	Same recommendation as mentioned above	Prioritized. Responsible entity: Cabinet
8	Potential of exemption from sales tax for tenders	There are provisions permitting exemption from sales tax, but they are unsustainable	General Budget Law No. 1 of 2018 Article 6/H: No tender for any project whose cost exceeds the appropriations allocated for in this law shall be awarded except by the approval of the Minister of Finance upon the	Provision of Paragraph (P) can be utilized in case of signing an international agreement	N/A

			recommendation of the Director General of the General Budget Department. I. The local tender committees in the ministries and government departments shall not invite for and /or award any tender except after making sure of the availability of the necessary appropriations, taking into consideration the provisions of Article (6) of Supplies Bylaw No. (32) of 1993, and amendments thereto. J. The tender committees formed under the applicable Government Works Bylaw and Supplies Bylaw shall not invite for and/or award any tender exceeding JOD 10,000 except after verifying the availability of the necessary appropriations and upon a financial commitment voucher certified by the Director General of the General Budget Department. P. No projects financed by the General Budget shall be exempted from the taxes and fees unless they are financed by grants/donations		

			or stipulated within the provisions of any other law or any international agreement. Exemption from tax shall be pursuant to Cabinet's decision, including Cabinet Decisions No. 7283 dated 14/10/1979 and No. 3378 dated 6/8/1986 under agreements signed between the Government represented by the Minister of Industry and Trade and pharmaceutical companies under the condition of producing a recommendation from the Ministry of Industry and Trade and a recommendation from JFDA.		
9	Income tax	Tax was increased on drug industry from 14% to 20% in a period of 5 years (from 10% first year -14% second year -16% third year -18% fourth year -19% fifth year). Export tax was also levied at the end of the previous exemption for the domestic industry under the System of Exempting Profits of Exports of Goods and Services from Income Tax and amendments thereto No. 106 of 2016.	Income Tax Law and its amendments No. 34 of 2014 Article 11: B. Tax on the taxable income of the legal person shall be levied according to the following rates: 1. (20%) Twenty percent for all legal persons except those provided for under items (2) and (3) of this Paragraph. 2. (24%) Twenty four percent on each dinar of	Consideration should be directed to build a strategy encouraging the local pharmaceutical industry and creating a package of governmental and international benefits to encourage the establishment of private factories in the field of biological industries and vaccines, especially in light of the results of the meeting	Strategic option. Relevant parties: international organizations, government and JAPM

		According to Article 3: The net income of the taxpayer from the export of goods of local origin outside the Kingdom shall be exempted from tax until 31/12/2018.	main telecommunication companies, electricity distribution and generation companies, basic mining material companies, insurance companies, reinsurance companies, financial intermediaries, financial companies, and legal persons undertaking financial leasing activities. 3. (35%) Thirty five percent on each dinar for banks. C- The percentages shown below shall be reduced and for a period not exceeding five years from the effective date of this amended Law from the tax due on industrial activities as per the below: 1. Industrial activities except pharmaceutical and clothing: Year Rate 2019 25% 2020 20% 2021 15% 2022 10% 2023 5% 2. Pharmaceuticals and clothing: Year Rate 2019 50% 2020 30%	held by the economic team chaired by the Prime Minister Dr. Omar Razzaz on 15/12/2018[14] with the Jordanian Association of Pharmaceutical Manufacturers (JAPM), under which a council was formed to formulate the ideas and procedures required to enhance the capacity of the Jordanian pharmaceutical companies and to produce biopharmaceuticals, which Jordan still depends on importing from abroad. In light of the trend of international agencies to support the establishment of new factories in the world to produce vaccines, and to be certified by such agencies, Jordan should take advantage of the support of international organizations and coordinate with them to be the center of the	

[14] https://www.jo24.net/post.php?id=300646

			2021 20% 2022 10% 2023 5% Article amendments: After replacing its previous text with the current text under the amended Law No. 38 of 2018, where the previous text was as follows: B. Tax on the taxable income of the legal person shall be levied according to the following rates: 1. (14%) Fourteen percent for the industrial sector.	vaccine industry in the Middle East and North Africa), to be able to face the multinational companies that monopolize vaccine production.	
10	Payment currency	Sometimes, payment in local currency is an obstacle to contracting with international agencies and companies in some types of long-term contracts	New Procurement Regulation - Article 31: Procurement documents A. The purchasing entity shall prepare the procurement documents involving complete information on the tender, including the following: 1. Nature of purchase, quantity and execution period, in addition to execution of the purchase contract. 7. A statement indicating if the prices are fixed or can be adjusted and in this case the formulas to be followed shall be identified. 8. Currency (currencies) on which proposals will be	The provision permitted payment in foreign currency should be reactivated or should be permitted through the drug instructions that will be issued based on the government procurement system.	Cabinet as first option and Procurement Policies Committee as second option

			submitted, and the currency to be used for comparison of proposals in the different currencies, in accordance with the Central Bank Bulletin of Currency Rates and on the date specified in the procurement documents. Before it was amended, the framework agreement permitted payment in foreign currency.		
Third: Contractual Provisions					
1	Direct contracting with UNICEF and priority for implementation	The special nature of vaccine procurement, especially vaccines, which are funded by external parties, requires the development of legislative provisions granting special treatment and positive amendment in this respect. This provision does not exist in current legislation and allows for direct contracting with UNICEF without a competitive tendering process	Article 3/F: Notwithstanding the provisions of this Law, the following shall be applied: 1. The procurement rules of any donor or funding party, which shall be applied in accordance with the Government's obligations towards such entities, if any. 2. Procurement rules in accordance with international protocols and agreements concluded between the Government and international or regional governments or organizations, if any.	It is preferable to develop instructions identifying how to apply this exclusion, while considering the requirements of vaccine procurement carried out in accordance with the international agreements	Prioritized. Responsible Entity: Procurement Policies Committee
2	Quality assurance by the contracting party	Quality shall be guaranteed by the contracting party, especially if significant provisions are	N/A	N/A	N/A

		excluded upon requirement of registration			
3	Contract language	Contract language shall be specified	Article 20/B: International procurement documents, contract agreement and conditions, specifications, plans, technical reports and correspondence shall be prepared in both Arabic and English. In case of conflict between the two languages, the Arabic language shall prevail.	N/A	N/A
4	Arbitration	Sometimes, international arbitration is required for some procurement processes	Procurement system approved local and international arbitration and the application of foreign laws, as will be shown later in the component of unified procurement	N/A	N/A
5	Need for local agent	One of international organizations' procurement requirements is to not to contract local agents in order to save expenses, as will be shown later	The legal status now does not allow this, and under the amended draft drug and pharmacy law, it was permitted to import unregistered drugs, but the local agent is required in this process, as will be shown later	It is required to exclude the local agent requirement from the amended draft law, as will be shown later	Prioritized. Responsible entity: Government and Parliament
6	Pricing vaccines	Currently, vaccines are not priced and this leads to high vaccines prices in the private sector and the unavailability of information about the costs of importing them	Article 3: Registration rules These rules shall be adopted for the purpose of registration, renewal of registration and cancellation of registration of drugs. They are applied to new	Pricing vaccines is required to prevent high prices in the private sector and to allow reinforcements and disclose the cost of purchasing when pricing	Prioritized.

			drugs, drugs having no registered alternative, preventive serums, vaccines and biological drugs. No such provision exists in the pricing rules. Joint injections were recently priced as they are considered health supplies under the rules of joint injections pricing for year 2018, published on 16/1/2019.	them, which contributes to create a reference on its cost.	
7	Multi-year procurement	In the field of vaccines, it is sometimes required to have long-term contracts due to the lack of suppliers and the lack of manufacturers in the world because of the high cost of production and low profit margin and the absence of generic vaccines. However, since the so-called manufacturing through the pre-market commitment between international funding agencies or a government, with international support, vaccines are now provided at low prices, as all studies indicate, for example, pneumococcal vaccine[15]	New government procurement system allowed procurement for several years as Article 57 provides for: Contracting parties may establish a framework agreement of maximum period of two years under one of the following contracts: Closed: limited to contractors hired while new contractors may not be included. Open: not limited to contractors hired and allows a new contractor to submit proposals to the purchasing entity in compliance with	It is preferable that the maximum period of framework agreement lasts for three years rather than two years in cases of drug security, including vaccines. Suggested solutions: - Amend the Article to increase the period of the framework agreement. - Add an Article in the system permitting the development of instructions involving special provisions when purchasing vaccines.	Prioritized. Responsible entity: Cabinet

[15] (Report on Access to Medical Technology and Innovations - Common Areas between Public Health and Intellectual Property, issued by WHO, WTO and WIPO), prepared under international organizations' supervision.

			the requirements of the procurement documents at any time during the validity period of the contract.		
8	Framework agreement	An example of using framework agreement procedures: when the market is very competitive and there are usually regular or recurrent procurements, and their required quantities may vary. It is also appropriate for the procurement of items from multiple sources, such as electricity, and items that are expected to be needed urgently in the future, such as drugs (when a key objective is to avoid excessively high prices and the bad quality resulting from making procurement from a single source in urgent cases).[16] Only purchase in urgent and emergency cases). Framework agreement also allows to predetermine prices. It is also recommended in cases of patents. Competitive negotiation or procurement from a single source may be appropriate to conclude a closed framework agreement in urgent cases. In certain cases, some parties involved in procurement have	Article 58: Development and implementation of the Framework Agreement A. Framework agreements are developed in accordance with the principles and procedures referred to in this Regulation and the instructions issued thereunder for all phases up to conclusion of contracts, including principles of transparency and competition, tendering procedures, evaluation of bidders' qualifications and procurement methods. B. When inviting for bidding, the procuring entity shall disclose the information required to enable bidders to understand the nature of the framework agreement and related procedures, whether the framework agreement is open or closed, the forms, terms and conditions of the framework agreement, the method of contracting with the	Prior to amendment thereof, the draft agreement included provisions clarifying special cases but they were canceled by the legal committee, including: D. The framework agreement shall be generally based on pre-agreed prices or specified in applications. T. In case the number of suppliers is limited, a framework agreement may be developed to procure goods (e.g. fuel, iron, copper, etc.) with these suppliers directly by issuing periodic invitations for bidding to them on the following bases: 1. Bidders may be invited to submit proposals related to the market price during or before shipment.	Prioritized.

[16] Guidelines of general procurement model law http://www.uncitral.org/uncitral/ar/uncitral_texts/procurement_infrastructure/2011Model.html

		special requirements and in such case, it should be taken into account that the beneficiary in the project is the one for whom procurement was made. This party can be the Royal Medical Center or King Hussein Cancer Center (usually having special requirements).	participants in the framework agreement, and any other information required to participate in the development and implementation of framework agreement. C. The beneficiary may communicate with the procurement committee in order to participate or enter into the framework agreement during the contract's validity period to become a party thereto. D. The procurement committee shall contract with the suppliers, contractors or service providers that subsequently applied to join the framework agreement after considering the application, provided that the rejected applicants are notified accordingly with the reasons of rejection.	3. Unified currency in which the goods is normally priced in the market may be used for both tender and payment. This can be addressed by instructions.	
9	Payment method	The key challenges faced by the procurement department were the delay of transfers to JPD which leads to the delay of payment of tender values to the suppliers and accumulation of arrears and this is negatively reflected on JPD credibility and the provision of drugs to the	Article 79 93. Method of payment A. Payment of financial dues shall be based on submission of a financial claim involving any information required by payment conditions. B. Procurement contract may provide for payment of	It is useful to seriously consider the provision of a part of the allocations before procurement or that payment for drugs by a financial guarantee issued by MOF and that the committee is	Prioritized.

		participating entities. This is included under the challenges faced by JPD in the Chapter on JPD budget. In the government procurement draft system before the amendment of the proposal, it was included that JPD shall pay for drugs and medical supplies provided by the contractors. A previous study conducted by the Anti-Corruption Commission in cooperation with MOH, JPD, JFDA and General Supplies Department to assess procurement integrity in the health sector recommended to conduct a feasibility study of the development of a financing system for drug procurement to help provide financing before starting the procurement process and bidding, where page 58 included the recommendation to establish drug financing fund. A fund established for one purpose and operates on a commercial basis. As stated in the report of the Audit Bureau, Item 8, page 318, payment to suppliers is delayed due to the delay in transfer of the amounts from the entities requesting procurement. On 3/6/2019, the Minister of Health stated that this delay leads	the value of the procurement contract in interim payments based on progress of work and achievements after the contractor submits the documents required by the beneficiary and such documents being accepted by the beneficiary. Current instructions provide for the following: Article 1: First: Local tenders (local companies or local agents): 1. JPD shall open an account (JOD) in the Central Bank. 2. Each entity shall provide JPD with a financial obligation bond covering the value of drugs to be purchased through JPD along with the purchase order. 3. JPD shall provide the financial departments of the entities participating in the joint procurement with copies of purchase orders and payment documents. 4. Each entity shall transfer the cash within a period not exceeding (120) days after the date of final receipt of drugs from the committee formed by the	provided by the credit as well as providing allocations from the entities requesting procurement. Prevent reluctance of some suppliers or accumulation of debt, which makes the entity authorized to purchase mortgaged to creditors as payment on time enhances competition and creates savings of prices outweigh the benefits of payments delay, because the cost of delay is added to the tender price and therefore options to impose delay fines (such as refunds tax) should be considered to enhance commitment This was reflected on Health Insurance in its contracts, as it purchases drugs from pharmacies or private hospitals at the highest price. It is necessary to amend the instructions to comply with the new system and to allow prepayment.	

		to accumulation of receivables to suppliers, which amounted by the end of 2018 to be approximately 92 million JD. He pointed out that payment of dues on drugs enhances drug security and that the payment was made in cooperation between MOH, MOF and JPD in coordination with Jordan Pharmacists Association (JPA). Advance payments for bail are required, especially in vaccines, as they contribute to obtaining the advance payment discount.	representatives of the entities participating in joint purchase to the Central Bank in JPD account. Article 2: Second: International tender (international companies): 1) Entities participating in joint procurement shall transfer (30%) of the referral value to that entity as insurance to the Central Bank. 2) Remaining cash shall be transferred to the Central Bank pursuant to the referral decision. C. Procurement contract may provide for: 1. Reserve a percentage of the amounts due until the completion of the procurement contract. 2. Advances, provided that the procurement contract indicates the conditions to be met for this purpose, including payment by deduction from the interim payments. D. Total payments amount made under the purchase contract shall not exceed the rates specified in the procurement documents.		

			E. No advance payments may be made unless a financial guarantee covering the complete value of such payment is submitted.		

Component 2: Legislation related to drug registration, patents and intellectual property

Fair access to drugs is included within the right to health, a right that is recognized in many international and regional conventions on human rights. Access to drugs is a universal right and common issue that several national and international actors are working to improve globally[17]. In this component, the impact of intellectual property laws on the provision of pharmaceutical products will be assessed. Proposed solutions that can be adopted to provide drugs to patients at affordable prices, within the framework of the global principles will be recommended based on the assessment.

The National Medicine Policy[18] revealed that Jordan encounters several challenges in provision of drugs. Exclusive rights such as patents and data protection create monopolies in the market, limiting competition in the sector. Limited quantities are made by a small number of pharmaceutical producers, with the support of bilateral and international trade agreements which results in increasing costs and hinders the local production of drugs.

Intellectual property classes in the TRIPS Agreement are known to create negative effects on pharmaceutical industries[19] in the developing countries related to patents and undisclosed information[20]. However, the TRIPS Agreement is flexible in certain cases, in which WTO member states can benefit. The Doha Declaration, adopted by WTO Ministerial Conference in 2001, recognized the aspects related to the impact of intellectual property on the price of drugs and reaffirmed the right of member states to benefit from TRIPS flexibilities to meet public health needs and to

[17] Special Rapporteur Anand Grover's Report on Access to Medicines dated 1/5/2013
http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session23/A-HRC-23-42_ar.pdf

[18] The National Medicine Policy prepared in collaboration with Medicines Transparency Alliance (MeTA)
http://www.jfda.jo/Pages/viewpage.aspx?pageID=177

[19] Intellectual property and its impact on the provision of pharmaceutical products in developing countries is important concerning the historical development of Doha Declaration and taking advantage of exceptions
https://www.wipo.int/edocs/mdocs/arab/ar/wipo_ip_jd_cai_07/wipo_ip_jd_cai_07_1.doc

[20] Article 39/3 of the Agreement requires WTO member countries to protect such data or information from unfair commercial use and to disclose it only when necessary, stating that: "3- Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

promote universal access to drugs. All relevant international organizations[21] recommend that states can benefit from the flexibilities the TRIPS Agreement provides, specifically: (A) benefiting fully from transitional periods, (B) identifying standards for protection under patent, (C) issuing mandatory licenses and providing for government use thereof, (D) adopting the principle of international exhaustion to facilitate parallel importation, (E) identifying limited exceptions to patent laws, and (F) enabling objection and cancellation procedures.

In this component several exceptions will be reviewed, especially "parallel importation", since the most critical condition for benefiting from these exceptions are for commercial purposes. These exceptions, developed with patented drugs in mind, include where certain provisions of trade agreements and regulations could be suspended due to the importance of the right to access to drugs. This allows parallel importation of registered and non-patented drugs and should be a priority to improve the health status of the population. In a recent interview, JFDA Director General, Dr. Hayel Obeidat mentioned that parallel importation in Jordan is permitted.[22]

The principle of parallel importation was first introduced in South Africa, a country heavily affected by HIV. Drugs needed to treat this epidemic are patented and monopolized by major pharmaceutical companies which sell them at extremely high prices. On December 12, 1997, President Nelson Mandela issued a law authorizing the Minister of Health to take measures to provide affordable drugs in line with the income of patients. This law authorized importing patented drugs into South Africa, as long as they were introduced by the major pharmaceutical companies owning the patents abroad, establishing the principle of parallel importation.

Canada took the lead in this regard and was the first country to pass a law giving effect to the resolution of WTO General Council of August 2003, Jean Chretien Pledge to Africa Act (Bill C-9). This law amended the Canadian Patent Act to permit generic pharmaceutical companies to obtain a compulsory license to manufacture patented drugs for export to countries that do not have the industrial capacity to produce them. The law requires the Canadian government to ensure the safety and efficacy of drugs exported for this purpose in accordance with Canadian standards in order to ensure the quality of the exported drugs. The law includes the right of the patent owner to have recourse to the federal court to demand the cancellation of the compulsory license in the event the licensee violates the license conditions or when smuggling drugs to countries other than the designated country. On December 6, 2005, the General Council of WTO member states adopted a resolution amending Article 31 of TRIPS in line with the previous resolution suspending the application of Article 31, Paragraphs (F) and (H) of TRIPS. Accordingly, the temporary resolution to suspend the application of Article 31, Paragraphs (F) and (H) of TRIPS was adopted into a permanent amendment of both paragraphs.

Legislation on drug registration, availability of a legal system governing the work of drug agents the process of providing drugs, and participation in bids will be reviewed in the assessment. This component will review legislative flexibility for the purpose of permitting the import of unregistered drugs, or drugs registered by an entity other than their agents, or drugs registered by the government. Cases of drug security provided for in the

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21 Special Rapporteur Anand Grover's Reports referred to in the references.

22 To import a monopolized drug by the British manufacturer in the world, he indicated that they were contacted to agree on a solution to reduce the price of the drug and enter the Jordan market at an appropriate price, but the parent company strongly rejected and adhered to its decision and the new price. Obaidat added that we will currently issue a letter to permit parallel importation of 500 pieces of a drug having similar formula of Camcolit to solve the problem temporarily and alleviate the suffering of patients https://www.sarayanews.com/print.php?id=393600

Drug and Pharmacy Law will be reviewed, and the proposed amendments to the revised Drug and Pharmacy Law will be considered as they are related to drug security.

Provisions of the Competition Law will also be evaluated due to the importance of its provisions in procurement. Utilizing competition laws aims to act against companies that abuse their dominant market position. This includes measures to combat practices such as imposing high prices and creating obstacles for other companies to deny access to markets, and collusive bidding practices.

First: TRIPS Flexibilities Provisions					
#	**Issue**	**Solution Rationale**	**Legislative Status**	**Proposed Legislative Solutions**	**Priorities Assigned and Responsible Entities**
I	Identify free treatments	Identification of free treatment types provided by MOH to all people is crucial, as the drug purchased will not be used for commercial purposes, this allowing some flexibility regarding intellectual property as we will illustrate later.	**Civil Health Insurance Regulations and its Amendments No. 83 of 2004 promulgated under Article 66 of Interim Public Health Law and its Amendments No. 54 of 2002** Article 19: The Ministry shall provide the following free services: **A- Administering serums and vaccines for the purpose of prevention and treatment of communicable diseases.** B- Maternal, child health care and family planning services in accordance with the instructions issued by the Minister for such purpose. C-Medical examination for missioned persons in any scholarships and for applicants who referred by departments under provisions of these regulations. D- Premarital Thalassemia Test. E- Blood test for blood donation purposes. F- School health services in accordance to issued instructions by Minister for such purpose.	N/A	N/A

			G- Any other case determined by Minister to preserve public health. Article 17: Treatment and medication expenses shall not be collected in the following cases: A- If the patient has communicable disease and requiring quarantine according to issued lists by Minister for such purpose. B- If the person is under health quarantine. C- If treatment provided as a result of incidents caused by natural disasters, epidemics caused by communicable diseases, collective poisoning or collective accidents not caused by direct party. Article 18: In accordance with issued instructions by the Cabinet upon Minister recommendation, the conditions for not collecting treatment fees in hospital or center shall be identified for any of following persons or cases: A- Patients with mental illnesses according to Minister decision in such regard. B- Hospitalized patients recommended by Ministry of Social Development. C- Alcoholics, drug addicts, psychotropic substances and medicines poisoning cases. D- Snake and scorpion bites. E- Patients with Acquired Immune Deficiency Syndrome (AIDS). F- Patients with any chronic blood diseases, including the following: 1- Hemophilia 2- Thalassemia		

			3- Sickle cell anemia 4- Aplastic Anemia 5- Acquired Hypogammaglobulinemia 6- Hypogammaglobulinemia G- Patients with cystic fibrosis H- Patients with cancer diseases and complications thereof I- Early detection of breast cancer		
2	Additional protection periods	Law granted a 5-year additional protection period. Under flexibilities, such as Bolar Exception for pre-production of drugs prior to expiration of protection term of granted by the patent[23]. "Early work" exception or Bolar exception allows competitors to import, manufacture and utilize the patented product for the purpose of seeking regulatory approval. Completing registration	Patents Law and its amendments No. 32 of 1999 Article 36: A. Patents of invention shall be granted for manufacturing and chemical processes relating to chemical products, pharmaceuticals and foodstuffs. B. After the enforceability date of this law, it shall be permissible to file patent applications for registering inventions involving the protection of final products for chemicals relating to pharmaceuticals or medicines or foodstuffs. C. Deciding the applications referred to in the previous paragraph (B) shall only be made after the enforceability date of this Article. D. Without prejudice to the provisions of any other law, the Minister may grant the applicant for a patent registration the exclusive right to market the chemical products relating to medicines or pharmaceuticals or foodstuffs covered by the patent subject for five years or until the date of patent grant or rejection	Feasibility of granting such additional protection should be considered.	Strategic.

[23] Master Thesis: Impact of TRIPS Protection to Patents on the Reality of Pharmaceutical Industries in Palestine, p. 156 et seq. on exceptions of TRIPS Agreement and parallel importation

		requirements before the patent period expires will facilitate the immediate entry of generic drugs into the market once the patent period expires. In 2000, WTO Dispute Settlement Panel endorsed such an exception by Canada as permissible under Article 30.	whichever is shorter if the following takes place after the enforceability date of this Article: 1. Filing application to obtain invention patent in Kingdom relating to the products mentioned in this Article. 2. Filing application to obtain invention patent in another country member of the World Trade Organization (WTO) and patent to be granted. 3. Granting a marketing permit for the product in the country where the patent obtained. 4. Registration permit for the medicine in the Kingdom by Ministry of Health.		
3	Parallel Importation	There is no doubt that international exhaustion of intellectual property rights is an effective method to prevent the division of world markets and price discrimination among them, since it allows states where the owners of intellectual property rights provide pharmaceutical products at high prices to import these pharmaceutical products from abroad and provide them in local markets at the lowest globally-prevailing prices. This	Article 37: Import from third party has legal protection. A. The provisions of this law shall not prevent any person from importing any materials or goods from a third party if that party has legal protection of same patent protected in the Kingdom and if that importation is lawful, complies with the principles of commercial competition and takes into account the economic value of protected patent. B. In spite of what comprised in paragraph (A) of this article and without prejudice to provisions of related International conventions, goods covered by patent of invention may not be imported by any Licensee, if the Licensing contract prohibit him from importation to the kingdom, provided that the patent owner notify in writing the Customs Administration and the registrar in this respect. The Registrar shall, at the expense of the patent owner, publish this notification in at least one of Local daily gazettes; and the applicable legislations shall apply to this case.	Patents Law prohibits parallel importation without the prior consent of the patent holder, while it only permits drug import by its agent even if it is not patented. Exceptions permitting parallel importation should be utilized in procurement as such exemptions are available in case there are patents. In absence of patents and lack of competition and suppliers controlling bidding prices (as tender prices	Strategic to patented drugs and prioritized for other drugs.

		type of import is known as Parallel Importation. TRIPS Agreement adopted a negative position on the issue of international exhaustion, as indicated in Article 6 of the Agreement, which provides for: "For the purposes of dispute settlement under this Agreement, without prejudice to the provisions of Articles 3 and 4, this Agreement shall include no procedures to be used to address the issue of exhaustion of intellectual property rights".[24]		should be normally compared to international prices and regional prices rather than local prices), exceptions should be utilized. Egyptian law provisions can beneficial: "The right of the patent owner to prevent third parties from importing, using, selling or distributing the goods shall be exhausted if the owner markets the goods in any state or third parties are licensed to do so".	
4	Information Exclusivity	Information exclusivity means to prevent clinical trials when registering the drug in order to verify drug efficacy for five years and this will delay and prevent competition. Pharmaceutical companies often rely	Trade secrets and unfair competition law of 2000 No. 15 / Article 8 Further Provisions: If an official party stipulated, for approving for the marketing of pharmaceuticals, or agrochemical products in which new chemical materials are used, the submission of secret formulae or any data attained through considerable efforts such party should observe the following: A. The protection of such data from the unclassified commercial use, through preventing any other	Study the possibility to restricting this right should be considered and the legislation imposing restrictions as the Egyptian law provides for in Article 44: Exclusive right of marketing	Strategic

[24] Intellectual Property and its Impact on the Provision of Pharmaceutical Products in Developing Countries - Dr. Hussam El Dein Abdulghani Al Saghir https://www.wipo.int/edocs/mdocs/arab/ar/wipo_ip_jd_cai_07/wipo_ip_jd_cai_07_1.doc

		on information exclusivity more than registration of patents. High drug prices and delay in entering many of drugs in Jordan designate to information exclusivity.	person who did not obtain the applicant approval from depending thereon for marketing his pharmaceuticals and products except after 5 years as of the date of the applicant obtaining any approval for marketing his products. B. Protecting such data from disclosure, unless: 1. The disclosure is necessary for protecting the public. 2. The official party has taken the necessary steps for the protection from unclassified commercial use of such data **Article 2 of Drug registration and amendment requirements thereto of 2015**, defined new chemical material (for data protection purposes) as drug containing an active substance or substances to which physiological or pharmacological effect is attributable, and none of its substances, whether individually or in combination, have been registered for more than 18 months in first country in the world, and regardless of any difference, including, but not limited to a difference in the type of salt, ester, ether, isomer, whether complex or any other derivatives, and the drug is considered to contain the same active chemical even in the case of differences in polymorph, metabolite, enantiomer, solvent, particle volume, combination, mixture, method of use, pharmaceutical form.	shall not be granted if it is clear from the documents submitted to the patent office to obtain the certificate of exclusive marketing right and that the application filed with the patent office was published about one year prior to the application filing date. The entity requesting the exclusive marketing rights of its product which the competent government authority grants thereto shall have such right. The previously granted exclusive marketing right shall be canceled by revoking the circulating decision issued by the competent ministry or if the right	

				holder arbitrarily used this right.	
5	Compulsory licensing	Article 22: Compulsory Licenses for Patent Exploitation The Minister may grant a license to use a patent to third parties without obtaining the patentee's consent in any of the following cases exclusively: A. If the use of the patent by the state authorities or licensed third parties is a necessity for national defense or emergency or for noncommercial public good provided that the patentee is notified as soon as it becomes possible. B.1. If the patentee doesn't exploit it or exploits it insufficiently before elapse 4 years as of application date or 3 years of granting date, the period to be applied is the one that elapses later. However, Minister may grant the patentee an additional grace period if he deems that reasons beyond the control of the patentee have prevented exploitation. 2. Clause (1) of this paragraph, and without prejudice the international provision related conventions, the importation of patent subject goods to the kingdom shall be deemed as utilization of the patent. C. If the patentee exercises his rights in such a way as to prevent others from competing fairly. Article 23: Requirements of licensing The following shall be taken into consideration when compulsory licenses are granted: A. Each application for a license shall be decided separately for its specific conditions and circumstances. B. The applicant shall have tried to obtain a license from the patentee under reasonable remuneration and conditions but did not reach an agreement during a reasonable period of time in the case provided for in paragraph (B) of Article 22 of this law.	Law No. 82 of 2002 on Protection of Intellectual Property Rights (Egypt) detailed the regulation of compulsory licensing in drugs field[25]: Article 23/ Second: Upon Minister of Health request, when the quantity of patented medicine, made available fail to adequately meet national needs, due to their poor quality **or if they are offered at a prohibitive price,** or if the patent is related to medicines addressing critical cases, incurable or endemic diseases … In all these cases, the decision of granting non-	Strategic. This is supported by the National Medicine Policy in terms of preparing clear bases for voluntary and compulsory licensing.

[25] WIPO Specialized National Symposium for Members of the Jordanian Judicial Institute organized by the World Intellectual Property Organization (WIPO) in cooperation with the Jordanian Judicial Council and King Abdullah II Center for Intellectual Property - 2004

		C. The scope and duration of the license shall be limited to the purpose for which it is granted. If the license application relates to semiconductor technology, then it shall only be granted for noncommercial public good or to rectify practices deemed by the competent judicial or administrative authority to be anticompetitive. D. The license to exploit shall not be exclusive. E. The license shall not be assignable to third parties. F. The license shall only be granted for meeting the demand in the local market other than for the case provided for in paragraph (C) of Article 22 of this law. G. The patentee shall receive an equitable remuneration which takes into account the economic value of the patent.	voluntary license shall be notified promptly to the owner of patent. The Law also set measures to control prices rising or non-availability of patented products in market or providing them under unfair terms. Fifth: If it is determined that the patent owner has abused of or exercised the rights conferred by the patent in a manner that is contrary to fair competition, such as: 1. Fixing exorbitant prices for patented products or preferential treatment of agents with regards to prices and sales conditions. 2. Failure to supply local market with patented product or	

				supplying it under prohibitive terms. 3. Ending the production of patented item or its production in a disproportionate manner, given production capacity and the market needs. 4. Undertaking acts or practices which have adverse effect on free competition, according to prescribed legal norms. 5. Exercising of rights conferred by this Law in a manner that adversely affects technology transfer. **These exceptions should be utilized.**	
Second: Provisions Relating to Competition					
#	**Issue**	**Solution Rationale**	**Legislative Status**	**Proposed Legislative Solutions**	**Priorities Assigned and Responsible Entities**

I	Encouraging the Competition	One of the international standards to encourage competition is the need for cooperation[26] between the authority concerned with competition (in Jordan, Competition Directorate) and the authority concerned with procurement (JPD). This may require time for joint work, cooperation and shared training. Some countries provide guidelines of suspicious practices (such as Qatar) and others there is legislation identifying possible forms of collusion, including refraining from participations bids (such as Egypt). Article 6/C of Law No. 3 of 2005 on	Law No. 33 of 2004 on Competition Article 5: Anti-Competitive Practices: Practices, alliances and agreements, explicit or implicit, that prejudice, contravene, limit or prevent competition, shall be prohibited, especially those whose subject or aim is to: 1. Fix the prices of products, services or conditions of sale, and the like. 2. Fix quantities of production or service provision. 3. Share the market based on geographical regions or quantities of sales or purchases or customers or any other basis that negatively affects competition. 4. Set barriers to entry of Enterprises into the market or eliminate them there from. 5**. Collusion in tenders or bids, whether in overbidding or underbidding, but it shall not be considered collusive to submit joint offers in which the parties announce such joint offer ab initio, and without the goal of such joint bidding being to prevent competition in any way.** B- **The provisions of paragraph (A) above shall not apply to agreements with weak effect wherein the total share of the Enterprises party thereto shall not exceed a rate to be set by instructions issued by the Minister, and which shall not exceed 10% of total transactions in the market, and provided that such agreements do not include procedures that fix price levels and market sharing.**	Collusion in tenders should be criminalized regardless market share of companies. Collaborate with Competition Directorate will be useful to produce a manual on collusive bidding practices and to train staff to monitor such practices. In order to prevent manipulation in tenders[27], the largest possible number of potential bidders should be given the opportunity, and no conditions should include unnecessary restrictions. Procurement policies may include deterrent actions to improper contact. For example, the requirement to	Prioritized.

[26] Role of Competition in the Pharmaceutical Sector (UNCTAD 2015), Item 44
https://unctad.org/meetings/en/SessionalDocuments/tdrbpconf8d3_ar.pdf

[27] Competition policies and the public procurement sector, Note prepared by UNCTAD secretariat -2012
https://unctad.org/meetings/en/SessionalDocuments/ciclpd14_ar.pdf (as well as references 12 and 14)

		Competition Protection and the Prohibition of Monopolistic Practices (Egypt) provides for: Coordinate regarding proceeding or **refraining from participating in tenders**, auctions, negotiations and other calls for procurement. Article 11 of the Executive Regulations included the violating practices: 1. Submitting similar offers, which include the agreement on common rules for the calculation prices or the determination of offer conditions. 2. Agreeing on the person who will submit the offer, which includes the prior agreement on the person who will be awarded the tender either by alternation, or on geographical basis or on customer division basis.	Article 27 of Drug and Pharmacy Law: A. Pharmaceutical institution shall be prohibited to refrain from dispensing any prescription or selling any drug or any material included in paragraph (B) of Article (3) of this law, whether illegally or for monopoly purposes. B. The warehouse shall have no right to oblige the pharmacy or any licensed party to sell any of materials included in Article (3) of this law to purchase a specific quantity.	formally advertise independent proposals and declare communications that may have occurred. This would serve as deterrent actions and facilitate the prosecution of any violations that may occur. If authorities concerned with competition prove improper contacts, companies may face serious legal consequences (especially if they have signed the declaration on independent bidding). **Bidders may be required to disclose their reasons for not desiring to participate in bids.**	

		3. Agreeing on fictitious offers submissions. 4. Agreeing on preventing a person from submitting or participating in submitting offers.			
Third: Agents Provisions					
#	**Issue**	**Solution Rationale**	**Legislative Status**	**Proposed Legislative Solutions**	**Priorities Assigned and Responsible Entities**
1	Limit import to agents under Commercial Agents and Mediators Law	(Jordanian law does not include exclusive import from the agent contrary to what is applied in drug field)		Considering the justification of limiting importation to agents under drug legislation	Strategic.
2	Agents' obligations	There is no legal regulation on suppliers' obligations in terms of meeting market needs (minimum inventory/ meeting market demand, including government procurement) by reviewing Article 20 of Drug Pricing Bases of 2016, which authorized suspension of drug registration	Consumer Protection Law No. 7 of 2017 did not includes any requirements on the supplier regarding goods provision, except the provision of after-sales services, maintenance and spare parts (Article 5). Commercial Agents and Mediators Law No. 28 of 2001. By reviewing the law, no obligations include on agent except for Article 11: Commercial agent shall provide sufficient spare parts and maintenance centers for the products, goods or services covered by the commercial agency. The provisions are only related to the relationship between client and agent and do not include any obligations on the client to public. **Circular addressed all concerned entities on 15/1/2017 included that unavailable drugs shall**	It is important to seriously consider imposing obligations on agents to secure market needs of drugs under liability of exceeding purchase and obligation to justify non-participation in tenders. The National Medicine Policy also indicated the need to prepare lists of	Prioritized.

		under misinformation or failure to report decrease in prices within six months, and Article 15 of Drug Registration Instructions which cancel the registration of the drug in cases of improper quality, suspend using the drug in the country on which it was approved when it was registered or registered based on incorrect information. These cases do not include cases of non-importation of the drug or minimum importation (which were included under Article 11 of Technical Committee for Drug Control and amendments No. 15 of 1973).	**be reported to investigate unavailability reasons according to reporting form of unavailable drugs.** **However, there is no legislative framework on verification criteria and procedures to be taken in this case.** http://www.jfda.jo/Pages/viewpage.aspx?pagesID=171	drugs to be available on a permanent basis, identify the strategic stock of each substance, set instructions for drugs to be available on a permanent basis, and secure drugs strategic stock to registered with their agents or manufacturers to ensure that the stock does not run out in private and public pharmacies. As well, reporting stock shortage and the procedures to be followed in such case should be regulated under instructions for this purpose.	
3	Pharmacovigilance (Monitoring agents)		**Pharmacovigilance Instructions of 2016** **Article 3: Scope of Application:** The instructions applied to healthcare providers, reporting persons, pharmaceutical agents and companies to achieve system of monitoring drug side effects and identify use problems.	Procurement system includes no mechanism to monitor effectiveness. This influenced the supplier as drugs may have side that	Prioritized. Competent party: JPD and JFDA

			Article 6: These reports or copies thereof shall not be used for purposes that may affect procurement decisions or bids results of government or private institutions or for unfair competition purposes. **Article 10:** JFDA shall immediately inform the company about any serious and unexpected side effects of drugs. **Article 11:** JFDA is the only authorized entity to verify and assess reports based on reviewing reports actualities, including medical files of concerned patients, doctors' reports, hospitals and available information to company holding the right of marketing or manufacturer and international references. **Article 13:** A. After considering, verifying and evaluating reports and information, JFDA shall issue the appropriate decision, including prohibition of circulating or importing the drug or suspending registration or retrieval, or amending the pamphlet or method of dispensing the drug. B. The company should implement JFDA decisions, including but not limited to: 1. Amend the pamphlet or other safety measures in response to the new drug safety information if the information affects balance between the benefits and risks of drug usage. 2. Change the dispensing method. 3. Retrieve the drug. C. The company should inform health care providers and recipients of all actions taken and changes in drugs' information.	are subsequently noticed, such as those contained in pharmacovigilance instructions of 2016, particularly Article 13 with a provision permitting retrieval of price or setting penalty and/or undertaking to return drugs. This should be added pursuant to procurement instructions. Article 13 should also include notifying the entity responsible for procurement.	

			Article 24: Penalties provided for in the effective Drug and Pharmacy Law shall be applicable to any party violating these instructions.		
Fourth: Drug Registration and Pricing					
1	Requirement of drug registration.	circulated the drug after registration and circulation shall include importation. However, in many cases, unregistered drugs are imported. JPD annual report of 2017 indicated that 4.2% of procurements are unregistered with value amounting to JOD 5 million, in addition to other entities, such as King Hussein Cancer Center and Royal Medical Services.	Article 2 of Drug and Pharmacy Law defines circulation as: "Transport, possession, distribution, offer for sale, endowment, donation, purchase, importation or use". Article 3/A: 1. Prohibited to circulate any drugs, serums and vaccines unless after registering the same with the Ministry and passing proper decision defining the prices for them according to the provisions of this law under legal penalty of responsibility in case of any breach of its provisions.	Legislative intervention is required to address importation of unregistered drugs for bidding purposes.	Prioritized.
2	Requirement of drug registration by procurement legislation.	In particular cases, importation of unregistered drugs is required due to scarcity of drugs and lack of manufacturers, such as vaccines, and so this is included in special conditions of joint procurement tenders in several countries, such as Joint Procurement	The draft regulations include no provision on this issue. No provision is included in the regulations or instructions, but Article 6 of Special Conditions of Contract provides for: Sixth: A. **Proposals shall be only submitted for items registered JFDA**. B. Proposals for unregistered items shall be accepted from companies that are registered and/or accredited by JFDA in case no proposals **are submitted for registered items**.	Drug registration is often required but in limited cases and under the approval of Minister of Health, this requirement is excluded. However, many international practices **permitted submitting for tenders with**	Prioritized.

		Company in Iraq where consequent registration or requirement cancelation of minister's approval were permitted. The conditions expressly provided for: If vaccines are supplied through a UN agency, then the measures adopted by WHO should be taken in this case". In the case of applying for unregistered items in Saudi Arabia, NUPCO permitted submitting product marketing certificate in the country of origin. NUPCO also gave preference for the drug to be from a company registered FDA or EMA.	C. Proposals of companies that are not registered and/or accredited by JFDA shall be accepted in case no proposals conforming to items A and B of (Sixth) above are submitted, only upon providing JFDA with all required documents.	**commitment to register subsequently in addition to expediting registration procedures. This is required for drug security considerations, and procurement legislation should include this provision, particularly regarding vaccines.** The National Medicines Policy included that in case no registered alternative is submitted for tenders, registered companies' proposals for unregistered drugs shall be accepted, after providing documents ensuring quality and effectiveness of drug determined by JFDA and formation of a joint committee of JFDA and JPD to	

				set the rules for cases for which no alternatives from registered companies are submitted, as according to the definition of counterfeit drug in Article 31 of the Public Health Law and Article 81 of Drug and Pharmacy Law, importation from entities other than agent, the drug imported in this way and the unregistered drug shall not be considered counterfeit.	
3	Drug import is limited to agents.	Drug import is limited to the agent even if the agent does not meet the market needs except drug security cases.	Article 49: A. Import drugs by the drugstore that is acting as an agent for the drug company. B. The drugstore sells the drugs in their original registered packages. Article 51: A. It is not permissible to make any change to the items mentioned in Article (3) of this Law unless in accordance with the rules approved in JFDA. B. It is not permissible to any drugstore to import registered medicines from the products of companies for which it is acting as agent other than its approved manufacturing sites, unless upon	Feasibility of such protection should be reconsidered, especially in cases covered by drug security concept, including cases of non-active participation in bids as a large proportion of bids were awarded as (single bidder).	Prioritized. Competent party: Government and Parliament.

			approval of the Director General, recommend by competent committee. Drug registration bases of 2015 applicable to drugs, vaccines and serums. Article 4 permits drug circulation only after registration and taking appropriate decision on pricing and issuance registration number. Article 5 permits registration of the drug only after manufacture site/sites approval.	As for vaccines import from international organizations, the current provision requires amending as proposed amendment to the Drugs and Pharmacy Law requires having an agent for the purposes of importing unregistered drugs. In cases of drug security, the Law permitted replacing the agent and importing through a drugstore, so it is urgent to amend the provision proposed in the amended draft law so that instructions identify the functions and duties of drugstore, financial return and contract termination cases.	
4	Requirement for local agent under procurement legislation	As mentioned above, there is a need to allow procurement without local agent	The new government procurement does not include provision regulations on this issue, but current instructions indicate that commercial registration in Jordan is required.	Drugs should have special rules in qualification as setting general rules	Prioritized.

		requirement for some suppliers of drugs and vaccines.	**Regulation of the rules and conditions for participation of manufacturers and suppliers in JPD tenders No. 1 of 2007** **Article 1:** The rules and conditions listed below adopted permitting manufacturers and suppliers to participate in JPD tenders: 1. Obtain accreditation for the company/branches from JFDA. 2. Obtain commercial registration certificate from Ministry of Industry and Trade. 3. Obtain valid profession license. **Article 2:** Suppliers shall submit valid documents indicating the following: 1- Obtain license for drugstore issued by Ministry of Health. 2- Obtain merchant registration certificate in the Commercial Register. 3- Obtain valid profession license. **Article 19:** A bidder desiring to purchase RfP shall submit a certified copy of a valid profession license authorizing the bidder to practice pharmaceutical industry or medical supplies or trade, and the commercial register indicating all conditions required by Ministry of Industry and Trade for commercial registration. The competent employee may request these documents when selling any RfP or request them once or more per year. **Article 63:** In case of contradiction or conflict between instructions, general conditions and special conditions, the special conditions shall prevail.	regardless poor competition may result in negative. An article permitting exceptional provisions for drug procurement under instructions should be set, or special instructions considering this situation should be issued.	

5	Drug security, importation of unregistered drugs and requirement for local agent.	**Article 5:** A. The Higher Committee responsible for setting up standards in the following matters: 1. Fulfillment of medical safety. 12. Approval of circulation of non-registered drugs imported in non-commercial quantities for certain patients defined by name. Drug security **Article 62:** The Minister, in coordination with the Association, may issue any instructions by which he defines the types of any registered drugs, which must always be made available in any drugstore, and are produced by the companies which he acts as an agent for. In case of failure to secure those drugs, he has to inform the Ministry of such incident and shall be subject to penalty of giving the right to import those drugs by any other pharmaceutical institution on condition that they are sold to public against determined price. **Article 63:** A. The Minister, in coordination with JFDA and the Association Board, may determine types of drugs and items that must be available in some public pharmacies as required by public interest. B. Upon Director General recommendation, the Minister may issue a list specifying essential drugs to be available in private pharmacies of hospitals and quantities for patients' interest. **Article 64:** Upon Director General recommendation and based on Higher Committee decision, the Minister may determine permission to any pharmaceutical institution or official entity for drug security reasons to import any of the registered drugs. **Article 65:**	This section should be utilized to include non-commercial vaccines, and linked to joint procurement, in order establish consistency on authority used in vaccines and serum procurement from original sources, licensed/approved by WHO, or manufacturers registered in countries with an approved regulatory system, or procurement from international organizations such as UNICEF. **Clear provision to be set on cases of procurement from unregistered or registered drugs and vaccines having no competition or their prices exceed the global prices from**	Top Prioritized.

		Upon Director General recommendation, the Minister may prohibit exporting any locally manufactured drugs in case they are needed in the Jordanian drug market. **Article 88:** A. Any pharmacist involved in the following actions shall pay a fine not less than JOD 1000 and not exceeding JOD 3000: 1. If joins another pharmacist in the ownership of a pharmaceutical institution, where in such case the license will be cancelled. 2. If sells any drugs to any drugstore unauthorized to purchase the same. 3. If dispenses any drugs from a private pharmacy to non-authorized persons. 4. If breaches the provisions of Article (30) of this law. 5. If refrains, for monopoly purposes, to dispense any prescription or selling any drug or any of items permitted to sell if they are available at his pharmacy. 6. If grants the right to distribute drugs in capacity as the owner of the drugstore and agent of the pharmaceutical companies to another drugstore without informing JFDA of such distribution contracts which concluded. 7. If does not inform JFDA regarding contracts distribution, concluded with the local manufacturer. 8. If does not adhere to the price of the drug identified by JFDA or concealed or provided false information regarding the pricing of drugs. 17. If circulates drugs without the Director General approval, in capacity as agent of manufacturer in sites other than the approved manufacturing sites or changes country of origin of any registered drug without Director General approval. 18. If circulates any of the items listed in Article (3) of this Law from an entity other than the authorized one for selling.	**manufacturers qualified by WHO.** **This should be explicitly provided in joint procurement legislation.** Proposed amendments need consideration the new complications affecting the smooth supply as financial acquittal requirement should not prevent the continued drugs flow. Expand Article 64 to include vaccines and essential drugs or those which agents do not participate in their tenders with no justification and consider that they do not include unregistered drugs. **Cases should be organized according to instructions issued for this purpose in which**	

		Under the amended draft law, 27. If refrains from providing drugs in contravention of the provisions of Article 62 of the Law or JFDA Instructions issued in this regard. It should be noted that the draft law amending Drug and Pharmacy Law contained the following provisions: Article (4), Paragraph (A), Item (4) of the original law shall be amended by cancelling "Association Board" and replaced with "recommendation of the Director General to the Minister". Article (5), Paragraph (A) of Article (12) of the original law shall be amended by canceling "imported in non-commercial quantities for specific patients by name" and replaced with "for purposes of realizing drug security, provided that it is for official entities **and through an authorized agent**, and upon the Director General recommendation, and based on Higher Committee decision, and the approval of JFDA Board, and under Higher Committee rules, and provided that they pass the laboratory examination". Article (49), Paragraph (A) shall be amended by adding the following provision thereto: **Transfer of agency may be approved at the Directorate only after completion technical and administrative files transfer, and submission technical and financial acquittal by former agent.** In order to realize the drug security policy, the pharmaceutical policy included the following requirements: Prioritize registration classes that JFDA deems necessary and which have no alternative by expediting registration in conformity with requirements and rules of registration in force. **Amend the legislation to permit direct international importation when needed for the purposes of drug security.** **As included in the study of Assessment of Integrity Level in Health Sector (Procurement of drugs and medical supplies and equipment)[28]:**	**the role and duties of drugstore identified, in addition to method of contracting with it, the revenues it receives as a result of contracting and contract termination cases.** Instructions for providing drugs should include provisions for participation in bids.	

[28] ttp://www.arabstates.undp.org/content/rbas/ar/home/library/Dem_Gov/Informal_sector_gov.html

		Page 17: In case of lack of competition, the study recommended to purchase from outside Jordan in coordination with JFDA to expedite registration of drugs and the potential of accreditation of drugs from countries which have approved drug procedures or participating in Drug Inspection Agreement and Cooperation Project for Drug Testing (the International Council for Harmonization "ICH"). **Page 20: Necessity to provide a mechanism to expedite registration of important drugs in case no suppliers submit for tender or in case of sole supplier in the market.** **Page 32: It is recommended to permit foreign companies to apply for direct registration for drugs without local agents.**		
6	Registration priority.	Article 7 of registration rules states that drugs shall be prioritized in examining their application for registration if: (3) the drugs included in list of "drugs required in pharmaceutical market", and in Item (B) drugs containing a New Chemical Entity (NCE), Biological drugs, serum and vaccines having certificate of free sale from FDA and EMA shall be prioritized in examining their application for registration and approving their manufacturing sites, provided that an assessment/review report is attached with the registration application from health authorities and they should be registered within a period not exceeding 60 days as from the date of application with completed documents in accordance with instructions approved by the Director General in this regard, and according to the last amendment (2019), if they are registered in one of the two administrations, the period shall be 90 days. **Article 9 of Drug Registration Instructions 2015:** Drugs Registration requirements: A- The drug should be registered and circulated in the country of origin with the same composition. B- The drug to be registered should have been in circulation for at least one year in the country of origin or one of the countries accredited by JFDA. C- Serum and vaccines including allergy preparations should be permitted for use and actually used in the country of origin with the same composition. In case of non-circulation, the reasons should be indicated and certificate of free sale from one of the countries accredited by JFDA should be submitted with the same composition. D- Upon Committee recommendation, the Director General may exclude drugs used to treat epidemic and endemic diseases and therapeutic drugs from the	WHO-recommended vaccines should be prioritized, as well as drugs included in the list of "drugs required in the pharmaceutical market" should have the same status as cancer drugs in Article 9 of the Instructions for drug security purposes. Regarding Article 13, it should include a provision indicating that Government Procurement Department – JPD.	Prioritized.

		provisions of Items (B) and (C) of this Article above for drug security purpose. **Article 13**. A. The Committee shall decide on any drug registration application received within a period not exceeding 180 days from the date of submission of application with completed documents. JFDA shall inform the concerned parties of the registered drugs such as Pharmacists Association, Medical Association, Association of Pharmaceuticals Manufacturers, Associations of Drug Importers, and owners of drugstores and others, about each drug registered and publishes drugs registered and submitted for registration on JFDA website.			
7	International cooperation in registration.	Cooperation between states is always useful. The National Medicine Policy report[29] included that cooperation between states can be useful in preventing the counterfeit drugs flow and taking advantage from scientific knowledge gained in other states in the region and across the international agencies/organizations. Such cooperation can be achieved through: Associating with international regulatory bodies in drug analysis field and testing;	Article 7 of registration rules provides for: B) Drugs containing a New Chemical Entity (NCE), Biological drugs, serum and vaccines having certificate of free sale from FDA and EMA shall be prioritized in examining their application for registration and approving their manufacturing sites, provided (report assessment/review) attached with the registration application from health authorities and they should be registered within a period not exceeding 60 days from application date with completed documents in accordance with instructions approved by the Director General in this regard. According to drug registration rules amendment at the beginning of 2019, Article 7 was amended to prioritize registration in case the drug has certificate of free sale from FDA or EMA after priority was only given to the drug having the certificate of free sale from both FDA and EMA to be 60 days and 90 days (This is applied in Egypt since 2016 by one month and two months). On page 51 of Committees report for Rational Drugs Use in the Public Sector, it is indicated that it is possible to add an unregistered drug to the rational drug list in case it has no registered	Pre-qualification program should be seriously considered. Cooperation should be enhanced in this field, and factories having WHO pre-qualification should have special treatment.	Prioritized.

[29] National Medicine Policy Report of 2014 – P 23 http://www.jfda.jo/Pages/viewpage.aspx?pageID=177

		Sharing information on registration files, and information on product quality assessment and price; Globally, according to WHO[30], it is useful to enhance the relationship with global funding mechanisms (such as: GFATM, GDF, Gates Foundation, UNITAID, UNICEF); Partnership with WHO/HIA Drug Pricing Project to establish a repository of global price standards; Support WHO/UN pre-qualification program to cover a wide range of essential drugs. In fact, there is no mutual recognition of drug registration, but there is a precedent to consider the drug registered in Jordan as if it is registered in Yemen and vice versa as stated in the	alternative if it is registered with FDA or EMA for at least 3 years.		

[30] Multi-country Regional Pooled Procurement of Medicines http://www.who.int/medicines/publications/PooledProcurement.pdf

		cooperation protocol between the two countries which is published on JFDA website.			
8	Drug Pricing	**Instructions of drug pricing and amendments thereto of 2016** **Article 4:** The price for public in Jordan is calculated from the drug cost based on the factory price included in the invoice/certificate issued by the party responsible for issuance of invoices/certificates plus customs duties, bank expenses, insurance, clearance, internal transport, and (profits of drugstore, pharmacy and administrative expenses) if the goods is CIF, while if the goods is FOB, shipping costs shall be added to the above costs. **Article 5:** The price for public in Jordan is calculated from the imported-drug cost based on selling price for public in the country of origin after deducting VAT in the country of origin, if any, and after deducting profits of wholesalers and retailers there plus shipping costs, customs duties, bank expenses, insurance, clearance and internal transport (profits of drugstore, pharmacy and administrative expenses). **Article 7:** First: Price of original drug shall be determined for Jordanian public at the lowest price resulting from the application of one of the following mechanisms: A. Price calculated by application of Article (4) B. Price calculated by application of Article (5) C. (Median) price resulting from prices for public in the following countries: (UK, France, Spain, Italy, Belgium, Greece, Netherlands, Australia, Cyprus, Hungary, Ireland, New Zealand, Portugal, Czech Republic, Croatia and Austria)		No pricing distinction between chronic and non-chronic drugs. No discount on the prices of original drugs when registering an alternative drug and graduating in price as benchmark legislations[31]. Vaccines are not priced. Medical supplies are not priced. Accordingly, recommended to consider these proposals.	Strategic.

[31] Pricing Rules of Centrally Registered Drugs in the GCC - http://ghc.sa/ar-sa/Pages/crpricing.aspx

		calculated by application of Article 5 of these instructions, provided that number of states shall be at least four. D. Price calculated from the drug export price (imported to Jordan) to Saudi Arabia pharmaceutical market. Price of pharmaceuticals unregistered in Saudi Arabia will be reviewed in Jordan once registered there. The agent shall provide JFDA with the export price to Saudi Arabia within a period not exceeding four months from the date of pricing it there. E. If the drug is unregistered and priced only in the country of origin and three other countries (i.e. the drug is registered in three countries or less of the ones mentioned in Paragraph (C) of this Article), it will be priced on average of these countries and cost-effectiveness study, whichever is less. Second: A. Price for Jordanian public for the new generic drug shall be determined as stated in Item (First) of this Article. B. When registering new original drug, the price of drug that is priced according to Paragraph (A) of this Article shall be re-priced according to Article (8) of these instructions. **Article 21:** Subject to not exceeding the previously determined price, the Committee shall: A. Reconsider the prices of new drugs two years after registration according to these instructions. B. Reconsider the prices of all categories of registered drugs upon renewal of registration according to these instructions.		
9	Margin Profit	**Article 16:** A. The Ministers Council, in pursuance of the provisions of Paragraph (B) of this Article and upon the Minister and Higher Committee's recommendation, may decide the following: 1. Determine the percentage of profit declared to the Pharmaceutical Institution on any drugs dispensed by a medical prescription.	There is no distinction by type of drugs (this should be considered so that chronic drugs cost is lower). There should be serious	Strategic.

		2. Determine a percentage to cover any administrative expenses for each drug and pharmaceutics drugstores, to be added to the cost for any drug, serums, vaccines, infants milk formula, their special formula and supplementary food and any other materials deemed to be priced by a decision from the Minister. B. The Director General may, upon a recommendation from the Pricing Committee, determine the price for each drug, infant milk formula and their special formula and supplementary food regardless of the cost price and the determined percentage of profit. **In the current situation, pharmacies are allowed to have profit by 19.5% and 5.5% as administrative expenses for all items from cost price with no distinction, and drugstores shall have 15.5% profit and 4.5% administrative expenses from cost price with distinction.**	consideration on the materials permitted to be sold in pharmacies and fees of consulting services for certain types of drugs should also be considered, and the materials associated with the drug should be increased then profit rates can be reduced.	
10	Consumer's right to know the price	**Article 37:** A. Pharmaceutical institution shall not violate drug price prescribed by JFDA and in case the drug price is changed, the drugstore obliged to change the new price tags within 45 days from the date of change. (Under the draft law, the period shall be 90 days) B. Pharmaceutical institution shall provide the correct information needed for pricing the drug according to pricing instructions issued by JFDA. C. Without prejudice to penalties identified under this law, the pharmaceutical institution violating the provisions of Paragraphs (A) and (B) of this Article shall pay the price difference of drug to JFDA calculated difference basis between the violating price and the price determined by JFDA during violation period and quantity sold. **Article 87 of Drug and Pharmacy Law:** Pharmacist referred to the Disciplinary Council of the Association and pay a fine not less than JOD 250 and not more than JOD 2000 in case of committing any of the following violations: E- Circulate any drug or preparation of which price is determined by JFDA without fixing the approved price tag. **Article 88 of Drug and Pharmacy Law:**	Consumers' right to know alternatives should be considered. In order to take advantage of competition, consumers should be enabled to activate competition (consumer education) in addition to facilitating consumer access to information and prices. Reference 8: Role of Competition in the Pharmaceutical	Strategic.

		A. Any pharmacist committing any of the following violations shall pay a fine not less than JOD 1000 and not more than JOD 5000: 8. Does not abide drug price determined by JFDA or conceals or provides false information on the drug price.	Sector (UNCTAD 2015), p. 23. The recommendation of **studying the feasibility of issuance and publication of lists of therapeutically equivalent drugs with their prices** has been included in the National Medicine Policy.	

Component 3: Legislation relating to joint procurement

The Joint Procurement Department (JPD) was enacted in Jordan under the bylaw of Joint Procurement of Drugs and Medical Supplies and Amendments thereto No. 91 of 2002 and contributed to reducing the cost of the drug bill. The new Government Procurement Bylaw was issued and published in the Official Gazette No. 5572 on 1/5/2019. Article 1 of the regulation stipulated that it shall be enforced 180 days after the date of publication in the Official Gazette. Accordingly, the analysis compared the adoption of the new provisions, noting that the instructions issued under the Joint Procurement Regulation will remain in force until being replaced.

Joint procurement of drugs is one of the most significant factors in reducing expenditures. Special Rapporteur Anand Grover's Report on Access to Medicines[32] stated that efficiency and transparency are essential in procurement to ensure availability of medicines adequately in all public health facilities. Procurement of drugs takes place at the international, national, regional, and local levels. Discrepancies at each level in this process may lead to lack of supply of drugs and increased costs. An efficient procurement system is the one based on transparency in management, selection of a limited range of drugs based on a regulated list (such as the National List of Essential Drugs), accurate and scientific forecasting of needs, competitive bidding, procurement of large quantities, pre-sorting of bidders, monitoring of the selected bidders, and stable financing.

With regard to estimation of drug quantities required, states support developing more scientific, reliable and evidence-based methods to be adopted in forecasting needs and estimating quantities, such as utilizing computerization in estimation, and relying on evidence relating to actual consumption whenever reliable records are available.

Strategic procurement should be adopted rather than passive procurement. The entity responsible for procurement should have sufficient experience and tools to plan and assess the procurement process rather than just applying its formal procedures. Accordingly, the significance of informed procurement based on sharing information on prices, conducting market research, sharing information on supplier performance and prices by the entities participating in procurement, conducting cost benefit analyses and feasibility studies, developing a consistent systematic approach for price measurement, and taking advantage of the international efforts in this context, are evidently required. Addressing the Global Shortage of Medicines and Vaccines[33] indicates significant progress in the price and procurement initiative. This enables the receipt of purchasing prices in 80% of countries and aims at increasing price transparency and seeks to develop methods for negotiating prices. Platforms for sharing information on procurement prices, including the Global Mechanism for Reporting Prices, Vaccine Products and the Price and Procurement Initiative provide opportunities to improve the negotiation of prices. Government procurement legislation should be in line with the general principles and best practices established by the UNCITRAL Model Law on Public Procurement and Guidelines. Good procurement practices, including long term contracts, central negotiations, e-procurement and innovative solutions should be used. These include connecting to procurement from UNICEF[34] and other global providers as well as utilizing other innovative procurement methods.

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[32] Special Rapporteur Anand Grover's Report on Access to Medicines, dated 1/5/2013
http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session23/A-HRC-23-42_ar.pdf

[33] http://apps.who.int/gb/ebwha/pdf_files/EB142/B142_13-ar.pdf

[34] Addressing the Global Shortage of Medicines and Vaccines – WHO – 12/1/2018, Item 63A

First: Provisions related to regulation and framework of the law					
#	**Issue**	**Solution Rationale**	**Legislative Status**	**Proposed Legislative Solutions**	**Priorities assigned and responsible entities**
I	Regulating entity responsible for procurement	The Department does not have legal personality or independence, nor does it have an independent budget that generates revenues. The General Supplies Department and JPD were cancelled and their mandate was transferred to the Government Procurement Department with no provisions which outline functions such as the appointment of a director and where the department is housed (This may cause difficulties in application, for example, the JPD was associated with the Minister of Health whereas the General Supplies Department was associated with a different Minister.) In the initial draft, it was decided that the JPD was to remain as	Article 2 defined the Department as: the Government Tenders Department or the Government Procurement Department (Dependent on case) Article 65/D: Government Procurement Department shall assume the duties and tasks which were previously carried out by JPD and the General Supplies Department and shall replace them in all legal obligations and shall be considered **the legal successor thereafter.** The draft provision before amendment: Article 69/D- The General Supplies Department, the Government Tenders Department, and JPD, which were established before the enforcement of the provisions of this Law shall be deemed to have been established under the provisions thereof.	Consider scenarios where an independent entity (government-owned company or an independent body) will be responsible for the purchase and import of drugs from abroad and then sell those pharmaceutical drugs to the Ministry of Health, RMS, public and private sector) in return **for commission.** This will help enhance competition. This will help overcome the complexities of government procurement regulations, and provide **allocation of funds**, and promote financial sustainability where the company shall have bylaws and board of directors comprised of the	Strategic option, taking into account the need to form a board of directors and give the board the powers as set out below.

		independent institution under the draft law, however, it was cancelled and unified to reduce general expenditure. This emergency cancellation is not sufficient to justify the reduction of administrative expenses as the JPD staff are skilled and the nature of their work should be taken into account. There are countries[35] that have mandated procurement to government owned companies (or commission based independent institutions which also have legal precedent that allows payment to them. Private sector companies can also be involved in the ownership of the company in order to share its expertise, funds, and management systems. This partnership can utilize market experience in stock options and trades as well as		beneficiaries of its services. This will enable the company to develop modern governance systems in line with the developments of the market. The company can obtain commercial loans to accelerate and expand its business and it can be a privatization tool for government entities responsible for drug procurement. The company can overcome the obstacles and limitations of government entities bureaucracy leading to flexible and expedited decision-making. The company will be able to establish modern storage and distribution channels that maintain the validity of drugs as long as possible. The entity will become specialized in storage and distribution for	

[35] Such as Saudi Arabia (NUPCO), UAE (SEHA), Iraq and amongst others

		in acquisition of modern technology. Private sector market knowledge may help in the development of the health sector, acquisition of asset management systems, modern procurement represented in ERP system.		commission, in addition to practice its business on a commercial basis.	
2	Establishment of Government Procurement Department	The government procurement department was not established under explicit provision.	Article 65/D- Government procurement department shall assume the duties and tasks that were carried out by JPD and the general supplies department and shall replace them in all legal obligations and shall be considered the legal successor thereafter.	**There is a need to establish the department legally and to indicate the related regulatory provisions.**	Top priority
3	Appointment of Director General	There is no provision stating how to appoint the Director General of the department, however it was stipulated (in the draft prior to amendment) that s/he shall be appointed by a decision of the Cabinet upon the recommendation of the Minister and shall be associated and tied to that particular minister. Provided	Article 2: The Director is the director general of Government Tenders Department or Government Procurement Department, **as deemed appropriate.**	It is necessary to determine the entity authorized to appoint the director general.	Top priority

		that the decision is approved by a Royal Decree. B- The Minister may, upon the recommendation of the Director General, appoint one of the Department's senior staff to act on their behalf, provided that his/her duties and powers are identified in the appointment decision.			
4	Functions of the Department	The functions of the Department are currently based on the completion of the procurement process. The functions are executive, and they are not related to planning or classifying procurement processes in terms of success, competition, attracting suppliers, assessment of quality of procurement and setting criteria for this evaluation, whether in terms of efficiency, savings, collection of information on international prices, determination of	Article 65/A: The Department shall assume the following functions and powers: 1. Purchase works, supplies and technical services required by the government entity or unit. 2. Cooperate with the Procurement Policy Committee, to develop the general policy for procurement management and to develop plans and programs to implement this policy. 3. Review and audit procurement documents and purchase orders to verify that they comply with the provisions of this Regulation and the instructions issued. 4. Gather information on the procurement procedures it	It is important that the instructions provide the functions that are not provided for in the Regulation itself. It is necessary to issue a basis (or foundation) regarding the evaluation and assessment of procurement quality (so that the procurer has criteria and prior perception of the price to assess procurement quality). Functions do not include searching for alternatives, requesting quotations, establishing supplier databases and evaluating	Top priority

		the target price before procurement or provision of alternatives for procurements. In the draft, the proposed functions for JPD were: - Receiving drugs and medical supplies provided by contractors through one or more committees formed from the representatives involved in joint procurement process. - Payment of the value of drugs and medical supplies provided by contractors. - Regulating requests from the parties involved in joint procurement and setting a timetable for procurement dates. - Following up the implementation of contracts on the items purchased.	undertakes and submit such information to the Procurement Policy Committee. 5. Keep entries, records, files and samples of purchases. 6. Cooperate with the Procurement Policy Committee and coordinate with government entities and units to improve the skills of staff in procurement. 7. Provide the government entity with advice on procurement. 8. Issue periodical publications and guidance materials related to procurement. 9. Evaluate performance of contractors and consultants based on the reports received from the beneficiary. 10. Review tenders of works, supplies, technical services, consultancy services, and collect, analyze and keep related information. 11. Set and develop general and special conditions for tenders of supplies, works, technical services, consultancy services, terms of reference, tender procedures, forms and plans in coordination with the	bids based on specific criteria (including comparison to the international prices, rather than the local ones). Establish an observatory to collect information on prices and thus it may be useful to give the Department the right to request information on the procurement of drugs carried out by other entities for analytical purposes (Even if the institution is established by law such as King Hussein Cancer Center or the private sector).	

			Procurement Policy Committee. 12. Participate in implementation of agreements and protocols concluded between the Government of Jordan and any international bodies. 13. Any other functions or duties assigned to the Department to enforce the provisions of this Law and the instructions issued. 65/C: In addition to the aforementioned in paragraph (A) of this article, the Government Procurement Department shall have the following functions: 1. Maintain the records of joint supplies and surplus supplies with the government entity/ unit and take the necessary procedures and arrangements to keep, store and classify the supplies (and surplus supplies) and thus distribute to the government entities according to their needs. 2. Conduct the studies necessary to develop supplies management, improve their performance and maintain standard specifications for supplies of common use.		

			3. Conduct inventory of supplies with government entities/units whenever the General Supplies Department deems necessary. 4. Maintain the documents of long-lasting supplies. 5. Cooperate with government entities/units to learn about ways and means of improvement methods of keeping and maintaining supplies. 6. Purchase drugs, medical supplies and equipment for the Ministry of Health, Royal Medical Services, Prince Hamzah Hospital, Jordanian University Hospitals, and any other entity approved by the Cabinet.		
5	Board of Directors	In the present situation, there is a Board of Directors formed under Article 7. A. JPD Board of Directors shall be chaired by the Minister of Health and include: 1. MOH Secretary General. 2. MOF Secretary General. 3. Secretary General of the	Article 62: Procurement Policy Committee A. The Prime Ministry Cabinet shall appoint from among its ministerial committees a separate committee called "Procurement Policy Committee" C. Procurement Policy Committee shall have the following functions and powers: 1. Develop the general procurement policy and design the means	The draft maintained the Board of Directors and its functions. However, in the recent amendment, formation of this Board was canceled, as well as the functions assigned thereto despite its seriousness. These functions (exchange drugs and provision of liquidity) are	Cooperation with the entities. Competition should be included.

		Ministry of Industry, Trade and Supply. 4. RMS Director. 5. Director General of Jordan University Hospital. 6. Director of Prince Hamzah Hospital. **7. JFDA Director General.** 8. KAUH Director General. 9. Director General of any hospital established in any of the Jordanian official universities. 10. The Director General of the JPD.	to implement this policy in coordination with the relevant authorities. 2. Submit proposals to the Cabinet to amend the procurement regulation, in coordination with the competent authorities 3. Adopt forms for tender conditions and general conditions. Establish and adopt forms in coordination with the relevant competent authorities, which will be considered binding on the procuring entities in the event they are approved. 4. Evaluate the performance of the procuring entities and their compliance with the provisions of this Law and the executive instructions and submit reports to the Cabinet. 5. Develop and build human resources capacities in the field of public procurement through the preparation and implementation of strategies and programs aimed at upgrading the professional level and developing human resources. 6. Manage and collect data on procurement processes, analyze, study them and make the necessary	related to the control drug waste and remove significant obstacles related to the participation of new competitors in the drug bids. Liquidity and non-payment are deemed of the most important reasons for refraining from participating in bids for drugs. Procurement Policy Committee formed under the new draft included mandatory membership of the Minister of Health, but after the amendment of the draft, it is not certain that the minister shall have membership in the committee. The Committee became one of the Cabinet's committees. It should be noted that the functions to be added, either on the current regulation or the draft include market intelligence management. It is also very necessary to enhance the link	

			recommendations to improve performance in order to enable public access to the database interactively through modern means of communication. 7. Adopt policies, standards, and guidelines for the application of modern ICT by the procuring entities in the procurement processes, in coordination with the relevant competent authorities. 8. Issue the necessary instructions to implement the provisions of this Law. 9. Approve the "denied requests" based on the recommendation of the competent committees. 10. Any other functions assigned thereto by the Cabinet.	between JFDA, which is responsible for the registration and pricing of drugs and JPD, and JFDA Director General was included only recently at the end of 2018, but under the draft, there is no link between both entities leading to hinder procurement.	
6	Definition of drug, medical supplies and equipment	There should be a specific definition of drugs, medical supplies, and equipment as the absence of definition may cause problems in application. Especially since the definition of supplies under the instructions of circulating and dispensing medical supplies in MOH hospitals and health	The new regulation lacks definition of drug as the new regulation introduced medical devices in procurement process without a definition. As for the definition of the term drug; the definition included in the Drug and Pharmacy Law can be adopted.	It is preferable to add a new definition of drugs, and medical devices, and supplies. The proposed solutions are as follows: - Add definitions in the regulation. - Add definitions in instructions.	Priority Responsible party: Cabinet or the Minister of Health, based on the solution selected.

		centers includes medical devices and under Article 3 of Regulation No. 89 of 2017 on examination of drugs, medical supplies, sterilizers, disinfectants and cosmetics.			
7	Legal framework for drug procurement management, including vaccines	Specialization is required for drug procurement. Specificity is needed for some types of drugs such as vaccines, essential drugs, non-competitive drugs, as well as drugs provided by the government for free which are not intended for trade. International practices and WHO recommendations indicate that procurement accumulation has a significant role in reducing prices and advises negotiation and adoption of non-traditional procurement methods.	Supplies: the movable funds required for the government entity/unit, in addition to maintenance and insurance of: drugs and medical supplies, devices, raw materials, products, and equipment; whether in solid, liquid, gas or electricity state. Services associated with the provision of these supplies, advisory services and any other services required by the government entity/unit should be included as well.	It is preferable to add an article in the regulation allowing exceptional provisions to deal with procurement of drugs, especially vaccines under instructions, while maintaining the general provisions of usual procurement of other drugs.	Priority Responsible party: Cabinet.
8	Exceptions to joint procurement	One of the problems associated with joint procurement is the lack of commitment of entities subject to	Article 65: Functions of department Purchase drugs, medical supplies and equipment for the Ministry of Health, Royal Medical Services, Prince Hamzah	Procurement ceiling without obligation to purchase through joint bids was significantly increased as the amount of JOD	Not a priority

		procurement through joint procurement, leading to fragmentation of purchasing power. Accordingly, the introduction of an explicit provision for mandatory procurement through JPD shall be enforced. This is stated in the Audit Bureau report of 2017, pages 315-318, which pointed out in its recommendations to oblige all entities to purchase through JPD to correct the situation where participating entities are not purchasing their needs through the JPD. At times these entities' participation does not exceed 20% when purchasing through the JPD.	Hospital, Jordan University Hospitals, and any other entity approved by the Cabinet. **Article 70: No government entity or unit may purchase drugs and medical supplies of which value exceeds JOD 40,000 or purchase medical devices of which value exceeds JOD 100,000 except through the Government Procurement Department.**	40,000 is relatively high compared with some drug applications, although the model law stated in Article 12 that procurement contracts should not be split into separate contracts to avoid being governed by tender provisions in the legislation.	
9	Covering procurement of Royal Medical Services	One of the most important advantages of the new regulation is the introduction of an explicit provision on covering the mandatory procurement for the Royal Medical Services	Article 3: Scope of application Subject to the provisions of paragraph (B) of this Article, the provisions of this Law shall apply to procurement made by the procuring entity. **B/1: Procurement of the Jordanian Armed Forces and**	N/A	N/A

			the security apparatuses of weapons, ammunition, military vehicles, their requirements, maintenance requirements, equipment and systems of a defensive or security nature, and urgent or emergency supplies shall be excluded from the application of this Law. B/2: The supplies referred to in item (1) of this paragraph shall be purchased in accordance with the provisions of the Military Supplies Regulation No. 3 of 1995 and the instructions issued pursuant thereto. C: Notwithstanding the provisions of this Law, the Royal Medical Services of the Jordanian Armed Forces may purchase drugs and medical supplies necessary to meet the requirements of emergency needs in accordance with the provisions of the Military Supplies Regulation in force. D: The Cabinet may postpone or suspend the application of the provisions of this Law to any of the government entities or		

			units for the period as it deems appropriate.		
10	Accumulation of procurement	The provision does not cover all non-private procurement of drugs, including the National Diabetes Center established under the National Center for Diabetes, Endocrinology and Genetics. Its amendments No. 26 of 1996 issued under Article 11 of the Higher Council for Science and Technology Law and its amendments No. 30 of 1987 and King Hussein Cancer Center established under King Hussein Cancer Foundation Law and its amendments No. 7 of 1998.	Article 65: Functions of department Purchase drugs, medical supplies and equipment for the Ministry of Health, Royal Medical Services Directorate, Prince Hamzah Hospital, Jordan University Hospitals and any other entity approved by the Cabinet.	It is recommended that involvement of other parties is subject to the decision of the Council, rather than its approval. This requires an amendment so that it is mandatory rather than optional. It was included in the national drug policy that the good practice of drug procurement requires the study of feasibility of drug procurement in large quantities to obtain the cheapest prices and apply direct drug procurement from manufacturers and thus apply the joint drug procurement by all entities in the public sector.	Priority Responsible party: Cabinet.
11	Issuance of instructions	There is uncertainty about who issues the instructions, which may expose them to judicial disputes before the court. Publishing in the Official Gazette is	One function of the Procurement Policy Committee is to issue the instructions necessary to implement the provisions of this Law. Article 110: The Cabinet, Procurement Policy	The draft does not indicated the responsible the party issuing these specialized instructions, such as instructions of drug circulation that require the participation of the relevant	Top Priority Responsible party: Cabinet.

		not required. Instructions were issued by the Procurement Policy Committee (Article 97) in the draft before being amended.	Committee and the competent Minister shall issue the instructions as necessary to implement the provisions of this Law.	parties in decision-making. Specialized instructions are required	
Second: Provisions related to regulation of procurement					
#	**Issue**	**Solution Rationale**	**Legislative Status**	**Proposed Legislative Solutions**	**Priorities assigned and responsible entities**
1	Procurement plan	One of the most important obstacles facing drug procurement is the inability to predict the needs scientifically. The proposed article in the draft is very important for two reasons: 1. It establishes systematic work (provided that scientific criteria are set for this plan). 2. It contributes to the control of the fragmentation of procurement (provided that the plan is assessed and followed up). However, it is noted that duty to submit the plan is not subject to assessment.	Article 4: Annual Procurement Plan: A. Each government entity/unit shall prepare a plan that includes their future needs of items to be purchased for a period of at least one year to rationalize and control public expenditures. B. The government entity/ unit shall prepare the plan provided for in paragraph (A) of this Article at least one month before the end of the fiscal year in accordance with their budget preparation procedures. A copy of this plan shall be sent to the Procurement Policy Committee within (14) days from the date of preparation D. The government entity/unit shall publish a summary of its annual procurement plan on the official website established in	Interaction between the procuring entities is absent, especially after the abolition of the Board of Directors as they are now dealt with individually. While the best practices and guidelines of UNCITRAL Model Law state that procurement regulation should have closer interaction with the final procuring entities prior to commencement of procurement to make better and more appropriate decisions to standardize and accommodate divergent needs. This should be addressed as stated regarding	Significant and a top priority Responsible party: Cabinet.

			accordance with the provisions of this Law.	the Board of Directors.	
2	Planning for procurement	It is noted that the current regulation does not include procurement planning units. The planning committee is responsible for coordinating the work of the department only. The draft created this unit for each of the procurement entities which indicates the need to determine the role of the procuring entity as a party carrying out procurement without planning, leaving planning to the entity requesting procurement.	Articles 69-64: Procurement Units A. An organizational unit shall be established by decision of the Secretary General (of the government entity/unit) to plan the procurement operations, implement the relevant procedures, and provide the services required by the procurement committees. B. The organizational unit shall be staffed by specialized personnel in procurement.	This needs to be clarified as the purpose of the JPD (or any unit) is to undertake the procurement accumulation to reduce the price rather than procurement accumulation itself. The idea is not to combine the procurement mechanism, but to reduce the price by accumulating purchase orders and increase quantities and build relationships with suppliers and manufacturers.	Significant and a top priority Responsible party: Cabinet.
3	Periodic reports	The provision of mandatory reports is crucial as it helps in assessment of requirements in a global dimension such as international prices and manufacturers in the world. There may be no provision, but JPD regularly issues annual reports.	Article 26: The procuring entity shall submit reports on procurement activities and records of procurement procedures to the Procurement Policy Committee as appropriate.	It should be stated that periodic reports and their contents should be made, including the establishment of performance evaluation criteria. A copy of this report should be provided to the Minister of Health.	Significant and a top priority Responsible party: Cabinet.

4	Estimated cost	**General Budget Law No. 1 of 2018** Article 6: H. No tender for any project where cost exceeds the appropriations allocated for (in this law) shall be awarded except by the approval of the Minister of Finance and upon the recommendation of the Director General of the General Budget Department. J. The tender committees formed under the applicable Government Works Bylaw and Supplies Bylaw shall not invite and/or award any tender exceeding ten thousand JDs except after verifying the availability of the necessary appropriations and upon a financial commitment voucher certified by the Director General of the General Budget Department.	Article 6: A. No procurement shall be carried out until the estimated cost of the procurement has been determined and the financial allocation is available. B. Purchase orders may not be split in violation of the financial powers stipulated in this Law, except with the approval of the competent minister C. Any split of purchase orders and their reasons shall be recorded in the Procurement Procedure Register.	The provision in the draft that orders may not be split is constructive, especially as it can be measured. This will be shown we under the control of the purchase plan.	N/A
5	Permit negotiation	Negotiation[36] is seen as one of the	The current regulation does not include	It is recommended to	Priority

[36] Reference 2, page 6 and reference 14, page 150

		most important factors for low prices. Prices are negotiated through bulk purchasing or by committing to purchase for years. The use of competitive negotiation or procurement from a single source may be appropriate to establish a closed framework agreement in urgent cases. There are also cases where some of the parties involved in the purchase of special requirement. In some cases, the beneficiary is the entity that the purchase is being made for and may be the Royal Medical Services or King Hussein Cancer Center (usually have special requirements).	negotiating power except in cases of direct purchase. In the new regulation negotiating power is referred to only in the cases of consultation and two-staged tenders. This is undesirable as negotiation is one of the most important tools used considering weak competition, where it can be used before the award of bids permanently if they do not fundamentally change the specifications and conditions contained in the purchase documents. Special and general conditions do not include negotiation or the right to negotiate in situations such as requesting equal prices. Although competitive negotiation is a global practice that is permitted and recommended in the pharmaceutical field, it is also applied in many procurement regulations in the Kingdom.	add an article in the regulation that allows for exceptional provisions to deal with the purchase of medicines, especially vaccines under instructions. Keeping the general provisions of the usual purchases of other medicines. Or the introduction of an article that allows negotiation, such as (M9/8 Central Bank or 8 military or 27 Hashemite University)	
6	Payment method	Explained earlier	Explained earlier	Explained earlier	Explained earlier
7	It is permissible to add quantities at the same price	To avoid any shortage of medicines, a regulated allowing standardized prices of 30% of quantities was	Article 99 / (A) stipulates that any amendment to the purchase contract must be approved by both parties and permits change requests under	Treated as part of specialized instructions for the purchase of medicines	Priority

		granted. This is impactful however was not incorporated in the new regulation.	unforeseen/urgent circumstances. Article (60) of the current instructions: The Committee may decrease or increase the quantities required in the call for tender before the award without reference to the tender, or after the award with the consent of the contractor, provided that the total increase or decrease does not exceed (30%) thirty percent. However, if the total increase or decrease exceeds (30%), this shall be done by justification from the joint entity to buy. The approval of the tenderer and the committee must be given for it to remain at the same price and the terms of the contract.		
8	Ability to modify the procurement price	Providing room for price adjustment may be necessary by special circumstances. A provision to allow room for price adjustment within controls may give flexibility.	Article 97 (A) of the Procurement Regulation allows prices to be adjusted in exceptional cases to meet changes in economic or commercial conditions, documents must be provided within the conditions specified in Article 97 (B).	N/A	N/A
9	Central Procurement Committee	Article 73 (C) If a tender is issued for the purchase of medicines, medical supplies and equipment, the Central Procurement Committee shall be formed under the chairmanship of the Director General or an authorized		The unified procurement tenders committee will remain however will undergo a name change to	Priority

		representative provided that their hierarchy second degree. Membership will include: 1-A representative of the Ministry of Finance to be appointed by the Minister of Finance. 2- A pharmacist from the Ministry of Health nominated by the Minister of Health. 3-A pharmacist from the Royal Medical Services nominated by the Director General of the Royal Medical Services. 4-Two delegates with extensive experience in medical supplies affairs representing university and government hospitals nominated by the Minister of Health. (D) The Central Procurement Committee shall purchase supplies, medicines, medical equipment and consultancy services, whatever their value may be. E) It is stipulated that the degree of any member of the Central Procurement Committees shall not be less than the second degree and the rank of the representative from the Royal Medical Services shall not be less than a colonel. 1-The Central Procurement Committee shall hold its meetings to purchase supplies and services of general use in the presence of its full members. 2. The Central Procurement Committee shall meet in with the presence of a quorum of four members, with mandatory attendance of the Chairman to purchase special supplies, medicines, equipment and medical supplies. F) 1. The Minister shall approve the decisions of the Central Procurement Committee concerning the purchase of supplies and services of general use. 2. The relevant Minister will approve the decisions of the Central Procurement Committee to purchase special supplies. 3. The Minister of Health shall approve the decisions of the Central Committee regarding the purchase of medicines, medical equipment and medical supplies.	become the Central Procurement Committee for Medicine Purchasing. There are no standards for qualifications or competency of the members for any requirements except the degree (must be second). The number and quorum of the committee were changed The committee added the task of purchasing medical devices without the necessary representation by a medical devices engineer.	

10	Entity responsible for the execution and clearance of the contract	In the current situation, The JPD follows up the clearance procedures on the materials that are purchased. However, in the draft, it did not clearly state if the requesting entity or the government procurement department was the entity responsible for this. In general, it is recommended to fall under the responsibility of the department because of the technical experience in this area and to prevent double standards.	Article 77 91- The entity responsible for managing the contract (A) The procuring entity, or any governmental entity/unit, shall be responsible for managing the procurement contract and following its implementation in accordance with the provisions of this Law as well as responsible for securing the necessary financial and human resources. (B) The procuring entity, or the government entity/unit responsible for contract management, shall provide the Procurement Policy Committee or the accredited entities with documents, reports and any information relating to the implementation of the procurement contract. The procuring entity or government unit responsible for managing the contract or the entity responsible for execution on its behalf shall be bound to execute the purchased items contained in the purchase contract documents. Article 10 of the Appendix: The government agency or	Clarification needed about responsible entities managing the contract as the current text is unclear	Top Priority

			government unit shall, as appropriate: A- Follow up the implementation of contracts for the purchase of supplies and services. B- Clearance procedures and insurance on supplies purchased from outside the Kingdom directly.		
11	Early delivery fees and delay fines	Fines associated with early delivery or delay need to be furthered analyzed. The JPD found that there is no restriction on this fee since it is not related to the actual cost of storage. However, it should be ensured that it is not a reason for refraining from participating in the tenders. (Penalty fees quadrupled in 2017 according to annual report)	There is no provision for any fees levied in the case of early delivery. However, delay penalties are mentioned in article 87 101. Delay penalties: The contract shall stipulate a fine for the delay in the execution of the contract. The delay penalty amount will be set in the instructions of the law, which will not exceed 15% of the contract's worth. The maximum penalty amount should be outlined in the purchase documents and contract terms. The imposition of a delay fine on the contractor shall not prevent the right of the procuring entity or the procurement committee from claiming damages and damages arising from	The continuation of charging early fees requires an explicit provision to allow this, as the continuation of the instructions is a transitional phase until issuing instructions compatible with the regulation. Article 101 did not specify who was responsible for the late fines It is recommended to allocate these fines to finance purchases	Priority

			the delay in the execution of the contract. B) The mechanism for determining the amount of daily fine Unless otherwise specified in the procurement documents or instructions issued under this Law, the amount of delay penalties for all types of contracts may be determined by a lump-sum daily fixed in the procurement documents and contract terms not exceeding the percentage specified in paragraph (A) of this Article.		
12	Classification	The classification is an important element, especially in the stages after increased competition in the field of medicines. The evaluation of the performance of suppliers in terms of price in addition to performance is essential. As of now and as mentioned above, there is no set criteria to evaluate the quality of the bid in terms of price compared to the	Article 13 - Classification A- The JPD shall classify contractors, consultants, suppliers and service providers into categories or grades according to financial, technical and administrative qualifications, competence and experience in implementing procurement operations in accordance with the instructions issued by the Council of Ministers for this purpose. B- The tenderer must submit certificates of classification	Evaluation criteria must be developed, including the participation rate, evaluation of prices, and quality	Top Priority

		global reference price (not domestic).	conforming to what is required in the purchase documents.		
13	Right to multiple proposal applications	Article (39): Once the tender has been submitted, it serves as confirmation that there is no relationship with another tender submitted for one or more of the materials mentioned in the tender submitted. In this case, the bidder shall not submit one specific offer. The tenderer may attach some optional alternatives if requested by the Department as an annex. Article (41) The tenderer may bid on the tender representing several companies (if they are an agent or broker). If the bid is submitted multiple times by the same agent, the JPD reserves the right to pursue legal actions.	The tenderer may not submit more than one offer for one tender.	The procedure followed shows the specificity of the situation in the pharmaceutical market, although the best practice avoids this procedure (making several offers from the same agent).	Priority
14	Guarantees	In the current situation, the term being used is guarantees, not insurance. In the draft, the term	Article 35 34 - Insurance to enter the tender A-The purchase documents shall	The current instructions stipulate the guarantees in different proportions, for example the	Top Priority

		insurance was used. Within the instructions, guarantees to enter the tender have a minimum of 3% (with the authority to be excused in the terms of the tender) Whereas in the in the draft prior to amendment, there was a minimum of 1-3% without granting the authority for exemption from the guarantees. It should be noted that most of the tenders in previous years were exempted from the guarantees to enter the tender in full. For example the call for number 33/1/2019 (drugs of the nervous system and the musculoskeletal system), where it was stated: 7-Bidders shall be exempted from submitting a guarantee of entry. 8- The Tender Committee shall have the right, in case the bidder refrains from an	include the request for bid insurance. B- The Procurement Committee shall not request entry insurance for purchases made by other means of purchase other than public tender and purchase of technical services C-The bid entry insurance amount shall be specified in the purchase documents and shall be determined by the procuring entity between (1%) to (3%) of the total tender offer value or the estimated cost of the tender as determined by the purchase documents. D-The Purchasing Committee shall remove the tender entry insurance in whole or in part in the tenders of works, technical services and supplies in any of the following cases: 1- Tender withdrawal or amendment of the tender after the expiry of the period of submission of the tender or non-compliance with part or part of it. 2- The tenderer refused to accept the correction of the arithmetic error shown in the offer.	guarantee of entering the tender not less than 3% unless stated otherwise by explicitly inviting the tender. Performance bond 10% It is necessary to harmonize the ratios in the system with the instructions so that the bids will not be challenged before the judiciary because of the violation of the instructions of the rules of the regulation.	

		obligation to bid or fails to complete the required requirements for contracting and signing the purchase order within the period specified by the Director General, to confiscate 3% of the value of the medicines mentioned in the tender. It is collected from its financial dues with the Department or any other department or under the Amiri Funds Collection Act. In other cases they are not provided for.	3-The purchase contract is not signed within the period specified in the final assignment notice or a good performance insurance was not provided with the purchase documents if the instructions stipulated that it must be submitted. 4. If incorrect information is submitted or the information or documents submitted have an element of fraud for the purposes of participating in the tender. 9. Any requirements or conditions regarding the nature, form and value of any insurance required to be submitted in accordance with the provisions of this Law and the instructions issued. Article 41 (d) The tenderer who is awarded the tender is obliged to provide a good performance insurance and to sign the contract within the period specified in the purchase documents. (E) If the bidder referred fails to provide the proper execution insurance and sign the contract, the matter shall be referred to the Procurement		

			Committee to take the decision it deems appropriate. In the draft there is no reference to addressing maintenance and poor workmanship		
15	Dealing with surplus drugs	Fear of surplus medicine is an important reason behind the reduction of quantities, and the existence of a mechanism that allows the circulation of excess quantities for sale contributes to the reduction of the pharmaceutical bill. To address the cessation of sales, the entities resort to purchase at the market price at prices much higher than the bid price. One of the major drawbacks of the new regulation is that the specificity of the drug is not observed in the Annex. In the case of unavailability of the medicine, the Health Insurance Fund buys it at market prices according to the instructions for providing medication to	Article 23 of the Annex The responsible minister or the authorized representative may lend, lease or transfer any supplies to a government agency or other government unit in need, provided that the General Supplies Department is notified thereof and that such action shall be recorded in the supply's restrictions of each party. Article (24) A- The responsible minister may gift or donate surplus government supplies whose total value shall not exceed (5000) five thousand dinars to civil institutions, charitable societies, sports clubs, cultural and artistic bodies, or any government or regional unit. Or foreign countries, for the purpose of improving relations between them and the Kingdom. Article 20 If the Secretary General determines, upon the	The proposed text does not take into account the specificity of medicines by recycling. In any case, allowing the sale can be through the tender conditions, taking into account the provisions of the law of medicine and pharmacy and should not be on commercial grounds (in case the agent refuses to replace them) Excess medicines may be disposed of in accordance with the provisions of the Military Supplies Regulation and its amendments No. 3 of 1995, authorizing the sale of supplies, including perishable medical items, at the agreed price. Especially since the MOH purchases medicines from the market or	Strategic

		patient No. 1 of 2010 The other alternative is to buy it in accordance with the agreements signed between the Ministry of Health and hospitals (private and university, King Hussein Cancer Center and the National Center for Diabetes), stating: C. The price of the medicine to the beneficiary and the non-beneficiary is calculated on the basis of the tender price of the hospital plus (25%). In the event the medicine is not available through the tender, the price is calculated at the industry price plus an additional 10% The price of the medical necessity for the beneficiary and the non-beneficiary is calculated in the hospital medical bill according to the tender price, plus 20% of the tender price. In the absence of any medical	recommendation of a technical committee formed for this purpose, that any supplies valid in the governmental entity or the government unit become redundant and unnecessary for work, the General Supplies Department shall be notified to circulate them to other governmental entities and units for their use. (C) Valid and surplus government supplies shall be sold after the exhaustion of all avenues for their utilization by virtue of a public bid at fair price estimated by a tripartite committee formed by the Secretary-General through the announcement of the sale (in no less than two newspapers) The Committee is responsible for the selling of the supplies. Article 21 1. If the Secretary-General is convinced, on the basis of the report of a technical committee, that the supply of unfit supplies is not feasible, or that the costs of selling them exceed the price obtainable, it may be decided to dispose of them or destroy them, and remove them from the restrictions duly.	hospitals is estimated in the millions.	

		necessity for the beneficiary and non-beneficiary through the tender, the price is calculated according to the average purchase price in the local market plus a percentage ranging between 5-30% This bill can cost in the millions.	2. Where any unusable supplies have been destroyed or sold, the output documents organized shall be supported by a certificate stating that they have been destroyed, or a copy of the sales list. The certificate shall state the authorizing entity responsible for the destruction or sale.		
16	Purchase drugs from the Health Insurance Fund	Flexibility in procurement is sometimes required, excessive flexibility leads to the fragmentation of purchasing power. Therefore this process should be evaluated and studied for economic feasibility and if the purchasing process should be done through the JPD.	There have been many cases of the purchase of medicines by the Health Insurance Fund without resorting to standardized purchase through the JPD according to the instructions to provide medicine to the patient. These regulations were amended as follows: No. 1 of 2010 issued under the Civil Health Insurance Regulation and amendments No. 83 of 2004 According to Article 9 of the Instructions, prescribed or unregistered medicines (which is not purchased through tenders) shall be dispensed as follows: if the price of the medicine is 200 JD or less per prescription.	Carry out an analysis on this subject considering the previous recommendations on the disposal of excess quantities	Strategic.

			If the price of the prescription is more than 200 dinars, the Health Insurance Department issues a letter to the Directorate of Procurement and Supply to provide medicine and the process is signed by the Minister or Secretary-general according to the value of the prescription. The (MOH) pharmacies will open a file for the patient in the pharmacy proving the minister's approval for the dispensing of unscheduled or unrecorded medicine and the date of dismissal.		
17	Exchange of drugs and dealing with excess drugs	Current situation: There are instructions for the exchange or lending of medicines and medical supplies between the entities involved in the unified procurement for the year 2018 published on 1/3/2018 and will remain in force until replaced Article 3 A. The provisions of these Instructions shall apply to exchanges or lending of medicines and medical supplies between the parties involved in the unified purchase if such medicines and medical supplies were purchased through the unified purchasing department tenders. B. Unified procurement agencies should cooperate with each other to avoid shortages of medicines, medical supplies and waste of public funds. Article 4 A. The joint purchasing entity that has medicines or medical supplies close to expiration or surplus need to address the		Reconciling instruction and regulation	Priority

		joint procurement bodies by letter, a copy of which shall be sent to the unified purchasing department at least three months before the expiry of such materials to be exchanged or loaned. Quantities needed by each destination. C. If there is an agreement from the supplier or the contractor to replace the medicine or medical supplies subject of exchange or lending and the remaining quantity is expired, then this quantity shall be returned to the joint entity that has transferred those materials to them within a period not exceeding three months from the expiry date to be replaced by the supplier or the contractor. Article 5: Clearance between the parties participating in the consolidated purchase at the end of each financial year shall be made on the materials exchanged or seconded.			
Second: Provisions related to procurement methods					
#	**Issue**	**Solution Rationale**	**Legislative Status**	**Proposed Legislative Solutions**	**Priorities assigned and responsible entities**
1	Electronic Procurement	Article 3 / G- In accordance with the instructions issued for this purpose, transactions for the purchase of supplies, works and services shall be conducted using electronic means as follows: 1- The Jordanian Electronic System for Managing Electronic Purchases. 2- Electronic system for the management and organization of government stock of supplies and control. Article 7 - Means of communication and electronic procurement Subject to the provisions of paragraph (B) of this Article, notices, decisions and correspondence relating to the procurement process shall be submitted in writing between the procuring entity and the bidder or contractor.		There is a conflict in the draft over the mandatory e-procurement (The electronic purchase must be activated and the instructions that outline its implementation should be activated. With regard to the text proposed in the draft, it must be stipulated that the outputs of electronic systems provided for in this article	Not a priority

		B - In the case of the use of electronic means in the procurement process must take into account the following: 1. The procurement process is carried out using IT systems and software, including those related to documentation and information encryption, which can be used interchangeably with other available IT systems and software. 2. Adopt mechanisms to ensure the integrity of applications and offers, including scheduling of deposits and preventing access to them from unauthorized persons. Offers may not be submitted by electronic means unless outlined in the purchase documents. The use of electronic means in the procurement process shall include an element that allows the recording of transactions on the Jordanian Electronic Procurement System for review and allows the Audit Bureau to verify the security and integrity of the systems at any time.		are certified and have legal effects. Current text: Article 27 / b. Consolidated purchase transactions may be carried out using electronic means: 1. To make purchases of medicines and medical supplies. 2. Management, organization and control of inventory. C. The outputs of electronic means provided for in paragraph (B) of this Article shall be deemed to be certified and productive for their legal effects.	
2	Procurement methods available	The draft included new methods of purchase, but does not consider the specificity of medicines, specifically vaccines. International tenders (a procedure that was available without restriction, but not enforced) were provided for in two cases: 1-If the local suppliers do not	Article 26 - Methods of purchase Procurement of works, technical services, supplies and non-consultancy services shall be by public tender method, provided that the following method are justified: A-Limited tender (solicitation). B- Tender in two stages. C-Request for offers. D - Purchase from a single source (binding).	N/A	N/A

		meet the conditions, specializations and expertise required to carry out the purchase. 2 - If it is not possible to obtain any of the supplies from local bidders at reasonable prices.	E-Direct execution by the employer. Article 28 - Domestic and International Tenders A- The tender must be submitted locally unless the agreements and protocols provided for in Article (4 / C) of this Law stipulate the tender in other ways in accordance with the provisions of those agreements and protocols. Subject to the provisions of paragraph (A) of this Article, the tender may be offered internationally in any of the following cases: 1-If the contractors, suppliers or local service providers do not meet the conditions, specializations and expertise required to carry out the procurement process upon the recommendation of a technical committee formed by the responsible minister. 2 - If it is not possible to obtain any of the supplies, works or services required from local tenders at reasonable prices. C- Local tenders may participate in the international tender procedures.		

3	International bidding for external procurement	In the current situation, the Instructions are (99): - Foreign purchases are made in accordance with their agreements. C&F, CIF, or equivalent terms (INCOTERMS) which are equal in meaning, and payment may be made on account provided that the contracted foreign party provides a financial guarantee or money transfer certified by a bank in that country. Or a local bank is worth the value of Amounts paid on the account except those purchased from Arab and foreign government sources.	Article 2 The international tender is defined as the tender in which Jordanian and non-Jordanian bidders are allowed to participate. Article 29 - Domestic and International Tenders A- The tender shall be submitted locally unless the agreements and protocols provided for in Article (4 / C) of this Law stipulate the tender in accordance with the provisions of those agreements and protocols. Subject to the provisions of paragraph (A) of this Article, the tender may be offered internationally in any of the following cases: 1- If the contractors, suppliers or local service providers do not meet the conditions, specializations and expertise required to carry out the purchase on the recommendation of a technical committee formed by the competent minister for this purpose. 2 - If it is not possible to obtain any of the supplies, works or services required from local tenders at reasonable prices.	There is no international bid application in the current regulation It is also noted that the purchase from outside the Kingdom is not implemented despite the legislation authorizing it The report of the Audit Bureau for 2017, pp. 315-318, reinforces the results reached, including: JPD does not import from abroad in case the materials to be purchased from a single supplier even if the price from abroad is lower than the local price, contrary to the provisions of Article 16 of the Law. The permissibility of local participation in international tenders is encouraging	N/A

			C- Local tenders may participate in the international tender procedures. Article 30 specifies that the announcement shall be in Arabic and English. In Article 33, the minimum deadlines for submission of bids and 30 days in case of international tenders are specified.		
4	Reverse auction	Reverse auction is a type of auction in which the roles of the buyer and the seller are reversed. In most cases, the electronic reverse auction represents the last stage prior to the award of the public contract. It may also be useful in cases where competition is available (which is not available in the Jordan case)	Article 27 - Electronic reverse auction A-The purchasing committee may use the electronic reverse auction method through the Jordanian electronic procurement system to carry out the procurement procedures or to complete any of the procurement methods mentioned in this system. Including the award of bids under the framework agreements, with evaluation criteria set out in the procurement documents and measurable. B- Policy Committee will issue instructions for this purpose and around the use of the electronic reverse auction method and any provisions related.	New method.	N/A
5	Limited tender (solicitation).	This method of draft requires bids from at least three bidders,	Article 44 - Limited tender (solicitation). The offers may be solicited directly in the	N/A	N/A

		which is a rare case in the current standardized procurement situation, which is characterized mainly by the scarcity of competition. However, it may be useful if the purchasing agency is able to determine the expected prices in advance based on international standards and not in comparison with local prices (which are priced by the JFDA).	limited tender method in any of the following cases: 1-If the public works, supplies or services required are available only to a certain number of tenders known to the procuring entity. 2 - If the time and cost in the study is not proportionate with the value of the purchase due a large number of offers 3. If there is an unpredictable emergency. 4. If the tender is re-launched for any reason and no suitable offers are offered upon re-tender. 5 - If the value of supplies does not exceed 5000 dinars. Article 45 - Limited tender procedures (solicitation). (A) In the case of procurement through a limited tender, bidders shall be invited to obtain procurement documents and to submit their bids accordingly. (B) It is required that offers from at least three tenders be requested. (C)The notice of the request for tenders shall be published through the limited		

			tenders on the portal and in any other means required by the instructions issued under this Law. (D) Notwithstanding the procedures for solicitation of tenders referred to in this Article, the public tender procedures shall apply to the limited tender method, subject to the provisions of Article 34 of this Law. (Tender Entry Insurance)		
6	Single Source Procurement (Mandatory)	Article 49 - Purchase from a single source: Procurement may be made from a single source by a decision of the Procurement Committee, provided that this method is not used to avoid competition or to exclude certain bidders, in the following cases: (A)If the subject of the purchase can be obtained only from one source and there is no suitable alternative. (B) If a tender is submitted and re-tendered or offers have been solicited and it is not possible to obtain appropriate offers (or if the prices are not reasonable or when the whole quantity of supplies to be purchased is not obtained). (C) If the purchase relates to rights, artistic and literary works or for reasons related to the protection of exclusive rights to sell the items to be purchased, including patents and copyrights, or in the absence of competition for technical reasons, and the absence of any acceptable alternative. (D) If there are exceptional or urgent cases that do not allow the conduct of tender procedures or solicitation of offers. (E) If the additional works are not included in the original purchase contract, it is necessary to complete the original works		It should be noted that medicines are priced by the government under the Medicines and Pharmaceutical Law In many cases, the drug can only be obtained from a single source (due to non-tendering or a single agent). It must be stipulated that negotiations should be made	Priority

		that the procuring entity shall grant additional contracts to the executor of the original purchase contract. Provided that it is practically not possible to separate the additional and original works technically and economically, and not exceed the value of additional contract (50%) of the original contract value. (F) If the prices are determined by the official authorities. (G) If there is a legal provision or international agreements, it is necessary to purchase from one source. (H) If the purpose of the purchase is to standardize the item or minimize diversification or to save in the acquisition of spare parts. (I) Purchasing and selling supplies and services between two governmental entities, two governmental units, one governmental entity and one governmental unit at the agreed price.			
7	Bidding in two stages	Used for technical projects Successes and Examples: -High-tech procurement such as large passenger aircraft, communications systems or technical equipment -Infrastructure procurement, including large-scale facilities or construction operations of a specialized nature (guidance on procurement regulations to be issued in accordance with	Article 47 - Tender in two stages. Procurement may be conducted in the manner of tender in two stages in the following cases: (A)If the procuring entity finds that it is not possible to prepare accurate and detailed technical specifications for the supplies and works or to determine their needs due to the complex nature of the items to be purchased. (B)If the procuring entity seeks to enter into a contract for the purpose of conducting research, experiments, studies or development unless the contract	New method.	N/A

		article 4 of the Act UNCITRAL Model for Public Procurement).	provides to produce supplies in quantities to prove its commercial viability or to recover the costs of research and development.		
8	RFPs	In accordance with best practice, it must be ensured that an adequate level of transparency is ensured, since procurement through this method does not require the publication of advance notice of procurement. The use of electronic methods for requesting quotations may be a better option for low-value purchases, and also ensure a more transparent choice. However, it may be useful if it is allowed to negotiate and this is not available in the draft	Article 49 - Requests for quotations (A) The procuring entity may purchase by requesting quotations if the nature of the procurement is of small value and is readily available commercially or from small businesses. (B) The request for quotation shall be submitted in writing to not less than three tenders. (C)The request for quotation shall include the requirements of the procuring entity in terms of quality, quantity, terms of delivery, time and any other requirements. Tenders should be given sufficient time to prepare and submit their quotations. (D)The procuring entity shall request from lowest priced tenderer and match the offer with the delivery requirements and other requirements for the supply of the required purchases.	New style and negotiation must be allowed	Not a priority
9	Coalition	The provision for a coalition is a step forward,	Article 13 - Coalition (A) Procurement documents may include	N/A	N/A

		especially given the varying financial capacity of suppliers. It will be useful in the case of large quantities.	the authorization of bidding in the form of a consortium, and procurement or prequalification documents shall indicate the following: 1.The way in which the qualifications of bidders are assessed in a coalition, including criteria that can be met collectively, and criteria that must be met by each member of the consortia individually. 2. Submitting a certified coalition agreement or a letter of intent from all members of the consortium as part of the offer, as well as pre-qualification request or expression of interest, to formally enter into the consortium when the bid is submitted to the consortium. 3. A-The members of the Coalition shall nominate the President of the Coalition who shall be responsible for following up all the procedures of the purchasing process. B-All members of the consortium shall be jointly and separately liable for the execution of the contract in accordance with its provisions. C-Purchasing documents shall include the procedures to be taken against the		

			Coalition in the even one of its members withdraws before referral.		
10	Justification of the price below cost		Article 14 of the procurement system stipulates that the procurement committee may ask the tenderer who submitted at prices below the cost price to provide clarifications or justifications. The Committee will vet the justification and if they do not meet criteria, they will exclude the offer.	Prices that are purchased lower than the prices of medicines by the JFDA will require either entity to ensure fair pricing or to justify the progress of prices below the cost and current prices. Or be compared to international prices. The request for price clarification should be for all cases, including higher prices	Strategic.
11	Tender awarding cases	Current Status under Instruction Article (57): Bids shall be awarded with the reasons for the winners according to the following: A. Cheaper Conformity: If the cheapest offer includes quality medicines or medical supplies in the required supplies and conforms to the specifications and conditions in the tender invitation. B. Cheaper Match: If there are irregular	Article 42 - The award of the tender and the signing of the contract: A- The tender shall be submitted to the winning bidder.	There is a conflict between the instructions and the regulation Referring to the annual reports, a large number of bids were awarded because of a single agent or sole bidder According to the annual report issued by JPD for 2017 on page 38, the reason for the award of bids (according to the number of items) was an average of 32% due to (sole agent) and 24.2% (sole applicant)	Priority

		offers, and other matching offers it is best practice to exclude the irregular offers. The referral is made on the cheapest matching offers. C. Appropriate: In case of irregularities in all offers submitted, the Committee may choose the most suitable offers in terms of quality, price, type and conditions that satisfy the required purpose. D. Any other reason that is consistent with the provisions of JPD regulation, provided that it is sufficiently justified.		and this means that 56.2% of the cases of purchase were made without competition. With regard to vaccines, the percentage was 7% due to (sole agent) and 57.7% (sole applicant), which means that 64.7% of purchases were made without competition.	
12	Testing procurement	It is noted that the functions of JPD included contracting, receiving, examining, and clearing. These tasks are now the responsibility of the requesting entity and this is contrary to the idea of assembling purchases and the availability of experience dealing with suppliers	Article 80 94 (B) The procuring entity or any other entity responsible for managing the contract shall form one or more receiving committees for the examination and receipt according to the nature of each contracting process. (C) Committee(s) shall conduct the examination in accordance with the terms of the contract. Designated committees may seek the assistance	Details need to be addressed in the instructions such as the responsible entity for inspection. Preferably the Procurement Department due to their experience in this area. It is important to establish criteria to avoid duplication of screening, especially with medicines that	Priority

		It also contradicts the text of paragraph 80 of Article 80 of the draft, which does not allow the receiving committee to include those who participated in the drafting of the technical conditions. In fact, those who formulate the technical conditions were the applicants and are now the recipient	of technicians and experts if necessary. (D)The receiving committees shall not include in their membership those who have participated in the drafting of technical conditions, specifications, purchase or analysis documents, evaluation procedures, procurement procedures and supervision of the execution of the contract. **Annex Article 13** (A) Any committee which finds an issue or problem will act in accordance with the provisions of this Law: Inspection and verification of the specifications of the supplies and their conformity with the conditions stipulated in the procurement contracts in terms of quality, quantity, place of delivery, date, installation and operation. Conducting the necessary examination for supplies requiring installation and operation, subject to the provisions of the agreements concluded.	have been tested when registered, especially since the examination is at the expense of the supplier.	
13	Receipt of procurement	It is preferable that the task of receiving is a joint task. The JPD should have a role	Article 80 94 / A - receipt (A) The procuring entity or any other body responsible for contract management	This should be considered in a strategic approach to enhance the role of the entity	Strategic.

		in this to expand their expertise.	shall monitor, inspect and deliver all contracted technical and consultancy works, supplies and services, and verify their conformity with the technical specifications and conditions set forth in the contract.	responsible for procurement. It will strengthen its resources to become a competent entity responsible for purchasing. Over time it will maximize its role across all stages of the procurement process, from selection to receipt and storage.	
14	Supervision of warehouses and warehouse custodian	Under the current situation, the Procurement Department is responsible for the warehouses for a temporary period until the delivery of the purchased materials to the requesting parties. In the event of missing stock or shortages, it is the responsibility of the warehouse custodian. The shortage amount is fined (but there is no indication what the value of the shortage is calculated at; the purchase price or the market price)	Article 3 The Procurement Policy Committee shall issue the necessary instructions for the management and organization of warehouses, control of the inventory, the types of custody records, the data and restrictions to be shown, the forms and records to be used, and the information to be included, in the latest methods used in the management of supplies and warehouses. Article 4 The Government Procurement Department shall take the necessary measures and arrangements to preserve, organize, store and classify common supplies, surplus supplies, durable materials and	It is important to discuss the role of the procuring entity whether it is only related to procurement (or whether it extends -by virtue of expertise- to include the entire supply chain from specification and quantities, procurement, receipt and storage), especially since there are experiences that involve the financial savings. Unified storage works provide cost savings.	Strategic.

			materials for crises and emergencies. Article 10 The government agency or government unit shall, as appropriate: A-Follow up on the implementation of contracts for the purchase of supplies and services. B- Clearance procedures and insurance on supplies purchased from outside the Kingdom directly. Article 22 /C – The entrusted party or employee with the supplies shall be fined no less than the value of the shortage, or damage resulting from negligence, on the date of the damage or shortage.		
15	Competitive Consideration	According to best practice, the specification should not lead to a single supplier. Therefore, the trademark or patent may only be referred to in cases of inability to describe except by reference. Reference can be made to a trademark in order to allow the suppliers or contractors to understand the	Article 7 / (B) and (C) It is prohibited to mention any requirements or references in the technical specifications or any document of purchase for a particular trademark, name, patent, design, type, original producer or service provider, in which case phrases such as (or equivalent in performance) or any similar phrase in the specifications or requirements to which any national or international standard	There should be effective coordination between the Procurement Service and the Competition Directorate (IP-related).	Top Priority

		needs of the procuring entity. The text presented in the draft complies with these criteria, but the paragraph that has been canceled may lead to a restriction on some purchases.	shall be rejected as applicable.		
16	(Objection)	The following provisions are stated in the procurement regulation: Article 59: A tenderer who claims to have suffered a loss or any damage as a result of a decision, action, or inaction from the procuring entity, or claims that the procurement committees violated the provisions of the purchase documents or the provisions of this Law and the instructions issued; may submit an objection to the first stage. Followed by a formal complaint in the second phase in accordance with the provisions of this regulation. Article 60: The objection shall be submitted as follows: A- The objection shall be submitted in writing with the purchase documents, the conditions of the advertisement, or other forms of solicitation, pre-qualification, abbreviated regulations, decisions or actions taken by the procuring entity in the pre-qualification procedures or abbreviated regulations, or the decisions or actions taken by the procuring entity or any abstention. To take a related action to the procuring entity within five working days from the date of publication and before the deadline for submission of offers; whichever comes first. B-The objection shall be submitted in writing to the purchasing committees related to the initial award or entity related to the tender or the procurement procedures within the period specified by		One of the most important advantages of the draft regulation is the comprehensive organization of the objection and complaint this article, but there is the following observation: - The complaint has led to the inevitable suspension of the tender procedures pending resolution without distinction between serious and malicious complaints. - Failure to specify the responsible court.	Priority. Needs to be reviewed (especially in the field of medicine) by the responsible entity and the Council of Ministers

		the decision of the purchasing committee or the purchasing documents. C- The procuring entity or the procurement committee shall consider the objection and decide its decision thereon within a maximum period of (7) working days in respect of public works and technical services tenders and within a period of (30) days in respect of supplies bids. The tenderer shall be notified of the committee's decision within a period not exceeding three working days from the date of the decision. D- If the objection is accepted in whole or in part, the resolution shall include the necessary measures to rectify the situation. E- If the tenderer does not accept the decision issued, in accordance with the provisions of paragraph (c) of this article, they may file a complaint with the Procurement Complaints Review Committee in accordance with the provisions of this Law. F- The value of the objection or complaint allowance shall be collected in accordance with the values stipulated in Table (1) of Appendix (2) of this Law in respect of the Government Procurement Department. Article 66 - Independent administrative review in the second phase by the Procurement Complaints Review Committee A-The Procurement Complaints Review Committee formed under the provisions of Article (76) of this Law shall be the designated authority to deal with the complaints of tenders for the second stage. B- Entities that have submitted tenders shall submit their complaints to the Procurement Complaints Review Committee referred to in paragraph (A) of this Article as follows: 1.If the bidder refuses to accept the decision of the procuring entity or the procurement committee regarding the objection, They are entitled to submit the complaint to the procurement complaints		

		review committee within 5 working days from the date of being notified of the decision of the procuring entity or procurement committee. 2. The Procurement Complaints Review Committee shall notify the procuring entity in writing of the complaint in order to suspend the procurement procedures until a decision has been taken. 3. The Procurement Complaints Review Committee shall issue its decision on the complaint within a period not exceeding (21) working days from the date of its receipt. C-The Procurement Complaints Review Committee shall oblige the procuring entity or the Procurement Committee to correct its procedures, including re-procurement. D-The decision of the Procurement Complaints Committee shall be announced on the website and the electronic portal. Article 76 - Formation of the Procurement Complaints Review Committee A-The Council of Ministers shall form a committee to review procurement complaints with specialized expertise. This committee may form specialized technical committees to deal with complaints submitted to it. B- The specialized technical committees shall consider the complaints and submit their recommendations to the committee to review the procurement complaints, which shall decide on them once and for all. C-The instructions issued under the provisions of this Law shall determine the mechanism for reviewing complaints by the Committee, including the procedures for filing, handling the complaint and issuing decisions.			
17	Dispute settlement	A crucial advantage of the new regulation is the mechanism of settling disputes, which allows	Article 95 Settlement of Disputes at the Execution of Contracts A- The Jordanian courts shall be	- The draft did not provide the type of court responsible: administrative or civil.	Priority Responsible Entity: Council of Ministers

		arbitration and applying foreign laws, as this is required in some international purchases (whether by international organizations or major companies).	responsible to settle disputes arising from the execution of contracts concluded under the provisions of this Law. Jordanian legislation shall be applicable unless the contract documents stipulate otherwise. B- The contract may provide some methods of settling disputes, including amicable settlement before resorting to arbitration or litigation to give priority to a solution by mutual consent through negotiation. C- To assist Contracting Parties to settle disputes amicably, the contract may provide for the appointment of a third party to assist in the settlement of disputes in the conciliation and mediation format, as well as relevant mechanisms involving the appointment of dispute resolution experts or the Dispute Settlement Board and procedures for the appointment of conciliators.	- The draft did not stipulate that the dispute over part of the tender does not prevent contractors from continuing to implement the contractual obligations under it.	

			D- The Contracting Parties may agree within the contract or in a separate agreement to refer disputes arising from the execution of the contract to arbitration. In such cases, the institutional framework for arbitration and the procedural rules governing the conduct and place of arbitration shall be provided for in the Agreement. E- If the contract does not contain the arbitration clause and it is agreed to adopt the arbitration by concluding a separate agreement, this shall be in writing and signed by both parties. Unless otherwise specified in the contract document, Arabic shall be the language of arbitration. F- The procuring entity may choose international arbitration to settle disputes when the contractor is a foreigner, provided that this is stipulated in the contract, taking into account the procedural mechanism agreed		

			upon in the contract when implementing this method, international arbitration bodies approved to settle the dispute shall be chosen.		
18	Penalties	Article (102) 88 - Breach of contract A: The purchase contract shall indicate the following: 1- Measures and procedures that the procurement committee is entitled to take in case of violation of the terms of this contract. 2. The reasons under which the Procurement Committee may terminate the Procurement Contract, in particular: a. The contractor failed to complete the contract. b. The contractor commits acts of fraud, manipulation or bribery. c. The force majeure provided for in the contract. d. Insolvency or bankruptcy of the contractor. 3 - The grounds for termination of the contract by the contractor. 4. Basis of settlement and financial compensation to be paid in case of termination of the contract. B: Notwithstanding the provisions of paragraph (2) of paragraph (A) of this Article, the Procurement Committee may terminate the purchase contract if the public interest so requires, subject to payment of the value of supplies, works or services completed prior to the date of termination of the contract and payment of the costs incurred by it; The value of supplies produced for the purchase contract. Article 103: The Procurement Committee shall reject any offer if it becomes apparent		The penalties and cases received, whether in the current regulation or in the JPD, do not deal with cases of collusion in tenders between bidders. This was addressed in the Competition Law but not activated as it is difficult to prove it. For limited goods such as drugs, it may be useful that agents and pharmaceutical companies that do not participate in tenders to be obliged to indicate the reasons of non-participation in writing (as having only one bidder submitting in large proportion of bids raises doubts about the reasons for others not to participate and in return for another tender, the other bidders participate).	Priority regarding the obligation to disclose the reasons for not participating in the tenders.

		that the bidder has exercised any of the actions provided for in Annex 3 and shall notify the concerned bidder of its decision and take the necessary action against them and inform the relevant authorities of such rejection. Article 104 – Confiscation A: The Procurement Policy Committee shall approve decisions to deny the bidder / contractor / contractor / supplier / consultant from participating in the procurement operations for a period not exceeding two years issued by the procurement committees based on the investigation reports in any of the following cases: 1. Providing false information when submitting offers. 2. Collusion with any employee of the procuring entity or the procurement committee. 3. Committing practices involving corruption, fraud, coercion, obstruction or breach of confidentiality. 4. Committing a material breach of the contractual obligations stipulated in the purchase contract. 5. Conviction of a crime or felony related to obtaining, attempting or attempting to acquire the purchase contract or a sub-contract. 6. Conviction of an offense of an economic nature. B- Decisions on confiscation shall be published on the procurement portal and shall be subject to appeal before the Procurement Complaints Review Committee	No penalties are enforced on drug agents, including warning them to cancel their registration in case they violate the contractor. Refer to Article 105 Ministry of Public Works and Housing for penalties with contractors. The topic of allowing bypassing of the agent in the import of medicines has been discussed within the legislation relating to registration extensively. .	
19	Code of conduct	In the draft, an appendix was allocated to set standards of conduct for government employees A: Any government employee involved in any procurement procedure shall comply with the following: 1. Perform their duties neutrally to ensure fair competition between	The draft was positively received, especially in the absence of competition	N/A

		bidders and the proper execution of procurement contracts in the public interest and in accordance with the objectives and procedures set forth in the provisions of this Law and the instructions issued. 2. Avoid corrupt and fraudulent practices, conflicts of interest, or to retreat when there is a potential conflict of interest and to report such incidents. 3. Maintain the confidentiality of the information in possession regarding the procurement procedures. B: Each member of the Procurement Committees and any employee involved in the procurement process prior to commencing the procurement process, or performing any other related task, shall sign a declaration stating that: 1. There is no direct or kinship by any bidder involved in the procurement procedures, including lawyers and officials involved. 2. Was not an employee or official of a tenderer involved in the procurement procedures or had a financial interest in the tenderer company for the past three years 3. Has not negotiated or arranged for a position in a joint bidder in procurement procedures. Each member of the procurement committees and any employee involved in the procurement process shall disclose any conflict of interest, whether actual or potential. Any individual aware that there is a relationship with the tenderer shall immediately report such relationship to the immediate superior and request that they do not participate in Purchase procedures. Article 90 - Professional and ethical obligations of suppliers / contractors / consultants A- Suppliers, bidders, contractors, service providers and consultants shall comply in the performance of their duties in accordance with the		

		provisions of this Law, the Instructions, Purchase Contracts and other regulations, behaviors and activities related to procurement. B- Suppliers, bidders, contractors, service providers and consultants are prohibited from engaging in any practices involving corruption, fraud, collusion, coercion, or disability. Practices prohibited under the provisions of this Law shall include payment of any amount or the giving of anything of personal or financial value in any way for the purpose of influencing procedures. the purchase. C- Suppliers, bidders, contractors, service providers and consultants shall not engage in or incite any action contrary to the provisions of this Law, including acts involving corruption, obstruction, fraud, coercion or collusion. D- The procurement committee shall reject any offer if it becomes clear that the bidder has practiced any of the actions stipulated in the provisions of this Article, and shall notify the concerned bidder of its decision and take the necessary actions against then and inform the relevant authorities of such rejection, including the procurement policies committee. Article 90 / d of the Law stipulates that: -The formation a specialized committee for procurement complaints to consider the complaint shall be independent and impartial, and none of its members shall be a member of the purchasing committees. 94-D The receiving committees shall not include those who have previously participated in the drafting of technical conditions, specifications, purchase or analysis documents, evaluation, procurement procedures and supervision of the implementation of the contract, in their membership.		

Conclusion:

Based on the analysis above, it is evident that the regulations governing procurement of vaccines and drugs have several gaps that must be addressed. There is very limited competition in the majority of tenders, as stated in the JPD Annual Report, (2017, page 38). The main reason for awarding tenders was due to having a sole agent (on average 32% of the time) or sole applicant (on average 24.2% of the time). This indicates that 56.2% of procurement was carried out without competition. In the specific case of vaccines, awardees were the sole agent or sole applicant 7% and 57.7% of the time, respectively. This implies that a large majority of vaccine procurement was carried out without competition.

The minimal competition is exacerbated by the absence of coordination between the entity responsible for procurement and the competition directorate in the Ministry of Industry, Trade and Supply which is the directorate concerned with competition matters in the kingdom. The analysis also showed the lack of coordination amongst stakeholders. For example, the JPD Director is not a member in the Drug and Pharmacy Higher Committee or the technical committee of new drug registration (Articles 4, 7, 9 and 10 of the Drug and Pharmacy Law). In addition, the JFDA Director was a member of JPD Board of Directors only after 2nd of September 2018, and shortly after the Board was canceled under the new bylaw. This makes it increasingly difficult for the JPD to increase competition, as there are no legislative tools to collect information and impose penalties when there is only one agent or one applicant. Low level of coordination between entities reduces efficiency and effectiveness and leads to improper elimination and lack of transparency and accountability. The lack of competition is closely related to drug and vaccine registration legislation as well as JFDA's policy of registration and pricing, particularly for vaccines, most of which are free of charge. Increasing competition will require increasing the level of legislative interdependence and level of coordination between stakeholders.

The procurement mechanism is in dire need of effective international practices in the field of external procurement and procurement from international organizations and entities. There is a regulatory and supervisory failure due to the absence of legal framework that provides control and follow-up to all drug providers in the public sector in terms of active participation in tenders and lack of accountability of drug agents. In addition, guarantees to provide market needs are not available. This leads to a financially unstable procurement regulation with significant governance deficiencies.

However, the analysis shows that there is a great opportunity for improvement as there is a strong, but inconsistent legislative basis, for regulating procurement and supplier obligations. In addition, there are legal provisions and legal options that are available, but not activated or not used properly to support international procurement. The new government procurement bylaw and the proposed amendments to the Food and Drug Law will contribute significantly to the improvement of the current situation as legislation is the foundation and legal instrument through which the drug policy is implemented. The new law will also determine the qualifications, duties, privileges and obligations of individuals, organizations, institutions and other concerned entities involved in the procurement process, as well as stipulate the penalties in the event of violations. In order to effectively implement legislation, there is a need to review and update the relevant laws regularly to have a comprehensive legal foundation, in consultation with the relevant stakeholders in order to achieve the desired objectives.

The study also indicates that procurement through international organizations may contribute to the reduction of drug expenditure, since international organizations do not aim to profit from procurement, but rather aim to support improving the health status of the world's population. Legislation, along with the amendments and proposed amendments, meets the requirements of procurement through

international organizations, which will create the opportunity to leverage expertise in other procurement from external entities.

The study recommends the need to re-assess legislation and take advantage of flexibilities in the TRIPS Agreement and thus apply it to non-patented drugs. The regulations in Jordan prohibit importing from non-agents and gives the agent absolute legal protection even if the drugs are non-patented, and without identifying the duties of the agent on quantities to be provided. Drug security articles are taken advantage of and therefore require the issuance of specialized regulations and instructions to take into account the duties of the agent in providing drugs to the private and public markets through supervision, and encouragement of submission to tenders.

The priority results and issues to be considered aim to facilitate dialogue on effective and efficient procurement principles and practices achieving increased savings and improved quality. This study can be used to broadly raise awareness of policymakers to the legislative amendments needed to support implementation of a sustainable, efficient, and flexible procurement regulation.