

 <p>ISSN NO. 2320-5407</p>	<p>Journal Homepage: - <a href="http://www.journalijar.com">www.journalijar.com</a></p> <h2 style="text-align: center;">INTERNATIONAL JOURNAL OF ADVANCED RESEARCH (IJAR)</h2> <p style="text-align: center;">Article DOI: 10.21474/IJAR01/4860 DOI URL: <a href="http://dx.doi.org/10.21474/IJAR01/4860">http://dx.doi.org/10.21474/IJAR01/4860</a></p>	
---	--	---

### RESEARCH ARTICLE

#### MEDICINE IMPORTATION PROCESS ASSESSMENT IN AFGHANISTAN DISSERTATION SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENT FOR THE AWARD OF THE DEGREE OF MASTER OF PUBLIC HEALTH.

**Sayed Murtaza Sadaat, Pharm D.**

MPH Student, Department of Public Health Maulana Azad University, Jodhpur.

#### *Manuscript Info*

##### *Manuscript History*

Received: 15 May 2017

Final Accepted: 17 June 2017

Published: July 2017

#### *Abstract*

**Background:** For largely historical reasons of development in a post-or ongoing conflict situation, the current essential medicines importation mechanisms in Afghanistan are characterized by multiple funding sources and a large number of active players, giving rise to fragmented and, currently, largely uncoordinated service from multiple, vertical importation streams of varying efficiency. At present there is no formal platform to coordinate these activities.

**Method:** The Medicine Importation Process Assessment was jointly carried out by the General Directorate of Pharmaceutical Affairs. The study is a cross-sectional study which questionnaires were made and data collected from stakeholders through direct interview and email. The questionnaire was made based on best practices in pharmaceutical importation system in Afghanistan.

**Result:** Lack of coordination and absence of a coordination platform within the Ministry of Public Health is a big issue to be considered in the future. The importers didn't hire technical staff to deal with the documentation process technically, the importers submitting incomplete or non-original / fake documents for the General Directorate of Pharmaceutical Affairs and Quality Control laboratory for analysis process, most of them bring incomplete information in the proforma; the importers who import narcotic and controlled medicine didn't submit consumption reports for narcotics and the General Directorate of Pharmaceutical Affairs will not prove the next shipment documents till not receiving the consumption report. Some challenges still exist in the processing of the importers' documentation and some steps are redundant in the whole importation process like: Bureaucracy in the General Directorate of Pharmaceutical Affairs, existence of the Licensed Medicine List, short sampling, submitting incomplete or non-original documents to the Quality Control laboratory by the General Directorate of Pharmaceutical Affairs. Therefore, most documents are rejected by the Quality Control laboratory, General Directorate of Pharmaceutical Affairs: poor storage conditions during sampling, delivery to the QC lab which has no standards for chain of custody, time-consuming in the QC lab for analyzing the medicine samples, in the Drug Regulation Committee of the Ministry of Counter Narcotics, time-consuming. This committee works parallel to MoPH, Tariff coding.

**Corresponding Author:- Sayed Murtaza Sadaat.**

Address:- Department of Public Health Maulana Azad University, Jodhpur.

system and poor storage condition for the pharmaceuticals are a big challenge in the Afghanistan customs. The above mentioned challenges are need to consider and make a coordination body among all stakeholders and active players in Afghanistan.

**Conclusion** The people and the pharmaceutical system harm from dis coordination, there is need for a formal platform to coordinate activities among several ministries.

*Copy Right, IJAR, 2017,. All rights reserved.*

.....

### **Introduction:-**

It will be essential to have a comprehensive understanding of the current medicine importation system with challenges. As Ministry of Public Health of Islamic Republic of Afghanistan has the responsibility to ensure that medicines being distributed in the country are safe, effective, and of standard quality.

The Pharmaceutical Law deals with selection, production, importation, distribution and consumption of pharmaceutical products in the country. Many ministries like ministry of defense, ministry interior affairs, national security department, ministry of public health, UN agencies, Donors are importing medicine into the country but there were no coordination between them, the private sector which mostly supplies the private market demand and are legally permitted to import medicine into the country.

The importers do not hire professional staff and are not aware of legal and regulatory documents. Some importers Put pressure by politicians on government regulatory bodies for accelerating approval and releasing of their shipments. The importers wish to import the medicines that are not in LML, they claimed that the current LML is not valid and cannot cover all medicine needed for the health care system. The Tariff Coding System (TCS) are time consuming and charge high tax on importers therefore the taxes are not paid on time. The police checkpoints stop vehicles, request unnecessary documents, Physical collision and extorting from importers. Very lengthy approval procedure and releasing shipments, Bureaucracy Potential redundant steps, lack of guidelines and SOPs for importation. Insufficient resources (Technical Staff, financial, equipment, work place...etc) to carry their analysis in QC lab. Fragile regulatory bodies for importation process in the MoPH.

The medicine law permits importation of medicine and other pharmaceuticals into the country but the pharmaceutical is varies from other goods and needed to regulate according international standards and other national regulatory requirements, The management of pharmaceutical and enforcement of law need multi sectorial coordination and cooperation both in public and private sectors. The new regulatory efforts by MoPH are appreciating which is going to control in pre and post market of the medicine. Appropriate policies, legal framework, and organizational structures are required for the whole ministries to go in the same stream, now the responsible department is GDPA under the supervision of the MoPH, has the primary mission of overseeing and regulating equitable pharmaceutical services in all over the country but successful implementation and enforcement of revised and updated law and other regulatory documents, therefore regulation need collaboration between different governmental authorities, at present there is no formal platform to coordinate these activities also there is insufficient information sharing between the above entities and need be coordinate for betterment of the importation.

### **Background and Rationale:-**

For largely historical reasons of development in a post- or ongoing conflict situation, the current essential medicines importation mechanisms in Afghanistan are characterized by multiple funding sources and a large number of active players, giving rise to fragmented and, currently, largely uncoordinated service from multiple, vertical importation streams of varying efficiency.

This is not to say that the medicines importation service has been unsuccessful but most cases the private, donors, public entities which import medicine in to the country face the problem and discourage the active players to import medicine into the country specially the narcotic and controlled medicine importers. Clearly, however, if the service is to be expanded to meet increased importation of the medicine provision and if significant improvements are to be made in the quality and reliability of that service, then improved oversight, good governance principles of management, and much greater coordination are needed.

As noted, the service is functional—medicines are reaching patients—but the operational environment is fragile and complicated. It will be imperative to ensure that any changes and developments do not threaten to disrupt existing operations and the security of medicine provision to patients. Change is essential to bring the necessary improvements, but that change must be designed and implemented in ways that maintain continuity of importation, and to achieve that aim, it will be essential to have a comprehensive understanding of the current medicine importation system with challenges. As ministry of Public Health of Islamic republic of Afghanistan has the responsibility to ensure that medicines being distributed in the country are safe, effective, and of standard quality.

The Pharmaceutical Law deals with selection, production, importation, distribution and consumption of pharmaceutical products in the country. It was enacted at a time when there was significant need for pharmaceutical products in Afghanistan, which the law addressed by over-simplifying much of the importation process. Given the dramatic increase in the volume of pharmaceutical imports, this law is need of substantial revision as recently MoPH started the revision of the medicine law.

Aside from the highly permissive environment the Pharmaceutical Law provides importers, it is deficient in addressing conflict of interest issues, several organizations like ministry of defence, ministry of interior affairs, national security department, ministry of public health, UN agencies, Donors are importing medicine into the country but there were no coordination mechanism among these organizations, the private sector which mostly supplies the pharmaceuticals market demand and are legally permitted to import medicine into the country face to some challenges with the stake holders like: ministry of public health, ministry of interior affairs, ministry of finance specially the custom department in case of importation of narcotic and controlled medicine ministry of counter narcotics, the donor NGOs UN agencies that import medicine for the public sector have complain in importation of the donated medicine as well.

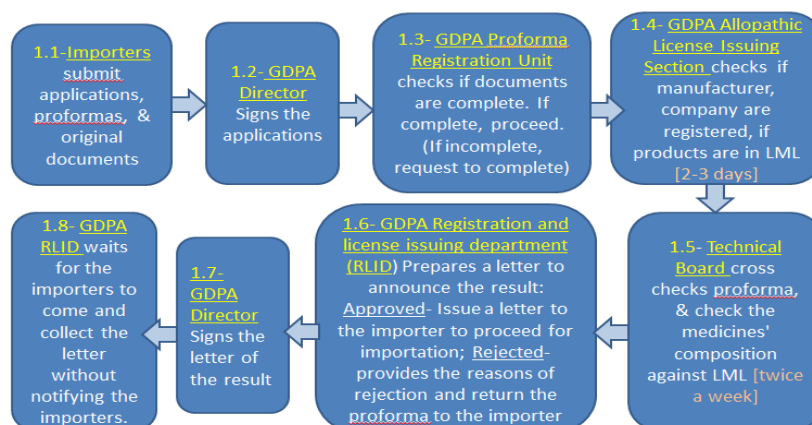
During the assessment, the Team learned that amendments/revisions to the Pharmaceutical Law are currently being drafted to address several deficiencies. It is hoped that recommendations from this will be used to facilitate the revision process. There were some other challenges which are indicated as below:

Appropriate policies, legal framework, and organizational structures are required for the whole organizations to go in the same stream, now the responsible department is GDPA under the supervision of the MoPH, has the primary mission of overseeing and regulating equitable pharmaceutical services in all over the country but successful implementation and enforcement of revised and updated law and other regulatory documents which some involved entities don't have the regulatory and legal documents of the pharmaceuticals therefore regulation need collaboration between different governmental authorities, at present there is no formal platform to coordinate these activities also there is insufficient information sharing within the mentioned and need be coordinate for betterment of the importation.

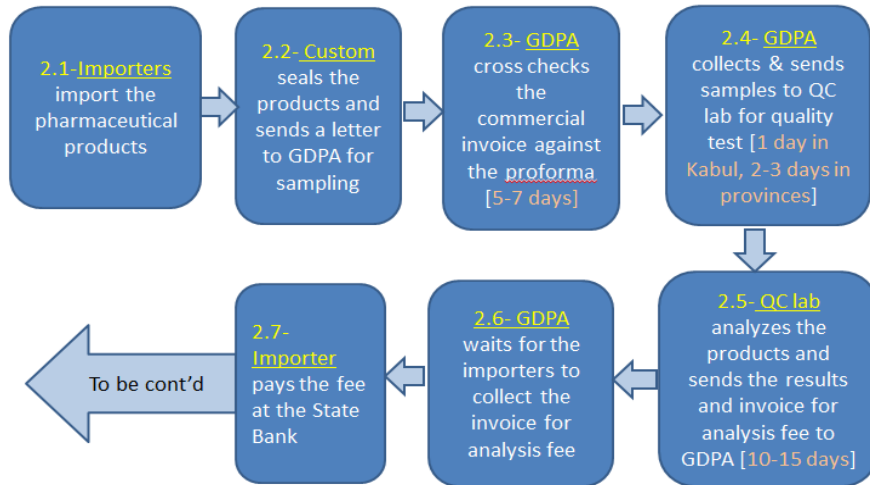
### Medicine Importation Process

The general importation process of medicine importation is (Figure 1, 2, 3) but it varies in importation of Narcotic and controlled medicine which indicated **Annex-I**.

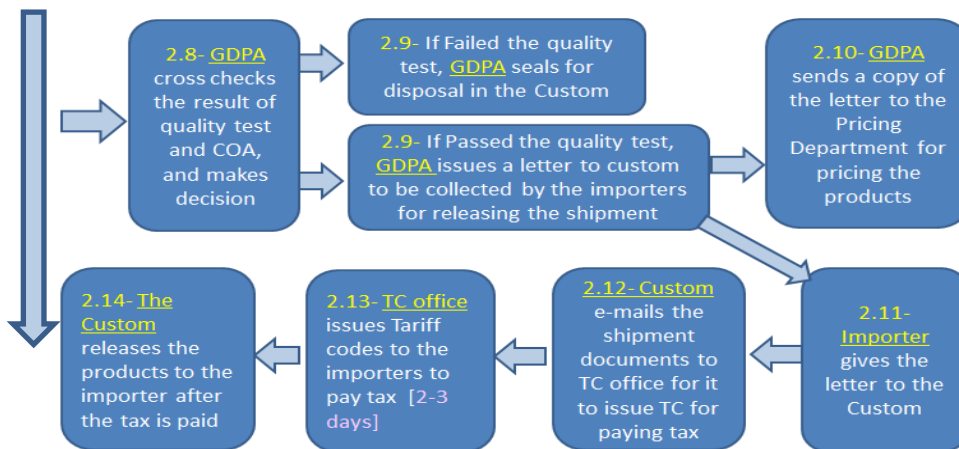
**Figure -1- General Importation Application Procedure (2-3 weeks)**



**Figure- 2- General Importation Custom Procedure (2-3 weeks) (1/2)**



**Figure- 3- General Importation Custom Procedure (2-3 weeks)- (2/2)**



**Objectives:-**

**Primary:-**

To overview of the existing Pharmaceutical importation management situation in regulatory authority and other steps exist in the importation procedures.

**Secondary:-**

To identify existing gaps, weakness, and strengths of the current systems for betterment of the importation.  
To recommendations and way forward

**Study Design:-**

The Medicine Importation Process Assessment was jointly carried out by the General Directorate of Pharmaceutical Affairs (GDPA). The study is cross section study which questionnaires made and data collected from stakeholders through direct interview and email. The questionnaire made based on best practices in pharmaceutical importation system in Afghanistan.

**Review of Literature:-**

**Literature Review:-**

Fifteen units report responsibility for importation permissions. It is hardly surprising that the fragmented process is subject to confusion and delays. Here also rationalization may greatly benefit the GDPA. The process is subject to confusion and delays.

It is strongly recommended that GDPA to produce a full-flow pattern and resulting structure necessary for the effective control of importation and permission systems for pharmaceutical products and then GDPA to implement the new structure and operations.

**Methodology:-**

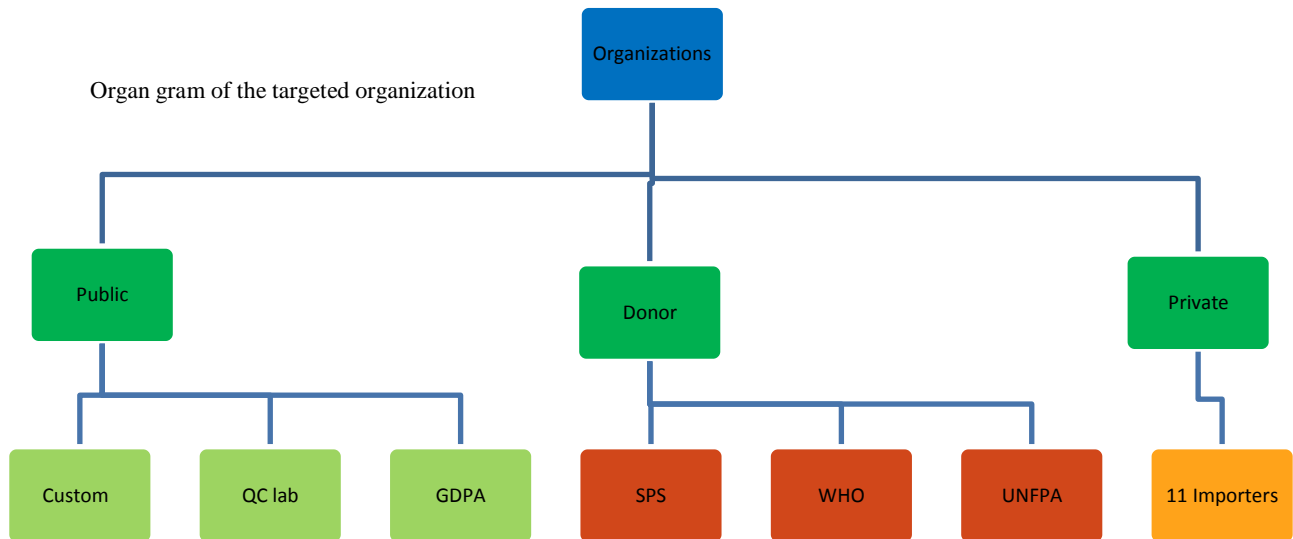
The methodology of the assessment which are questionnaires based on best practices in pharmaceutical importation, the assessment was cross sectional qualitative research and the research approaches – qualitative data.

The geographical area for implementation of questionnaire is central office of selected organizations

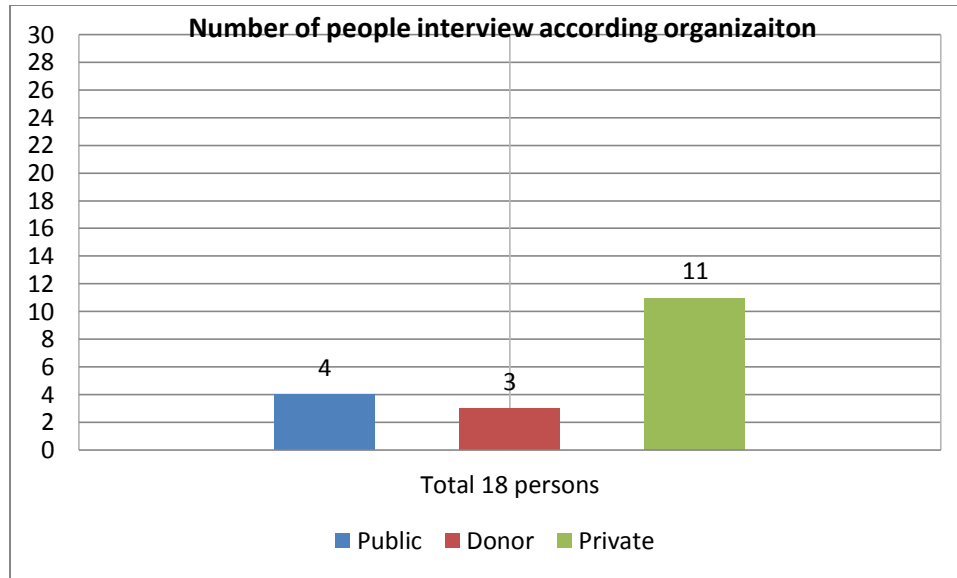
Which were 19 organizations and we were able to collect data from 16 organizations, the method of sample collection was convenient sampling. The data collection method was through interview (questionnaire) which contain several parts like: Internal review and approval process, Collaboration of Importers with GDPA, Warehouse storage space, Collaboration with custom clearance office in neighbouring countries, Importation policies and guidelines, Recommendations for improvement. A sample of questionnaire shown in **Annex-II**  
Validity of the data from 5% of organizations (double checked)

**Sample Size:-**

The sample size was 21 persons due to some challenges we could collect from 18 persons, there were 11 importers, 2 persons from General Directorate of Pharmaceutical Affairs (GDPA), 1 person from Quality Control Laboratory of MoPH(QC lab), 1 person from custom department of ministry of finance and 3 persons from donors which they import medicine into the country. The total number of interviewees was 18 persons from all stakeholders.



*shows the number of sampling entities during assessment*



#### **Sample Selection:-**

The sampling was convenient which was easy to collect the data, the interviewees selected based on recommendation of the GDPA and selected the importers which they were active in the market, import more medicine in to the country. (All the importers provided the similar information's)

#### **Permission and invitation:-**

The details of assessment (plan, objectives, data collections methodology , data collection tools and etc) within an assessment proposal were presented to GDPA leadership and related department for further consensus and approval, later on that through an officially later of GDPA for all selected organisations the data collection team went to organizations for collecting the data/information (face to face interview).

The official letter is in **Annex III**

#### **Key Findings:-**

The assessment shows the bottle necks in several stakeholders GDPA, custom, QC Lab, Donors, and Importers performance which are as below:

#### **Importers:-**

The importers submit incomplete, non-original, or fake documents to GDPA and custom, the lack of the professional technical staff and unawareness of the importers causes delay of importation. The importers which import controlled and narcotic medicines the GDPA asks for past consumption of narcotic and controlled medicine, actually there is no clear surveillance for the narcotic and controlled medicine reporting and the importers do not submit past consumption report for imported narcotics, Some importers put pressure on GDPA, Custom and QC lab for accelerating approval and sampling, this cause delay to approve other applications were submitted their documents before, the interviewees told that their products mostly delay in QC lab of MoPH for 15-30days. In the other side only 30% of respondents thought that the regulatory documents (guidelines) are easy to understand for non-professionals most of the respondents believe that the guideline and other regulatory documents are too much technical and are not written based on Afghanistan conduction and the importers don't know the content of the guidelines and other pharmaceutical regulatory documents, they claim the policies and procedures are not clear. Most of the importers wish to import the medicines that are not in LML, in particular the multi-ingredient combinations they claimed that the current LML cannot cover all medicine needed for the healthcare system, The GDPA regularly invited the private sector representative to LML revision committee but their participation was not regular. The ministry of finance launched a new Tariff Coding System (TCS) the importers claim that this system are time consuming and charge high tax on us therefore the taxes are not paid on time.

The other challenge is the police checkpoints which stopping vehicles, request unnecessary documents, Physical collision and the police extorting from the importers.

**General Directorate of Pharmaceutical Affairs(GDPA):-**

GDPA developed the LML which strict medicine importation they asked the GDPA must be flexible in adding new medicine into the LML especially multi-ingredient combinations. Most of the interviewees told the registration procedure are very lengthy procedure for approval, for importation application and releasing shipments, Bureaucracy Potential redundant steps are still in GDPA also the administration suffer from lack of guidelines and Standard Operation Procedures (SOPs) for importation. The interviewees told there are some gaps in reviewing medicines- sometimes the Allopathic License Issuing Section (ALIS) didn't complete the review of ingredients before forwarding to technical Board and technical board consumes more time on reviewing on the proformas. They told that inexistence of trained staff and existence of unprofessional staff in document review and sampling in GDPA is a big challenge, they claim that the staff didn't equipped and trained well for sampling which sometimes the samples collect insufficient samples and wrong sampling, inexistence of any standard written document is a (bottle-neck) for the administration to be considered in the future.

**Quality Control laboratory(QC lab):-**

Delay the analysis of medicines within the QC lab (15 to 30 days) may causes of insufficient technical staff and lab equipment, QC lab doesn't have the medical supplies analyzing section and send the samples to faculty of pharmacy, Kabul University for analyzing which time consumer for the importers.

**Custom:-**

The interviewees responded the lengthy & bureaucratic procedure for releasing the shipments in custom is a big challenge for them, they believe that multiple stakeholders involved in the importation system which sampling is done by GDPA, analysis done by QC lab, shipment releasing by custom, therefore the importation delay too much in every entity. The ministry of finance custom department assigning TSC (Tariff System Code) to each product is time consuming (average 2 days) and delay the release of the pharmaceutical products in custom.

The interviewees responded that in ministry of foreign affairs there are too much lengthy procedures in approving of donation medicines also the interviewees told there are too much lengthy procedures in approving tax exemption for donated medicines.

The responders answered that understanding of regulations and donation guidelines varies among donors and NGOs. Insufficient storage space within the custom is concern for all importers, donors and MoPH/GCPA.

**Data collection and Management:-****Data Collection:-**

Based on the best practices of pharmaceutical importation, procurement, distribution the questioners developed, translated, tested and revised afterward all identified data sources investigated the data collected by face to face interview and email from all stakeholders. Usually two people were attending in interview one was arranging and organizing the interview and the other were writing the note from the responder. See questionnaire in **Annex II**.

**Data collection team.**

No	Name	Position	Organization
1	Dr. Ajmal Yadgari	CPDS Technical Coordinator	MoPH
2	Ph. Sayed Abdulllah Hashemi	Manager	GDPA/API
3	Ph. Mohammad Salih	Manager	GDPA
4	Ph. Mohammad Faisal Zamani	Technical Officer	SPS
5	Ph. Sayed Murtaza Sadaat	Technical Officer	MHP candidate

**Data Entry:-**

All collected data tabulated, organized, reviewed, and translated a data entry matrix developed by the assigned team, the data entered into the data entry matrix, the data collected from February 1st to March 08, 2016.

**Data Analysis:-**

The collected data analysis in a simple data analysis in MS.EXCELL.

**Limitation and Challenges:-**

Some of organizations didn't provide the required information (NTP, UNICEF, importers) and some of the organization provided poor and insufficient information, due to security concern the data collection delayed.

**Recommendation of interviewees:-**

**Based on the interview's questions the organization's recommended the following recommendations:**

1. Train importers and government staffs
2. Revision of licensed medicine list
3. Introduction of guidelines or SOPs
4. Improving coordination among stakeholders and establishment of a coordination committee within the MoPH

**Results and Discussions:-**

The purpose of the Medicine Importation Assessment to provide an overview of published data and available information on medicine importation situation in Afghanistan and to identify gaps in importation of the medicine in the country. In the present we attempt to determine if there was any change in the recent years.

As a summary, during almost 15 years, a number of studies published in peer reviewed journals were conducted the Afghanistan in relation to different aspects of pharmaceutical. Concerning the importation of the medicine fifteen units report responsibility for importation permissions. It is hardly surprising that the fragmented process is subject to confusion and delays. Here also rationalization may greatly benefit the GDPA. It is strongly recommended that GDPA to produce a full-flow pattern and resulting structure necessary for the effective control of importation and permission systems for pharmaceutical products and then GDPA to implement the new structure and operations.

The Pharmaceutical Law deals with selection, production, importation, distribution and consumption of pharmaceutical products in the country. Many ministries like ministry of defence, ministry interior affairs, national security department, ministry of public health, UN agencies, Donors are importing medicine into the country but there were no coordination between them, the private sector which mostly supplies the private market demand and are legally permitted to import medicine into the country.

As a second key priority highlighted by this review is the most number of importers do not hire professional staff and are not aware of legal and regulatory documents. Some importers Put pressure by politicians on government regulatory bodies for accelerating approval and releasing of their shipments. The importers wish to import the medicines that are not in LML, they claimed that the current LML is not valid and cannot cover all medicine needed for the health care system. The Tariff Coding System (TCS) are time consuming and charge high tax on importers therefore the taxes are not paid on time. The police checkpoints stop vehicles, request unnecessary documents, Physical collision and extorting from importers. Very lengthy approval procedure and releasing shipments, Bureaucracy Potential redundant steps, lack of guidelines and SOPs for importation. Insufficient resources (Technical Staff, financial, equipment, work place...etc) to carry their analysis in QC lab. Fragile regulatory bodies for importation process in the MoPH.

The medicine law permits importation of medicine and other pharmaceuticals into the country but the pharmaceutical is varies from other goods and needed to regulate according international standards and other national regulatory requirements, The management of pharmaceutical and enforcement of law need multi sectorial coordination and cooperation both in public and private sectors. The new regulatory efforts by MoPH are appreciating which is going to control in pre and post market of the medicine. Appropriate policies, legal framework, and organizational structures are required for the whole ministries to go in the same stream, now the responsible department is GDPA under the supervision of the MoPH, has the primary mission of overseeing and regulating equitable pharmaceutical services in all over the country but successful implementation and enforcement of revised and updated law and other regulatory documents, therefore regulation need collaboration between different governmental authorities, at present there is no formal platform to coordinate these activities also there is insufficient information sharing between the above entities and need be coordinate for betterment of the importation.



**Conclusion:-**

Lack of coordination and absence of a coordination platform within the MoPH is a big issues to be consider in the future , the importers didn't hire technical staff to deal with documentation process technically, the importers submitting incomplete or non-original / fake documents for GDPA and QC lab for analysis process, most of them bring incomplete information in the proforma ; the importers who import narcotic and controlled medicine didn't submit consumption reports for narcotics and GDPA will not prove the next shipment documents till not receiving the consumption report . Some challenges are still exist in the processing of the importers documentation and some steps are redundant in the whole importation process like: Bureaucracy in GDPA, existence of LML, short sampling, submitting incomplete or non-original documents to QC lab by GDPA therefore most documents rejected by QC lab, GDPA: poor storage conditions during sampling delivery to QC lab which there is no standards for chain of custody, time consuming in QC lab for analyzing of the medicine samples, in Drug Regulation Committee (DRC) of ministry of counter narcotics time consuming this committee works parallel to MoPH, Tariff coding system and poor storage condition for the pharmaceuticals are a big challenge in the Afghanistan customs. The people and the pharmaceutical system harm from dis coordination, there is need for a formal platform to coordinate activities among several ministries.

**Recommendations:-**

1. Improve coordination among all organization's which involved in the importation of medicine in the country through establishing a coordination platform within the MoPH
2. Finalize the importation guidelines, translate, distribute and provide the trainings for all responsible staff of organizations
3. Regular supervision and monitoring from importation process by relevant departments of MoPH to avoid any overlapping of activities

**References:-**

1. Functional Analysis of the General Directorate for Pharmaceutical Affairs of the Ministry of Public Health of Afghanistan
2. Good Procurement Practice (GPP) and Good Distribution Practice (GDP), WHO.
3. Managing Access to Medicines and Health Technologies MDS – 3, MSH, distribution and procurement sections.
4. Afghanistan medicine law
5. Afghanistan Regulation on Manufacturing and Importing Medicine and Medical Appliances
6. Afghanistan Medicine Quality Assurance Assessment
7. Assessment Report of Quality Control Laboratory Ministry of Public Health Islamic Republic of Afghanistan Under Capacity Building & Access to Medicines Project (CBAM), 15/08/2010- 06/09/2010
8. Quality assurance of pharmaceuticals, A compendium of guidelines and related materials, Volume 2, 2nd updated edition, World Health Organization 2007
9. ASSESSMENT REPORT ON REGULATORY FRAMEWORK AND STRUCTURE FOR MEDICINES AND FOOD IN AFGHANISTAN November 2010
10. National Licensed Medicines List of Afghanistan 2014
11. ICH. Quality risk management (Q9); 2005.
12. WHO Expert Committee on Specific cations for Pharmaceutical Preparations. Multisource (generic) pharmaceutical products: Guidelines on registration requirements to establish interchangeability (Annex 7 to TRS 937). Geneva: WHO; 2006.
13. WHO Expert Committee on Specific cations for Pharmaceutical Preparations. National drug legislation: Guiding principles for small national drug regulatory authorities (Annex to TRS 790). Geneva: WHO; 1990.
14. WHO Expert Committee on Specific cations for Pharmaceutical Preparations. Guiding principles for small national drug regulatory authorities (Annex to TRS790); 1990.
15. WHO/DMP/RGS/98.2. How to introduce computer-assisted drug registration. Geneva: World Health Organization; 1998.
16. WHO/DMP/RGS/98.3. A model system for computer-assisted drug registration: User Manual. Geneva: World Health Organization; 1998.
17. Winship K HD, Lawson DH,. The review of medicines in the UK. British Journal of Clinical Pharmacology.1992; 33(6):583-7.

**Annex- I**  
Narcotic Medicine Importation Follow

**Findings 1B- Narcotics Importation Application Procedure (2-3 weeks)**

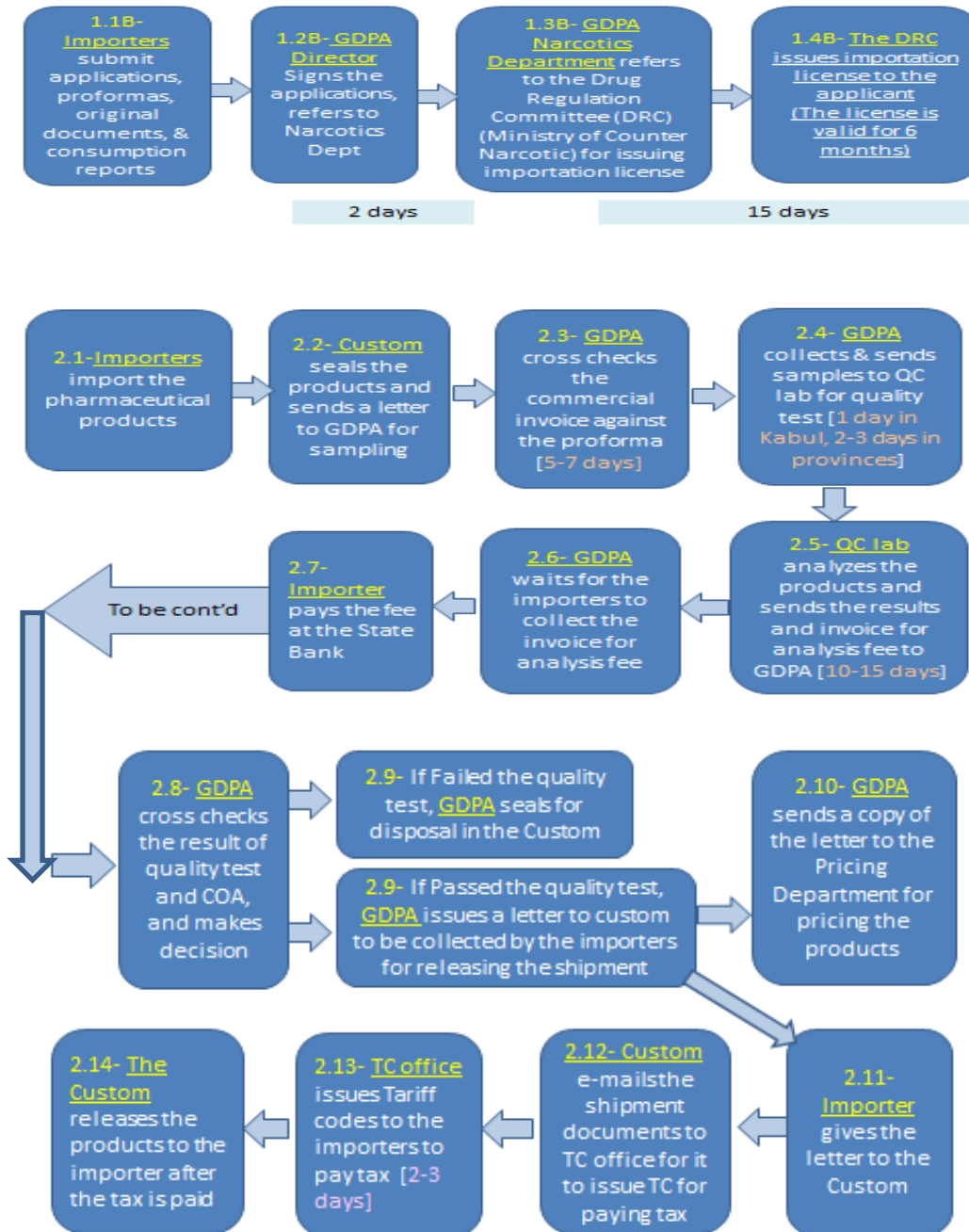


Figure 5:- Narcotic and controlled medicine importation follow.

**Annex II:-****The questionnaire which made for General Directorate of Pharmaceutical Affairs**

#	Topic	Question	Answer
1	Internal review and approval process	What are the different types of roles and responsibilities of staff who are involved with the importation process within the GDPA office?	
2	Internal review and approval process	Have you felt that there are some steps which are redundant and can be combined or reduced?	
3	Internal review and approval process	How much time need for the approval of the GDPA director regarding pro forma?	
4	Internal review and approval process	What is official due date for you to review and finalize the shipment documents once you receive the application from importers?	
5	Internal review and approval process	Have you experienced that the due date is too short to proceed within the due date or unnecessarily too long?	
6	Internal review and approval process	What are your main challenges with approval process?	
7	Internal review and approval process	How much time required reviewing and checking the shipments documents?	
8	Internal review and approval process	Which departments are involved with the importation documents process?	
9	Internal review and approval process	Is the process well defined?	
10	Internal review and approval process	What are the main challenges during the review of pro forma and other related documents?	
11	Internal review and approval process	How much time the allopathic/ herbal sections need for the review and check of the documents?	
12	Internal review and approval process	How much time the GDPA technical board need to review the documents and makes decision?	
13	Internal review and approval process	Is the process well defined within the GDPA technical board?	
14	Internal review and approval process	What are the main challenges with the GDPA technical board?	
15	Internal review and approval process	Do you often experience incomplete documents?	
16	Internal review and approval process	What do you believe the reason for importers bring the incomplete documents?	
17	Recommendation for improvement	What would you suggest to reduce the incomplete shipment document submission?	
18	Samples collection	How much time need for sampling process e.g. sample taker, sampling method, handling sample, send to GDPA for review and approval and forward to QC-Lab and Faculty of Pharmacy?	
19	Samples collection	Which departments are involved with the sampling process?	
20	Samples collection	Is the process well defined?	
21	Samples collection	What are the main challenges in sampling process?	
22	Collaboration with the QC-Lab	How much time need the QC-Lab to analysing of the samples and sends the result back to GDPA?	
23	Collaboration with the QC-Lab	What are the main challenges with QC-Lab?	
24	Collaboration with the Importers	What are the main challenges with the importers?	
25	Collaboration with the FoPH	How much times need the Faculty of Pharmacy to analysing the medical supply?	
26	Collaboration with the FoPH	What are the main challenges with the analysis of medical supply?	
27	Collaboration with the	What are the main challenges regarding the Narcotic, Psychotropic and	

	narcotic, psychotropic department and DRC	under control medicine department and with Drug Regulatory Committee?	
28	Human Resources	Do you have sufficient staff for carrying out the activities?	
29	Regulations, policies and guidelines	Do you aware about the MoPH/GDPA regulations, policies and guidelines e.g. registration guidelines...etc?	
30	Regulations, policies and guidelines	Do you think the regulations, policies and guidelines are easy to understand and detailed	
31	SOPs	Are there SOPs for you to follow to do your work?	
32	Capacity building	Did you provide trainings for importers, custom's staff, QC-Lab and etc, regarding the guidelines and policies if there are any changes?	
33	Complain	Do you have any appealing or complain system?	
34	Complain	Did your receive any complain regarding the process?	
35	Complain	How did you solve it?	
36	Recommendations for improvements	What would you suggest to improve the current regulations, policies and guidelines?	
37	Recommendations for improvements	What are your recommendations for the improvement of importation process?	