Islamic Republic of Afghanistan

Ministry of Public Health

National Medicine and Healthcare Products Regulatory Authority

User Manual for the National Inspection Checklist for Pharmaceutical Importers

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The National Medicine and Healthcare Products Regulatory Authority (NMHRA) was established under the Ministry of Public Health (MoPH) in 2016, with the mission to regulate and control production, importation, exportation, distribution and use of medicine and healthcare products in order to "access to quality, safe and efficacious medicines and health products with the objective of development and enforcement of effective standards in order to optimize the safety, efficacy, quality and affordability of medicines and health products throughout the country.

To ensure that the inspection of pharmaceutical importers is carried out with good standard, MoPH initiated the development of the pharmaceutical importers inspection checklist user manual. The objective of using the checklist for inspection is to enforce the implementation of the relevant law and regulations by the pharmaceutical importers for assuring the quality and safety of their practices and the pharmaceuticals during procurement, storage, and distribution of medicines; and delivering high quality services to the population.

To ensure technical quality and appropriate to the Afghanistan context, the national inspection checklist user manual was developed by a MoPH-delegated technical committee with the financial and technical support of the SPS project.

The NMHRA in the MoPH wishes to acknowledge the contributions of the individuals who comprised the Taskforce for the development of the national inspection checklist user manual. Acknowledgement is given to the following people in particular:

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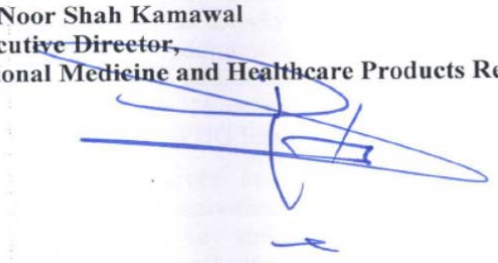
Dr. Noor Shah Kamawal
Executive Director,
National Medicine and Healthcare Products Regulatory Authority



Introduction

The purpose of this manual is to provide support to inspectors. This manual contains detailed information on procedures for implementing the Inspection Checklist. All inspectors and others who participate in the implementation process should familiarize themselves with the contents of this manual.

Instructions for Inspectors

This section provides general instructions for inspectors.

I. Keys to Interviews and Successful inspection

Successful interviewing and observation is an art and should not be treated as a mechanical process. Each interview or observation is a new source of information, so make it interesting and pleasant. The art of interviewing develops with practice, but there are certain basic principles, which, if followed, will help you to become a successful interviewer and inspector.

1. **Building Relationship with the Technical In-Charge (Pharmacist) and Others Assisting with Implementation of the Checklist:** At the beginning of the inspection process, you and the technical in-charge and others, may be strangers to each other. The first impression technical in-charge and other staff have toward you may influence his/her willingness to cooperate with the implementation of the checklist. Be sure that your manner is professional but friendly as you introduce yourself. Show the respondent the ID card that you have been given that states you are working with the NMHRA-MoPH. The following principles help to build relationship:
   - *Make a good impression:* When first approaching technical in-charge and other staff, do your best to make them feel at easy. With a few well-chosen words, you can put technical in-charge and other staff in the right frame of mind for the implementation of the checklist.
   - *Adopt a positive approach:* Never adopt an apologetic manner, and do not use words such as "sorry" or "are you too, busy?" such questions may give rise to resistance. Rather, tell the respondent: "I would like to have your assistance while I implement this checklist."
2. **Tips for Asking Questions and inspection**
   - *Be neutral throughout the process.* Most people are polite and will tend to give answers that they think you want to hear. Many people will be eager to give you information that makes the importer company look good and hesitant to provide information that makes the importer company and its staff looks bad. It is therefore very important that you remain absolutely neutral as you implement the checklist. Never, either by the expression on your face or by the tone of your voice, allow the respondent to think that he/she has given the "right" or "wrong" answer to a question.
   - *Never suggest answers to the respondent.* If a respondent's answer is not clear or not relevant, do not prompt him/her by saying something like "I suppose you mean that….Is that right?" In many cases, respondents will agree with your interpretation of their answer, even when that is not what they meant. You should probe in such a manner that the respondent comes up with the relevant answer themselves, in their own words.
   - *Do not hurry your work.* Ask the questions slowly to ensure that technical in-charge and other importer company staff understands what is being asked. After you have asked a question, pause and give the respondent time to think. If the respondent feels hurried or is not allowed to formulate an answer, he/she may respond with 'I don't know" or give an inaccurate answer. Remind the respondent that there is no hurry and that his/her response is important.
3. **Correcting Mistakes**
   - It is very important that the inspectors record all answers neatly and correctly. If you made a mistake in entering information or the staff assisting you provide contradictory information, be sure that you cross out the incorrect response and enter the right answer. Do not try to erase the answer. Put two lines through the incorrect response.
4. **Checking Completed Checklist Forms**

- ❖ It is the responsibility of the inspectors to review each section of the checklist when finished. You can make minor corrections yourself, but any serious error should be verified by going back to technical in-charge and importer company staff. Simply explain to the technical in-charge that you made an error and ask the question or check the information again. Not important the checklist should be clean enough do not recopy the checklist.

II. How the Checklist is to be Implemented

Three methods are involved in implementing the checklist:

1. **Direct observation:** This involves looking at various parts of the importer company . To the greatest extent possible, specific criteria have been described for how to address each question on the checklist. For most questions, this involves looking—directly observing—for oneself rather than depending on what the technical in-charge or other staff reports. For example, the inspectors should not rely on what the technical in-charge says regarding the presence of a functioning refrigerator. Rather, he should check for him or she to see whether a refrigerator is present and he/she should examine the refrigerator to see if it is functional.
2. **Review of importer records:** For many questions the inspectors will have to review the importer records. Sometimes this will involve checking to see whether the Narcotic Registration Book have been completed thoroughly and accurately.
3. **Asking questions of the technical in-charge:** Many questions require the inspectors to ask questions of the technical in-charge of the importer. For many of these questions, asking questions of the technical in-charge is followed by verification through direct observation.

Introduction to Pharmaceutical Establishment Inspection

To "inspect" is "to look closely at something, especially to check that everything is in good order." Inspection is the general examination of affairs or activities related to an administrative unit to measure the level of compliance of the unit with standards, good operational methods, and all other disciplines as well as to make recommendations for reforms.

A "Pharmaceutical Establishment inspection" is an official visit by the National Medicine and Healthcare Products Regulatory Authority (NMHRA) inspectors to a pharmaceutical establishment to check if relevant laws, regulations and standards are being followed, and if any corrective measures are required to improve their practices.

The overall objective is to ensure that the establishment meets the requirements of the laws, regulations, and standards in their services and medicines provided to the general public.

What Needs to Be Inspected?

To ensure the quality of drugs entering or circulating in the Afghanistan market, the following establishments associated with drug supply and the distribution chain should be inspected regularly:

1. Local manufacturing companies (both established and new ones before they are licensed)
2. Importing companies (both established and new ones before they are licensed)
3. Wholesalers (both established and new ones before they are licensed)
4. Retail pharmacies (both established and new ones before they are licensed)

Types of Inspections

There are four types of inspections:

1. Routine/comprehensive inspection
2. Concise inspection
3. Follow-up inspection
4. Special inspection

1. Routine/Comprehensive Inspection

Routine or comperhensive inspection is a full review of all components of practices and products in an establishment or facility. This type of inspection should be announced to the targeted pharmaceutical establishments.

A routine inspection is conducted under the following circumstances:

a. Initial inspection to a newly established pharmaceutical establishment or facility
b. When there is change of technical in-charge, modification of the premises, or moving to a new location
c. When the technical in-charge's certificate for practice is expired
d. When the pharmaceutical establishment's certification is expired
e. There was history of major or repeated non-compliance in certain pharmaceutical establishments.
f. The establishments which have not been inspected in the last 5 years.
g. Regular inspection to existing establishments

2. Concise Inspection

Concise inspection is the evaluation of limited components in a pharmaceutical establishment. In a resource limited setting, a concise inspection can be used to identify areas or establishments that require general and routine inspection. This type of inspection can be announced or un-announced to the targeted establishments.

A concise inspection is conducted under the following circumstances:

a. When a sample of components can be taken as indication of the overall level of compliance, or trigger comprehensive or routine inspection
b. When an establishment has a consistent record of compliance in the past
c. To identify significant changes for the limited components

3. Follow-Up Inspection

A follow-up inspection is a reassessment or a re-inspection of a pharmaceutical establishment to monitor the result of corrective actions recommended in the previous inspection. It could be carried out within the agreed timeframe after the previous inspection. This type of inspection should be unannounced.

4. Special Inspection

The special inspection is mostly on ad-hoc basis. This type of inspection could focus on limited aspects, such as one product, a group of related products; or specific practices, such as labeling or compounding. It could be investigative to verify any malpractice or product quality concerns. This type of inspection should be un-announced.

A special inspection is conducted in the following circumstances:

a. When any specific or suspect products or practices are prioritized for inspection
b. When there are complaints about product defeat or malpractice in the market or in a specific pharmaceutical establishment, which often followed by investigations.
c. When there is a product recall due to events such as adverse drug reactions.
d. To investigate or gather information for specific products or operations
e. The time required for special inspection is normally shorter than general inspection. However, it also depends on the amount of information requested by NMHRA, or relevant legal authorities for any specific objectives.

Objectives of the Pharmaceutical Establishment Inspection

The objective of the pharmaceutical establishment inspection is to ensure that all the pharmaceutical establishments comply with all legal requirements and regulatory standards. The goal is to ensure quality and safety of pharmaceutical products produced, procured, stored, dispensed; and quality of practices and services provided to the general public.

Purpose and Use of the Inspection Checklist and User Manual

The inspection checklist is a tool that provides prioritized items in a structured manner to help inspectors conduct inspection at any pharmaceutical establishments. It is also a documentation tool that keeps the inspection findings, recommendations and corrective actions. It can be used for follow-ups or monitoring of progress for improvements, and an evidence for any legal sanctions should violation of any law or regulation occur.

The inspectors are the ones that enforce the implementation of the related laws and regulations, they should be familiar with the contents (know-what) of an inspection checklist, and practice (know-how)

of the inspection procedure. The user manual of an inspection checklist provides instructions on key procedures of inspection, and how to document the findings, recommendations and proposed actions. It can be used for the preparation of an inspection for experienced inspectors, and for the training or orientation of new inspectors. In this user manual, the instructions of inspection procedure will go along with the items in the checklist so that the inspector can have all required information in one place. The instructions are shaded; therefore, it is easy to differentiate the original contents and the instructions.

The inspection checklist and user manual should be updated or revised as soon as any relevant new law or regulation has launched. The inspectors are required to be updated about the changes of the regulatory requirements and the checklist.

Laws, Regulations, Policies and Guidelines Applied in this Checklist

This inspection checklist is developed according to the most recent effective laws and regulations governing pharmaceutical practices and services. The laws and regulations applied in this checklist are listed below with their acronyms:

1. ML: Medicine Law, official gazette issue number 963, November, 18, 2008
2. MIMMAR: Manufacturing and Importing Medicines and Medical Appliance Regulation, official gazette issue number 916, February, 24, 2007
3. PR: Pharmacy Regulation, official gazette issue number 916,February, 24, 2007
4. NMP: National Medicines Policy, 2014
5. NPQAP: National Pharmaceutical Quality Assurance Policy, 2105
6. NPNCM: National Policy for Narcotic and Controlled Medicines, 2016
7. NPWMSDPP: National Policy for Waste Management & Safe Disposal of Pharmaceutical Products, 2016
8. MRG: Medicine Registration Guidelines, 2014

To help the inspectors easily apply regulatory references in the inspection, the laws and regulations governing each inspection item are provided in the bracket with the article or section number, name of the documents, and its launched year at the end of each item, for example (50 ML, 2007) refers to "*Article 50 of the Medicine Law launched in 2008"*. Inspectors are encouraged to be familiar with all the specified regulatory references before carrying out inspection activities.

Pharmaceutical Importers Inspection Procedure

Importer inspection is an exercise of which the inspectors examine whether an importer is compliant with the relevant regulatory requirements with the aim of securing and promoting safe and effective pharmaceutical products and handling practice. The inspectors should involve in the pre-, during-, and post-inspection activities for a complete procedure.

Pre-inspection Preparation

The pre-inspection preparation includes the following activities:

1. **Planning**: Develop an inspection schedule for a defined period of time (such as every quarter, 6 months, or year). Each inspection team should have two inspectors. Planning the inspection schedule should take into consideration geographical factors (direction, travel time, seasonal weather, security, etc.) and existing resources to promote cost effectiveness.
2. **Information**: Collect information about the targeting areas or pharmacies for inspection Such as:
    - List of importers whose registration (importer or technical in-charge) have been expired
    - List of importers whose major corrective actions required follow-up.
    - Any suspect importer with product quality or malpractice issues.
    - The updated category 2 controlled medicines list (a current list is in Annex 3)
3. **Notification**: Depending on the purpose or types of the inspection, inform the importers scheduled for routine or concise inspection
4. **Tools and stationary**: Make the following documents or tools ready for inspection:
    - Blank copies of checklists, carbon papers, and pens. The page of section 13 must have two sheets.

- Previous inspection checklists or reports, copies of regulatory measures notices (if any), etc. for the importers to be inspected.
- The laws and regulations applied in the checklist.
- A list of most updated registered medicines and LML
- A medicine sample collection form (annex 1 in the checklist)
- Quarantined and confiscation form (Annex 2 in the checklist)-
- A list of the cold room medicines
- The registered addresses of the targeted pharmaceutical establishments
- Inspectors' official authorized identification for performing inspection
- GPS tool
- Area measuring tool(to measure importer companyarea)

During-inspection Activities

The inspectors are expected to perform inspection in the following steps:

1. Upon arrival at the importer's premise, the inspectors should present their identification or authorization document to the technical in-charge or proprietor; introduce themselves and the purpose of the visit.
2. If there was a previous inspection, request the technical in-charge to present the previous records (findings and recommended corrective actions and timelines).
3. If it is an initial regular inspection, start to conduct inspection using the checklist. If it is a follow up, check the progress of the required corrective actions first, then complete other inspection items.
4. If both the proprietor and the technical in-charge are not present, and there is no legally authorized pharmacy professional on duty, fill the checklist in Section 1 (General information), and record the issue of absence of technical in-charge in the Section 12 and 13 of the checklist.
5. If the importer does not hire a technical in-charge, fill the checklist in Section 1 (General information), and record the issue of absence of technical in-charge in the Section 11 and 12 of the checklist.
6. For other details, refer to the instructions for the sections of the checklist.

Post-inspection Activities

After conducting each inspection, the inspectors should perform the following activities:

1. Write a summarized inspection report for each importer. The report should include key findings of specific violations that require regulatory measures, and next steps.
2. Collaborate with related regulatory authorities to take actions on the importers that require regulatory measures.
3. Entering the filled checklist into the database.
4. File the filled checklists at the designated files.
5. Plan for follow up visits.

Instructions for Using the Pharmaceutical Importer Inspection Checklist

Introduction of the Sections

The inspection checklist applies prioritized laws, regulations, and regulatory guidelines in a structured manner for a systematic inspection. It contains the following sections:

1. Laws, Regulations and Guidelines Applied in this Checklist
2. Section 1. General Information
3. Section 2. Registration Certificates
4. Section 3. General Inspection and Legality of the Stocked Products
5. Section 4. Product Label Examination
6. Section 5. Management of Controlled Medicines and Other Documentations
7. Section 6. Storage Conditions
8. Section 7. General Condition of the Premises
9. Section 8. Staff and Services
10. Section 9. Reference Materials
11. Section 10. Scoring

12. Section 12. Any Other Observations and Remarks
13. Section 13. Recommendations and Actions
14. Section 14. Owner's/Technical In-Charge's Declaration
15. Section 15. Time Completed
16. Section 16. Names and Signatures of Inspectors
17. Annexes

The "**Laws and regulations applied in this checklist**" contains the list of effective laws, regulations, regulatory guidelines, and policies used in this check list, and the way they are presented in each inspection item. It is a quick reference to the inspectors whenever needed.

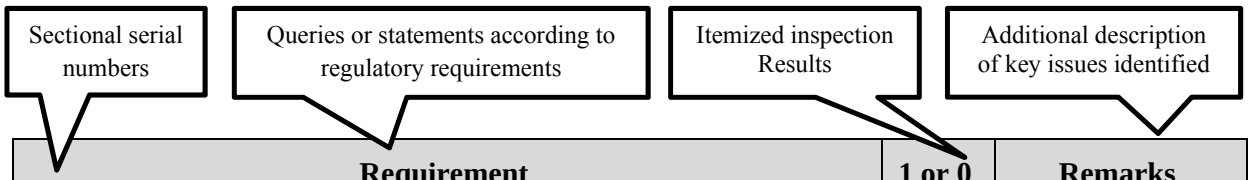
Section 1 is for the confirmation of the importer's basic information. **From section 2** to **section 8** are the actual inspection for registration status, products, premises and practices. Scoring is required for these sections. **Section 9** is only to check the availability of reference materials without scoring. **Section 10** and **11** are the scoring results of the inspection. **Section 12** and **13** are used for additional remarks and recommendations. The rest of the sections are for declaration and signatures.

The instructions in this manual focus on the items (under "Requirements" column) that require clarifications, or attention on procedure. Instructions will not be provided for the items whose description is straightforward and clear.

General Instructions for the Sections for Inspection

From **Section 2** to **Section 8** are the sections for inspection. They are categorized and sequenced according to the priorities of the regulatory requirements. Each section has a matrix with four columns [**sectional serial number, requirement, result (1 or 0), and remarks**]. The queries or statements under "Requirements" are developed according to the laws, regulations, regulatory guidelines, or policies indicated at the end of each query or statement in a *bracket*. The inspectors should make themselves familiar with those specified regulatory references in order to perform inspection properly and be able to communicate with the importer staffs with clear information. The third [**1 or 0**] and fourth [**Remarks**] columns are for documenting the results of the inspection which will be introduced in the next section.

The introduction of the matrix is indicated in text boxes below using Section 2 as an example:



	Requirement	1 or 0	Remarks
2.1	Is the importing company registration certificate(Inauguration letter) Available? *(16 MIMMAR, 2007)*		
2.2	Is the importing company registration certificate Displayed in a prominently visible location? *(16 MIMMAR, 2007)*		
2.3	Is the valid certificate of practice of the technical in-charge Available? *(35 MIMMAR, 2007)*		
2.4	Is the valid certificate of practice of the technical in-charge Displayed in a prominently visible location? *(35 MIMMAR, 2007)*		
Score for Registration Certificate Index Add up the importer's score for question "**2.1**" to "**2.4**" and record			

Specific regulatory references for this

the score in the space provided in the next column. The range for this index is "**0 – 4**".	**Score: ( )** **Score: (/ X 100) = %**

General Instructions for Documenting the Inspection Results

There are two ways (quantitative and qualitative) of documenting the inspection results in the following sections:

a) **Section 2** to **8** for itemized scoring (quantitative) and remarks (qualitative), and sectional sum-up scores (quantitative)
b) **Section 9** does not require score, but respond to whether the reference materials are available,
c) **Section 10** for sectional summarized scores and grand total scores (quantitative)
d) **Section 11** for overall performance rating (quantitative)

From **Section 2** to **8**, the inspectors should document the inspection results for each requirement under the "**1 or 0**" column.

- If the requirements are met, fill "**1**" for Yes or Passed;
- If the requirements are not met, fill "**0**" for No or Failed.
- If inspection is not conducted for any reason, fill "**N/A**" (none applicable).

At the end of each section, sum up the score by adding up the number of "**1**" (yes or passed), and divide it by the total items inspected (total numbers of "**1**" and "**0**", do not count "**N/A**").

For example: **Score (2/4)** means **2** passed (1+1) out of **4** inspected [2 passed (1), 2 failed (0)]

The "**Remarks**" column can be used to specify any key issues identified, in particular for those that **"0"** or **"N/A"** are indicated for their results.

All the sum-up scores in **section 2** to **8** should be filled in the **section 10** to come up with a grand total score. Then such score shall be transformed to a rating in **section 11**. The instructions for filling the inspection results in **section 2** to **8** are indicated in text boxes below with examples. The instructions for scoring and documenting the results for **section 10** will be provided in the corresponding sections.

Illustrative examples for filling the inspection results in section 2 to section 9:

	Requirement	1 or 0	Remarks
2.1	Is the importing company registration certificate (Inauguration letter) Available? *(16 MIMMAR, 2007)*	**1**	Fill the sub-results for each bullet
2.2	Is the importing company registration certificate Displayed in a prominently visible location? *(16 MIMMAR, 2007)*	**0**	
2.3	Is the valid certificate of practice of the technical in-charge Available? *(35 MIMMAR, 2007)*	**1**	
2.4	Is the valid certificate of practice of the technical in-charge Displayed in a prominently visible location? *(35 MIMMAR, 2007)*	**0**	
	Score for Registration Certificate Index Add up the importer's score for question "**2.1**" to "**2.4**" and record the score in the space provided in the next column. The range for this index is "**0 – 4**".	**Score: (2)** **Score: (2/4 X 100)= 50%**	

The inspector can circle the serial number for critical issues that needs to be highlighted and addressed.

Sectional score (numerator/ denominator x 100) = %
The percentage will be used in Section 10

In this manual, the individual instructions for each requirement or question in sections **1** to section **8** are provided in shaded rows under each of them.

Section 1: General Information

The inspection starts at the documentation of date, time, type of inspection, and basic information of the importer regarding identification and location. The inspectors should review the importer's registration information before heading out for inspection. Such preparation would be helpful for identification of any potential fraud in legal documents or status during inspection. Some of the information requires verification from valid documents which the inspectors should request from the technical in-charge or the proprietor while on site. To ensure accountability, the inspectors should **fill the information in the table below with the witness of the technical in-charge of the importer.**

The instructions for filling key information are in the "*Instructions*" column below.

Required information to be filled		***Instructions***
Date of Inspection *(Persian/Shamsi Calendar)*	/ / / (day/month/year)	
Date of Last Inspection *(Persian/Shamsi Calendar)*	/ / / (day/month/year)	**Pre-inspection**: check if the importer has been inspected before and the date of the last inspection. **During inspection**: check the inspection records in the importer, and fill the correct date accordingly. If no previous inspection is confirmed, fill "No"; if unknown, fill "N/A".
Time Started	_____: _____ am/pm (hour and minutes)	
Type of Inspection (circle one)	a. Routine/Comprehensive b. Concise c. Follow up d. Special	Circle the appropriated type of inspection according to the purpose and their definitions.
Name of the Importer		Fill exactly the same as that in the registration certificate
Importer Registration Certificate Number		Fill exactly the same as that in the registration certificate
Date of Establishment		Fill exactly the same as that in the registration certificate
Location	Province: _____ District: _____ Village/town: _____ Street:_____ Road:_____ GPS (Latitude) optional: GPS (Gratitude) optional:	
Physical Address		
Telephone Number		
E-mail Address		The proprietor's or the technical in-charge's or the importer's official e-mail address

Name of the Proprietor		
Name of Technical in-charge		
Technical in-charge's Certificate of Practice Number:		

Section 2: Registration Certificates

The instruction for examining the registration certificates is given at the top of the matrix, followed by a general instruction for documenting the results as the texts below:

Inspect the registration certificates of the importer and the technical in-charge according to the requirements in the indicated laws or regulations. **If the requirements are met, please indicate "1" for *Yes* or *Passed*; if the requirements are not met, indicate "0" for *No* or *Failed* in the "1 or 0" column.**

The instructions are indicated below the "requirement" and shaded:

Requirement		1 or 0	Remarks
2.1	Is the importing company registration certificate (Inauguration letter) Available? *(16 MIMMAR, 2007)*	**1**	
2.2	Is the importing company registration certificate Displayed in a prominently visible location? *(16 MIMMAR, 2007)*	**0**	
2.3	Is the valid certificate of practice of the technical in-charge Available? *(35 MIMMAR, 2007)*	**1**	
2.4	Is the valid certificate of practice of the technical in-charge Displayed in a prominently visible location? *(35 MIMMAR, 2007)*		
Look for the importing company registration certificate (currently, it is an inauguration letter issued by GDPA or NMHRA) and the technical in-charge's certificate (TIC), and see if it is displayed at a location that is visible from the clients' positions. Score each question separately. If the establishment is active without inauguration letter from MoPH and is selling medicine opinionated, act based on the article (39) of medicine law.			
Score for Registration Certificate Index Add up the importer's score for question "**2.1**" to "**2.4**" and record the score in the space provided in the next column. The range for this index is "**0 – 4**".		**Score: (3)** **Score: (3/4 X 100) = 75%**	

Section 3: General Inspection and Legality of the Stocked Products

After inspecting the certificates, the inspectors walk through the warehouse and do a quick look of the products, including randomly check the products hidden at the back or beneath of any covering objects or products. This general inspection would be helpful for scoring some requirements in other sections.

Inspect the medicines or products stored or displayed in the warehouse according to the requirements in the indicated laws or regulations. If any suspect medicines are found, collect the samples for QC test and fill the sampling form (Annex 1). If any nonconformity is found, confiscate or quarantine the medicines or products, and fill in the "Confiscation/Quarantine Form" (Annex 2). **Randomly select at least 5 items for inspection. If the requirements are met, please indicate "1" for *Yes* or *Passed*; if the requirements are not met, indicate "0" for *No* or *Failed* in the "1 or 0" column.**

Requirements	1 or 0	Remarks

3.1	Are *all* the inspected medicines in accordance with the National Licensed Medicines List? *(9 ML, 2008)*	**1**	
If any of the items are found not in LML, score "0", ask the importer or technical in charge to present the invoice of such medicines, confiscate them using (annex 2) form and report the violation for corrective actions. If any of the items are found not in LML but has an approval from MoPH, score: "1" and note the issue to check in the minutes of meetings of National Board.			
3.2	Are *all* the inspected medicines registered with the NMHRA (GDPA) and have a registration certificate? ***(*check and obtain a copy of registration certificate*)*** *(16 MIMMAR 2007, section 5 of NMP, 2014. Section 5 of NPQAP, 2015)*	**1**	
Ask from technical in charge or proprietor about product registration certificate and compare the medicine with the prepared medicine list by NMHRA (GDPA). If the medicine was not registered note the issue and report for next steps.			
3.3	Is there a copy of medicine and healthcare products purchase bill from registered importers available?(NMP 2014 and NPQAP 2015)	**1**	
During general inspection, ask about price letter or latest documents which show that NMHRA has given exit permission from customs. In the investigational inspection ask for the documents of those products which are under investigation.			
3.4	Are there no counterfeit and substandard medicines found for sale in the importer's premise. (*16 MIMMAR, 2007and section 7 of NPQAP 2015*)	**N/A**	Sampled 2 medicines for QC test
If the inspector found any confirmed counterfeit or substandard medicines (through previous reports or findings in other places), score "0", confiscate such medicines and fill the confiscation form. If any counterfeit or substandard medicines are suspected, collect samples for QC test, fill the sample collection form, score "N/A", and specify "sampled N medicines for QC test" in the "Remarks" (See the example provided in the "Remarks")			
Score for General Inspection & Legality of the Stocked Products Index Add up the importer's score for question "**3.1**" to "**3.4**" and record the score in the space provided in the next column. The range for this index is "**0 – 4**".		**Score: (3)** **Score: (3/3 X 100) = 100%**	

Section 4: Product Label Examination

In this section, there are two types of medicine sampling for inspection: 1) randomly select at least 5 items according to the purpose of the inspection. For example, if NMHRA or other relevant entities requested to focus on certain types or categories of medicines; or if conducting a follow-up inspection to review the medicines that previously found that had violations. This type of sampling is mainly for initial, follow up inspections. 2) Select the medicines that are suspect for quality or legality concerns. For example, if certain medicines were found in the market that are non-LML, unregistered, counterfeit, substandard, with unidentifiable labeling or without labels, or with any violations; or if NMHRA or other relevant entities received reports regarding such concerns. This type of sampling is mainly for special or investigative inspection. Article 39 of the Medicine Law contains the information of penalties for violations.

Closely examine the product labels according to the requirements in the indicated laws or regulations. **Randomly select at least 5 items for inspection. If the requirements are met, please indicate "1" for *Yes* or *Passed*; if the requirements are not met, indicate "0" for *No* or *Failed* in the "1 or 0" column.**

Requirements		1 or 0	Remarks
4.1	Are <u>*all*</u> the labels of the inspected medicines printed in at least one of the national languages or English? *(Section 2 of MRG, 2014)*	**1**	
If the medicines' labels are totally in foreign language, and the inspector could not identify what they are and if they are in LML, they should be considered violated and should be deal according to the law.			
4.2	Are <u>*all*</u> the labels of the inspected medicines in accordance with the labeling requirements specified in the regulation and/or guidelines? *(24 MIMMAR,2007 and section 2 of MRG, 2014)*	**0**	
If any of the items mentioned in the regulation and guidelines are found violated, score "0", and specify the issues in the "Remarks", and record them for reporting to NMHRA.			
4.3	Is the information of <u>*all*</u> the inspected medicines' leaflets in accordance with the requirements specified in the regulation and/or guidelines? *(25 MIMMAR, 2007, and section 2 of MRG, 2014)*	**0**	
If any of the items mentioned in the regulation and guidelines are found violated, score "0", and specify the issues in the "Remarks", and record them for reporting to NMHRA.			
4.4	Are <u>*all*</u> the inspected medicines in valid shelf lives? *(Section 7 NPQAP, 2015)*	**1**	
If any of the items are found violated, score "0", remove the expired or damaged items from the shelves, advice the technical in-charge or proprietor to record them and keep them in a secure quarantined area for disposal.			
Score for Product Label Examination Index Add up the importer's score for question "**4.1**" to "**4.4**" and record the score in the space provided in the next column. The range for this index is "**0 – 4**".		**Score: (2)** **Score: (2/4 X 100) = 50%**	

Section 5: Management of Narcotics and Controlled Medicines

Ask the technical in-charge on which of the category 2 controlled medicines (See Annex 4) the importer keeps, and ask the TIC to take the inspector to the place where those medicines are stored. If the importer does not keep any controlled medicines, the questions of this part are not applicable. However, the inspector should verify whether the importer indeed does not keep such medicines. Therefore, a pre-inspection preparation about such information and pay attention to such medicines during general inspection (Section 3) is required.

Inspect the controlled medicines including physical examinations and storage, as well as documentation of both controlled medicines and other medicines. **If the requirements are met, please indicate "1" for <u>*Yes*</u> or <u>*Passed*</u>; if the requirements are not met, indicate "0" for <u>*No*</u> or <u>*Failed*</u> in the "1 or 0" column.**

Requirements		1 or 0	Remarks
5.1	Is there lockable cabinet(s) for the storage of all the controlled medicines (category 2) in the premise? *(Section 5 of NPNCM, 2016)*	**NA**	
Check if there is a designated lockable cabinet or drawer for keeping such medicines. If there is no lockable cabinet, or if the cabinet is not lockable, score "0". If the cabinet is lockable, but it was not locked right before the inspection, score "1", but record the issue in the "Remarks", and circle the			

Requirements		1 or 0	Remarks
serial number for recommendation in Section 12.			
5.2	Are the entire category 2 controlled medicines kept in the lockable cabinet(s)? (*Section 5 and 12 of NPNCM, 2016*)	**NA**	
Through general inspection (section 3) and other observations, if any category-2 controlled medicines are found outside the lockable cabinet, score "0". Advise the technical in-charge to bring them into the cabinet. If there is no designated lockable cabinet at the time of the inspection, advise the TIC to keep narcotics and controlled medicines category-2 in a lockable drawer.			
5.3	Are all the inspected controlled medicines in valid shelf lives? **Randomly inspect 3 items**. *(Section 7 of NPQAP, 2015)*	**NA**	
If any expired or damaged items are found, check others in the cabinet, and remove them from the cabinet, advice the importer to record them and keep them in a secure quarantined area for disposal.			
Score for Management of Controlled Medicines and other Documentations Index Add up the importer's score for question "**5.1**" to "**5.3**" and record the score in the space provided in the next column. The range for this index is "**0 – 3**".		**Score: (NA)** **Score: (/ X 100) = %**	

Section 6: Storage Conditions (Storage of Pharmaceutical Products)

Inspect the storage conditions at the premise as per the following requirements. **If the requirements are met, please indicate "1" for *Yes* or *Passed*; if the requirements are not met, indicate "0" for *No* or *Failed* in the "1 or 0" column.**

Requirement		1 or 0	Remarks
6.1	Is the temperature in the warehouse compatible with drug storage requirements? (15 to 25^{o}C or depending on climatic conditions up to 30^{o}C) *(50 ML, 2008)*	**0**	
Check the temperature of warehouse, If the temperature within the specified temperature is either above or below score"0", and specify it in the "Remarks".			
6.2	Is there a temperature monitoring device available for recording the temperature within the warehouse? *(50 ML, 2008)* • If yes, how often is the temperature recorded? (select one that applies) Regularly; Irregularly; No Records;	**1**	
Check any device for manual or automatic temperature monitoring and recording. If there is one, score "1", then check and record how the temperature is recorded (specify the frequency, or circle "Regularly", "Irregularly" or "No Records").			
6.3	Does the importer's stock have a functional refrigerator(s) for storing temperature-sensitive items? *(38 MIMMAR, 2007 and 50 ML, 2008)*	**0**	
If there is no refrigerator, or if the refrigerator is not working, score "0" and specify the problem in the "Remarks".			
6.4	Are the temperature-sensitive medicines stored or displayed in the refrigerator(s)? *(38 MIMMAR, 2007 and 50 ML, 2008)*	**0**	
This inspection can be done during general inspection (Section 3) or look around again specifically looking for temperature-sensitive medicines. If any temperature-sensitive medicines are found out of the refrigerator, score "0". And circle the serial number for recommendations and actions in			

Requirement		1 or 0	Remarks
Section 12.			
6.5	Are ***all*** the inspected medicines in the refrigerator(s) in valid shelf lives? **At least check 3 items**. *(Section 7 of NPQAP, 2015)*	**1**	
If any expired or damaged items are found, check a few more in the refrigerator, and remove them from the refrigerator, request the importer to record them and keep them in a secure quarantined area for disposal.			
6.6	Is there a temperature monitoring device available for recording the temperature in the refrigerator(s)? *(38 MIMMAR, 2007 and 50 ML, 2008)* - If Yes, How often is the temperature recorded? (select one that applies) Regularly; Irregularly; No Records;	**0**	
Check any device for manual or automatic temperature monitoring and recording. If there is one, score "1", then check and record how the temperature is recorded (specify the frequency, or circle "Irregularly" or "No Records").			
6.7	Is there a dedicated area for placement of expired, returned, recalled and quarantined medicines and if such area is clearly labeled? *(NPWMSDPP, 2016, and section 7 of NPQAP, 2015)*	**1**	
If there is no such area, or if such area is not confined or not labeled, score "0". Fill the observations in the "Remarks". (warehouse responsible should specify a place with a label in the warehouse).			
Score for Storage Conditions Index Add up the importer's score for question "**6.1**" to "**6.7**" and record the score in the space provided in the next column. The range for this index is "**0 – 7**"		**Score: (3)** **Score: (3/7 X 100) = 43%**	

Section 7: General Condition of the Premises

Dose the general condition of the premises of the importers considered appropriate in accordance with the following requirements? **If the requirements are met, please indicate "1" for *Yes* or *Passed*; if the requirements are not met, indicate "0" for *No* or *Failed* in the "1 or 0" column.**

Requirements		1 or 0	Remarks
7.1	Does the importer operates at the address as registered for the business. *(14 MIMMAR, 2007)*	**1**	
If the physical location of the importer is different from the address registered in the certificate/letter, score "0". Ask the proprietor about the reason why the company is not located at the registered address, and fill it in the "Remarks" in order to report to NMHRA.			
7.2	Does the importer have a stock to store medicine?(38 MIMMAR, 2007 and 50 ML, 2008)	**1**	
Inspect that if the company has a standard stock to keep and store imported medicine. The stock should have cabinets, shelves and palates to keep the medicine.			
7.3	Do the walls, floors, and celling are in good condition without signs of humidity, mold, and cracking. *(38 MIMMAR, 2007 and 50 ML, 2008)*	**1**	

Requirements		1 or 0	Remarks
Check if there are signs of cracking, water leakage or mold on the ceiling, wall, or floor; if there is unpleasant odor in the importer company due to mold or humidity. If any problems are identified, score "0" and specify it in the "Remarks".			
7.4	Is the entire warehouse area clean? *(38 MIMMAR, 2007 and 50 ML, 2008)*	**0**	
Check if trash is found outside the bins; if there are litters anywhere, if it is dusting in the warehouse or cabinets, score "0".			
7.5	Is there a ventilation system, and is it functional? *(38 MIMMAR, 2007 and 50 ML, 2008)*	**0**	
If there is a ventilation system and it is functional, score "1"; if there is none, or there is one but not working, score "0", and specify the issue in the "Remarks".			
Score for General Condition of the Premises Index Add up the importer's score for question "**7.1**" to "**7.5**" and record the score in the space provided in the next column. The range for this index is "**0 – 5**"		**Score: (3)** **Score: (3/5 X 100) = 60%**	

Section 8: Staff and Services

Are the staff and services of the importer considered appropriate in accordance with the following requirements? **If the requirements are met, please indicate "1" for *Yes* or *Passed*; if the requirements are not met, indicate "0" for *No* or *Failed* in the "1 or 0" column.**

Requirement		1 or 0	Remarks
8.1	Is the technical in-charge present at the company on the day of the inspection? *(35 MIMMAR, 2007)*	**1**	
If the technical in-charge is present, score "1"; if not present, score "0". If he/she is on authorized leave, score "N/A", and specify it (such as on annual, vacation, sick leave, etc.) in the "Remarks".			
8.2	Does the invoice of the importer company has the following information: *(21 PR, 2007)* - Name of medicine (generic & brand with strength & dosage form) - Manufacture and expire date - Quantity - Batch number - Manufacturer - Date of transaction - Sign and stamp of the importer	**0**	
In a general inspection, ask for recent copies of receipts/invoices for the procurement of any medicines and medical equipment from importer companie s, retail pharmacies and other institutions. If the following characteristics are observed score "1" if not score "0", and specify it in the "Remarks".			
8.3	Does the percentage of profit sell in accordance with the provisions of the law? (**The profit of** importer company **in sales of medicine and medicinal products must not be more than 10% of purchase price**). *(31 MIMMAR, 2007)*	**0**	
Check the latest medicine selling bell and observe that the total benefit should be according to price letter of NMHRA. If any specific issue detected specify it in the "Remarks" in order to report to NMHRA.			

8.4	Does the importer has a stamp?(14 MIMMAR, 2007)	**1**	
Physically stamp on a white paper to check if it meets the following requirement: If the name of the importer is as in the inauguration letter.			
8.5	Does the importer has a standard sign?(14 MIMMAR, 2007)	**1**	
Check that the importer signboard is standard with size 60 to 180 cm, made of plastic(Fiber) Emblazoned with the logo of Pharmacy, the signboard should have a light in order to be seen during the night, the name of the importer company must be written in one of the national languages (Dari or Pashto) or English. Check that the name of the importer company that should be the same as importer inauguration certificate.			
Score for Staff and Services Index Add up the importer's score for question "**8.1**" to "**8.5**" and record the score in the space provided in the next column. The range for this index is "**0 – 5**".		**Score: (3)** **Score: (3/5 X 100) = 60%**	

Section 9: Reference Materials

The purpose of this section is to know if the importer staff is aware of the current laws, regulations, and regulatory guidelines. Prior to the inspection, the inspector should physically see these references and understood their objectives and technical value so that they can help the importer proprietor and technical in-charge to understand the importance of having them, being familiar and compliant with them.

Please ask the importer staff to present the following reference materials. There is no need to score for this section.

Requirements		Yes	No	Remarks
9.1	A copy of valid/effective Afghan Medicines Law (Official Gazette Number 963 2008)	√		
9.2	A copy of valid/effective Manufacturing and Importing Medicines and Medical Appliance Regulation (Official Gazette Number 916 2007)	√		
9.3	A copy of valid National Licensed Medicines List, 2014		√	
9.4	A copy of valid National Essential Medicines List, 2014		√	
9.5	A copy of updated National Medicines Policy, 2014		√	
9.6	A copy of updated National Pharmaceutical Quality Assurance Policy, 2015		√	
9.7	A copy of updated National Policy for Narcotic and Controlled Medicines, 2016		√	
9.8	A copy of updated National Policy for Waste Management and Safe Disposal of Pharmaceutical Products, 2016		√	
9.9	A copy of updated Foreign Pharmaceutical Manufacturing Companies Registration Guideline, 2014 available		√	
9.10	A copy of updated Medicines Registration Guideline, 2014 available		√	

Section 10: Scoring

Fill the result of each section for this and last inspections in the table. The "Total Score (A)" is the sum of the scores of these sections; the "Total Points (B)" is the sum of the denominators of all these sections. Therefore, the result is the percentage of A out of B (A/B*100). Examples are provided in the table.

Please fill the scores of sections "**2 – 8**" into the following table and determine the overall compliance score in the "Result":

Date	Sectional Scores Obtained(percentage)							Total Score (Obtain "A")	Total Points (B)	Result (%) (A/B*100)
	2	3	4	5	6	7	8			
This Inspection 20/03/1395	**50**	**75**	**50**	**NA**	**28**	**40**	**20**	**13**	**29**	**45%**
Last Inspection 10/01/1395	**75**	**100**	**50**	**NA**	**43**	**60**	**60**	**17**	**28**	**61%**
% of Changes	**25**	**25**	**0**	**NA**	**15**	**20**	**40**			**16%**

Note: Please fill the following fields in two copies (use carbon paper for writing, or make a photocopy if possible). The inspectors keep the original copy, and give the importing company the duplicated copy. Advise the proprietor and the technical in-charge to file it in a designated folder for records and actions, and for future inspections.

Section 11: Any Other Observations and Remarks

If the inspectors observe any product or practice issues related to laws or regulations which are not addressed in the checklist, record them in the following table.

Provide information about any observations in addition to the information obtained in this checklist, if available. Please use a separate sheet if the space provided below is not enough.

Section 12: Recommendations of inspection team

Summarize the un-compliance results by filling the "**Issues Require Attention & Correction**", and the corresponding regulatory measures or penalties in the "**Actions Agreed to Take and Timeline**". If the issues are in the checklist, write the sectional serial number for each issue. If the issue is not in the checklist, but observed by the inspector and filled in Section 12, write "12.n" for sectional number. The inspector should give a copy of this section to the importer for taking actions (use carbon paper to duplicate it).

From the inspection results, identify the most critical issues for correction or improvements, such as registration, legality or quality of products, etc. If regulatory measure or penalty should be applied, specify it in the "Action Agreed to Take and Timeline". Use a carbon paper to duplicate this section, give one copy to the importer for taking actions and follow-up.

Name of the importer company**:** _____ **Date:**_____

Address:

No.	Issues Require Attention & Correction	Actions Agreed to Take and Timeline	
		Agreed actions	Timeline
1	6.3 No refrigerator for storing heat sensitive products The sectional serial number of the issue	A functional refrigerator should be purchased to store heat sensitive products	Up to end of march 2017

Section 13: Owner's/Technical in-Charge's Declaration

The declaration should be signed at least by the technical in-charge or the proprietor if only one is in the importer at the time of inspection. Otherwise, both of them should sign the declaration.

I (**Ahmad Ramin**) the owner, and (**Mahmod**) the technical in-charge of the said importer, certify that the information and observations made in this from during the inspection of the importer were true and correct; and the identified issues and corrective actions were communicated and agreed.

Proprietor of Importer
Name: Ahmad Ramin
Signature:
Date:

Technical in-charge
Name: Mahmod
Signature:
Date:

Section 14: Time Completed

Fill the time at the end of the inspection. This information provides part of the evidence of the inspection, and would help the NMHRA to factor in the time required for inspection in revising the inspection procedure and checklist in the future.

Document the time when the inspection is finished, including completing the checklist, collecting samples for QC test and confiscation, scoring for this inspection, and communication with the proprietor and the technical in-charge.

Time completed:	**Hour : minute** am / pm

Section 15: Names and Signatures of Inspectors

The inspectors must fill the following matrix to ensure accountability.

Name(s) of Inspector(s)	Designation(s)	Signature(s)	Date

Acknowledge the proprietor, the technical in-charge, and other importer staff for their assistance for the inspection.

Annexes:

Annex 1. Suspect Medicine Sample Collection for Quality Test

Fill the sample collection form in two copies. The inspectors keep the original copy, and give the importer the duplicated copy. The importer should file it in a designated folder for records. If quarantine is required, fill the column of "**Total Quantity Quarantined**".

Ministry of Public Health

National Medicine and Healthcare Products Regulatory Authority

Head of integration of post market services

Laws and regulation inspection and enforcement department

Suspect Medicine Sample Collection for Quality Test

Name of the Importer									
Date					**Address:**				
Name of the Proprietor:			**Signature**		**Name of the TIC:**			**Signature**	
S/No	**Generic Name**	**Brand Name**	**Batch No**	**Mafg Date**	**Exp Date**	**Quantity**	**Manufacturer**	**Importer**	**Total Quantity Quarantined**
1									
2									
3									
4									
5									
6									

Samples collected by (inspector): _____: Signature: _____

Samples collected by (inspector): _____: Signature: _____

Annex 2. Quarantine and Confiscation Form

Ministry of Public Health

National Medicine and Healthcare Products Regulatory Authority

Head of integration of post market services

Laws and regulation inspection and enforcement department

Quarantine and Confiscation Form

Fill the Confiscation/Quarantine Form in two copies. The inspectors keep the original copy, and give the importer the duplicated copy. The importer should file it in a designated folder for records.			
Name of the Importer			
Date		**Address**	
Name of the Proprietor:	**Signature:**	**Name of the TIC:**	**Signature:**
Please select the appropriate option according to your purpose of use.			1. Quarantine 2. Confiscation

S/No	Generic Name	Brand Name	Batch No	Mafg Date	Exp Date	Manufacturer	Importer	Total Quantity Quarantined
1								
2								
3								
4								
5								
6								

Confiscated or Quarantined by (inspector): _____: Signature: _____

Confiscated or Quarantined by (inspector): _____: Signature: _____

Annex 3. List of Category 2 Medicines which are in the LML Controlled Medicine List

	Category 2 substances*	**Controlled medicines in LDL 2014 that are derived from the category 2 substances**
1	Fentanyl	Fentanyl 0.05mg/ml, in 2 ml ampule injection solution
2	Methadone	• Methadone 10mg/ml, in 1ml ampule injection • Methadone 10mg/ml, oral solution • Methadone 10mg tablet • Methadone 5mg/ml, oral solution • Methadone 5 mg tablet
3	Morphine	• Morphine hydrochloride 10mg/ml, in 1ml ampule, injection • Morphine sulfate 10mg/ml, in 1ml ampoule, injection
4	Opium	Opium tincture 10% oral solution
5	Pethidine Medium A,B,C	• Pethidine 100mg tablet • Pethidine 50 mg tablet • Pethidine 50 mg/ml, injection ampoule

Annex 4. List of narcotic and controlled substances

Category 1 – Plants and Narcotic Substances Prohibited of Abuse with No Medical Use

S/No	Name Items	S/No	Items Name
1	(+)-LYSERGIDE	56	Hydroxypethidine
2	2C-B	57	Ketobemidone
3	3-methylfentanyl	58	Levomoramide
4	3-methylthiofentanyl	59	Levophenacylmorphane
5	4-MTA	60	MDE, N-ethyl MDA
6	Acetorphine	61	MDMA
7	Acetyl-alpha-methylfentanyl	62	Mecloqualone
8	Acetyldihydrocodeine	63	Mescaline
9	Acetylmethadol	64	Methaqualone
10	Allylprodine	65	Methcathinone
11	Alphameprodine	66	Methyl-4 aminorex
12	Alphamethadol	67	Methyldesorphine
13	Alpha-methylfentanyl	68	Methyldihydromorphine
14	Alpha-methylthiofentanyl	69	MMDA
15	Aminorex	70	Morpheridine
16	Benzethidine	71	Morphine methobromide and other pentavent nitrogen morphine derivative
17	Benzylmorphine	72	MPPP
18	Betacetylmethadol	73	Myrophine
19	Bêta-hydroxyfentanyl	74	N-hydroxy MDA
20	Bêta-hydroxy-methylfentanyl	75	Nicocodine
21	Betameprodine	76	Nicomorphine
22	Betamethadol	77	Noracymethadol
23	Betaprodine	78	Norlevorphanol
24	Brolamfetamine	79	Normethadone
25	Butyrate de dioxaphetyl	80	Normorphine
26	Cannabis and cannabis resin	81	Norpipanone
27	Cathinone	82	Para-fluorofentanyl
28	Clonitazene	83	Parahexyl
29	Concentrate of poppy straw	84	PEPAP
30	Desomorphine	85	Phenadoxone
31	DET	86	Phenampromide
32	Dextromoramide	87	Phenomorphane
33	Diampromide	88	Phenoperidine
34	Diethylthiambutene	89	Pholcodine
35	Difenoxine	90	Piritramide

36	Dimenoxadol	91	PMA
37	Dimepheptanol	92	Poppy seeds
38	Dimethylthiambutene	93	Poppy straw
39	Dipipanone	94	Proheptazine
40	DMA	95	Properidine
41	DMHP	96	Propiram
42	DMT	97	Psilocine, psilotsin
43	DOET	98	Psilocybine
44	Drotebanol	99	Racemoramide
45	Ethylmethylthiambutene	100	Rolicyclidine
46	Eticyclidine	101	STP, DOM
47	Etilamfetamine	102	Tenamfetamine
48	Etonitazene	103	Tenocyclidine
49	Etorphine	104	Thebacone
50	Etoxeridine	105	Thiofentanyl
51	Etryptamine	106	Tilidine
52	Fenetylline	107	TMA
53	Furethidine	108	Trimeperidine
54	Heroin	109	Tetrahydrocannabinol, the following isomers and their stereochemical variants: - tetrahydro-7,8,9,10 trimethyl-6,6,9 pentyl-3 6H-dibenzo[b,d] pyranne o1-1 - (9R, 10aR)-tetrahydro-8,9,10,10a trimethyl-6,6,9 pentyl-3 6H-dibenzo[b,d]pyranne o1-1 - (6aR,9R, 10aR)-tetrahydro-6a,9,10,10a trimethyl-6,6,9 pentyl-3 6H-dibenzo[b,d] pyranne o1-1 - (6aR,10aR)-tetrahydro-6a,7,10,10a trimethyl-6,6,9 pentyl-3 6H-dibenzo[b,d] pyranne o1-1 - tetrahydro-6a,7,8,9-trimethyl-6,6,9 pentyl-3 6H-dibenzo[b,d] pyranne o1-1 - (6aR,10aR)-hexahydro-6a,7,8,9,10,10a dimethyl-6,6 methylene-9 pentyl-3 6Hdibenzo [b,d] pyranne o1-1
55	Hydromorphinol		

Category 2 – Strictly controlled plants and substances with a medical use

S/No	Name Items	S/No	Items Name
1	Alfentanil	31	Methadone
2	Alphaprodine	32	Methadone intermediate
3	Amfetamine	33	Methylphenidate
4	Amobarbital	34	Metopon
5	Aniledirine	35	Moramide, intermediaire du
6	Bezitramide	36	Morphine
7	Coca, (leaf)	37	Nicodicodine
8	Cocaïne	38	Norcodeine
9	Codeine	39	N-oxymorphine
10	Codoxime	40	Opium
11	Delta-9-tetrahydro cannabinol and its variants	41	Oxycodone
12	Dexamfetamine	42	Oxymorphone
13	Dextropropoxyphene	43	Pethidine
14	Dihydrocodeine	44	Pethidine, intermediate A
15	Dihydromorphine	45	Pethidine, intermediate B
16	Diphenoxylate	46	Pethidine, intermediate C
17	Dronabinol	47	Phenazocine
18	Ecgonine, its esters and derivatives	48	Phencyclidine
19	Ethylmorphine	49	Phenmetrazine
20	Fentanyl	50	Piminodine
21	Glutethimide	51	Racemate de metamfetamine
22	Hydrocodone	52	Racemethorphane
23	Hydromorphone	53	Racemorphane
24	Isomethadone	54	Remifentanil
25	Levamfetamine	55	Secobarbital
26	Levomethamphetamine	56	Sufentanil
27	Levomethorphane1	57	Thebaïne
28	Levorphanol	58	Zipeprol
29	Metamfetamine	59	
30	Metazocine	60	

Category 3 – Controlled plants and substances with a medical use

S/No	Name Items	S/No	Items Name
1	Acetyldihydrocodeine	41	Lorazepam
2	Allobarbital	42	Lormetazepam
3	Alprazolam	43	Mazindol
4	Amfepramone	44	Medazepam
5	Barbital	45	Mefenorex
6	Benzfetamine	46	Meprobamate
7	Bromazepam	47	Mesocarbe
8	Brotizolam	48	Methylpheno-barbital
9	Buprenorphine	49	Methyprylone
10	Butalbital	50	Midazolam
11	Butobarbital	51	Nicocodine
12	Camazepam	52	Nicodicodine
13	Cathine	53	Nimetazepam
14	Chlordiazepoxide	54	Nitrazepam
15	Clobazam	55	Norcodeine
16	Clonazepam	56	Nordazepam
17	Clorazepate	57	Oxazepam
18	Clotiazepam	58	Oxazolam
19	Cloxazolam	59	Pemoline
20	Codeine	60	Pentazocine
21	Cyclobarbital	61	Pentobarbital
22	Delorazepam	62	Phendimetrazine
23	Diazepam	63	Phenobarbital
24	Dihydrocodeine	64	Phentermine
25	Estazolam	65	Pholcodine
26	Ethchlorvynol	66	Pinazepam
27	Ethinamate	67	Pipradrol
28	Ethylmorphine	68	Prazepam
29	Fencamfamine	69	Pyrovalerone
30	Fenproporex	70	Secbutabarbital
31	Fludiazepam	71	Temazepam
32	Flunitrazepam	72	Tetrazepam
33	Flurazepam	73	Triazolam
34	GHB	74	Vinylbital
35	Halazepam	75	Zolpidem
36	Haloxazolam		
37	Ketazolam		
38	Lefetamine		
39	Loflazepate Ethyl		
40	Loprazolam		

Category 4 – Substances frequently used in the manufacture of narcotic drugs and psychotropic substances (chemical precursors)

S/No	Name Items
1	Acid N-acetylanthranilic
2	Acid lysergic
3	Anhydride acetic
4	Ephedrine
5	Ergometrine
6	Ergotamine
7	Isosafrole
8	Methylenedioxy-3,4 phenyl propanone-2
9	Norephedrine
10	Potassium Permanganate
11	Phenyl-1 propanone-2
12	Piperonal
13	Pseudoephedrine
14	Safrole
15	Acetone
16	Acid anthranilic
17	Acid chlorhydric
18	Acid phenylacetic
19	Acid sulfuric
20	Methylethylcetone
21	Piperidine
22	Toluene
23	Ethylether

Annex 5. Glossary

Controlled medicines: Are medicines containing controlled substances or Medicinal products under control to spice that gets called by the Ministry of public health has been classified among the Spice production, distribution, supply and trading (purchase, sale, import and export) them in the context of the law and regulations and under the supervision of special is possible. 1.2. This definition is all the chemicals with the name of the medicine or the international non-proprietary name (INN) in the current list of the international drug control board, INCB corresponds to seasoning drugs (1961 Convention and the 1972 reformed) and Spice psychotropic (1971 Convention) are on the take.

Substandard medicines: Are the medicines whose qualitative descriptions do not meet accepted standards.

Counterfeit medicine: A medicine that is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products, and may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients, or with fake packaging.

Essential medicines: Medicines that satisfy the priority health care needs of the population.

Over-the-counter medicines: Medicines that are generally regarded as safe for the consumer to use by following the required label directions and warnings, and which may be purchased without a prescription

Prescription only medicines: Medicines that may only be made available to the consumer through a written order signed by a duly qualified and registered medical prescriber and dispensed by a registered pharmacist.

Legislation: Refers to all rules having binding legal force at the national, state, or local level.

Inspector: Is an eligible individual who has been assigned to inspect medicines, health products, or the relevant facilities to ensure their compliance with certain conditions, including the specified regulations and the licenses issued under this law.

Inspection: Is the general examination of affairs or activities related to an administrative unit to measure the level of compliance of the unit with standards, good operational methods, and all other disciplines as well as to make recommendations for reforms.

Expiry date: The date given on the individual container (usually on the label) of a product up to and including the date at which the API and FPP are expected to remain within specifications, if stored correctly. It is established for each batch by adding the shelf life to the date of manufacture.

Importer: A person to whom an import license has been issued under Regulation on Manufacturing and Importing Medicine and Medical Appliances issue number 916 dated 24 February, 2007

Registration of medicines: The process of registering medicines to be allowed to be sold on the market. The process includes the evaluation of safety, efficacy, and quality of the pharmaceutical product.

Product recall: A process for withdrawing or removing a pharmaceutical product from the pharmaceutical distribution chain because of defects in the product or complaints of serious adverse reactions to the product.

License: Is a document issued to a special individual, organization, or company to be involved in or facilitate a specific activity and is valid for a specific period of time mentioned therein in compliance with the terms of the relevant authority.

Drug: Any substance or pharmaceutical product for human or veterinary use that is intended to modify or explore physiological systems or pathological states for the benefit of the recipient.

Pharmacy: Is a health facility that is established based on the license issued by the National Medicine and Healthcare Product Regulatory Authority and that provides health services and sells medicine, medical equipment, cosmetic and hygiene products, nutrition supplements, baby supplementary food, and all other products that have been allowed by this license, under the supervision of a licensed and eligible pharmacist.

Storage condition: The storage condition that guarantees the maintenance of the quality of the product in relation to its safety, efficacy, and acceptability throughout the shelf life, as may be predicted from the stability studies. The described conditions should indicate the temperature or temperature range in degree Celsius, as well as humidity, light, and other relevant conditions.

Dosage form: The form of the FPP, e.g., tablet, capsule, elixir, or suppository

Pharmacist: An individual who is fully licensed and approved by the relevant national authorities to practice pharmacy in Afghanistan.

Law: refers to collection of legal rules that are mandatory in accordance with the 94th sentence of article Afghan Constitution and have been adopted during the stages of both the Houses, and the President of Afghanistan has endorsed; or refers to a set of rules on a specific topic enacted by the legislative body at the national, state or local level and having binding legal force.

Strength: Strength of a pharmaceutical product refers to the amount of active pharmaceutical ingredient existing in each dose, volume, or weight of the product, based on its form.

Quality control: An integrated and complete process that documents all measures taken, including the setting of specifications, sampling, testing, and analytical clearance to ensure that raw materials, intermediates, packaging materials, and finished pharmaceutical products conform to established specifications for identity, strength, purity, and other characteristics.

Essential medicines list: A list of medicines approved for use in public sector health facilities.

Licensed medicines list: All medicines that are approved for use in Afghanistan at different levels of the health system

Label: A printed text attached to or comprising part of a medicine container or package, specifying the name, dosage form, composition, batch number, manufacturing date, and expiry date of the contents as well as the name and address of the manufacturing company and/or importer of the product, the product license holder, the permitted retail price, and other relevant information (e.g., recommended storage conditions)

Finished pharmaceutical product: A product that has undergone all stages of production, including packaging in its final container and labeling, an FPP may contain one or more APIs.

Registered drug products: Pharmaceutical products that have a marketing authorization

Technical officer in charge: Is a pharmacist or pharmacy technician, based on the law and related regulations, who is responsible for the professional affairs of a pharmaceutical facility.

Controlled substances: Are the substances listed in the international drug control conventions.

Narcotic: Natural or chemical compounds that cause abnormal changes in the function of the central nervous system and consciousness level. They create increasing psychological and physiological dependency or addiction in humans, with the consequence of adverse effects on human physical, mental, and social performance.

International nonproprietary name: The shortened scientific name (also known as the generic name) of a pharmaceutical substance assigned by the WHO program on the selection of INNs, the INN is recognized worldwide.

Generic name: A unique name identifying a particular pharmaceutical substance Generic names are officially assigned by international medicines nomenclature commissions, and nowadays mostly conform to those assigned by the WHO program on the selection of INNs.

Prescription: A written instruction signed by a registered and authorized health care practitioner to dispense specified medicines in specified quantities to a named patient.

Registration number: A number assigned to a medicinal product after being given marketing authorization.

Patient information leaflet: A leaflet containing information for the patient

Wholesaler: A person who has obtained license to sell medicines and other medical equipment and devices as a wholesaler a under Regulation on Manufacturing and Importing Medicine and Medical Appliances issue number 916 dated 24 February, 2007

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The Strengthening Pharmaceutical Systems (SPS) Program strives to build capacity within developing countries to effectively manage all aspects of pharmaceutical systems and services. SPS focuses on improving governance in the pharmaceutical sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to the most efficacious, safe and cost-effective medicines and appropriate use of medicines.

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