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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USAID
از طرف مردم امریکا

SPS Strengthening Pharmaceutical Systems

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About SPS

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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ABBREVIATIONS AND ACRONYMS

LML	licensed medicine list
MIMMAR	Manufacturing and Importing Medicines and Medical Appliance Regulation, official gazette issue number 916, February, 24, 2007
ML	Medicine Law, official gazette issue number 963, November, 18, 2008
MOPH	Ministry of Public Health
MRG	Medicine Registration Guidelines, 2014
MSH	Management Sciences for Health
NMHRA	National Medicine and Healthcare Products Regulatory Authority
NMP	National Medicines Policy, 2014
NPNCM	National Policy for Narcotic and Controlled Medicines, 2016
NPQAP	National Pharmaceutical Quality Assurance Policy, 2105
NPWMSDPP	National Policy for Waste Management & Safe Disposal of Pharmaceutical Products, 2016
PR	Pharmacy Regulation, official gazette issue number 916,February, 24, 2007
SPS	Strengthening Pharmaceutical Services
TIC	technical in-charge
USAID	US Agency for International Development

FOREWORD

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 health care products to provide 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 standards, MOPH initiated the development of the pharmaceutical importers inspection checklist user manual. The objective of using the checklist for inspection is to enforce implementation of relevant laws and regulations by pharmaceutical importers for ensuring the quality and safety of their practices and pharmaceuticals during procurement, storage, and distribution of medicines and to deliver high-quality services to the population.

To ensure technical quality and appropriateness for the context of Afghanistan, the user manual was developed by a MOPH-delegated technical committee with the financial and technical support of the Strengthening Pharmaceutical Services (SPS) Project.

The NMHRA in the MOPH wishes to acknowledge the contributions of the individuals who comprised the taskforce for developing the user manual. Acknowledgement is given to the following people from NMHRA-MOPH, in particular:

- Pharmacist Mohammad Zafar Barry
- Pharmacist Sayed Asadullah Akhlaqizada
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- Pharmacist Mohamed Basir, Pharmaceutical Regulatory System Program Manager
- Pharmacist Sohail Nazari, Pharmaceutical Regulatory System Technical Officer
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- Pharmacist Shiou-Chu (Judy) Wang, Senior Technical Adviser
- Dr. Paul Ickx, Senior Principal Technical Advisor

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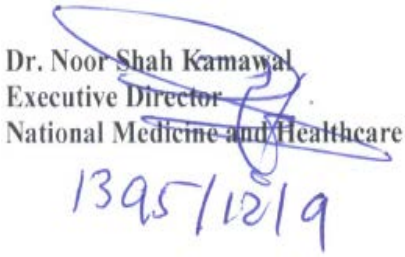
Development Task Force and all those who contributed to the development of this user manual.



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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.

GENERAL INSTRUCTIONS FOR INSPECTORS

Keys to Interview 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 become a successful interviewer and inspector.

Building Relationships 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 (TIC) and others may be strangers to each other. The first impression that the TIC and other staff have of you may influence his/her willingness to cooperate with 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 relationships:

- **Make a good impression:** When first approaching the TIC and other staff, do your best to make them feel at ease. With a few well-chosen words, you can put the TIC and other staff in the right frame of mind for 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."

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 pharmacy and its staff look 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 questions slowly to ensure that the TIC and other importer company staff understand 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.

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.

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 the TIC and importer company staff. Simply explain to the TIC that you made an error and ask the question or check the information again. It is not important that the checklist be clean, so do not recopy it.

Methods for Implementing the Checklist

Direct Observation

This involves looking at various parts of the importer company. Specific criteria have been described on how to address each question on the checklist. For most questions, this involves looking—directly observing—for oneself, rather than depending on what the TIC or other staff reports. For example, inspectors should not rely on what the TIC says regarding the presence of a functioning refrigerator. Rather, the inspector should check to see whether a refrigerator is present and examine it to see if it is functional.

Review of Importer Records

For many questions, the inspectors will have to review importer records. Sometimes this will involve checking to see whether the Narcotic Registration Book has been completed thoroughly and accurately.

Asking Questions of the Technical In-Charge

Many questions require that the inspectors ask questions of the importer's TIC. For many of these questions, the inspector must verify the answers 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 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.

Types of Establishments to Be Inspected

To ensure the quality of drugs entering or circulating in the Afghanistan market, the following establishments (both established and new ones before they are licensed) associated with drug supply and the distribution chain should be inspected regularly:

- Local manufacturing companies
- Importing companies
- Wholesalers
- Retail pharmacies

Types of Inspections

- Routine/comprehensive
- Concise
- Follow-up
- Special

Routine/Comprehensive Inspection

Routine or comprehensive 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 when:

- An initial inspection of a newly established pharmaceutical establishment or facility is required

- There is a change of the TIC, modification of the premises, or move to a new location

- The TIC’s certificate for practice has expired

- The pharmaceutical establishment's certification has expired
- There is a history of major or repeated noncompliance
- The establishments have not been inspected in the last five years
- A regular inspection for an existing establishment is needed

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 not to the targeted establishments.

A concise inspection is conducted when:

- A sample of components can be taken as an indication of the overall level of compliance or trigger a comprehensive or routine inspection
- An establishment has a consistent record of compliance in the past
- Identification of significant changes of limited components is needed

Follow-Up Inspection

A follow-up inspection is a reassessment or reinspection 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.

Special Inspection

The special inspection is mostly on an 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 unannounced.

A special inspection is conducted when:

- Any specific or suspect products or practices are prioritized for inspection
- There are complaints about product defects or malpractice in the market or in a specific pharmaceutical establishment, which are often followed by investigations
- Products are recalled due to events such as adverse drug reactions
- An investigation or information for specific products or operations is needed

The time required for a special inspection is normally shorter than a general inspection. However, it also depends on the amount of information requested by NMHRA or the 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 pharmaceutical establishments comply with all legal requirements and regulatory standards. The goal is to ensure the quality and safety of pharmaceutical products produced, procured, stored, and dispensed and the 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 establishment. It also provides a record of the inspection findings, recommendations, and corrective actions. It can be used for follow-up or monitoring progress of improvements and as evidence for any legal sanctions, should violation of any law or regulation occur.

The inspectors enforce implementation of the related laws and regulations; they should be familiar with the content (know what) of an inspection checklist and practice (know how) of the inspection procedure. The user manual for an inspection checklist provides instructions on key procedures of inspection and how to document findings, recommendations, and proposed actions. It can be used to prepare for an inspection by an experienced inspector and for training or orienting new inspectors. In this user manual, the instructions of the inspection procedure go along with the items in the checklist so that inspectors have all the required information in one place. The instructions are shaded, making it 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 is launched. Inspectors are required to keep up with changes in regulatory requirements and the checklist.

Laws, Regulations, Policies, and Guidelines Applied in this Checklist

This inspection checklist was 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:

- MIMMAR: Manufacturing and Importing Medicines and Medical Appliance Regulation, official gazette issue number 916, February, 24, 2007
- ML: Medicine Law, official gazette issue number 963, November, 18, 2008
- MRG: Medicine Registration Guidelines, 2014
- NMP: National Medicines Policy, 2014

- NPNCM: National Policy for Narcotic and Controlled Medicines, 2016
- NPQAP: National Pharmaceutical Quality Assurance Policy, 2105
- NPWMSDPP: National Policy for Waste Management & Safe Disposal of Pharmaceutical Products, 2016
- PR: Pharmacy Regulation, official gazette issue number 916, February, 24, 2007

To help the inspectors easily apply regulatory references in the inspection, the laws and regulations governing each inspection item are provided in parentheses with the article or section number, the abbreviation of the name of the law, and the year launched; for example 7 PR 2007 refers to article 7 of the Pharmacy Regulation launched in 2007. Inspectors are encouraged to become familiar with all the specified regulatory references before carrying out inspection activities.

PHARMACEUTICAL IMPORTERS INSPECTION PROCEDURE

Importer inspection is an exercise in 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 pharmacy practice. The inspectors should be involved in the pre-, during-, and post-inspection activities for a complete procedure.

Preinspection Preparation

Planning

Develop an inspection schedule for a defined period of time (such as every quarter, six months, or a year). Each inspection team should have two inspectors. Planning the inspection schedule should consider geographical factors (direction, travel time, seasonal weather, security, etc.) and existing resources to promote cost-effectiveness.

Information

Collect information about the targeted areas or importers for inspection, such as:

- A list of importers whose registration (importer or TIC) has expired
- A list of importers whose major corrective actions require follow-up
- Any suspect importers with product quality or malpractice issues
- The updated list of category 2 controlled medicines (a current version can be found in Annex 3)

Notification

Depending on the purpose or types of inspection, inform the importers scheduled for routine or concise inspection.

Tools and Stationary

Collect the following documents or tools to get ready for inspection:

- Blank copies of checklists, carbon paper, and pens; two copies of Section 12
- Previous inspection checklists or reports, copies of regulatory measures notice (if any), etc., for the importers to be inspected
- The laws and regulations applied in the checklist
- The most updated registered medicines list and licensed medicines list (LML)
- A medicine sample collection form (Annex 1 in the checklist)
- Quarantine and confiscation form (Annex 2 in the checklist)

- A list of 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 the pharmacy area)

During-Inspection Activities

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

1) Upon arrival at the importer's premises, the inspectors should present their identification or authorization document to the TIC or proprietor, introduce themselves, and describe the purpose of the visit.

2) If there was a previous inspection, the inspector should request the TIC to present records from the previous inspection (findings, recommended corrective actions, and timelines).

3) If it is an initial regular inspection, start the 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 TIC are not present, and there is no legally authorized pharmacy professional on duty, fill the checklist in Section 1 (General Information) and record the absence of the TIC in the Sections 11 and 12 of the checklist.

5) If the pharmacy has not hired a TIC, fill the checklist in Section 1 (General Information) and record the absence of the TIC in Sections 11 and 12 of the checklist.

6) For other details, refer to the instructions in 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 pharmacy. 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) Enter the filled checklist into the database.

4) File the filled checklists in 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:

- Laws, Regulations, and Guidelines Applied in this Checklist
- Section 1. General Information
- Section 2. Registration Certificates
- Section 3. Legality of the Stocked Products
- Section 4. Product Label Examination
- Section 5. Management of Controlled Medicines and Other Documentation
- Section 6. Storage Conditions
- Section 7. General Condition of the Premises
- Section 8. Staff and Services
- Section 9. Reference Materials
- Section 10. Scoring
- Section 11. Any Other Observations and Remarks
- Section 12. Recommendations and Actions
- Section 13. Owner's/Technical In-Charge's Declaration
- Section 14. Time Completed
- Section 15. Names and Signatures of Inspectors
- Annexes and glossary

The Laws, Regulations, and Guidelines Applied in this Checklist section lists the various laws and policies used in this checklist and the way they are presented in each inspection item. It is a quick reference for inspectors.

Section 1 is for confirmation of the importer's basic information. Sections 2−8 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 and is not scored. Section 10 is the scoring results of the inspection. Sections 11 and 12 are used for additional remarks and recommendations. The rest of the sections are for declaration and signatures.

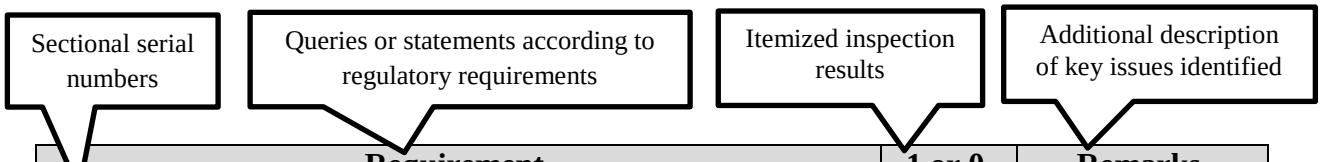
The instructions in this manual focus on the items (under the Requirements column) that require clarification or attention to procedure. Instructions are not provided for items whose description is straightforward and clear.

General Instructions for the Sections for Inspection

Sections 2−8 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 have been developed according to the laws, regulations, regulatory

guidelines, or policies indicated at the end of each query or statement in parentheses. The inspectors should make themselves familiar with those specified regulatory references to perform the inspection properly and to be able to communicate with the pharmacy staff 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 matrix for section 2 is used below as an example.



	Requirement	1 or 0	Remarks
2.1	Is the importer registration/inauguration certificate/letter available? (16 MIMMAR 2007)		
2.2	Is the importer registration certificate/letter displayed in a prominent 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 TIC displayed in a prominent location? (35 MIMMAR 2007)		
Score for Registration Certificate Index Add up the importer's scores for questions 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:** **Score: (/ × 100) = %**	

General Instructions for Documenting Inspection Results

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

- Sections 2 to 8 for itemized scoring (quantitative), remarks (qualitative), and sectional sum-up scores (quantitative)
- Section 9 is not scored, but whether reference materials are available is noted.
- Section 10 for sectional summarized scores and grand total scores (quantitative)
- Section 11 for key additional observations (qualitative)

For sections 2−8, inspectors should document the inspection results for each requirement under the 1 or 0 column.

- If the requirements are met, fill in 1 for yes or passed
- If the requirements are not met, fill in 0 for no or failed
- If inspection is not conducted for any reason, fill in NA for not applicable

At the end of each section, sum up the number of 1's (yes or passed) and divide it by the total number of items inspected (total number of 1's and 0's; do not count the NAs).

For example: score 2/5 means 2 passed (1 + 1) out of 5 inspected (2 passed [1] + 3 failed [0])

The Remarks column can be used to specify any key issues identified, in particular for those inspection items that received a 0 or NA.

All the sum-up scores in sections 2−8 should be filled in section 10 to come up with a grand total score. If the inspectors identify any **critical** issues related to other regulatory requirements that were not listed in the checklist, those can be documented in section 11. The matrix for section 2 is filled below as an example for filling sections 2−8. Section 10 contains the instructions for scoring and documenting the results.

	Requirement	1 or 0	Remarks
2.1	Is the importer registration/inauguration certificate/ letter available? (16 MIMMAR 2007)	1	
2.2	Is the imporer registration certificate/letter displayed in a prominent location? (16 MIMMAR 2007)	0	
2.3	Is the valid certificate of practice of the TIC available? (35 MIMMAR 2007)	1	
2.4	Is the valid certificate of practice of the TIC displayed in a prominent location? (35 MIMMAR 2007)	0	
Score for Registration Certificate Index Add up the importer's scores for questions 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 × 100) = 50%**	

Fill in the results for each item

The inspector can circle the serial number for critical issues that need to be highlighted and addressed in Section 12.

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

In this manual, the individual instructions for each requirement or question in Sections 1−8 are provided in shaded rows under the item.

Section 1. General Information

The inspection starts with the documentation of date, time, type of inspection, and basic information about the importer regarding identification and location. The inspectors should review the pharmacy's registration information before heading out for inspection. Such preparation is helpful for identifying 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 TIC or the proprietor while on-site. To ensure accountability, the inspectors should fill in the information in the table below with the TIC of the pharmacy looking on as a witness.

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 at the importer and fill the correct date accordingly. If no previous inspection is confirmed, fill in No; if unknown, fill in NA.
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 definition.
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 (longitude) optional:	
Physical Address		
Telephone Number		
E-mail Address		The proprietor's, TIC's, or importer official's 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 instructions for examining the registration certificates are given at the top of the matrix; any other instructions for documenting the results are given below the checklist item in the shaded box.

Inspect the registration certificates of the importer and the TIC according to the requirements in the indicated laws or regulations. **If the requirements are met, please indicate 1 for yes**

or passed in the 1 or 0 column; if the requirements are not met, indicate 0 for no or failed.

Requirement		1 or 0	Remarks
2.1	Is the importer registration/inauguration certificate/ letter available? (16 MIMMAR 2007)	1	
2.2	Is the importer registration certificate/letter displayed in a prominent location? (16 MIMMAR 2007)	0	
2.3	Is the valid certificate of practice of the TIC available? (35 MIMMAR 2007)	1	
2.4	Is the valid certificate of practice of the TIC displayed in a prominent location? (35 MIMMAR 2007)		
Look for the importing company registration certificate (currently, it is an inauguration letter issued by GDPA or NMHRA) and the TIC's certificate; both should be displayed at a location that is visible to the public. Score each question separately. If the establishment is active without an inauguration letter from MOPH and is selling medicine, act in accordance with article 39 of the Medicine Law.			
Score for Registration Certificate Index Add up the importer's scores for questions 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 × 100) = 75%**	

Section 3. Legality of the Stocked Medicinal Products

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

Walk through the warehouse and do a general scan of 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 quality control (QC) testing 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 in the 1 or 0 column; if the requirements are not met, indicate 0 for no or failed.**

Requirements		1 or 0	Remarks
3.1	Are **all** the inspected medicines in accordance with the national LML? (9 ML 2008)	1	
If any of the items are found not in the LML, score 0, ask the importer or TIC to present the invoice of such medicines, confiscate them using the Quarantine and Confiscation Form (Annex 2) and report the violation for corrective actions. If any of the items are found not in the LML, but the importer has an approval from MOPH, score 1 and note the issue to check in the minutes of meetings of the National Board.			

3.2	Are **all** the inspected medicines registered with the NMHRA (GDPA) and does the importer have a registration certificate? (Check and obtain a copy of the registration certificate.) (16 MIMMAR 2007, 5 NMP 2014, 5 NPQAP 2015)	1	
Ask the TIC or proprietor about the 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	Are there copies of receipts/invoices for the procurement of medicines and medical equipment from manufacturers? (5 NMP 2014 and 15 NPQAP 2015)	1	
During general inspection, ask for invoices for the latest medicines and health care products purchased from manufacturers; compare the medicines with the NMHRA's (GDPA) prepared medicine lists to clarify that the purchased medicines were purchased from registered manufacturers. In an investigational inspection, ask for the documents for those products that are under investigation.			
3.4	Are there no counterfeit and substandard medicines found for sale on the importer's premises? (16 MIMMAR 2007 and 7 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 out the confiscation form (Annex 2). If any counterfeit or substandard medicines are suspected, collect samples for QC testing, fill the sample collection form, score N/A, and specify "sampled N medicines for QC test" in the Remarks column (see the example provided under Remarks).			
Score for General Inspection and Legality of Stocked Products Index Add up the importer's scores for questions 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 × 100) = 100%**	

Section 4. Product Label Examination

There are two circumstances in which medicines should be sampled. The first is the standard initial or follow-up inspection. For example, if NMRHA or other relevant entities requested that inspections focus on certain types or categories of medicines, or if the follow-up inspection is to review medicines that had previously been found in violation. To sample, randomly select at least five items according to the purpose of the inspection. The second is a special or investigative inspection for suspected 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; with any violations; or if NMHRA or other relevant entities received reports regarding such concerns. Article 39 of the ML contains information on 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 in the 1 or 0 column; if the requirements are not met, indicate 0 for no or failed.**

Requirements		1 or 0	Remarks
4.1	Are **all** the labels of the inspected medicines printed in at least one of the national languages or English? (2 MRG 2014)	1	
If the medicine's labels are in a totally foreign language, the inspector could not identify what they are, and they are in the LML, they should be considered in violation and should be dealt with according to the law.			
4.2	Are **all** the labels of the inspected medicines in accordance with the labeling requirements specified in the regulation and/or guidelines? (24 MIMMAR 2007 and 2 MRG 2014)	0	
If any of the items mentioned in the regulation and guidelines are found in violation, score 0, and specify the issues under Remark; record them for reporting to NMHRA.			
4.3	Is the information in **all** the inspected medicines' leaflets in accordance with the requirements specified in the regulation and/or guidelines? (25 MIMMAR 2007 and 2 MRG 2014)	0	
If any of the items mentioned in the regulation and guidelines are found in violation, score 0, and specify the items under Remarks; record them for reporting to NMHRA.			
4.4	Do **all** the inspected medicines have valid expiry dates? (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 outlet's score for questions 4.1−4.4 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 × 100) = 50%**	

Section 5. Management of Narcotics and Controlled Medicines

Ask the TIC which category 2 controlled medicines (Annex 3) the importer keeps and have the TIC take the inspector to the place where those medicines are stored. If the importer does not keep any controlled medicines, the questions in this section are not applicable. However, the inspector should verify whether the importer indeed does not keep such medicines. Therefore, prior to the inspection, the inspector should look up this information and pay particular attention to these types of medicines during the general inspection (Section 3).

Inspect the controlled medicines including physical examinations and storage, as well as documentation of controlled medicines. **If the requirements are met, please indicate 1 for yes or passed in the 1 or 0 column; if the requirements are not met, indicate 0 for no or failed.**

Requirements		1 or 0	Remarks
5.1	Are there lockable cabinet(s) for storage of all controlled medicines (category 2) on the premises? (5 and 12 NPNCM 2016)	NA	

Requirements		1 or 0	Remarks
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 column and circle the serial number for recommendation in Section 12.			
5.2	Is the entire inventory of category 2 controlled medicines kept in a lockable cabinet? (5 and 12 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 TIC to put them into the cabinet. If there is no designated lockable cabinet at the time of the inspection, advise the TIC to keep category 2 narcotics and controlled medicines in a lockable drawer.			
5.3	Are all the inspected controlled medicines within their labeled expiry dates? Randomly inspect 3 items. (7 NPQAP 2015)	NA	
If any expired or damaged items are found, check others in the cabinet, remove them from the cabinet, and advise 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 outlet's score for questions 5.1–5.3 and record the score in the space provided in the next column. The range for this index is 0–3.		**Score: NA** **Score: (/ × 100) = %**	

Section 6. Storage Conditions (Storage of Pharmaceutical Products)

Inspect the storage conditions at the pharmacy as per the following requirements. **If the requirements are met, please indicate 1 for yes or passed in the 1 or 0 column; if the requirements are not met, indicate 0 for no or failed.**

Requirement		1 or 0	Remarks
6.1	Is the temperature in the warehouse compatible with drug storage requirements? (15–25 °C or depending on climatic conditions up to 30 °C) (50 ML 2008)	0	
Check the temperature of the warehouse. If it is above or below the required temperature range, score 0 and specify it in the Remarks column.			
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) Frequency: _____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 frequency or circle Irregularly or No records).			

Requirement		1 or 0	Remarks
6.3	Does the importer 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 column.			
6.4	Are any temperature-sensitive medicines found stored or displayed outside 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 for temperature-sensitive medicines. If any are found out of the refrigerator, score 0 and circle the serial number for recommendations and actions in Section 12.			
6.5	Are all the inspected medicines in the refrigerator within their labeled expiry dates? Randomly select 3 items. (7 NPQAP 2015)	1	
If any expired or damaged items are found, check a few more in the refrigerator and remove them and request that the importer 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) Frequency: _____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, or quarantined medicines and if so, is it clearly labeled? (9 NPWMSDPP 2015 and 7 NPQAP 2015)	1	
If there is no such area, or if it is not confined or not labeled, score 0. Fill the observations in the Remarks column (the warehouse should specify a place with a label or sign in the facility).			
Score for Storage Conditions Index Add up the outlet's score for questions 6.1–6.7 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 × 100) = 43%**	

Section 7. General Condition of the Premises

Is the general condition of the importer's premises considered appropriate in accordance with the following requirements? **If the requirements are met, please indicate 1 for yes or passed in the 1 or 0 column; if the requirements are not met, indicate 0 for no or failed.**

Requirements		1 or 0	Remarks
7.1	Does the importer operate 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 the reason the company is not located at the registered address and fill it in the Remarks column to report to NMHRA.			
7.2	Does the importer have a warehouse for storing medicines? (38 MIMMAR 2007 and 50 ML 2008)	1	
Inspect to see if the company has a standard warehouse to store imported medicine. The warehouse should have cabinets, shelves and pallets to keep the medicine.			
7.3	Are the walls, floors, and ceiling in good condition without signs of humidity, mold, and cracking? (38 MIMMAR 2007 and 50 ML 2008)	1	
Check if there are signs of cracking, water leakage, or mold on the ceiling, wall, or floor; also check for an unpleasant odor in the importer's facilities due to mold or humidity. If any problems are identified, score 0 and specify it in the Remarks column.			
7.4	Is the entire warehouse area clean? (38 MIMMAR 2007 and 50 ML 2008)	0	
If there is trash outside the bins, litter anywhere, or dust in the pharmacy, 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 functional ventilation system, score 1; if there is none or there is one, but it is not working, score 0 and specify the issue in the Remarks column.			
Score for General Condition of the Premises Index Add up the outlet's score for questions 7.1–7.5 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 × 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 in the 1 or 0 column; if the requirements are not met, indicate 0 for no or failed.**

Requirement		1 or 0	Remarks
8.1	Is the TIC present at the company on the day of the inspection? (35 MIMMAR, 2007)	1	
If the TIC is present, score 1; if not present, score 0. If he/she is on authorized leave, score NA and specify it (such as on vacation, sick leave, etc.) in the Remarks column.			
8.2	Do the importer's invoices contain the following information: (21 PR 2007) • Name of medicine (generic and brand with strength and dosage form) • Manufacture and expire date • Quantity	0	

	• Batch number • Manufacturer • Date of transaction • Sign and stamp of the importer		
In a general inspection, ask for recent copies of receipts/invoices for any medicines and medical equipment that the importer has procured from any companies, retail pharmacies, and other institutions. If the 7 pieces of information listed above are observed score 1; if not score 0 and specify it in the Remarks column.			
8.3	Is the percentage of profit in accordance with the provisions of the law? (**The importer's profit in sales of medicine and medicinal products must not be more than 10% of the purchase price**). (31 MIMMAR 2007)	0	
Check the latest medicine invoices/receipts and observe that the total profit should be according to price letter of NMHRA. If any specific issue is detected, specify it in the Remarks column to report it to NMHRA.			
8.4	Does the importer have a stamp?(14 MIMMAR 2007)	1	
Physically stamp on a white piece of paper to check if the name of the importer is the same as given in the inauguration letter.			
8.5	Does the importer have a standard signboard?(14 MIMMAR 2007)	1	
Check that the importer's signboard is standard size 60 to 180 cm, made of plastic (fiber), and emblazoned with the logo of the importer; the signboard should have a light to be seen during the night. The name of the importer company must be written in Dari, Pashto, or English and should match the name on the 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 × 100) = 60%**	

Section 9. Reference Materials

The purpose of this section is to determine if the importer staff is aware of current laws, regulations, and regulatory guidelines. Prior to inspection, the inspector should read or look over these references and understand their objectives and technical value so that they can help the importer proprietor and TIC understand the importance of having them available and being familiar and compliant with them.

Please ask the importer staff to present the following reference materials. This section is not scored.

Requirements		Yes	No	Remarks
9.1	Valid/effective Afghan Medicines Law (Official Gazette Number 963 2008)	√		
9.2	Valid/effective Manufacturing and Importing Medicines and Medical Appliance Regulation (Official Gazette Number 916 2007)	√		

9.3	Valid National Licensed Medicines List, 2014		√	
9.4	Valid National Essential Medicines List, 2014		√	
9.5	Updated National Medicines Policy, 2014		√	
9.6	Updated National Pharmaceutical Quality Assurance Policy, 2015		√	
9.7	Updated National Policy for Narcotic and Controlled Medicines, 2016		√	
9.8	Updated National Policy for Waste Management and Safe Disposal of Pharmaceutical Products, 2016		√	
9.9	Updated Foreign Pharmaceutical Manufacturing Companies Registration Guideline, 2014 available		√	
9.10	Updated Medicines Registration Guideline, 2014 available		√	

Section 10. Scoring

Fill in the scores from each section for the current and last inspections in the table. The Total score (A) is the sum of the numerators; 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 in the scores for Sections 2–8 into the following table and determine the overall compliance score in the Result column.

	Sectional scores obtained (%)							**Total score (A)**	**Total points (B)**	**Result (%) (A/B*100)**
Date	**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%
% point change	25	25	0	Na	15	20	40			16%

Note: Please make two copies (use carbon paper for writing or make a photocopy if possible) for Sections 11−15. The inspectors keep the original copy and give the duplicate copy to the importer. Advise the proprietor and the TIC to file it in a designated folder for records and actions and for future inspections.

Section 11. Other Observations and Remarks

If the inspectors observe any product or practice issues related to laws or regulations that are not addressed in the checklist, they should be recorded in the following table.

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

Section 12: Recommendations of Inspection Team

Summarize the noncompliant results by filling the "Issues that require attention and correction" column and the corresponding regulatory measures or penalties in the "Actions agreed to take and timeline" column. If the issues are in the checklist, write the section serial number for each issue. If the issue is not in the checklist, but observed by the inspector and filled in Section 11, write 11.n for the section 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 measures or penalties should be applied, specify it in the "Actions agreed to take and timeline" column. Use carbon paper to duplicate this section and give one copy to the pharmacy for taking actions and follow-up.

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

Address:

No.	**Issues that require attention and correction**	**Actions agreed to take and timeline**	
		Agreed actions	**Timeline**
1	6.3 No refrigerator for storing heat sensitive products	A functional refrigerator should be purchased to store heat-sensitive products	Up to end of March 2017

The sectional serial number of the issue

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

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

I (Ahmad Ramin) the owner and (Mahmod) the TIC of said importer certify that the information and observations recorded on this form during the inspection of the importer were true and correct and that the identified issues and corrective actions were communicated and agreed.

Proprietor of Importer	**Technical in-charge**
Name: Ahmad Ramin	**Name: Mahmod**
Signature:	**Signature:**
Date:	**Date:**

Section 14. Time Completed

Fill in the time at the end of the inspection. This information is part of the evidence of the inspection and helps the NMHRA determine the time required for inspection, should the inspection procedure and checklists be revised in the future.

Document the time that the inspection was finished, including completing the checklist, collecting samples for QC testing and confiscation, scoring for this inspection, and communicating with the proprietor and the TIC.

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 TIC, and other pharmacy staff for their assistance during the inspection.

ANNEX 1. SUSPECT MEDICINE SAMPLE COLLECTION FOR QUALITY TEST

The sample collection form should be filled in duplicate. 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 "Total quantity quarantined" column.

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 Testing

Name of importer									
Date		**Address**							
Name of proprietor			**Signature**		**Name of TIC**			**Signature**	
S/no	**Generic name**	**Brand name**	**Batch no**	**Mfg 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 2 copies of the quarantine and confiscation form. The inspectors keep the original copy and give the importere the duplicate copy. The importer should file it in a designated folder for records.			
Name of importer			
Date	**Address**		
Name of proprietor	**Signature**	**Name of TIC**	**Signature**
Please select the appropriate reason for sampling. 1. Quarantine 2. Confiscation			

S/no	Generic name	Brand name	Batch no	Mfg 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. CATEGORY 2 MEDICINES IN THE LML CONTROLLED MEDICINE LIST

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

ANNEX 4. NARCOTIC AND CONTROLLED SUBSTANCES

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

S/no	Name	S/no	Name
1	(+)-Lysergide	39	Dipipanone
2	2C-B (2,5-dimethoxy-4-bromophenethylamine)	40	DMA (dimethoxyamphetamine)
3	3-Methylfentanyl	41	DMHP (dimethylheptylpyran)
4	3-Methylthiofentanyl	42	DMT (N,N-dimethyltryptamine)
5	4-MTA (4-methylthioamphet-amine	43	DOET (2,5-dimethoxy-4-ethylamphetamine)
6	Acetorphine	44	Drotebanol
7	Acetyl-alpha-methylfentanyl	45	Ethylmethylthiambutene
8	Acetyldihydrocodeine	46	Eticyclidine
9	Acetylmethadol	47	Etilamfetamine
10	Allylprodine	48	Etonitazene
11	Alphameprodine	49	Etorphine
12	Alphamethadol	50	Etoxeridine
13	Alpha-methylfentanyl	51	Etryptamine
14	Alpha-methyl-thiofentanyl	52	Fenetylline
15	Aminorex	53	Furethidine
16	Benzethidine	54	Heroin
17	Benzylmorphine	55	Hydromorphinol
18	Betacetylmethadol	56	Hydroxypethidine
19	Beta-hydroxyfentanyl	57	Ketobemidone
20	Beta-hydroxy-3-methylfentanyl	58	Levomoramide
21	Betameprodine	59	Levophenacylmorphane
22	Betamethadol	60	MDE, N-ethyl MDA (3,4-methylenedioxy-N-ethylamphetamine)
23	Betaprodine	61	MDMA (3,4-Methylenedioxymethamphetamine)
24	Brolamfetamine	62	Mecloqualone
25	Cannabis and cannabis resin	63	Mescaline
26	Cathinone	64	Methaqualone
27	Clonitazene	65	Methcathinone
28	Concentrate of poppy straw	66	Methyl-4-aminorex
29	Desomorphine	67	Methyldesorphine
30	DET (N,N-diethyltryptamine)	68	Methyldihydromorphine
31	Dextromoramide	69	MMDA (3-methoxy-4,5-methylenedioxyamphet-amine)
32	Diampromide	70	Morpheridine
33	Diethylthiambutene	71	Morphine methobromide and other pentavalent nitrogen morphine derivatives
34	Difenoxine	72	MPPP (Desmethylprodine, 1-methyl-4-phenyl-4-propionoxypiperidine)
35	Dimenoxadol	73	Myrophine
36	Dimepheptanol	74	N-hydroxy MDA (3,4-meth-ylenedioxy-N-hydroxyam-phetamine)
37	Dimethylthiambutene	75	Nicocodine
38	Dioxaphetyl butyrate	76	Nicomorphine

S/no	Name	S/no	Name
77	Noracymethadol	107	TMA (trimethoxyamphetamines)
78	Norlevorphanol	108	Trimeperidine
79	Normethadone	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
80	Normorphine		
81	Norpipanone		
82	Para-fluorofentanyl		
83	Parahexyl		
84	PEPAP (phenethylphenyl-acetoxypiperidine)		
85	Phenadoxone		
86	Phenampromide		
87	Phenomorphane		
88	Phenoperidine		
89	Pholcodine		
90	Piritramide		
91	PMA (para-methoxyamphetamine)		
92	Poppy seeds		
93	Poppy straw		
94	Proheptazine		
95	Properidine		
96	Propiram		
97	Psilocine, psilotsin		
98	Psilocybine		
99	Racemoramide		
100	Rolicyclidine		
101	STP, DOM (2,5-dimethoxy-4-methylamphetamine)		
102	Tenamfetamine		
103	Tenocyclidine		
104	Thebacone		
105	Thiofentanyl		
106	Tilidine		

Category 2–Strictly Controlled Plants and Substances with a Medical Use

S/no	Name	S/no	Name
1	Alfentanil	31	Methadone
2	Alphaprodine	32	Methadone intermediate
3	Amfetamine	33	Methylphenidate
4	Amobarbital	34	Metopon
5	Aniledirine	35	Moramide, intermediate
6	Bezitramide	36	Morphine
7	Coca (leaf)	37	Nicodicodine
8	Cocaine	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	Metamfetamine racemate
22	Hydrocodone	52	Racemethorphane
23	Hydromorphone	53	Racemorphane
24	Isomethadone	54	Remifentanil
25	Levamfetamine	55	Secobarbital
26	Levomethamphetamine	56	Sufentanil
27	Levomethorphane	57	Thebaine
28	Levorphanol	58	Zipeprol
29	Metamfetamine		
30	Metazocine		

Category 3–Controlled Plants and Substances with a Medical Use

S/No	Name	S/No	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	Methylphenobarbital
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 (gamma-hydroxybutyric acid)	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
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 hydrochloric
18	Acid phenylacetic
19	Acid sulfuric
20	Methylethyl ketone
21	Piperidine
22	Toluene
23	Ethylether

ANNEX 5. GLOSSARY

Active pharmaceutical ingredient (API): Any substance or mixture of substances intended to be used in the manufacture of a drug product and that, when used in the production of a drug, becomes an active ingredient in the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body. (Source: FDA 2015, https://www.fda.gov/downloads/ICECI/ComplianceManuals/CompliancePrograMManual/UCM125420.pdf)

Controlled medicines: Medicines that are deemed essential to the practice of modern medicine that have the potential to be abused by individuals and lead to addiction and harm to health if not used responsibly.

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

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.

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

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

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

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

Expiry date: The date given on the individual container (usually the label) of a product up to and including the date on 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.

Finished pharmaceutical product (FPP): 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.

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

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

Inspection: 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.

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

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

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).

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

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

License: A document issued to a special individual, organization, or company that is involved in or facilitates a specific activity; a license is valid for a specific period of time stated therein in compliance with the terms of the relevant authority.

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

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 adverse effects on human physical, mental, and social performance.

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.

Patient information leaflet: A leaflet containing information for the patient.

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

Pharmacy: A health facility that is established based on the license issued by the National Medicine and Healthcare Product Regulatory Authority 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.

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

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.

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.

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 FPPs conform to established specifications for identity, strength, purity, and other characteristics.

Registered drug products: Pharmaceutical products that have a marketing authorization.

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

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

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

Strength: Refers to the amount of API in each dose, volume, or weight of the product, based on its form.

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

Technical in-charge (TIC): Pharmacist or pharmacy technician, based on the law and related regulations, who is responsible for the professional affairs of a pharmaceutical facility.

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