Government of Pakistan
Ministry of National Health Services, Regulations and Coordination
(Drug Regulatory Authority of Pakistan)
*****

Islamabad, the 23rd November, 2022.

NOTIFICATION

The following draft of the Therapeutic Goods (Federal Inspectors, Laboratories and Federal Government Analysts) Rules, 2022, which is proposed to be made by the Drug Regulatory Authority of Pakistan, with the approval of the Federal Government, in exercise of the powers conferred by section 23 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), is hereby published for the information of all persons likely to be affected thereby and notice is hereby given that objections or suggestions thereon, if any, may, for consideration of the Federal Government, be sent within fourteen days of the publication of this Notification.

Any objections or suggestions which may be received from any person in respect of the said draft before expiry of the aforesaid period shall be taken into consideration by the Federal Government.

DRAFT THERAPEUTIC GOODS (FEDERAL INSPECTORS, LABORATORIES AND FEDERAL GOVERNMENT ANALYSTS) RULES, 2022

1. Short title and Commencement: (1) These rules shall be called the Therapeutic Goods (Federal Inspectors, Laboratories and Federal Government Analysts) Rules, 2022.

(2) They shall come into force at once.

2. Definitions: (1) In these rules, unless there is anything repugnant in the subject or context,--

(i) "Act" means the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012);

(ii) “Drugs Act” means the Drugs Act, 1976 (XXXI of 1976);

(iii) "Form" means a form set forth in the Schedule;

(v) “Risk based GMP inspections” means inspection carried out under rule 13;

(vi) “Drugs” means drugs and biologicals as defined in Schedule-I of the Act;

(vi) “Substandard and Falsified (SF) therapeutic goods” include:

(a) Substandard therapeutic goods means a drug, medical device, alternative medicine, nutraceutical product and health & OTC product which fail to meet

either their quality standards or their specifications and/or both. This also includes out of specification therapeutic goods.

(b) Unregistered or un-enlisted therapeutic goods means therapeutic goods that have not undergone evaluation and/or approval by the Drug Regulatory Authority of Pakistan.

(c) Falsified therapeutic goods means therapeutic goods that deliberately or fraudulently misrepresent their identity, composition and/or source. This may include any substitution, adulteration, reproduction of registered or enlisted therapeutic good or manufacture of a therapeutic good that is not registered or enlisted.

(vii) "BA&BE" means Bio-availability and Bio-equivalence as defined in the Bio Study Rules, 2017;

(viii) "GxP" is the set of current good practices as applicable to the therapeutic goods throughout their lifecycle as specified by the World Health Organization (WHO) and / or Pharmaceutical Inspection Cooperation Scheme (PIC/s) e.g. Good Manufacturing Practices (GMP), Good Distribution Practices (GDP), Good Clinical Practices (GCP), Good Pharmacovigilance Practices. (G: Stands for good; x: Variable; P Stands for practices);

(ix) "CRO" means Contract Research Organization as defined in the Bio Study Rules, 2017;

(2) The words and expressions used but not defined herein shall have the same meanings as are assigned to them in the Act and the Drugs Act.

3. Qualification of Federal Inspectors: (1) The Drug Regulatory Authority of Pakistan may appoint any officer as a Federal Inspector who has five (5) years practical experience in,

(i) the manufacture, testing or analysis of therapeutic goods, or
(ii) in drug control administration or Drug Regulatory Authority of Pakistan:

(2) The Federal Government may, by notification in the official Gazette, for the exercise of powers as specified in the Act, appoint an ex officio Inspector, amongst the officers of Drug Regulatory Authority of Pakistan having above prescribed qualification.

(3) The Federal Inspectors shall be under administrative control of the Incharge of respective field office of Drug Regulatory Authority of Pakistan.

4. Duties of Federal Inspectors: (1) The duty of a Federal Inspector is to assist in the enforcement of the Act, The Drug Act 1976 and rules framed thereunder, by market surveillance, collecting samples of therapeutic goods for test & analysis, collecting evidence of suspected Substandard and Falsified therapeutic goods, and pave the way for successfully prosecuting the accused persons who violates the provisions of the Act, the Drugs Act 1976 and rules framed there under.

(2) The Primary duties of an inspector, within the local limits for which he is appointed, are:

(i) to inspect any premises licensed, enlisted, established or permitted for manufacturing, testing, clinical trial and BA&BE studies of therapeutic goods, nutraceuticals and health products;

(ii) to inspect any premises wherein any therapeutic good, nutraceuticals and health products is manufactured or sold or is stocked or exhibited for sale or is distributed, the storage arrangements and all relevant, manual and / or electronic, records and registers;

(iii) to send forthwith a detailed report to the concerned board or committee after each inspection;

(iv) to take samples of any therapeutic good, nutraceutical and health product which he has reason to believe that it is being manufactured, imported, exported stocked, sold or exhibited for sale in contravention of the provisions of the Act, the Drugs Act 1976 and the rules framed thereunder and send them for test or analysis;

(v) to investigate any complaint which he receives or comes in his knowledge or might have been made to him;

(vi) to institute prosecutions in respect of any violations of the Act, the Drugs Act 1976, and the rules framed thereunder after approval from concerned board or committee;

(vii) to give advice to a licensee who is manufacturer of drugs or medical devices, registration holder, or enlistment holder of alternative medicines, nutraceutical and health products, or CRO, clinical trial site, BA and BE center or laboratory in accordance with good practices compliance (GXP) i.e. cGMP, GCP, GDP, GVP, GLP etc., with a view to improve the standards of manufacturing, quality, efficacy and safety of therapeutic goods;

(viii) to conduct surveillance of the marketed therapeutic goods, nutraceuticals and health products for ensuring their quality and compliance of the various provisions of the Act, the Drugs Act 1976 and the rules framed there under;

(ix) to assist in organizing and conducting good pharmacovigilance practices (GVP) inspections and other programs for monitoring of the pharmacovigilance activities of therapeutic goods in coordination with pharmacy services and relevant provincial healthcare establishments;

(x) to evaluate the compliance in accordance to good clinical practices (GCP) at clinical trial sites, sites responsible for management, administration or data

collection activities for clinical trials (e.g. sponsor organizations, clinical research organizations), clinical trial testing laboratories, including bioanalytical facilities;

(xi) to coordinate and seek assistance from the law enforcement agencies and other Government officials related to the seizure proceeding, confiscation or destruction of either suspected or declared SF therapeutic goods, or the prosecution of any accused;

(xii) to act as a complainant and / or witness for at trials involving any violation of the implemented laws;

(xiii) to do surveillance of manufacture, storage, distribution of therapeutic good, nutraceutical and health product, collaborate with other departments for following up suspected channels of SF therapeutic goods in interprovincial and cross borders trade; and

(xiv) to assist the relevant divisions for performing functions of recall, advertisement control and conduction of therapeutic good's shortage survey.

5. Form of orders not to dispose of stocks: An order in writing shall be made on Form 1 by an Inspector under clause (i) of Section (1) under heading "Powers of Inspectors" in Schedule V of the Act requiring a person not to dispose of any stock in his possession.

6. Form of receipt for seized therapeutic goods: A receipt by an inspector shall be in Form 2 for the stock of any therapeutic good, nutraceutical or health product seized under clause (f) of Section (1) in Schedule V of the Act.

7. Form of intimation for purpose of taking samples: Where an Inspector takes a sample of therapeutic goods for the purpose(s) of enforcement of the provision of the Drug Act 1976, the DRAP Act 2012 or the rules framed there under, he shall intimate such purpose in writing in Form 3 to the person from whom he takes that sample.

8. Sealing Memo: Where an Inspector seals a factory, section, laboratory, shop, building, premises, store-house or godown, or a part thereof, under clause (h) of Section (1) in Schedule V of the Act, he shall fill the Form 7 and affix it on the sealed area, also keep and provide a copy to the person whose premises is being sealed.

9. Procedure for dispatch of sample to Federal Government Analyst: (1) The portion of sample or the container sent by an Inspector to the Federal Government Analyst for test or analysis under sub-section (a) of Section 3 in Schedule V of the Act shall be sent by courier registered post or by hand in a sealed packet enclosed together with a memorandum in Form 4 in an outer cover addressed to the Federal Government Analyst.

(2) A Copy of the memorandum and a specimen impression of the seal used to seal the packet shall be sent to the Federal Government Analyst.

10. Confiscation of Therapeutic Goods, Nutraceuticals and Health Products: When any person has been convicted under the Act and the Drugs Act 1976 or rules framed there under, the stock of the therapeutic good(s) or substance(s) or nutraceutical(s) or health products(s) in respect of which the offence has been committed may be confiscated, or otherwise directed by the court.

11. Prohibition of disclosure of confidential Information: Except for the purpose of official business or when required by a Court of Law, an Inspector shall not, without the sanction in writing of his official superior, disclose to any person any confidential information acquired by him in the course of his official duties.

12. Procedure for reporting of inspection proceedings: Every Inspector may maintain records of all proceedings of inspections of any firm/company and submit a report of each inspection on specified format to the Central Licensing Board or Registration Board or Medical Devices Board or Enlistment Evaluation Committee or authority or officer as the case may be.

13. **Risk Based GMP Inspections:** (1) For the purpose of risk based GMP inspections, all the manufacturing units, licensed or enlisted under the Act, the Drugs Act 1976 and the rules framed there under, shall be categorized on the basis of risk to compromise the overall cGMP compliance in manufacturing of therapeutic goods, nutraceuticals and health products. The categorization shall be done by utilizing guidelines i.e. ICH / PIC/s, WHO on Quality Risk Management or their equivalent as adopted by the Authority. A list of high-risk therapeutic goods, nutraceuticals or health products and high risks manufacturing sites shall be maintained.

(2) The manufacturing units, licensed or enlisted under the Act, the Drugs Act 1976 and the rules framed there-under, shall be inspected by the risk based GMP Inspection panel with a frequency depending upon manufacturers risk-based rating as determined under sub rule 1.

(3) Every manufacturing unit, even if it ranks highest in categorization of cGMP compliance, shall be inspected by risk based GMP Inspection Panel at least once in three (3) years.

(4) Risk Based GMP Inspection Panel shall comprise of officers of DRAP having successfully attained training on PIC/s GMP guide or the guidelines as may be adopted by the Authority from time to time and may or may not include FID(s). The panel with lead auditor shall be nominated by Chief Executive Officer, DRAP or Director Quality Assurance & Laboratory Testing as the case may be.

(5) Risk based GMP panel shall have power to take samples for test / analysis purpose and to forbid for a reasonable period, not exceeding eight (8)weeks or such further period, which shall not be more than three months, as the panel may, with the approval of the Licensing Board, the Registration Board or Medical Devices Board or Enlistment Evaluation Committee, as the case may be, specify, any person in charge of any premises from removing or dispensing of any

therapeutic good, article or other thing likely to be used in evidence of the commission of an offence under this Act or the rules.

(6) Inspection reports along with the recommendations, if any, shall be submitted by the Lead Auditor to the Secretary of the Committee constituted by the Authority for evaluation of these reports. The Committee shall work under the Division of the QA&LT.

(7) The Committee shall evaluate and submit its recommendations to the concerned Board or Committees for action or take action as per mandate assigned to it by the DRAP.

(8) The Authority may make mechanisms for ~~its~~ working of the committee.

(9) List of manufacturing units / establishments, after risk based GMP inspections, which are found to be GMP compliant shall be maintained by the Division of QA&LT and may be published on the DRAP's website.

14. Establishment of Laboratories: (1) The Authority may establish or notify in the official gazette of Pakistan its Laboratories and specify their functions thereof.

15. Function of Laboratory: The Laboratory shall have the following functions, namely;

(i) test and analyze such samples of Therapeutic Goods, nutraceuticals and health products as may be sent to it,
(ii) test or analyze such samples as may be sent to it by any Board or committee of the Drug Regulatory Authority of Pakistan or a Federal Inspector;
(iii) carry out such other functions as may be entrusted to it by the Drug Regulatory Authority of Pakistan.

16. Qualifications of Federal Government Analyst: (1) The Drug Regulatory Authority of Pakistan may appoint any officer as Federal Government Analyst who has five years practical experience in test and analysis of therapeutic goods, nutraceuticals or health products.

Provided that more than one government analyst may be notified for test and analysis for specific therapeutic goods or class of therapeutic goods or nutraceuticals or health products as may be specified in their notification.

17. Dispatch of samples for appellate test or analysis: (1) In case the Board portion of sample is being sent u/s 22(5) of Drugs Act 1976 read with schedule V & VI of the DRAP Act, 2012, for test or analysis, it shall be sent to the Additional Director /officer for the time being incharge of the Laboratory, by courier or registered post in a sealed packet, together with a memorandum in Form 5.

(2) The packet, as well as the outer cover shall be marked with a distinguishing number.

(3) A copy of the memorandum in Form 5 and a specimen impression of the seal used to seal the packet and a sample of the cloth and thread, if used, shall be sent Additional Director of the Federal Laboratory.

18. Recording of condition of seals: (1) On receipt of the packet, it shall be opened by the Additional Director of the Laboratory, a Federal Government Analyst or any responsible officer authorized in writing by any of them in this behalf who shall record the conditions of the seal on the packet, on the form accompanying the sample, and on a register maintained for the purpose.
(2) Immediately on receipt of the sample, the officer opening the packet containing the sample shall examine the sample for any contravention of provisions of the Act, the Drugs Act 1976 and the rules framed there-under in respect of labelling.

19. Report of result of test or analysis: (1) After test or analysis the result thereof together with protocols of the test applied, shall be supplied forthwith to the sender on prescribed Form 6.

(2) The Federal Government Analyst shall forward a copy of the report to the Registration Board or the Central Licensing Board MDB or EEC as the case may be.

(3) The report of test shall be made available to the Inspector within sixty days.

20. Signature on certificate: The Federal Government Analyst shall sign the test and analysis report.

21. Fees: (1) The fee for each test and analysis shall be notified by the Authority with the approval of Policy Board.

(2) The fees for test and analysis shall be paid by marketing authorization holder ~~or~~ registration holder enlistment holder as the case may be of the said therapeutic good, nutraceutical or health product.

(3) The charges of inspection shall be determined by the Authority with the approval of Policy Board.

22. Amendment in Forms: (1) The Authority may add, omit or amend the Forms, as deem appropriate.

23. Repeals and Savings: (1) The Drugs (Federal Inspectors, Federal Drug Laboratory and Federal Government Analysts) Rules, 1976 are hereby repealed.

(2) Notwithstanding such repeal, any investigation and legal proceedings initiated under the Drugs (Federal Inspectors, Federal Drug Laboratory and Federal Government Analysts) Rules, 1976 shall be finalized under the said rules.

SCHEDULE 1
FORM 1
[See rule 5]

ORDER UNDER SCHEDULE V OF THE DRAP ACT 2012, REQUIRING A PERSON NOT TO DISPOSE OF STOCK IN HIS POSSESSION

Whereas I have reason(s) to believe that the stock of therapeutic goods, or nutraceuticals or health products from the premises …… situated at ……. in your possession detailed below contravenes the provisions of the DRAP Act, 2012, the Drugs Act 1976 or rules made thereunder; and whereas I have to report facts to the Board/Committee concerned or the authority and have been authorized by it to take action under clause (i) of Section (1) under heading "Powers of Inspectors" in Schedule V of the Act;

I hereby require you not to dispose of the said stock for a period of .....days from this date.

Date..... **Inspector / Authorized Officer .....**

Details of stock of therapeutic goods

Sr.	**Product Name**	**Manufacturer/ Importer**	**Registration / Enlistment No**	**Batch No.**	**Expiry Date**	**Quantity**

Inspector / Authorized Officer .....

Signature of Concerned personnel of premises: ……
Name…….. CNIC……

Witnesses:-

Sr.	**Name**	**CNIC**	**Signature**
i.			
ii.			

FORM 2

[See rule 6]

RECEIPT FOR STOCK OF THERAPEUTIC GOODS SEIZED UNDER SECTION 1 (F) OF SCHEDULE V OF THE DRAP ACT 2012

The stock of therapeutic good(s) or nutraceuticals or health products /material(s)/article(s) detailed below has this day been seized by undersigned under the provision of clause (f) of Section (1) of Schedule V of the DRAP Act 2012, from the premises of..... situated at.....

Date..... **Inspector / Authorized Officer.....**

Details of stock of therapeutic goods

Sr.	**Product Name**	**Manufacturer/ Importer**	**Registration / Enlistment No**	**Batch no.**	**Expiry date**	**Quantity**

Inspector / Authorized Officer .....

Certified that the above items were actually present in my Store/Godown/ Premises referred above at the time of inspection by the Inspector of Drugs. I have signed this receipt form and I have got a copy of this Form-2.

Signature of the Owner of the Chemists Shop/Premises, Qualified Person or person present during inspection: ……

Name…….. CNIC……

Witnesses:-

Sr.	**Name**	**CNIC**	**Signature**
i.			
ii.			

FORM 3

[See rule 7]

INTIMATION TO PERSON FROM WHOM SAMPLE IS TAKEN

To: _____

I have this day taken from the premises of .....situated at ..... samples of the therapeutic good(s) or nutraceuticals or health products specified below for the purposes of test or analysis or violations of the DRAP Act 2012 and the rules framed thereunder.

Date..... **Inspector / Authorized Officer.....**

Details of sample taken

Sr.	**Product Name**	**Manufacturer/ Importer**	**Registration / Enlistment No**	**Batch no.**	**Expiry date**	**Quantity**

Inspector / Authorized Officer.....

<u>It is to certify that:-</u>

i) Sample(s) of therapeutic good(s) for which particulars are mentioned above was/were taken from my/our premises/store/warehouse/godown and sealed in my presence;
ii) Sample(s) were in original sealed container of the company/ manufacturer;
iii) A copy of this form-3, and a portion of the said sealed sample(s) as required under Section 19 of the Drugs Act, 1976 has been handed over to me;
iv) I shall provide prescribed bills/invoices with warranty of drugs taken for test/analysis within 7 (seven) days as per DRAP Act, 2012.

Signature of person from whom sample(s) is/are taken: ……

Name…….. CNIC……

Witnesses:-

Sr.	**Name**	**CNIC**	**Signature**
i.			
ii.			

FORM 4

[See rule 9]

MEMORANDUM TO FEDERAL GOVERNMENT ANALYST

Memorandum No.		**Date:**	
Sender Information			
	Name	Designation	Contact Details

To
The Federal Government Analyst.
(__address of the lab_____)

The portion of sample(s)/container(s) described below is/are sent herewith for test and analysis under the provisions of sub-section (a) of Section 3 of Schedule V of the DRAP Act, 2012.

The portion of sample or container has been marked by me with the following mark :-

_____

Details of portion of sample or container with name of therapeutic good(s) which it purport(s) to contain:-

Sr.	**Sample Identification Number**	**Product Name**	**Generic Name**	**Type of therapeutic good**	**Manufacturer/ Importer name and address**	**Registration / Enlistment No**	**Batch no.**	**Mfg. date**	**Expiry Date**	**Quantity**	**Environmental conditions at time of sampling**

The required storage conditions of the products sampled are;

Temperature	**Humidity**	**Light Sensitive Yes/No**	**Any special consideration**

Reason for sampling: □ Visible Quality Defect, □ Storage conditions inappropriate, □ High Risk molecule/Product,
□ Suspicion of contamination, □ On orders of _____(Board, committee, authority), □ Complaint, □ No warranty available.
□ testing required by Government & program purchase, □ Visible Quality Defect
□ Other reason:_____

Test (s) Required:

S. No.	Test	Reference to Specifications (if any)

Attachments (if any):

Signature of Inspector/ Authorized officer (along with Name & Designation)	**Date**

FORM 5

[See rule 16]

MEMORANDUM TO THE APPELLATE LABORATORY

Serial No .....

From .....

To the Officer in-charge, _____ Laboratory.

I send herewith, under the provisions of section 22(5) of the Drugs Act 1976, sample (s) of a therapeutic good or nutraceuticals or health products purporting to be ..... for test or analysis and request that a report of the result of the test or analysis may be supplied.

Sr.	**Sample Identification Number**	**Product Name**	**Manufacturer/ Importer**	**Registration / Enlistment No**	**Batch no.**	**Expiry Date**	**Quantity**

2. The distinguishing number on the packet is.....

3. Particulars of offence alleged.....

4. Matter on which opinion is required.....

Date.....

Authorized Officer .....

FORM 6

[See rule 18]

CERTIFICATE OF TEST OR ANALYSIS BY THE FEDERAL LABORATORY/FEDERAL GOVERNMENT ANALYST

1. Certified that the samples with following details has been tested at the laboratory

Test Report No.		Date:	
Sampling Memorandum No.		Date:	
Sample Identification No.		Date of receipt in laboratory	
Sampled By:		Seal Condition	
Brand Name with strength and dosage form		Generic Name	
Batch No.		Manufacturing Date:	
Registration/ Enlistment No.		Expiry Date:	
Manufacturer		License / Enlistment No.:	

2. The details of results of test & analysis: (With Protocols of tests applied):

S No.	Test	Acceptance Criteria	Results	Reference

3. Details of results of test or analysis: (with protocols of tests applied).

S.No.	Test	Specification	Result		Reference

The above mentioned results are on the basis of sample provided.

4. **Opinion and Interpretation:**

_____

_____

5. (Remarks if any):_____

(Name of Laboratory with Complete Address)_____

Test Report No.		Date:	

Hence, the sample is of _____ quality as per _____

(Specifications and/or clause of Act)

Approved by	**Signature and Date**
	Name and Designation

FORM 7

[See rule 8]

SEALING MEMO

In exercise of Power of Inspector conferred under section 18 (1)(h) of Drugs Act, 1976 read with Section 1(h) of Schedule V of the DRAP Act, 2012, the undersigned is sealing the premises of _____ situated at _____ _____ on this date, for the following violations:

_____

_____

_____

_____

I acknowledge the receiving of copy of sealing memo and / or sealed keys.

Name of Accused:_____
Signature: _____
CNIC #: _____

Inspector / Authorized Officer: _____
Name:_____
Date:_____

Witnesses:-

Sr.	Name	CNIC	Signature
i.			
ii.			

AAMAR LATIF,
Additional Director (Legal Affairs).