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

Islamabad, the 11th November, 2026.

NOTIFICATION

No. F.13-3/2025-LA.– The draft Therapeutic Goods (Federal Inspectors, Federal Government Analysts and Federal Quality Control Laboratories) Rules, 2026, 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), are hereby published for the information of all persons likely to be affected thereby and notice is hereby given that any objections or suggestions in respect of the said draft rules may be submitted to the Authority, for its consideration, within fifteen days of the publication of this Notification.

Any objection or suggestion received from any person before the expiry of the aforesaid period shall be duly considered by the Authority before finalization of the said rules.

DRAFT THERAPEUTIC GOODS (FEDERAL INSPECTORS, FEDERAL GOVERNMENT ANALYSTS AND FEDERAL QUALITY CONTROL LABORATORIES) RULES, 2026

1. Short title and Commencement:- (1) These rules may be called the Therapeutic Goods (Federal Inspectors, Federal Government Analysts and Federal Quality Control Laboratories) Rules, 2026.

(2) They shall come into force at once.

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

(a) "DRAP Act" means the Drug Regulatory Authority of Pakistan Act 2012 (XXI of 2012);

(b) "Federal Government Analyst" means the analyst as prescribed under rule 14 of these rules;

(c) "Form" means a form set forth in these rules;

(d) "Guidelines" means a set of principles, directions, conditions, standards or recommended procedures issued by the Authority in exercise of its powers and functions under section 7(c) of the DRAP Act 2012, for facilitating, clarifying or ensuring the consistent implementation, administration or enforcement of these rules;

(e) "Inspector" means the inspector prescribed under rule 3 of these rules;

(f) "Laboratory" means establishment as prescribed rules 13 of these rules;

(g) "Risk Based Inspection" means an inspection prioritized and conducted based on product classification, quality risk management principles, compliance history, and post-market safety signals.

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

3. Qualification of Federal Inspectors:- (1) A Federal Inspector shall be a person who:

(a) has a degree in Pharmacy from a Pakistani University or any other institution recognized for this purpose by the relevant accreditation body; and

(b) has for a period of, or for periods: aggregating, not less than ten-year practical experience in, (i) regulation, pharmacy services, manufacturing, quality control, quality assurance, and research & development of therapeutic goods or (ii) in Federal or Provincial drug administration:

Provided that the condition of experience may be relaxed, for a maximum period of two years, where the candidate; with requisite experience is not readily available.

(2) In case of unavailability or vacancy of a notified Inspector, the officer in-charge of the relevant DRAP field office shall exercise the powers of Inspector provided under Schedule-V of the DRAP Act in the respective area of jurisdiction.

4. Duties of Federal Inspectors:- (1) The Federal Inspector of Drugs shall, within the local limits for which he is appointed, perform the following duties:

(a) to inspect, not less than once every year or as per Risk Based Inspection plan, all premises licensed for the manufacture of Therapeutic Goods, including the plant and process of manufacture, the means employed for standardization and testing of such goods, the methods and places of storage, the location, construction and administration of the establishment insofar as these may affect the quality, safety, efficacy, performance, potency or purity of the products, and the records and registers maintained therein, ascertain compliance with the conditions of the license and the provisions of the Act and the rules made thereunder;

(b) to inspect, from time to time and in accordance with a risk-based approach, any establishment licensed for the import, export, distribution or sales of Therapeutic Goods, examine the conditions of storage, handling and distribution, and the records maintained therein, insofar as these may affect the quality, safety, efficacy, potency or purity of such goods. The inspector shall also ascertain compliance with the provisions of the Act and the rules made thereunder, undertake market surveillance and control activities in respect of such goods on a risk-based basis, including but not limited to carry out post-marketing surveillance in accordance

DRAFT

with the National Risk-Based Post-Marketing Surveillance Plan;

(c) to submit forthwith, after each inspection, investigation or verification related to Therapeutic Goods, a detailed report indicating the extent of compliance with the conditions of the license and the provisions of the DRAP Act and the rules made thereunder and identifying any non-compliance observed, to the Authority, Board, division or committee, as the case may be, by which such inspection, investigation or verification was ordered;

(d) to lodge the FIR with relevant law enforcement agency in case of cognizable offense under clause (1) of Schedule-III of the DRAP Act 2012, or sub-section (1) of Section 27 of the Act, which an Inspector may institute directly and intimate the secretary of Board or committee concerned within five working days;

(e) to take samples of any Therapeutic Goods which the Inspector has reason to believe is being manufactured, imported, stocked, sold, supplied or exhibited for sale in contravention of the provisions of the DRAP Act or the rules made thereunder, and to send such samples for test or analysis;

Provided that the sampling of Medical Devices which were previously defined as drug shall be continued as per parameters set forth for the sampling of drugs. However, for the rest of medical devices, guidelines shall be issued by the Authority.

(f) to investigate complaints relating to Therapeutic Goods received directly or referred by any Division or by Authority, and to take appropriate action, as necessary, in accordance with the provisions of the DRAP Act and the rules made thereunder;

(g) to institute, where necessary, prosecution under authorization from competent forum, in respect of any breach of the DRAP Act or the rules made thereunder;

(h) to assist the relevant divisions in performing regulatory functions including but not limited to recall, advertisement control, pricing and conduction of shortage surveys of Therapeutic Goods; and

(i) any other duty as may be assigned.

(2) A Federal inspector shall, for the purpose of sub-section (i) of section (l) of "Powers of Inspectors" under Schedule-V of the DRAP Act take the approval of, and for the purpose of sub-section (b) of section (3) and section (5) of "Procedure for inspectors" under Schedule-V of the DRAP Act, send the sample to, or inform the Board or the committee concerned, as the case may be.

5. Form of orders not to dispose of stocks:- An order in writing by an Inspector under clause (i) of sub section (1) of "Powers of Inspectors" under Schedule-V of the DRAP Act

DRAFT

requiring a person not to dispose of any therapeutic good, article or other thing in his possession shall be in Form 1 of these rules.

6. Form of receipt for seizure:- A receipt by an inspector for the stock of any Therapeutic Good, all material used in the manufacture thereof and any other articles including registered, cash memos, invoices and bills seized under clause (f) of sub- section (1) of "Powers of Inspectors" under Schedule-V of the DRAP Act shall be in Form 2 of these rules.

7. Form of Intimation of purpose of taking samples:- Where an Inspector takes a sample of Therapeutic Goods for the purpose of test or analysis, he shall intimate such purpose in writing in Form 3 of these rules to the person from whom he takes it.

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

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

10. Confiscation of Therapeutic Goods:- When any person has been convicted under the DRAP Act for contravening the provisions of clauses (a) to (e), (g) and (h) of Section (A) (1) of Schedule-II of the DRAP Act, the stock of the Therapeutic Goods or a substance in respect of which the contravention has been made may be confiscated if the Drug Court so directs.

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

12. Federal Quality Control Laboratories:- The Federal Quality Control Laboratories shall have the following functions:

(i) to test and analyze such samples of Therapeutic Goods as may be sent to it;

(ii) to test or analyze any such samples as may be sent to it by any Board or committee of the Authority or an Inspector or an Authorized Officer;

(iii) to carry out such other functions as may be entrusted to it by the Authority or the

DRAFT

Policy Board; and

(iv) to Test or analysis, performance and safety of Medical Devices.

13. Establishment of Federal Quality Control Laboratories:- (1) The Authority may establish and notify in the Official Gazette of Pakistan its Laboratories to perform the functions under DRAP Act.

(2) The Authority may notify any laboratory and analyst under DRAP Act to perform any specific function for a specified period.

14. Qualifications of Federal Government Analyst:- A Federal Government Analyst shall be a person who has relevant qualification as prescribed under the DRAP Service Regulations 2015 for the technical cadre and has not less than ten years of experience in the test and analysis of Therapeutic Goods.

Provided that more than one Government Analyst may be notified for test and analysis for specific therapeutic goods or class of Therapeutic Goods as may be specified in their notification.

15. Dispatch of samples for test or analysis:- (1) For Therapeutic Goods; the portion of sample or the container sent by an Inspector to the Government Analyst for test or analysis under sub- section (3) of "Procedure for inspectors" under Schedule-V of the DRAP Act shall be sent by registered post or any courier service or by hand in a sealed packet enclosed together with a memorandum in Form-4 in an outer cover addressed to the Government Analyst.

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

16. Recording of condition of seals:- (1) On receipt of the packet, it shall be opened by the Federal Government analyst of the laboratory or an officer authorized by him in writing in this behalf who shall record the conditions of the seals on the packet, on the form accompanying the sample, and on a register or log 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 DRAP Act in respect of labelling.

17. Report of result of test or analysis:- (1) After test or analysis the result thereof together with full protocols of the test applied, shall be supplied forthwith to the sender by the Federal Government Analyst on Form 5.

(2) A copy of the report shall be forwarded to the Board or committee concerned, as the case may be.

(3) The Federal Government Analyst, as far as may be, shall submit the report referred to in sub-rule (1) within sixty days of the receipt of the sample and, if he is not able to do so for reasons beyond his control, shall communicate the reasons to the sender in writing and shall

endorse its copy to the Board or committee concerned. The Board or Committee concerned shall extend the period not beyond the 30 days and shall make the test report available to the sender for further action.

(4) The Federal Government Analyst, is not able to perform test and analysis for reasons beyond his control, shall communicate the reasons to the sender in writing and shall endorse its copy to the Board or committee concerned. The Board or Committee concerned shall have the sample tested from any other Government Analyst or a Federal Quality Control Laboratory or any other Laboratory and shall ensure the receipt of results of such test and analysis within a further period as may be prescribed and shall make the test report available to the sender for further action.

(5) Notwithstanding anything contained in any other law for the time being in force, any document purporting to be a report signed by a Federal Government Analyst shall be admissible as evidence of the facts stated therein without formal proof and such evidence shall be conclusive unless the person from whom the sample was taken or the said warrantor has, within thirty days of the receipt of a copy of the report notified in writing to the sender that he intends to adduce evidence in controversion of the report.

(6) Where a person has, under sub-rule (5) notified his intention of adducing evidence in controversion of an Analyst's report, the Board or committee concerned may of its own motion or in its discretion at the request either of the complainant or the accused, cause the sample of the therapeutic good lying with the Board concerned under Schedule-V of the DRAP Act to be sent for test or analysis to the Appellate Laboratory which shall conduct the test or analysis and report in writing signed by, or under the authority of, the person for the time being incharge of the said Laboratory. The result thereof and such report shall be conclusive evidence of the facts stated therein.

(7) In the case of submission of samples under sub-rule (6), a copy of the memorandum in Form 6 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 to the officer for the time being Incharge of the Appellate Laboratory.

18. Signature on certificate:- Certificates issued under these rules by the Laboratory shall be signed by the concerned Federal Government Analyst.

19. Fees:- (1) The fee for each test or analysis shall be notified by the Authority with the approval of Policy Board in accordance with the DRAP (Fee and Levy) Rules, 2022.

(2) The fee for test and analysis shall be paid by marketing authorization holder or registration holder or enlistment holder of the said Therapeutic Goods or any Federal or Provincial entity which desires test or analysis of any Therapeutic Goods.

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

20. Risk Based Inspections:- Regulatory inspections under these Rules may, where appropriate, be conducted on a risk-based approach, under the guidelines issued by the Authority.

DRAFT

21. Amendment in Forms:- The Authority may add, omit or amend Forms so as to omit any entry therefrom, add any entry thereto or amend any entry therein.

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

(2) Notwithstanding the repeal of the Drugs (Federal Inspectors, Federal Drug Laboratory and Federal Government Analysts) Rules, 1976 by sub-rule (1), any case initiated or any action taken, before promulgation of these rules, as per the Drugs (Federal Inspectors, Federal Drug Laboratory and Federal Government Analysts) Rules, 1976, shall be concluded on basis of the same.

(3) The Federal Inspectors and the Federal Government Analysts validly notified prior to the commencement of these rules shall continue to exercise their statutory powers for the specific categories of therapeutic goods for which they possess demonstrated administrative and technical competence till further order.

(4) Any application, proceeding, enquiry or matter pending immediately before the commencement of these rules shall be continued and disposed of in accordance with the provisions of these rules, as if it were instituted thereunder.

DRAFT

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 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: _____ Time: _____ **Inspector / Authorized Officer _____**

Details of stock of therapeutic goods:

Sr.	Product Name	Manufacturer/ Importer	Registration / Enlistment No	Batch No.	Expiry Date	Quantity	Reason for order not to dispose of

Inspector / Authorized Officer: _____

Signature of Concerned personnel of premises: _____
Name: _____ CNIC: _____

Witnesses:

Sr.	Name	CNIC	Signature

DRAFT

FORM 2

[See rule 6]

RECEIPT FOR STOCK OF THERAPEUTIC GOODS SEIZED UNDER SECTION 1(F) OF HEADING "POWERS OF INSPECTORS" IN SCHEDULE-V OF THE DRAP ACT, 2012

The stock of therapeutic good(s) /material(s)/article(s) detailed below has this day been seized by undersigned under the provision of clause (f) of Section (1) under heading "Powers of Inspectors" in Schedule-V of the DRAP Act 2012, from the premises of _____ situated at _____

Date: _____ Time: _____ **Inspector / Authorized Officer _____**

Details of stock of therapeutic goods

Sr.	Product Name	Manufacturer/ Importer	Registration / Enlistment No	Batch no.	Expiry date	Quantity	Reason of Seizure

Inspector / Authorized Officer _____

Witnesses:

Sr.	Name	CNIC	Signature

DRAFT

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) specified below for the purposes of test or analysis.

Date: _____ Time: _____ **Inspector / Authorized Officer _____**

Details of sample taken:

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

Inspector / Authorized Officer _____

It is to certify that:

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 Schedule-V of the DRAP Act 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)			

DRAFT

FORM 4

[See rule 9]

MEMORANDUM TO FEDERAL GOVERNMENT ANALYST

Serial No: _____
From: _____

To,

The Federal Government Analyst.

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 under heading "Procedure for Inspectors" in Schedule V of the DRAP Act, 2012.

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

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

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

Inspector / Authorized Officer _____

Date _____

DRAFT

FORM 5

[See rule 17(1)]

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

Certified that the samples, bearing number _____ purporting to be a sample of _____ received on _____ with reference No. _____ Dated _____ from _____ has been tested/analyzed and that the result of such test/analysis is as stated below:

2. The condition of the seals on the packet on receipt was as follows: _____

3. In the opinion of the undersigned, the sample is not / is adulterated / sub-standard / misbranded / Spurious, as defined in the DRAP Act 2012 for the reasons given below;
Details of results of test or analysis (with protocols applied) _____ Reg. No. _____ Batch No. _____ Date/Mfg. _____ Date/Exp. _____ claimed to be manufactured by _____

Sr.	Test	Acceptance Criteria	Result	Reference

Remarks:

Federal Government Analyst

DRAFT

FORM 6

[See rule 17(7)]

MEMORANDUM TO THE APPELLATE LABORATORY

Serial No _____

From _____

To the Officer in-charge, _____ Laboratory.

I send herewith, under the provisions of rule 17(7) of The Therapeutic Goods (Federal Inspectors, Federal Government Analysts and Federal Quality Control Laboratories) Rules 2026, sample(s) of a therapeutic good 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 _____

DRAFT

FORM 7

[See rule 8]

SEALING MEMO

In exercise of Power of Inspector conferred under Section 1(h) of Schedule-V of the DRAP Act, 2012, the undersigned is sealing the premises of _____situated at _____ on date _____ and time_____, for the following violations:

_____

_____

_____

_____

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

Name of person present _____

Signature _____

CNIC # _____

Inspector _____
Name _____
Date _____

Witnesses:

Sr.	Name	CNIC	Signature
i)			
ii)			

AAMAR LATIF,
Director (Legal Affairs).

DRAFT