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

NOTIFICATION

Islamabad, the 17th March, 2026.

No. F.13-1/2025-LA.— The following draft of the Therapeutic Goods (Import and Export) Rules which are 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), read with clause (a) of section 7 thereof and section 43 of the Drugs Act, 1976 (XXXI of 1976), 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 Authority, be sent within fourteen days of the publication of this Notification in the official Gazette.

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 Authority.

CHAPTER I
PRELIMINARY

1. Short tile and commencement.- (1) These rules may be called the Therapeutic Goods (Import and Export) 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) **"Act"** means the Drugs Act, 1976 (XXXI of 1976);

(b) **"Active Pharmaceutical Ingredient (API)" or "Drug Substance"** means any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of 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;

(c) **"DRAP Act"** means the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012);

(d) **"Form"** means form appended to these rules;

(e) **"Integrated Risk Management System" or "IRMS"** means the electronic risk management platform for systematic application of trade controls, management procedures and actions to mitigate cross border trade related risks on import or export of therapeutic goods cleared through the system in a coordinated manner;

(f) **"licensing authority"** means such officer of the Drug Regulatory Authority of Pakistan authorized or designated by the Authority, by notification or office order to exercise powers and perform functions relating to the issuance of licences, permits, certificates, no-objection certificates or any other regulatory approvals for the import or export of therapeutic goods under these rules;

(g) **"LPCO"** means licenses, permits, certificates and other documents as issued by licensing authority for regulation of cross-border trade as per import or export policy orders for the time being in force;

(h) **"Other than finished therapeutic good"** means Active Pharmaceutical Ingredient (API) or Drug Substance, excipients, packaging materials, precursor chemicals, intermediates, solvents, components, accessories, Extracts, tinctures, herbal substances and any other items used in the manufacture of therapeutic goods;

(i) **"post clearance audit" or "PCA"** means the process of structured examination and other measures by which licensing authority satisfy itself as to the accuracy and authenticity of declarations through the examination of the relevant books, records, business systems and commercial data held by traders and other relevant entities associated with cross border trade after the goods have been released from customs and border controls to measure and improve compliance;

(j) **"re-export"** means the export from Pakistan of imported therapeutic goods that are rejected, defective, damaged, contaminated, mislabeled, or otherwise unfit for use for intended purpose, and are being returned to the original foreign supplier; and

(k) **"re-import"** means the return to Pakistan of therapeutic goods originally manufactured in Pakistan and exported abroad, which are received back.

(2) The words and expressions used but not defined herein shall have the same meanings as are assigned thereto in the Act or the DRAP Act.

CHAPTER II
IMPORT OF THERAPEUTIC GOODS

3. Import of finished therapeutic goods.- Finished therapeutic goods may be imported subject to the following conditions, namely:-

(a) the importer possesses a valid license of the therapeutic goods intended to be imported and has adequate facilities for proper storage to preserve its properties / specifications;

(b) the import of finished therapeutic goods shall be in accordance with conditions as specified in the guidelines approved by the Authority.

4. Import of finished therapeutic goods against indent.- The therapeutic goods may be imported against valid indents, in accordance with the conditions specified in the guidelines approved by the Authority, and such indents shall be issued by a duly authorized Marketing Authorization Holder or indentor.

5. Types of licences to import therapeutic goods.- Licenses to import therapeutic goods shall be of the following types, namely:-

(a) licence to import other than the finished therapeutic goods; and

(b) licence to import small quantities of therapeutic goods and other than finished therapeutic good for the purpose of clinical trial, examination, test or analysis.

6. Application for licence to import other than finished therapeutic goods.- (1) An application for licence to import other than finished therapeutic goods shall be made to the licensing authority in Form-1 in Schedule-A and shall be accompanied by such fee as notified by the Authority under the Drug Regulatory Authority of Pakistan (Fee and Levy) Rules, 2022 and by an undertaking in Form-2 in Schedule-A, signed by or on behalf of the manufacturer.

(2) An application for licence to import small quantity of therapeutic goods for the purpose of clinical trial, examination, test or analysis shall be made to the licensing authority in Form-3 in Schedule-A, and the licensing authority may require such other particulars to be supplied as it may consider necessary.

(3) Any fee deposited shall in no case be refunded.

(4) The conditions and requirements of above-mentioned licenses shall be in accordance with the guidelines approved by the Authority.

7. Licence to import therapeutic goods.- A licence to import other than finished therapeutic goods shall be issued in Form-7 in Schedule-B and for the import of small quantity of therapeutic goods for clinical trial, examination, test or analysis shall be issued in Form-8 in Schedule-B.

8. Duration of licence to import therapeutic goods.- A licence to import therapeutic goods unless earlier suspended or cancelled, shall be valid for two years.

9. Grant of licence to import therapeutic goods.- On receipt of an application for a licence to import therapeutic goods the licensing authority shall, on being satisfied that, if granted, the conditions of the licence shall be observed, issue an import licence.

10. Conditions of licence to import small quantities of therapeutic goods for clinical trial, etc.- A licence to import small quantities of therapeutic goods including therapeutic goods the import which is otherwise prohibited under the Act for the purposes clinical trial, examination, test or analysis shall be subject to the following conditions, namely:-

(a) the licence shall exclusively use the therapeutic goods for the purpose for which it has been imported and at the place specified in the licence, or at such other place as the licensing authority may from time to time authorize;

(b) the licensee shall allow the licensing authority or any person authorized by it in this behalf to enter, with or without prior notice, the premises where the therapeutic goods are kept and to inspect the premises and investigate the manner in which the therapeutic goods are being used and to take samples thereof;

(c) the licensee shall keep record of, and shall report to the licensing authority, the therapeutic goods imported under the licence, together with the quantities imported, the date of importation and the name of the manufacturer; and

(d) the licensee shall comply with such further requirements, if any applicable to the holders of licences for clinical trial, examination, test or analysis as may be specified in any rules subsequently made under the Act and of which the licensing authority has given to him not less than one month's notice.

11. Import of Therapeutic goods for personal use.- Small quantities of therapeutic goods, including finished therapeutic goods the import of which is otherwise prohibited under the Act may be imported for personal use subject to the following conditions, namely:-

(a) the therapeutic good shall form part of a passenger's bona fide baggage and shall be intended for the exclusive personal use of the passenger;

(b) the quantity of any single therapeutic good must not exceed a total dosage of three months per individual:

Provided that any therapeutic good imported for personal use but not forming part of bona fide personal baggage may be allowed to be imported subject to the following conditions, namely:-

(i) the licensing authority on an application being made to it prior to the import, and being satisfied that the therapeutic good is for bona fide personal use has granted permission for the import of the said therapeutic good; and

(ii) the quantity to be imported is, in the opinion of the licensing authority, reasonable and is covered by a prescription from a registered medical practitioner.

12. Import of therapeutic goods for institutions and hospital's patient's use.- Any therapeutic good, the import of which is otherwise prohibited on account of non-registration or non-enlistment, may be imported by institutions or hospital (public or private) subject to prior approval of the licensing authority or any officer authorized by it in this behalf as per following conditions, namely:-

(a) the therapeutic good shall not be sold or distributed in the market;

(b) the therapeutic good is allowed to be sold freely in its country of origin or is Pre-Qualified by the World Health Organization, or is available in any of Reference Regulatory Authority;

(c) the therapeutic good shall be used in the hospital or institution only and not for the purpose of clinical trial, examination, test or analysis;

(d) clearance certificate must be obtained from licensing Authority or officer authorized on his behalf, at the time of arrival of shipment, before customs clearance. Consumption or utilization record must be maintained by the importer, under the supervision of qualified technical staff as specified in these rules; and

(e) the therapeutic good is not enlisted or registered or available in Pakistan.

Provided that the conditions mentioned at serial numbers (b) and (c) shall not apply to medicines and vaccines used for the treatment and prevention of pandemics or health emergencies.

13. Import of therapeutic goods for donation.- (1) Therapeutic goods including those the import of which is otherwise prohibited without registration or enlistment under the Drug Regulatory Authority of Pakistan Act, 2012 and rules framed there under, may be imported for the purpose of donation, subject to the following conditions, namely:—

(a) it does not contain any narcotic drugs or precursor chemicals or psychotropic ingredients;

(b) it is allowed to be sold freely in its country of origin or is Pre-Qualified by the World Health Organization, or is available in any of Reference Regulatory Authority;

(c) it has a minimum expiry period of six months; and

(d) the therapeutic goods shall not be sold or distributed in the market;

(e) the therapeutic goods shall not be used for the purpose of clinical trial, examination, test or analysis;

(f) clearance certificate must be obtained from the licensing authority or the officer authorized on this behalf of the relevant field office at the time of arrival of shipment. Consumption of utilization record must be maintained by the importer under the supervision of qualified technical staff as with conditions as specified in the guidelines approved by the Authority.

Provided that the conditions mentioned at serial numbers (b) and (c) shall not apply to medicines and vaccines used for the treatment and prevention of pandemics or health emergencies. Furthermore, in special cases, the Authority may, for reasons to be recorded in writing, relax condition (b) and (c).

Provided further that for medical devices, conditions mentioned at serial number (b) may be read as documentary evidence or confirmation from website for free sale in the country of origin, however, where such evidence is not available, the importer shall be responsible for the safety and performance of the medical devices.

14. Re-import of therapeutic goods manufactured in Pakistan. (1) Therapeutic goods manufactured in Pakistan and exported abroad may be re-imported into Pakistan subject to the following conditions, namely:—

(a) the therapeutic goods are returned unchanged, unprocessed, and in the original packing, and the batch identity is verifiable;

(b) the re-import is necessitated due to buyer rejection, quality grade mismatch, commercial non-acceptance, damage during transit, or any other reason not attributable to adulteration, tampering or manipulation after export;

(c) the exporter or manufacturer applies to the licensing authority for permission to re-import such therapeutic goods, under this rule, accompanied by:-

(i) export documents including invoice, packing list, shipping documents;

(ii) justification for re-import and supporting correspondence from the foreign buyer;

(iii) certificate of analysis;

(d) the licensing authority may, if necessary, order sampling, inspection or testing of the therapeutic goods upon entry or at the premises of the applicant;

(2) Nothing in these rules shall prohibit the re-import of Pakistani-manufactured therapeutic goods that are returned unchanged unless otherwise restricted under the Act, the DRAP Act and any rules and guidelines framed there under.

15. Procedure at customs-ports.- (1) No therapeutic good shall be released from the Customs unless a clearance certificate has been obtained by the importer from licensing authority or an officer authorized in this behalf.

(2) If the Collector of Customs or an officer authorized by him has reason to suspect that any therapeutic good does not comply with the provisions of the Act or the rules made there under, he may, or if requested by an officer authorised in this behalf by the Federal Government shall, take samples of any therapeutic good from the consignment and forward them to the officer incharge of the laboratory appointed for the purpose by the Federal Government and may detain the therapeutic good from the consignment which samples have been taken until the report of the officer incharge of the said laboratory on such samples is received:

Provided that if the importer gives an undertaking in writing not to dispose of the therapeutic good without the consent of the Collector of Customs and to return the consignment

or such portion thereof as may be required the Collector of Customs shall make over the consignment to the importer.

(3) If an importer who has given an undertaking under the proviso to sub-rule (2) is required by the Collector of Customs to return the consignment or any portion thereof, he shall return the consignment or portion thereof within ten days of receipt of the notice.

(4) If the officer incharge of the laboratory appointed for the purpose by the Federal Government reports to the Collector of Customs that the sample of any therapeutic good in a consignment do not conform to the specification or that the therapeutic good contravenes in any other respect the provisions of the Act or the rules made there under and that the contravention is such that it cannot be remedied by the importer the Collector of Customs shall communicate the report forthwith to the importer who shall within two months of his receiving the communication, either export all the therapeutic goods of that description in the consignment to the country from which they were imported or surrender them to the Federal Government for disposal in such manner as it may deem fit:

Provided that the importer may, within fifteen days of the receipt of the report make a representation against the report to the Collector of Customs who shall forward the representation with a further sample to the licensing authority which after obtaining, if necessary, the report of the officer incharge of the laboratory, shall pass order thereon which shall be final.

(5) If the officer incharge of the laboratory appointed for the purpose by the Federal Government reports to the Collector of Customs that the samples of any therapeutic goods contravene in any respect the provisions of the Act or the rule made there under and that the contravention is such that it can be remedied by the importer, the Collector of Customs shall communicate the report forthwith to the importer and permit him to import the therapeutic goods on his giving an undertaking in writing not to dispose off that therapeutic goods without remedying the said contravention.

(6) A Federal Inspector, or a person authorized in this behalf by the licensing authority may physically inspect the consignment and draw samples from each batch for test and analysis as may be necessary and, if the consignment has been released by the customs, may order the importer not to sell or offer for sale or dispose of the therapeutic goods for a reasonable period not exceeding three months with a view to obtain a test report:

Provided that the Federal Inspector, or such authorized officer by the licensing authority may prohibit the disposal of therapeutic goods for a longer period if he has sufficient reason to believe that the import, in any way, is in contravention of any of the provision of the Act of these rules in which case, the importer shall not dispose off that therapeutic goods until a certificate authorizing the sale of the batch has been issued to him.

16. Suspension and cancellations of licence to import therapeutic goods.- If the manufacturer or licencee fails to comply with any of the conditions of a licence to import therapeutic goods or violates any of the provisions of the Act or the rules made there under, the licensing authority may, after giving the licencee an opportunity of being heard, by in order in writing stating the reasons therefore, suspend or cancel the licence for such period as it thinks fit or cancel for all time, either wholly or in respect of sum of the therapeutic goods, to which it

relates, or , if the nature of offence is so serious that it is likely to endanger the public health, may prohibit the import of all other therapeutic goods of the said manufacturer.

CHAPTER III
EXPORT OF THERAPEUTIC GOODS

17. Export of finished therapeutic goods.- Finished therapeutic goods may be exported if the exporter possesses a licence to manufacture or sell by way of retail sale or wholesale with conditions as specified in the guidelines approved by the Authority.

18. Licence to export other than finished therapeutic goods.- A licence to export therapeutic goods shall be required in Form 9 in schedule B for the export of other than the finished therapeutic goods with conditions and requirements as specified in the guidelines approved by the Authority.

19. Application for licence to export therapeutic goods.- (1) An application for licence to export therapeutic goods shall be made to the licensing authority in Form 5 in schedule A and shall be accompanied by a fee as notified by the Authority under the Drug Regulatory Authority of Pakistan (Fee and Levy) Rules, 2022.

(2) An application for a licence to export small quantity of therapeutic goods, including therapeutic goods the export of which is otherwise prohibited under the Act, for the purpose of clinical trial, examination, test or analysis shall be made to the licensing authority in Form 6 in schedule B and the licensing authority may require such other particulars to be supplied as it may consider necessary.

(3) Any fee deposited shall in no case be refunded.

20. Duration of a licence to export therapeutic goods.- A licence to export therapeutic goods, unless earlier suspended or cancelled, shall be valid for two years:

21. Grant of export licence.- On receipt of an application for an export licence, the licensing authority or any officer authorized in this behalf shall, on being satisfied that, if granted, the conditions of the licence shall be observed, issue an export licence.

22. Export of therapeutic goods for the purposes of clinical trial, examination, test analysis or personal use.- Small quantities of therapeutic goods, including therapeutic goods the export of which is otherwise prohibited under the Act, may be exported for the purposes of clinical trial, examination, test, analysis or personal use with the written permission of the licensing authority or any officer authorized in this behalf.

23. Statement to accompany therapeutic goods for export.- All consignments of therapeutic goods sought to be exported shall be accompanied by an invoice or other statement showing the name and address of the manufacturer and the names and quantities of the therapeutic goods or any other information as required by licensing authority or any officer authorized in this behalf.

24. Export of therapeutic goods for donation.- (1) Therapeutic goods that are registered, enlisted, may be exported for the purpose of humanitarian aid or donation to a foreign country, subject to the prior written approval of the licensing authority or any officer authorized in this behalf with the conditions as specified in the guidelines approved by the Authority.

25. Re-export of rejected or defective imported therapeutic goods and other than finished therapeutic goods.- (1) Imported therapeutic goods and other finished therapeutic goods that are rejected, found defective, or not registered, or are otherwise unfit for use due to quality failure, damage, contamination, mislabeling, or any similar reason, may be re-exported to the original foreign supplier subject to conditions as specified in the guidelines approved by the Authority.

26. Procedure at customs port.- (1) No therapeutic good shall be released from the customs unless an export permit / No objection certificate has been obtained by the exporter from licensing authority or an officer authorized in this behalf.

(2) If the Collector of Customs or an officer authorized by him has reason to suspect that any therapeutic goods does not comply with the provisions of the Act or the rules made thereunder, he may, and if requested by an officer appointed for this purpose by the Federal Government shall, take samples of any therapeutic goods from the consignment and forward them to the officer incharge of the laboratory appointed for the purpose by the Federal Government and may detain the therapeutic goods from the consignment of which samples have been taken until the report of the officer incharge of the said laboratory on such samples is received:

Provided that if the exporter gives an undertaking in writing not to export or dispose of the therapeutic goods without the consent of the Collector of Customs and to return the consignment or such portion thereof as may be required, the Collector of Customs shall hand over the consignment to the exporter.

(3) If an exporter who has given an undertaking under the proviso to sub-rule (1) is required by the Collector of Customs to return the consignment or any portion thereof, he shall return the consignment or portion thereof within ten days of the receipt of the notice.

(4) If the officer incharge of the laboratory appointed for the purpose by the Federal Government reports to the Collector of Customs that the samples of any Therapeutic goods in a consignment do not conform to the specifications or that the therapeutic goods contravenes in any other respect the provisions of the Act or the rules made thereunder and that the contravention is such that it cannot be remedied by the exporter, the Collector of Customs shall communicate the report forthwith to the exporter who shall cause them to be destroyed or surrender them to the Federal Government for disposal in such manner as it may deem fit:

Provided that the exporter may, within fifteen days of the receipt of the report, make representation against the report to the Collector of Customs who shall forward the representation with a further sample to the licensing authority or, as the case may be, the registration board which after obtaining, if necessary, the report of the officer incharge of the Laboratory, shall pass orders thereon which shall be final.

(5) If the officer incharge of the laboratory appointed for the purpose by the Federal Government report to the Collector of Customs that the samples of any therapeutic goods

contravene in any respect the provisions of the Act or rules made thereunder and that the contravention is such that it can be remedied by the exporter, the Collector of Customs shall communicate the report forthwith to the exporter and permit him to withdraw the Therapeutic goods on his giving an undertaking in writing not to export that therapeutic goods without remedying the said contravention.

27. Suspension and cancellation of licence to export therapeutic goods.- If the manufacturer or licensee fails to comply with any of the conditions of licence to export therapeutic goods or violates any of the provisions of the Act or the rules made thereunder, the licensing authority may, after giving the licensee an opportunity of being head, by an order in writing stating the reasons therefore, suspend or cancel it for such period as it thinks fit or cancel for all times, either wholly or in respect of some of the therapeutic goods, to which it relates or, if the nature of offence is so serious that it likely to endanger the public health, may prohibit the export of the all other therapeutic goods of the said manufacturer.

28. **Appeal.-** Any person aggrieved by decision of the licensing authority may prefer an appeal before the Appellate Board of the Authority within a period of sixty days.

29. Sanction for prosecution.— (1) Prosecution for an offence under these rules shall be instituted before a Drug Court only with the prior sanction of the licensing authority, which, upon receipt of a case referred by a Federal Inspector of Drugs or any other officer authorized in this behalf by the licensing authority, shall, after examination of the inspection report, record, evidence, and relevant provisions of law, by a reasoned speaking order, determine the nature of the contravention and fix responsibility upon the person or persons liable.

(2) While granting or refusing sanction for prosecution, the licensing authority shall record reasons in writing and clearly specify the provisions of law alleged to have been violated.

(3) Where sanction for prosecution is granted, the speaking order along with the relevant record shall be forwarded to the Federal Inspector of Drugs or any other officer authorized in this behalf by the licensing authority for institution of proceedings before the competent Drug Court in accordance with law.

CHAPTER IV
MISCELLIANEOUS

30. Power to add or amend forms.— The Authority may, on the recommendation of the licensing authority add or amend Forms so as to omit any entry therefrom, add any entry thereto or amend any entry therein.

31. Repeal and savings.— (1) The Drugs (Import and Export) Rules, 1976 are hereby repealed.

(2) Notwithstanding such repeal,—

(a) anything done, action taken, licence, permit, approval, clearance certificate, authorization or permission granted under the repealed rules, insofar as it is not

inconsistent with the provisions of these rules, shall be deemed to have been done, taken, granted or issued under the corresponding provisions of these rules;

(b) any application, proceeding, inquiry 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;

(c) any licence or permission validly issued under the repealed rules and subsisting at the commencement of these rules shall continue to remain valid until its expiry, unless earlier suspended, cancelled or modified under these rules; and

(d) any guideline, notification, order or instruction issued under the repealed rules, to the extent not inconsistent with these rules, shall continue to have effect until altered, amended or rescinded by the Authority.

SCHEDULE-A

FORM 1

[See rule 6(1)]

APPLICATION FOR LICENCE TO IMPOT OTHER THAN FINISHED THERAPEUTIC GOODS

I / We …….hereby apply for import of therapeutic goods specified below manufactured by …….of ……

NAME OF THERAPEUTIC GOODS

I/We …… enclose herewith an undertaking in Form 2 signed by or on behalf of the manufacturer as required by these rules.

Date……(Signature)…….

Name and address of the applicant

FORM 2

[See rule 6(1)]

FORM OF UNDERTAKING TO ACCOMPANY AN APPLICATION FOR LICENCE TO IMPORT OTHER THAN FINISHED THERAPEUTIC GOODS

Whereas……..or……..intends to apply for a licence under these Rules, for the import into Pakistan of the therapeutic goods specified below manufactured by us, We….....of ……. hereby give this undertaking that:

(1) The said applicant has made a contract with us for import of therapeutic goods mentioned if the undertaking;

(2) We declare that we are bona fide licensed manufacturer of the therapeutic goods covered under this undertaking at the premises specified below and we shall report change, if any, in the said premises;

(3) We shall comply with the conditions imposed on a licence in the rules framed under the DRAP Act, 2012, the Drugs Act, 1976 and such other requirements as may be laid down by the Authority in this behalf;

(4) The therapeutic goods mentioned below conform(s) to the provisions of the DRAP Act, 2012, the Drugs Act, 1976 and any rules, policy and guideline framed thereunder.

NAME OF THE THERAPEUTIC GOODS

Particulars of the premises where manufacture is carried on ……

Date …….. Signature of the manufacturer ……..

FORM 3

[See rule 6(3)]

APPLICATION FOR LICENCE TO IMPORT THERAPEUTIC GOODS FOR THE PURPOSE OF CLINICAL TRIAL, EXAMINATION, TEST OR ANALYSIS

I/We……..of…….by occupation ….. ……hereby apply for a licence to import the therapeutic goods specified below, for the purpose of clinical trial, examination, test or analysis at…… …….and I/We undertake to comply with the conditions applicable to the licence under these Rules.

Name of Therapeutic goods(s) Quantities

Manufactured by …….
Date……(Signature)…….

Name and address of the applicant

FORM 4

BATCH CERTIFICATION

Name and registration number of therapeutic goods ……

Batch number of therapeutic goods …….

Name and address of the Manufacturer ……..

Date of Manufacture ……..

Date of expiry, if any ……..

It is hereby certified that the abovementioned therapeutic goods has/have been manufactured and labelled in conformity with the provisions of the DRAP Act, 2012, the Drugs Act, 1976, and the rules made thereunder.

It is further certified that this/these therapeutic goods has/have been manufactured under a valid permit/license issued by the competent authority.

Signed
Name, designation and official seal of the Signatory
Place and date

Name and Registration No. of therapeutic goods ……
Batch number, of therapeutic goods……
Name and address of the manufacturer ……..
Date of expiry, if any……

It is further certified that this/these therapeutic goods has /have been manufactured under a valid permit/licence issued by the competent authority.

Signed……
Name, designation & official seal
of the Signatory……
Place and date……

FORM 5

[See rule 19(1)]

APPLICATION FOR A LICENCE TO EXPORT THERAPEUTIC GOODS

I/We …… of …… hereby apply for a licence to export the therapeutic goods specified below manufactured by……. of …….

Name(s) of therapeutic goods

I/We…… of ……. hereby apply for a licence to export the therapeutic goods specified below manufactured by…… of…….

Name(s) of therapeutic goods

I/We …….. enclose herewith an undertaking inform 11 signed by the manufacturer / exporter as required by rules framed under the DRAP Act, 2012 and the Drugs Act, 1976.

Date……..
Exporter…….

FORM 6

[See rule 19(2)]

APPLICATION FOR EXPORT OF SMALL QUANTITIES OF THERAPEUTIC GOODS FOR THE PURPOSE OF CLINICAL TRIALS, EXAMINATION, TEST OR ANALYSIS

I/We……..of……hereby apply for permission to export the therapeutic goods specified below manufactured by ……of …….for the purpose of clinical trials, examination, test or analysis or for personal use.

Name(s) of therapeutic goods
Date……..
Exporter ……

SCHEDULE-B

FROM 7
[See rule 7]

LICENCE TO IMPORT THERAPEUTIC GOODS

Number of licence……M/s ……of……is/are hereby licensed to import into Pakistan during the period for which this licence is in force the therapeutic goods specified below manufactured by …….of……

2. This licence is subject to the conditions prescribed in the DRAP Act, 2012, the Drugs Act, 1976 and rules framed thereunder, and shall be in force for a period of two years from the date stated below unless it is sooner suspended or cancelled under the said Rules……

Name of therapeutic goods to which this licence applied

(1) .
(2) .
(3) .

Date ……

Licensing Authority

FORM 8

[See rule 8]

LICENCE TO IMPORT THERAPEUTIC GOODS FOR CLINICAL TRIAL EXAMINATION, TEST OR ANALYSIS

No. of licence ……..M/s ……..of is / are hereby licensed to import from……the therapeutic goods specified below for the purpose of clinical trial, examination, test or analysis at ……or in such other place as the licensing authority may from time to time authorize.

2. The licence is subject to the conditions prescribed in these Rules and such other condition as may be prescribed by the Authority in this behalf.

3. This licence shall, unless, previously suspended or cancelled, be in force for a period of two years from the date specified below:

Name(e) of Therapeutic goods(s) with quantities which may be imported.

Date…….. Licensing Authority

FORM 9

[See rule 9]

LICENCE TO EXPORT THERAPEUTIC GOODS

Number of license …….M/s ……..of…….is are hereby licensed to export during the period for which this licence is in force the therapeutic goods specified below manufactured……

(2) This licence is subject to the conditions prescribed in the Rules framed under the DRAP Act, 2012, the Drugs Act, 1976 and shall be in force for a period of two years from the date stated below unless it is sooner suspended or cancelled under the said rules.

Name(s) of therapeutic goods(s) to which the licence applied:
Dated……..

Licensing Authority

[No. F.13-1/2025-LA]

AAMAR LATIF,
Director (Legal Affairs).