**Government of Pakistan**
**Ministry of National Health Services, Regulations and Coordination**
**(Drug Regulatory Authority of Pakistan)**
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Islamabad, the 3rd January, 2020

## NOTIFICATION

The following draft of further amendments in the Drugs (Licensing, Registering and Advertising) Rules, 1976, 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), read with clause (a) of section 7 thereof and section 43 of the Drugs Act, 1976 (XXXI of 1976), are hereby published for the information of all persons likely to be affected thereby and, as required by sub-section (3) of said section 43, notice is hereby given that objections or suggestions thereon, if any, may for consideration of the Federal Government be sent within fifteen 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 AMENDMENTS

In the aforesaid Rules,-

(1) after chapter 4, following new chapter shall be added, namely,-

### "CHAPTER 5
### LICENSE FOR TEST AND ANALYSIS OF DRUGS ON CONTRACT

**37. License for test and analysis of drugs on contract.-** (1) An application for grant or renewal of a license for test and analysis of drugs on contract shall be made on Form 1-B to the Central Licensing Board addressed to its secretary and shall be accompanied with such fee as may be specified by the Authority with approval of the Policy Board.

(2) The applicant shall comply with the requirements of international guidelines issued by the World Health Organization and Pharmaceutical Inspection Co-operation Scheme, from time to time, for establishment of quality control laboratory for test and analysis of drugs on contract.

(3) Any fee deposited under sub-rule (1) shall not be refundable.

**38. Site verification and approval of the layout plan.-** An application for site verification or approval of layout plan or an application for extension or revision of layout plan, as the case may be, shall be accompanied with such fee as may be specified by the Authority with approval of the Policy Board. The area for establishment of quality control laboratory for test and analysis of drugs on contract shall not be less than 5000 square feet.

**39. License for more than one premises.-** (1) If test and analysis of drugs on contract is required to be conducted on more than one premises, a separate application shall be made and a separate license shall be issued in respect of each premises.

**40. Grant of licenses.-** (1) The Central Licensing Board, before issuing a license under rule 37, may inspect the premises itself or by its sub-committee or by a panel of

Inspectors or experts appointed by it for the purpose, which may examine all portions of the premises, plant and appliances, inspect the process of testing intended to be employed and the means to be employed for standardizing, if necessary, and analyzing testing methods and enquire into the professional qualifications of the technical staff employed.

(2) If the inspection under sub-rule (1) is carried out by a sub-committee or panel of experts of inspectors appointed under the said sub-rule it shall forward a detailed report to the Central Licensing Board. The Central Licensing Board, after such further enquiry, if any, as it may consider necessary, is satisfied that the requirements of the rules have been complied with, it may issue a license on Form 2-B:

Provided that if the Central Licensing Board is not so satisfied, it shall reject the application and shall inform the applicant of the reasons for such rejection and of the conditions which must be satisfied before a license may be issued:

Provided further that no application shall be entertained within three months of the rejection of an application. An application for license under Rule 37 is made after the expiry of three months from the date of rejection of an application, such application shall be treated as a fresh application and fee shall have to be deposited.

**41. Duration of license.-** A license issued under this chapter shall, unless earlier suspended or cancelled, be in force for a period of five years from the date of issue and may thereafter be renewed for periods of five years at a time and shall be renewed for further period of five years if application is made before period of expiry of validity accompanied with prescribed fee:

Provided that if application for renewal is made before the expiry of the validity of a license, the license shall continue in force until order is passed by the Central Licensing Board on such application. If an application for renewal is made after the expiry of the period of validity of a license but within ninety days of its expiry, the license shall continue to be in force on payment of additional surcharge of rupees ten thousand for each day the application is delayed, and thereafter until order are passed on such application.

**42. Renewal of license.-** (1) On receipt of an application for renewal of license, any objection or shortcoming in the application observed by the Central Licensing Board may be notified to the applicant and he shall be given a time period of thirty days for rectification or completion of the application. In case the applicant fails to rectify or complete the application within the specified period, the application shall deem to be rejected.

(2) If the application for renewal of the license is made after the expiry of the period of the validity of the license, it shall be treated as a fresh application for the grant of the license.

(3) On application being made for renewal, the Central Licensing Board may cause an inspection to be made, and if satisfied that the conditions of the license shall issue a certificate of renewal:

Provided that if directed by the Central Licensing Board, the licensee shall rectify the observations made during the inspection within a period which shall not be less than one month and more than three months from the date of receipt of orders in this regard and during this period the testing in that particular area or the premises, as the case may be, shall remain suspended and, until after re-inspection the Board grants renewal of license, or otherwise rejects the application and inform the licensee accordingly.

**43. Issuance of duplicate copy of license.-** Fee as notified by the authority shall be paid for duplicate copy of the license referred to in rule 37 if the original is defaced, damaged or lost. Such copy of the license shall bear the words "Duplicate Copy".

**44. Change of title or legal status or management of a licensee.-** For change of title or legal status or management of a licensee a fee specified for renewal of a license shall be paid and all legal documents shall be submitted to ascertain change of management as applicable.

**45. Cancellation or suspension of licenses.-** (1) If licensee does not comply with any of the conditions of a license or violates any of the provisions of the rules, or fails to deposit the requisite amount of the Central Research Fund due from him, the Central Licensing Board may, by an order in writing stating the reasons thereof, cancel a license or suspend it for such period as it thinks fit, either wholly or partially:

Provided that in case of non-deposition of Central Research Fund, the license may be suspended till the settlement of the Fund. The Licensee shall deposit CRF as provided in Rule 19 and no exception shall be applicable.

(2) The Central Licensing Board shall, before cancelling or suspending a license under sub-rule (1), conduct an inquiry into the case and provide an opportunity of being heard to the licensee.

(3) When a license is cancelled or suspended, an entry to that effect shall be recorded on the license.

(4) A licensee whose license has been cancelled or suspended may appeal to the Appellate Board within sixty days of the date of receipt of the decision of the Central Licensing Board by the licensee and until the Appellate Board has given its order, the license shall remain cancelled or suspended, as the case may be.

**46. Conditions for the grant or renewal of license for test and analysis off drugs on contract.-** Before a license for test and analysis of drugs on contract is granted or renewed, the Central Licensing Board shall satisfy itself that the following conditions are being complied with by the applicant, namely:-

(a) the laboratory premises shall comply with the conditions of quality control department specified in B and B-II; and

(b) the testing shall be conducted under the active directions and personal supervisions of competent technical staff (being the Quality Control Incharge) consisting of at least one person who is a whole-time employee and who has a degree in pharmacy with minimum six years experience in testing of type of drugs intended to be tested, or a master degree in science with chemistry with minimum ten years experience in testing of type of drugs intended to be tested:

Provided that for pharmacological testing there shall be an additional employee who shall possess a degree in pharmacy or a master degree in pharmacology and shall have minimum six years experience in testing of type of drugs intended to be tested, and for microbiological testing, there shall be an additional employee who shall posses a degree in pharmacy or a master degree in Microbiology and shall have minimum six years experience in testing of type of drugs intended to be tested.".

(2) In the schedule A, after Form 1-A, the following new form shall be inserted, namely:-

**"FORM-1B**
*[See rule 37(1)]*

**APPLICATION FOR GRANT / RENEWAL OF LICENCE FOR TEST AND ANALYSIS OF DRUGS ON CONTRACT BASIS**

I/We _____ of _____ hereby apply for the grant/renewal of a Licence for test and analysis of drugs on contract on premises situated at _____.

1. The drug (s) or class (es) of drugs intended to be tested: -
   (a) Name (s) and class (es) of drugs.
2. I enclose: -
   (i) Particulars regarding legal status of the applicant (i.e. in case of proprietorship the name(s) of proprietors and their address (es), in the case of firm the name and names and addresses of its partners and in the case of company the name and address of the company and its directors) (In case if firm is Private Limited, the Certificate of Incorporation with SECP, Memorandum of Article of Association, Form-A and Form-29(updated)issued from Securities &Exchange Commission of Pakistan , In case of partnership, copy of Partnership deed duly executed in the court of competent jurisdiction/registrar of the firms, Form-C, In case of Sole proprietorship the firm must provide undertaking on affidavit as a Sole proprietor. Copy (ies) of CNIC of Chief Executive Officer / Managing Director /Directors/ Partners of the firm).

   (ii) Details of the premises including layout plan of the premises(endorsement letter issued from Licensing Division).
   (iii) Details of equipment and machinery.
   (iv) Names and qualification of the Qualified persons for supervising testing of drugs and primary packaging materials and other technical staff(Detail of pharmacist along with required documents).
3. No Objection Certificate for Central Research Fund (CRF) issued by Division of Budget &Accounts DRAP, Islamabad (Updated in case of Renewal application).
4. Copy of Licence for test and analysis of drugs on contract basis (in case of renewal application).
5. The premises will be ready for inspection on ……. or are ready for inspection.

Date……..Signed…….

Place ……. Name, designation and address of the signatory

……

(3) In the schedule A, after Form 2-A, the following new form shall be inserted, namely:-

**"FORM-2B**

*[See rule 40(2)]*

GOVERNMENT OF PAKISTAN

DRUG REGULATORY AUTHORITY OF PAKISTAN

**LICENCE FOR TEST AND ANALYSIS OF DRUGS ON CONTRACT BASIS**

_____

___ is /are hereby licensed to test and analysis of pharmaceuticals on contract at the following premises:-

_____

2. This license permits the test and analysis of pharmaceuticals on contract manufacture.

3. This licence shall, in addition to the conditions specified in the rules made under the Drugs Act 1976, be subject to the following conditions, namely:-

i. The licence will be in force for a period of five years from the dated of issue unless earlier suspended or cancelled.
ii. The licence authorizes the test and analysis of drugs and primary packaging material on contract basis.
iii. Names of approved expert staff.

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_____Quality Control Incharge_____

Date of issue/renewal:_____

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|---|---|---|
| Secretary,<br>Central Licensing Board | Seal | Chairman,<br>Central Licensing Board" |

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