To be published in the extra ordinary Gazette of Pakistan, Part-II

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

Islamabad, the 4th June, 2021.

NOTIFICATION

S.R.O. 421(I)/2021.— 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), is hereby published for the information of all persons likely to be affected thereby and, as required by sub-section (3) of section 43 of the said Act (XXXI of 1976), 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 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 Federal Government.

DRAFT AMENDMENTS

In the aforesaid Rules,--

(1) for rule 20A, the following shall be substituted, namely: --

"**20A. Contract manufacture.**— (1) Manufacture or analysis on contract either for local sale or export purpose is permissible on behalf of any of the following contract givers:-

(a) a licensed pharmaceutical manufacturer having license to manufacture by way of formulation; or

(b) an importer for its already registered drug products in Pakistan for permission from finished drug product import to contract manufacturing by a licensed pharmaceutical manufacturer; or

(c) a foreign pharmaceutical company (manufacturer or marketing authorization holder) having Drug Sale License in Pakistan for drug products already registered for sale in any country; or

(d) a special case and for genuine reasons, including break down, renovation, up-gradation, as may be determined by the Registration Board;

Provided that the contract manufacturing under this clause shall be for a period of thirty months extendable for a further period of twenty four months by the Registration Board on valid grounds.

(2) The provisions of sub-rule (1) shall be subject to the following conditions, namely: -

(a) the provisions of rule 26, 27, 28, 29 and 30 *mutatis mutandis* apply;

(b) contract manufacturing shall be allowed between human to human and veterinary to veterinary drugs only;

(c) contract manufacturing of controlled drugs (narcotic drug or psychotropic substances or precursor chemicals) shall not be allowed;

(d) contract manufacturing shall also be subject to the conditions laid down in Schedule-H."; and

(2) for Schedule-H, the following shall be substituted, namely: -

"SCHEDULE-H

1. Contract production and analysis.--

1.1 Contract manufacture or analysis shall be undertaken by a manufacturer (contract acceptor) that holds a valid drug manufacturing license and shall have adequate manufacturing, quality control and quality assurance facilities, knowledge, experience and competent personnel to satisfactorily carry out the manufacture or analysis of registered drug product.

1.2 For sale in Pakistan, relevant provisions of Drugs Act, 1976, DRAP Act, 2012 and rules framed thereunder shall be followed. For manufacturing of products for export purpose, manufacturing and analysis may be carried out as per product specification given by the contract giver.

1.3 There shall be a written Quality agreement between contract giver and contract acceptor (drawn by the people having suitable Knowledge in manufacturing, quality control and quality assurance Requirements). The contract shall clearly establish the duties of each party. The quality Management system of contract giver must clearly state responsibilities and the way in which the authorized person of each party shall exercise full responsibility in releasing each batch of product for sale or issuing the certificate of analysis. A copy of such contract shall be provided along with registration application.

1.4 The contract shall have explicit provision for auditing the facilities of the contract acceptor and contract giver at any time to ensure that manufacturing or analysis of contracted products are being done as per specifications and the contract.

1.5 Approval for release to sell the product shall be given by the authorized person(s) as mentioned in the contract. This authorization shall be in addition to the product released by the contract manufacturer.

2. Contract giver.--

2.1 The contract giver before submission of application for contract manufacturing permission shall be responsible for assessing the legality, suitability and competence of the contract acceptor in successfully carrying out the work or tests required and for ensuring that the principles of good manufacturing practices are followed. This assessment report shall be a part of contract manufacturing or analysis application submitted to the Registration Board.

2.2 Upon receiving of contract manufacturing or analysis application, the Registration Board may cause to inspect the manufacturing or analysis facility of contract acceptor by a panel of experts as determined by the Board to verify the report submitted by contract giver, evaluation of cGMP compliance for manufacturing, quality control, validation, stability and storage facilities of both contract giver and contract acceptor etc.

2.3 The contract giver shall provide the contract acceptor with all the information necessary to carry out the contracted operations correctly in accordance with the registration and any other legal requirements and the contract giver shall ensure that the contract acceptor is fully aware of any problem associated with the product, work or tests that might pose a hazard to premises, equipment, personnel, other materials or other products. Contract giver shall ultimately be responsible to ensure that processes are in place and complied with during contract manufacturing period and shall inform Registration Board in case of any breach of any facility of the contract.

2.4 The contract giver shall ensure that all processed products and materials delivered by the contract acceptor comply with their specifications or that the product has been released by the authorized persons.

3. Contract acceptor.—

3.1 The contract acceptor must have adequate premises, equipment, knowledge, facilities, experience and competent personnel to carry out satisfactorily the work ordered by the contract giver.

3.2 The contract acceptor shall not pass to a third party any of the work entrusted to him under the contract without the written consent of the contract giver and arrangements made between the contract acceptor and any third party shall ensure that the manufacturing and analytical information is made available in the same way as between the original contract giver and contract acceptor.

3.3 The contract acceptor shall refrain from making any change outside the terms of the contract or any activity that may adversely affect the quality of the product manufactured, packed and analyzed for the contract giver.

3.4 Any change required in manufacturing process, raw or packaging material by the contract acceptor shall be made through a change control mechanism approved by both contract giver and acceptor and properly validated through required processes like stability testing, validation etc. before the product is produced after change and is released for sale.

3.5 Contract acceptor is responsible for keeping the record of production and analysis. Both the contract giver and the contract acceptor shall retain sufficient number of samples of each batch to allow double testing of product, till the expiry of the product for reference. The record shall be made accessible to the contract giver or Registration Board or any other investigating agency etc. at all times for the purpose of compliance to law.

3.6 Contract manufacturer shall submit details of production of each batch of drug manufactured under contract on Form-7 to the Registration Board quarterly, as required by Drugs (Licensing, Registering and Advertising) Rules, 1976.

3.7 In case of change of source of raw material and machinery by the contract manufacturer, proper validation and stability study shall be conducted and recorded for cGMP compliance.

4. The contract.—

4.1 A contract shall be drawn up between the contract giver and contract acceptor that shall specify their respective responsibilities including but not limited to procurement, import, sampling, analysis, manufacture, quality control including in-process controls, quality assurance, quality management system, market release, knowledge management, technology transfer, supply chain, record keeping, retention samples, complaint handling, pharmacovigilance, rejection, recall, compliance to local regulations and laws under the Drugs Act, 1976, DRAP Act, 2012 and rules framed thereunder. However, import of raw materials is the responsibility of contract acceptor.

5. Miscellaneous.—

5.1 Fee for grant, renewal/extension and pre and post registration variation in contract manufactured products shall be applicable as levied by Authority with the approval of Policy Board. Fee for grant of registration for export purpose only shall be thirty thousand rupees per product.

5.2 Contravention to any provision of the Drug Regulatory Authority of Pakistan Act, 2012, Drugs Act, 1976 and rules made there under including Schedule-H, or any condition of registration by the contract giver or contract acceptor shall be placed before the Registration Board for appropriate decision as per law.

5.3 If any drug manufactured on contract basis is found or reported in contravention of any of the provisions of Drugs Act, 1976 and rules made thereunder, then both the contract giver and acceptor shall be liable to any action under the said Act and rules.

5.4 Apart from compliance to Drug (Labeling & Packaging) Rules 1986, name, address, and DML (in case of manufacturer) / DSL number (in case of foreign pharmaceutical company) of contract giver, shall also appear on all labels and packaging materials.

5.5 Contract manufactured products registered for export purpose shall not be permitted for sale in Pakistan. In case of violation, contract manufacturing permission shall be withdrawn in addition to other legal proceedings. Moreover, exporter shall also furnish confirmation about receiving of stock in importing country after export.

5.6 Change of contract manufacturer shall be allowed during contract period only on genuine reasons including Force Majeure, the fee for this shall be seventy five thousand rupees per product. New contract manufacturer shall ensure the stability and validation of the product and all other quality assurance specifications. If the previous contract manufacturer is still manufacturing the drug after change of its status, then it would be treated as spurious drug and would be dealt with under relevant provision of the Drugs Act, 1976 or the Drug Regulatory Authority of Pakistan Act, 2012.".

[File No.1-13/2013/DDG(Reg-I)]

AAMAR LATIF,
Deputy Director (Legal Affairs).