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

Islamabad, the 15th October, 2021.

NOTIFICATION

S.R.O. 1347 **(I)/2021.**– 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), the Drug Regulatory Authority of Pakistan, with the approval of the Federal Government, is pleased to direct that in the Drugs (Licensing, Registering and Advertising) Rules, 1976, the following further amendments shall be made, the same having been previously published vide Notification No. S.R.O. 421(I)/2021, dated the 4th June, 2021 as required by sub-section (3) of the said section 43, namely:--

In the aforesaid Rules,--

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

"**20A. Contract manufacture.**— (1) Manufacture or analysis, through contract, either for local sale or export purpose, shall be permissible by contract giver if:-

(a) a licenced pharmaceutical manufacturer having licence 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 licenced pharmaceutical manufacturer; or

(c) a foreign pharmaceutical company (manufacturer or marketing authorization holder) having drug sale licence in Pakistan for their research, innovator, originator drug products or drug products already registered for sale by any of reference regulatory authorities adopted by the Registration Board; or

(d) licenced pharmaceutical manufacturing unit, which is granted a certificate by Registration Board to the effect that the unit is unable to maintain its production or output level due to reasons beyond its control, including but not limited to repair or upgradation requirements:

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 shall *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; and

(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 licence 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 the Drugs Act, 1976, the Drug Regulatory Authority of Pakistan 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 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.

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.