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PART II

Statutory Notifications (S.R.O.)

GOVERNMENT OF PAKISTAN

MINISTRY OF NATIONAL HEALTH REGULATION SERVICES AND COORDINATION

(Drug Regulatory Authority of Pakistan)

NOTIFICATION

Islamabad, the 4th March, 2014

S.R.O. 152 (I)/2014.—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 Drug Act, 1976 (XXXI of 1976), the Drug Regulatory Authority of Pakistan, with the approval of the Federal Government is pleased to direct that the following further amendments shall be made in the Drugs (Licensing, Registering and Advertising) Rules, 1976. The same having been previously published *vide* Notification No. SRO 1086 (I)/2013 dated 2nd January, 2014 as required by sub-section (3) of the section 43, namely:—

In the aforesaid Rules,—

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

"20A. **Contract manufacture.**—(1) Manufacture or analysis on contract is permissible on behalf of a licensee or of a licensed

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pharmaceutical company whose products are registered for sale in Pakistan or as may be registered by the Registration Board and for the purposes including the following categories, namely:—

(a) for encouraging local production of imported drugs;

(b) for meeting export requirements of a local manufacturer or a foreign pharmaceutical company, provided that a drug manufactured under this arrangement shall not be sold in Pakistan; and

(c) as 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 not exceeding thirty months;

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

(a) The Provisions of rule 29 *mutatis mutandis* apply;

(b) Contract manufacturing shall be allowed only on the basis of similar category of drugs including human to human, veterinary to veterinary, cotton to cotton, medical devices to medical devices or as the case may be, etc;

(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-G, the following shall be substituted, namely:-

"SCHEDULE H

1. **Contract production and analysis.—**

1.1. Contract of manufacture or analysis shall be undertaken only by a manufacturer that holds a valid drug manufacturing licence and the contract acceptor shall have adequate facilities, knowledge, experience and competent personnel to satisfactorily carry out the work ordered by the contract giver.

1.2. General- contract production and analysis shall be correctly defined, agreed and controlled in order to avoid mis-understandings that could result in a product or work or analysis of un-satisfactory quality.

1.3. All arrangements for contract manufacture and analysis, including any proposed changes in technical or other arrangements, shall be in accordance with the regulation in force and condition of registration of the drug concerned if it is for sale in Pakistan. In case of a foreign pharmaceutical company getting its products manufactured in Pakistan the manufacturing specification shall be the responsibility of the contract giver however a copy of such specifications shall be provided to the Registration Board for the purpose of information.

1.4. There must be a written contract (drawn by the people having suitable knowledge in pharmaceutical technology, analysis and cGMP requirements) between the contract giver and the contract acceptor that 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 his full responsibility in releasing each batch of product for sale or issuing the certificate of analysis and a copy of such a contract shall be supplied to the Registration Board.

1.5. 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.

1.6. In the case of contract analysis, final approval for release must be given by the authorized persons.

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