



F.No. 1-2/2022-DMC
Government of Pakistan
Ministry of National Health Services, Regulations and Coordination
(Drug Regulatory Authority of Pakistan)
TF Complex Sector G-9/4

Islamabad the 13th June, 2023

NOTIFICATION

Subject: - Applications for contract manufacturing.

I am directed to refer to the subject captioned above. Registration Board in its 324th meeting held on 24-26 January, 2023 deliberated on the above agenda item to facilitate the registration applicants in submission of their applications on Form 5F and to streamline the assessment process without compromising on safety, efficacy and quality aspects of applied products.

2. The registration Board decided that the applicant shall submit an application of contract manufacturing of Human Pharmaceutical drug products with a covering letter, fee challan, filled and signed Form 5F (Module 1). For modules (2-5), the applicant shall refer to the previous approval of the Registration Board (on Form 5F) of same formulation with the product development and stability studies data from same manufacturing site with the condition that:

- i. Applicant shall submit a declaration that they will adopt the same source of drug substance, drug product formulation, specifications and container closure.
- ii. In case of any post-registration variation by the contract manufacturer, same shall be immediately applied by the applicant/ registration holder for requisite approval by Registration Board as per "Post Registration Variation Guideline for Pharmaceutical and Biological Products", available on DRAP's official website.
- iii. Applicant shall refer along with the extract of relevant minutes of Registration Board for the previous approval of the applied drug product on Form 5F from same manufacturer.

3. DRAP Authority in its 161st meeting held on 5th and 6th April 2022 decided to endorse exemption as specified above alongwith respective conditions.

cc

4. Accordingly, above decision of the Registration Board and Authority is hereby circulated for information and compliance by all relevant stakeholders / applicants.


(ASIF JALIL)
Deputy Director (PE&R) /
Incharge PEC

Distribution:

- i. Chairman, Pakistan Pharmaceutical Manufacturer's Association, Islamabad.
- ii. Executive Director, Pharma Bureau, Karachi.
- iii. Executive Director, Pakistan Chemist & Druggist Association, Karachi.

Through E-Office:

- i. PS to CEO DRAP, Islamabad.
- ii. Director (PE&R)/ Chairman, Registration Board.
- iii. Director (MIS), DRAP for uploading on DRAP's website.
- iv. Additional Director / Officer In-charge DRAP Karachi, Lahore, Islamabad, Peshawar, Quetta for circulation to pharmaceutical units located in their respective area of jurisdiction.


13/06/2023
Deputy Director (PE&R) /
Incharge PEC