No.F.3-2/2005-Reg-I/(Vol-II)
Government of Pakistan
Ministry of National Health Services, Regulations and Coordination
Drug Regulatory Authority of Pakistan
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Islamabad, the 06th July, 2022

CIRCULAR

SUBJECT: - **POLICY FOR INSPECTION OF MANUFACTURERS ABROAD FOR REGISTRATION OF FINISHED DRUGS AND BIOLOGICALS**

I am directed to refer to the subject cited above. Policy Board of the Drug Regulatory Authority of Pakistan (DRAP) in its various meetings has given policy guidelines for exemption of inspections of manufacturers abroad in certain scenarios. The Board in its 40th meeting held on 09th March 2022 again deliberated the matter and keeping in view the suggestions/guidelines of WHO for reliance on other regulatory authorities, decided to further expand the scope of exemptions of foreign inspections. Accordingly, the revised "Policy for inspections of manufacturers abroad" as approved by the Policy Board under Section 11 (1) (a) of the DRAP Act, 2012, is as under:

"a. Dosage form specific inspection of manufacturer abroad shall be carried out before grant and renewal of registration. However, products fulfilling below mentioned criteria are exempted from dosage form specific inspection of manufacturer abroad:

- **Any product approved by drug regulatory authorities of United States of America, Japan, Australia, Canada, UK, Germany, France, Switzerland, Netherlands, Austria, Belgium, Denmark, Finland, Sweden, Italy, Ireland, Luxemburg, Norway, Scotland, Spain and European Medicines Agency.**
- **Any product having approval of minimum three drug regulatory authorities of former Eastern Europe.**
- **Any product's manufacturer having GMP certificate (for applied dosage form facility) available on EUDRA-GMDP website. (http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do)**
- **Any WHO prequalified product and manufacturing facility (section) of such product.**
- **Any product approved by Pharmaceutical Inspection Co-operation Scheme (PIC/S) Participating Authority and manufacturing facility (section) of such product. (https://picscheme.org/en/members).**
- **Manufacturing site/facilities conformed to the regulatory inspection by any of the PIC/S Participating Authority.**

b. For cases not fulfilling the abovementioned exemption criteria, following mechanisms for inspection shall be adopted by DRAP in order of priority:

- **Third party audit/inspection on the expense of the applicants and/or**
- **Virtual/Onsite inspection of the manufacturers abroad by DRAP."**

2. In case of suspension or cancellation of registration of the product by exporting country or delisting of WHO-PQ status or suspension/cancellation by PIC/S Participating Authority, the registration holders shall be bound to inform the Registration Board about such suspension or cancellation within fifteen days. In case of non-compliance, the Registration Board may take action as per law against the importer, which may also lead to suspension/cancellation of registration of such product.

3. It is hereby circulated for compliance and information of all stakeholders.

Muhammad Sarfraz Nawaz
Assistant Director (I&V-I&II)

Distribution: -

i. Chairman, Pakistan Pharmaceutical Manufacturers Association, Islamabad.
ii. Executive Director, Pharma Bureau, Karachi.
iii. Executive Director/Chairman, Pakistan Chemist & Druggists Association (PCDA), Karachi.
iv. Director, MIS Division, with the request to upload on DRAP website.

Copy for information to: -

1. Director, Pharmaceutical Evaluation & Registration, DRAP, Islamabad.
2. Director, Biological Evaluation & Research, DRAP, Islamabad.
3. PS to Chief Executive Officer, DRAP Islamabad.
4. Office File.