भारतीय भेषजसंहिता आयोग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार
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INDIAN PHARMACOPOEIA COMMISSION
Ministry of Health & Family Welfare, Government of India
Sector 23, Raj Nagar
Ghaziabad 201 002 (U.P.), INDIA

डा. राजीव सिंह रघुवंशी
सचिव-सह-वैज्ञानिक निदेशक

Dr. Rajeev Singh Raghuvanshi
Secretary-cum-Scientific Director

No. T.11013/02/2018-AR&D

Dated: February 4, 2022

NOTICE

Subject: Ensuring Use of Indian Pharmacopoeia Reference Standards and Impurity Standards for Quality Testing of Drugs-reg.

In order to fulfill the requirements of the Drugs and Cosmetics (D&C) Act, 1940 and Rules 1945 there under, Ministry of Health & Family Welfare, Government of India has entrusted Indian Pharmacopoeia Commission (IPC) with mandates of publishing the Indian Pharmacopoeia (IP) at regular intervals along with the certification and distribution of IP Reference Standards (IPRS) and Impurity Standards.

2. IPRS are specifically required for establishing conformance to the IP standards. An IPRS, being an integral and essential component of the IP standard, is an official standard that alone is authoritative in assessing the quality of drugs and use of any unauthorised Reference Standard is a noncompliance of the IP standards.

3. Moreover, as per the Schedule M of the D&C Act, Part I, Quality Control System (16.14) - "Pharmacopoeia reference standards, working standards, references, spectra, other reference materials and technical books, as required, shall be available in the Quality Control Laboratory of the licensee".

4. IPC has been making efforts to promote the use of IPRS and Impurity Standards by the manufacturers and testing laboratories and steps are being taken to stop the use of unauthorized standards in quality control testing.

5. However, despite all these efforts, the current trends of the sale of IPRS and Impurity Standards from IPC do not match with the number of pharmaceutical manufacturers and testing laboratories in India. Rather, it has been observed that there is a tendency among the stakeholders to procure unauthorised Reference Standards from dubious sources and to use them in routine drug analysis.

6. Using unauthorised Reference Standards is an illegal act in accordance with the provisions of the Drugs and Cosmetics Act 1940. Also, such malpractices could be the cause of manufacture and marketing of counterfeit/spurious drugs in India which may have serious consequences on the health of its citizens.

7. In order to further ensure the use of authentic IPRS and Impurity Standards, IPC has taken an initiative to trace the details of the Reference Standards being used in quality control analysis by different stakeholders and to share with IPC necessary information w.r.t. purchase of IPRS and Impurity Standards.

8. Stakeholders are encouraged to purchase authentic IPRS and Impurity Standards by visiting IPC website (www.ipc.gov.in).

Yours sincerely,

(Dr. Rajeev Singh Raghuvanshi)

Copy to:

(i) Joint Secretary (Regulation), Ministry of Health & Family Welfare, Govt. of India, New Delhi 110 011.

(ii) The Drugs Controller General (India) with a request to ensure use of authentic IPRS and Impurity Standards.

(iii) All State Drug Controllers with a request to ensure use of authentic IPRS and Impurity Standards.