

डा. राजीव सिंह रघुवंशी
सचिव-सह-वैज्ञानिक निदेशक

Dr. Rajeev Singh Raghuvanshi
Secretary-cum-Scientific Director

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

Dated: 10th January, 2022

NOTICE

Subject: Promoting Use of Authentic Copies of the Indian Pharmacopoeia 2018 and its Addenda 2019 & 2021-reg.

In order to fulfill the requirements of the Drugs and Cosmetics (D&C) Act, 1940 and Rules 1945 there under, Indian Pharmacopoeia Commission (IPC) has published the Indian Pharmacopoeia (IP) 2018 and its Addenda 2019 & 2021 on behalf of the Ministry of Health & Family Welfare, Government of India.

2. IPC has been making efforts to promote the use of authorized copies of the IP by its stakeholders and steps are being taken to stop the use of unauthorized copies of the IP. In this regard, the Drugs Controller General (India) vide letter No.12.01/18-DC (Pt-241) dated 24-09-2018 instructed CDSCO Zonal/Sub-zonal Offices as well as all State/UT Drugs Controllers to ensure the availability of authenticated copies of IP 2018 during inspection of manufacturing premises/laboratories.

3. Moreover, as per 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. However, despite all these efforts, the current trends of the sale of IP 2018 and its Addenda do not match with the number of pharmaceutical manufacturers, testing laboratories, and other stakeholders of the IP in the country. Rather, it has been observed that there is tendency among some of the stakeholders to procure counterfeit copies of the IP from dubious sources.

5. Using counterfeit copies of the IP is an illegal act as IP is being published by the IPC on behalf of the Govt. of India and making its copy is an offence under the Copyright Act. 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.

6. In order to further promote the use of authentic copies of IPC publications, IPC has taken an initiative to trace the details of sold IP sets and letters have been issued to various stakeholders to share with IPC necessary information w.r.t. purchase of IP 2018 or its Addenda. In addition, necessary actions are being taken to stop use of counterfeit copies of the IP.

7. Stakeholders are encouraged to purchase their authentic copies of IP 2018 or its Addenda 2019 & 2021 by visiting IPC website (www.ipc.gov.in) for further details in this regard.

Yours sincerely,


(Dr. Rajeev Singh Raghuvanshi)

Copy to:

- Registrar of Copyrights, Copyright Office, Boudhik Sampada Bhawan, Plot No. 32, Sector 14, Dwarka, New Delhi 110 078.
- Joint Secretary (Regulation), Ministry of Health & Family Welfare, Govt. of India, Nirman Bhawan, New Delhi 110 011.
- The Drugs Controller General (India), Central Drugs Standard Control Organization, FDA Bhawan, Kotla Road, New Delhi 110 002.