Indian Pharmacopoeia Commission: A Decade of Excellence in Pharmaceutical Standardization and Vigilance

Dear Readers,

Dr. G. N. Singh
Secretary-cum-Scientific Director
Indian Pharmacopoeia Commission

I am delighted to share with you that on January 1, 2019 Indian Pharmacopoeia Commission (IPC) has successfully completed a decade of its glorious existence and we are celebrating the 10th anniversary of IPC this year. IPC came into existence on January 1, 2009 as an autonomous Institution under the Ministry of Health & Family Welfare, Government of India and is entrusted with the mandate to perform, *inter-alia*, functions such as revision and publication of the Indian Pharmacopoeia and National Formulary of India on a regular basis, besides providing IP Reference Substances and training to the stakeholders on pharmacopoeial issues. In addition, IPC has also been working as the National Coordination Centre for Pharmacovigilance Programme of India.

The Commission has a three-tier structure, comprising the General Body, the Governing Body and the Scientific Body, which are supported by the IPC Secretariat and the Indian Pharmacopoeia Laboratory (IPL). IPC has the vision "*to promote the highest standards of drugs for use in human and animals within practical limits of the technologies available for manufacturing and analysis*" and mission "*to promote public and animal health in India by bringing out authoritative and officially accepted standards for quality of drugs including active pharmaceutical ingredients, excipients and dosage forms, used by health professionals, patients and consumers*". In order to realise its vision and mission, the IPC Secretariat and the scientists of IPL work closely with different advisory Expert Working Groups and the Scientific Body.

Indian Pharmacopoeia (IP)

IPC exclusively deals with matters relating to timely publication of the Indian Pharmacopoeia (IP) which is the official book of standards for drugs included therein, in terms of the Second Schedule to the Drugs and Cosmetics Act, 1940 and Rules 1945 made thereunder so as to specify the standards of identity, purity and strength for the drugs imported, manufactured for sale, stocked or exhibited for sale or distributed in India. The IP Standards are authoritative in nature and are enforced by the Regulatory Authorities for quality control of medicines in India. During quality assurance and at the time of dispute in the court of law, IP standards are legally acceptable.

In 1948, the Indian Pharmacopoeia Committee was constituted with the mandate of publication of IP and the journey of publication of IP editions in chronological order is given below.

Journey of Publication of Indian Pharmacopoeia Editions, Addenda and Supplements

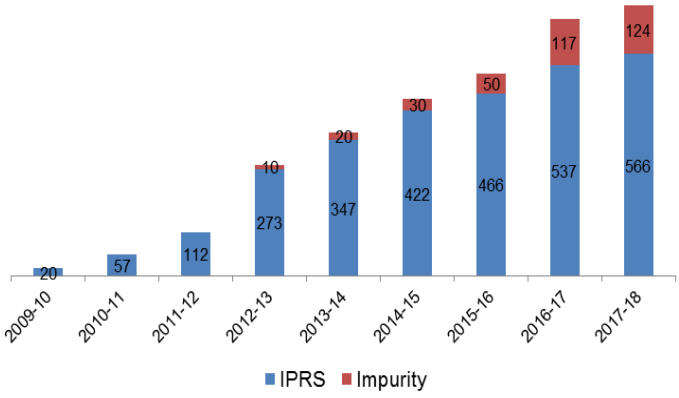
Release of IP 2018 by Sh. C. K. Mishra, the then Secretary, Health & Family Welfare, Government of India

Recently, IPC came up with the eighth edition of IP 2018 in four volumes which has been released by the Secretary, Ministry of Health and Family Welfare, Government of India.

The standards prescribed in IP adhere to the concept of harmonization, keeping in view the technological advancements in manufacturing and analysis of the drugs and pharmaceuticals in the country and abroad without compromising with the quality of the products. It strives to update the existing monographs as well as incorporate the new monographs of drug substances and drug formulations as per the specified inclusion and exclusion criteria.

IP Reference Substances (IPRS)

IPC also has the mandate to accelerate the process of preparation, certification and distribution of IPRS which are highly characterized substances that are used in the official methods prescribed in IP for the purpose of comparison to ensure the identity, purity, strength and quality of drug substances and drug products. They are also used by the stakeholders to qualify the working standards used for routine analysis in the laboratories such as for quantitative (e.g. assay and impurity) and qualitative (e.g., identification) analysis. IPRS characterization involves collaborative processes and additional procedures other than those used in routine testing. The information on the IPRS and impurities available with IPC and the procedure for their purchase is displayed on our website (www.ipc.gov.in).



Development of IPRS and Impurities by IPC

National Formulary of India (NFI)

NFI serves as a guidance document to medical practitioners, pharmacists working in hospitals and in sales establishments, nurses, medical and pharmacy students, and other healthcare professionals/stakeholders in healthcare system. The principal objective of NFI is to promote rational use and economic prescribing of medicines in the country. The Ministry of Health and Family Welfare, Government of India has assigned this mandatory responsibility to the IPC to publish NFI on regular basis and most recently IPC came out with the publication of NFI 2016. NFI includes general chapters, appendices and specific monographs of

Release of NFI 2016 by Sh. J. P. Nadda, Hon'ble Minister of Health & Family Welfare, Government of India in the presence of Gen. (Dr.) V. K. Singh (Retd.), Minister of State for External Affairs, Government of India

medicines listed in the National List of Essential Medicines, medicines commonly prescribed by clinicians, medicines for use in National Health Programmes and National Health Missions in the country, drugs listed in IP and other drugs considered appropriate by the experts. The specific monographs contain Pregnancy categories, indications, availability and dosages, contraindications, precautions, adverse effects and storage requirements etc.

Pharmacovigilance Programme of India (PvPI)

Since April 2011 IPC has been entrusted with the responsibility as the National Coordination Centre for Pharmacovigilance Programme of India (NCC-PvPI) with the aim of improving patient safety by monitoring drug safety and thereby reducing the risks associated with the use of medicines. Taking note of the quality of work in Pharmacovigilance, World Health Organization (WHO) has recognized the NCC-PvPI as the sixth global "WHO-Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services".

Inauguration of WHO Collaborating Centre for Pharmacovigilance by Dr. R. K. Vats, the then Additional Secretary, Health & Family Welfare, Government of India in presence of WHO officials

The major functions of NCC are to collect, collate and analyse adverse drug events and Adverse Drug Reactions (ADRs) to arrive at an inference to recommend regulatory interventions to Central Drugs Standard Control Organization besides communicating risks to healthcare professionals and the public. To collect the ADRs from patients, ADR Monitoring Centres (AMCs) have been set up under NCC across the country. As a step towards patient safety, NCC has launched Mobile App and also has a Toll Free Helpline 1800-180-3024 to report ADRs from all parts of the country. ADR reporting form and contact details of AMCs can be downloaded from the official website. NCC works closely with National Health Programmes, WHO, Geneva and Uppsala Monitoring Centre, Sweden and other international partners.

IPC has also launched Materiovigilance Programme of India (MvPI) as an integral part of PVPI to monitor adverse events due to medical devices and Haemovigilance Programme of India (HvPI) in collaboration with the National Institute of Biologicals, NOIDA to monitor adverse events due to transfusion of blood and blood products.

Accreditations and Certifications

The IPL has become the first 'WHO Prequalified Laboratory in the Government Sector in India in the area of physical and chemical analysis of active pharmaceutical ingredients and finished pharmaceutical products. Also, Quality Austria has certified IPC for Integrated Management System in accordance with OHSAS 18001: 2007, ISO 9001: 2008 and ISO 14001: 2004. IPC is also recognized as a Scientific Institute by the Department of Scientific and Industrial Research, Ministry of Science and Technology, Government of India.

IPC has been assessed and accredited in accordance with the requirements of ISO/IEC 17025:2005 in the discipline of chemical and biological testing by the National Accreditation Board for Testing and Calibration Laboratories (NABL). IPC has been assessed and accredited in accordance with the standard ISO/IEC 17043:2010 as proficiency testing provider in the field of chemicals by NABL. IPC has also been assessed and accredited as Reference Material Producers in accordance with the standard ISO 34:2009.

Skill Development Programme

One of the important objectives of IPC is to impart training to drug regulators, government analysts and other stakeholders on pharmacopoeial matters. At present IPC provides training on various healthcare

aspects including new techniques and methodology for government analysts, regulatory aspects for drug regulators, and training on NABL accreditations for laboratories' personnel.

IPC is well equipped with various sophisticated analytical instruments that provide a platform to raise awareness about instruments and new technologies available for pharmaceutical analysis. IPC conducts training and skill development for enhancing the technical competence of working professionals, including government analysts, regulators, research students and other stakeholders from India and abroad (e.g. SAARC & ASEAN countries). Working as NCC-PvPI along with the AMCs spread over the country, IPC regularly organizes trainings/awareness drives on basic and regulatory aspects of pharmacovigilance and materiovigilance for healthcare professionals and consumers.

National and International Collaborations

IPC has established working relations with national and international organizations to have collaborations in different areas of mutual interest. IPC collaborates with premier academic institutions like NIPER-Mohali, DPSRU-New Delhi, IIT-BHU, IIT-Delhi, Amity University-Noida etc. in the field of academics and pharmaceutical research. IPC also collaborates with major Indian research Institutions like IICT-Hyderabad, NCL-Pune, IIIM-Jammu, CDRI-Lucknow, NBRI-Lucknow and other Institutions in the area of pharmaceutical standardization and allied sciences.

IPC has been granted 'Observer' status by the European Directorate of Quality Medicine (EDQM), Council of Europe, France. IPC and United States Pharmacopoeia (USP) have signed an MoU to collaborate in the identification, development and dissemination of science-based standards at international level. In addition, IPC has participated in the collaborative studies and contributed to the development of WHO International Reference Standards for biotherapeutics.

On the 10th anniversary year, I am happy to note that during its short journey of ten years, IPC has claimed its rightful place on the scientific map of the country. IPC has made significant contributions in matters related to quality, safety and rational use of medicines which have been recognized and acclaimed at national and international level. I am sure IPC will continue its pursuit to meet its vision, mission and mandate by adopting the core operating principles of transparency and accountability. On this occasion I reiterate the organization's commitment to leave a global imprint in the arena of pharmaceutical standardization and vigilance.

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