Events at a Glance

10 Jan 2017	MHRA delegation visited IPC. MoU signed between NCC-PvPI, IPC and NABH.
01 Feb 2017	IPC inaugurated its Regional Office at Hyderabad.
02 Feb 2017	Workshop conducted for Stakeholders.
03 Mar 2017	MoU signed between IPC and DPSRU.
08 Mar 2017	IPC collaborated with Indian Drug Manufacturers for development of IPRS.
15 Mar 2017	The official of IPC and experts attended a meeting regarding inclusion of PET in IP draft general chapter.
17 Mar 2017	MoU signed between IPC and USP. Think Tank meeting held at IPC.
20-31 Mar 2017	Training conducted for Government Drugs Analysts.
24 Mar 2017	Visit to Sanat Products Private Limited for inclusion of possible BRS & PRS.
8-9 Apr 2017	IPC participated in the 17th Indian Veterinary Congress at IVRI.
26 Apr 2017	Conducted National Seminar on Role of Libraries in Health and Information System & Services at IPC.

New API Monographs included in IP-2018:	49
Excipients:	2
New Single Formulation Monographs included in IP- 2018:	64
New FDC Monographs included in IP- 2018 (Other Pharmacopoeia):	28
New FDC Monographs included in IP- 2018 (Non Pharmacopoeial):	25
New Antibiotic Monographs:	2
Radiopharmaceutical Monographs:	3
Herbal Monographs:	15
Biotechnology Derived Products:	6
Vaccines and Immunosera for Human Use:	2
Blood and Blood Related Products:	10
Veterinary Monographs:	14
New General Chapters included:	10

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IPC

NEWSLETTER

A QUARTERLY PUBLICATION OF INDIAN PHARMACOPOEIA COMMISSION

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Inside this issue

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Message from

Secretary-cum-Scientific Director

Dear Colleagues,

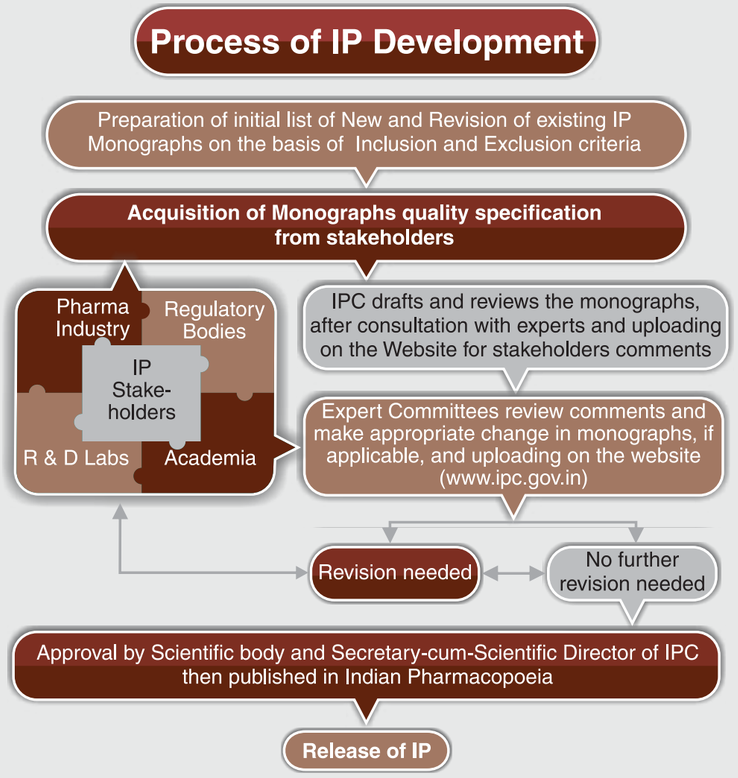
It is a moment of pride for me to reach you all through this Newsletter. India is one of the vast countries in the world with the population of about 1.3 billion people and a diversified talent pool is available. The Indian scientific fraternity is contributing a lot in different areas for the growth and development of the nation. After independence,there has been a tremendous expansion in Indian pharmaceuticals sector. The quality medicines produced in our country are being accepted worldwide. This has been possible because of dedicated efforts of responsible pharmaceutical manufacturers under the overall monitoring system of the central and state drug regulatory authorities.

The medicines of assured quality, safety and consistency are the need of the hour. In this specific domain, Indian Pharmacopoeia Commission has taken a lead in setting the standards of the medicines by bringing out authoritative and officially accepted book of standards, the Indian Pharmacopoeia (IP) amongst many other functions. During the last one and half decade the publication of this regulatory document has gained a rapid momentum. The work for bringing out the next edition of Indian Pharmacopoeia, IP 2018 is in full swing. The draft specifications of quality standards have undergone a rigorous process of consultation as well as scientific checks and balances.

I am sure that all stakeholders in general and the Industry stakeholders in particular will continue to provide all technical support to the IPC in keeping the standards of medicines in IP up to date.

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

Update on preparation of Indian Pharmacopoeia



Process flow for updation of monographs in IP

Indian Pharmacopoeia Commission (IPC) publishes Indian Pharmacopoeia (IP) for the implementation of requirement of Drugs and Cosmetics Act 1940 and Rules 1945 there under. It prescribes the standards of identity, purity and strengths for the drugs produced and/or marketed in India and thus contributes in the control and assurance of quality of medicines. The standards prescribed in Indian Pharmacopoeia are authoritative and legally enforceable. The principle of "Openness, Justice and Fairness" is followed during compiling, verifying/validating and editing the content of the IP monographs. To keep pace with the growth of pharmaceutical sector in India and public interest,efforts are on to publish IP every 4 years with Addenda in between. The Secretary-cum-Scientific Director is authorized to issue the amendments to IP. IP provides an account of the general chapters and specific monographs of active pharmaceutical ingredients (APIs), their formulations, excipients etc. The IP monographs feature about the title of monograph, synonym, molecular structure, molecular formula, molecular weight, description, potency, category, identification, tests, assay, impurity profile, storage specifications and labelling etc. requirements of pharmaceuticals articles.

Left to right: Dr Gerald W Heddell, Dr Samantha Atkinson, Dr. Ian Hudson and Dr G N Singh

MHRA Delegation Visits IPC

A three member delegation comprising of Dr Ian Hudson, Chief Executive, Medicines and Healthcare Products Regulatory Agency (MHRA), Dr Gerald W Heddell, Director Inspection, Enforcement & Standards and Dr Samantha Atkinson, Deputy Director Inspection, Enforcement & Standards and Scientific Director British Pharmacopoeia, visited IPC on 10th January 2017. The delegation was welcomed by Dr G N Singh, Secretary-cum-Scientific Director, IPC. The matters of Pharmacopoeial interest were discussed.

Interactive session with MHRA delegation, Secretary-cum-Scientific Director, IPC and staff

International Collaboration

Biologics Section of the IPC collaborated with the National Institute for Biological Standards and Control (NIBSC), UK for an 'International Collaborative Study to Establish 2nd International Standard for Parathyroid Hormone 1-34 (rh-PTH 1-34), Recombinant, Human'. The candidate standard (code 15/304) received from NIBSC was calibrated in terms of the primary calibrant of rh-PTH 1-34 supplied with the candidate standard using three independent HPLC assays. Also, purity of the candidate standard was determined using HPLC based method. The results of the study were compiled at IPC and communicated to the study coordinator Dr Ben Cowper at NIBSC, UK in February 2017.

MoU signed between IPC and USP

IPC and USP
join hands to provide better health care

The U.S. Pharmacopoeial(USP) convention is a scientific non profit organization that sets standards for the identity, strength, quality, and purity of medicines. USP's drug standards are enforceable in the United States by the US-FDA, and these standards are used in more than 140 countries. Since its founding in 1820, USP has helped secure the quality of the American drug supply. USP today works with scientists, practitioners, and regulators of many nations to develop and revise standards that help protect public health worldwide.

IPC is an Autonomous Institution of the Ministry of Health and Family Welfare, Govt. of India created to set standards of drugs in the country. Its basic function is to update regularly the standards of drugs commonly required for treatment of diseases prevailing in the country.

It publishes official documents such as IP for improving quality of medicines by way of adding new and updating existing monographs. It further promotes rational use of generic medicines by publishing National Formulary of India.

An MoU was signed by Dr G N Singh, Secretary-cum-Scientific Director, IPC and Dr Ronald T Piervincenzi, Chief Executive Officer, USP, on 17th March 20017 at IPC headquarter, at Ghaziabad.

The goal of the MoU is to enhance global public health by working together to:

- Increase awareness of the importance of quality, safety and efficacy of medicines, and
- Safeguard the integrity of the global supply chain by increasing the availability and access to needed public standards for medicines.


Meeting with drug manufacturers for the development of biological-IPRS

Collaboration with manufacturers for development of reference substances

FOR BIOLOGICS

With the objective to develop Indian Pharmacopoeia Reference Substances (IPRS) for biologics, a meeting was held at the IPC Zonal Office, CDSCO Bhavan, Hyderabad on 8th March, 2017. Representatives of various biologics manufacturers of Hyderabad region participated in the meeting and discussed the modalities to develop IPRS for biologics. Manufacturers in principle agreed to contribute in the development of IPRS by donating the candidate material for the same. IPC looks forward to collaborate with manufacturers, regulatory laboratories and stakeholders for the development of IPRS for biologics.

FOR HERBALS

Dr Shashi Bhushan, Sr Scientific Officer; Dr Sushma Srivastava, Sr Consultant; Mrs Ritu Tiwari, Scientific Assistant and Mr Pradeep Kumar, Pharmcopoeial Asistant; from Phytopharmaceuticals Division of IPC visited M/s Sanat Products Private Limited, Sikanderabad, on 24th March, 2017.

The IPC representatives held a meeting with the representatives of Sanat Products Private Limited to discuss about the inclusion of possible plant products as Botanical Reference Substance (BRS) and Phytopharmaceutical Reference Substance (PRS).


Meeting with representatives of Sanat Products Pvt Ltd

Think Tank meeting at IPC

A Think Tank meeting was held on 17th March 2017, at IPC, Ghaziabad under the chairmanship of Padmashree Dr Nitya Anand to draw roadmap for IPC.

Eminent scientists from academic institutions, health professionals, leaders from pharmaceutical industry, representative from WHO and civil society, senior officials from Ministry of Health and Family welfare, and Ministry of Commerce participated in the meeting.

In the meeting detailed deliberations were held highlighting the journey of IPC and CDSCO and their importance in protecting the public health in the country by assuring the quality, safety and efficacy of the medical products.

The Think Tank made several recommendations pertaining to IPC;and regulations of drugs, neutraceuticals and medical devices etc. One of the recommendations was to quickly provide well defined scientific standards for new medical products (already approved and marketed in several well regulated countries) having fast track approval in view of the disease burden in India, and to meet the unmet need of patients.

MoU signed between IPC and DPSRU

Dr G N Singh, Secretary-cum-Scientific Director, IPC with additional charge of Drugs Controller General (India), and Prof R K Goyal, Vice-Chancellor, Delhi Pharmaceutical Sciences and Research University (DPSRU) signed the MoU on 3rd March 2017 during the Opening Ceremony of Fifth National Conference of Pharmacoeconomics and Outcomes Research organized by the President - ISPOR India Chapter at DPSRU, New Delhi. Eminent personalities such as Prof S K Gupta and Prof J S Bapna and other dignitaries were present during the occasion. The MoU is expected to promote the cooperation between both the parties for achieving the common goal of improving the quality, safety and efficacy of medical products and skill development.

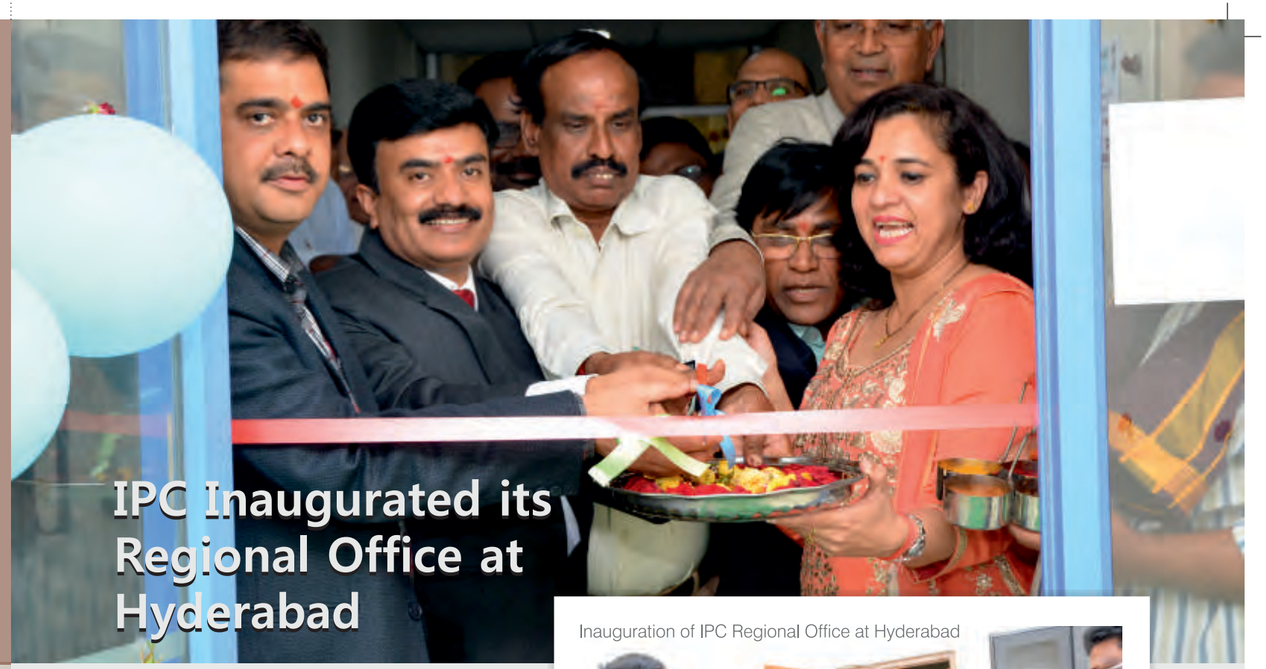
Group photo of Think Tank with IPC staff

IPC collaborated with NABH

Indian Pharmacopoeia Commission, National Coordination Centre-Pharmacovigilance Programme of India (IPC, NCC-PvPI), and National Accreditation Board for Hospitals and Healthcare providers (NABH) have mutually agreed to work together for promoting patient safety by effective monitoring & reporting of Adverse Events / Adverse Drug Reactions. For its effective implementation both the organization signed MoU for various activities of Pharmacovigilance on 10th Jan 2017 at DCG (I) Office, FDA Bhawan, New Delhi.

The MoU was signed by Dr G N Singh, Secretary-cum-Scientific Director, on behalf of IPC and Dr B K Rana, CEO In-charge, on behalf of NABH, in the auspicious presence of higher officials of Ministry of Health and Family Welfare, Govt. of India.

MoU signed between IPC and NABH



IPC Inaugurated its Regional Office at Hyderabad

Inauguration of IPC Regional Office at Hyderabad

With a vision to promote the highest standards of drugs for use in human and animals, IPC initiated to open its extended arm across multiple cities in the country as well as in other countries. This move is in line with our commitment to strengthen the standard setting body at national and international level by providing doorstep interaction with stakeholders and to establish global harmonization with international standards. Dr G N Singh, Secretary-cum-Scientific Director & Drug Controller General of India, IPC, Ministry of Health & Family Welfare, Government of India could not participate in the inaugural function because of other important official engagement. In this connection, he had deputed Dr P L Sahu, Principal Scientific Officer, Officer in-charge R&D, IPC and Dr P B N Prasad DDC(I), Hyderabad to inaugurate the function and to conduct the activities as per his direction. Dr G N Singh sent his best wishes as "I wish the function a great success and is one step forward for the expansion of IPC activities". Team of renowned industrialists, academicians & stakeholders along with the team of regulators and IPC (Dr Robin Kumar, Pr Scientific Officer, Dr Anuj Prakash, Sr Scientific Officer, Dr Meenakshi Dahiya, Sr Scientific Officer, and Prof Prakash Diwan, Technical Advisor, IPC) were also part of inauguration ceremony. With a dream of spreading wings of IPC across India and world, Dr P L Sahu and Dr P B N Prasad inaugurated the first regional office of IPC at Hyderabad on 1st Feb 2017 in the campus of CDTL, Hyderabad. In fact, he mentioned in his address that IPC is planning to set up its extended arm in Mumbai, Chennai and Kolkata also very soon. He said that if things go as planned, various offices in other countries would also be set up. Inauguration ceremony was followed by Interactive session with Mr P B N Prasad, Mr Uday Bhaskar, DG, Pharmexcil, Mr Amruth Rao, DCA, AP & Scientists of IPC and distinguished delegates from various Pharma Industries where several issues related to co-ordination activities with regulatory bodies were discussed.

Training for
Government Drugs Analysts

IPC conducted "7th Training Programme on Various Analytical Instruments & Techniques for Government Drugs Analyst" from 20th March 2017 to 31st March 2017. A total number of 40 participants from 15 government laboratories across the country participated in this training programme.

Meeting regarding inclusion of PET in IP draft General Chapter

Inclusion of
PET Containers in IP

IPC officials organized series of meetings with Experts from all over India to deliberate on the issues related to the inclusion of PET containers in IP draft General Chapter 'Primary Packages for Pharmaceuticals". Recently a meeting with the experts was held at All India Institute of Medical Sciences (AIIMS), New Delhi, on 15th March 2017 under the Chairmanship of Prof Y K Gupta, Head, Department of Pharmacology, AIIMS, New Delhi.

Dr Jai Prakash, Sr. Principal Scientific Officer, IPC delivering a lecture in 17th Indian Veterinary Congress, IVRI

Participation in
Indian Veterinary Congress

Dr Jai Prakash, Sr Principal Scientific Officer; Dr Gaurav Pratap Singh, Senior Scientific Officer; and Mr Uttam Semwal, Pharmcopoeial Associate; participated in the 17th Indian Veterinary Congress organized at Indian Veterinary Research Institute (IVRI), Izatnagar on 8-9th April, 2017. Dr Jai Prakash gave a talk on 'Current Status and Roadmap for Veterinary Standards in Indian Pharmacopoeia' during the congress.

Prof R K Goyal, VC DPSRU (Third from left) and Prof. D P Pathak, Registrar DPSRU (Second from left) welcomed by IPC Officials at IPC Ghaziabad on 6th January 2017

VC DPSRU visits IPC

Prof Dr R K Goyal, Vice Chancellor, faculty and students of Delhi Pharmaceutical Sciences & Research University visited IPC on 6th January 2017. The team was welcomed by Dr Jai Prakash, Sr Principal Scientific Officer and other IPC Officials. An audio visual film about IPC was projected to make them acquainted with the vision, mandate and working of the Commission. Later a tour to different departments of IPC was organised for the team, students were shown state of art laboratories and the working of various instruments were explained to them by the respective laboratory staff. The importance of IP, NFI, IPRS, etc were explained to them, besides the procedure for validation of analytical methods.

Prof R K Goyal, VC, DPSRU, interacting with IPC Officials

Workshop for Stakeholders

IPC had organized "One Day Workshop on Awareness of Indian Pharmacopoeia (IP) and Indian Pharmacopoeia Reference Standards (IPRS)" at Hyderabad 02nd February 2017 for stakeholders.

IPC Scientists and other dignitaries during one day workshop at Hyderabad

Seminar on 'Role of Libraries in Health and Information System & Services, IPC

National Seminar: Role of Libraries in Health and Information System & Services

A Seminar on 'Role of Libraries in Health and Information System & Services' was organized by the Library & Information Centre of IPC, on 26 April 2017 at the Conference Hall IPC, with the objective to create awareness among the participants about various issues relating to importance of Libraries in Proficiency development in Organization/ Institution in the country. Dr K K Singh, Library & Information Officer, IPC welcomed all the dignitaries and participants of the seminar. Dr K P Singh, Director National Medical Library, New Delhi, was the Chief Guest. Mr A K Pradhan, Deputy Drug Controller General (India) and Mr M Madhusudan Associate Professor, AIIMS graced the occasion. Dr Jai Prakash, Sr Principal Scientific Officer, IPC highlighted the importance of libraries in health system and wished that as the scientists follow GLP and GCP, a similar guidelines for Good Library Practices may also be framed and followed throughout the country. The seminar was attended by about 60 librarians and associated staff and other scientific fraternity from all over India.

Library and Information Resource Centre

The IPC library and Information Resource Centre is the leading Pharmacopoeial Library and Information centre in the country. It provides comprehensive resources and valuable services to support scientific and Pharmacopoeial works. The library has tremendous collection of reference books, scientific journals, pharmacopoeias of different countries, documents of national and international standards and other materials. Books are organized on open access shelves that can be consulted within the library. The centre also provides internet facility to the users for online access of Information.

The main objective of Library & Information Resource Centre is to acquire, organize and preserve the documents for reference purpose and make them available to cater the user's need. Library has access to a large number of e-resources, such as CD-ROM, databases and e-journals, etc. Library & Information Resource Centre subscribes about 45 national and international scientific journals and more than 330 online journals on various subjects.

Library and information resource centre bring out the following innovative information product and services providing access to the pertinent recorded knowledge for scientists, researchers and other users:

Online Selective Dissemination of Information (SDI/CAS), Article Alert of Journal, Newspaper Clipping and other reference services for the enhancement of professional skills.

- Indexing & Abstracting of Journals
- Current Content of Books
- Current Holdings
- Library Catalogue

Library and Information Resource Centre of IPC