



INDIAN PHARMACOPOEIA COMMISSION

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Current status and perspectives on 3Rs opportunities in IP monographs for veterinary vaccines

Indian Pharmacopoeia Reference Standards & Impurity Standards



Indian Pharmacopoeia (IP)



National Formulary of India (NFI)

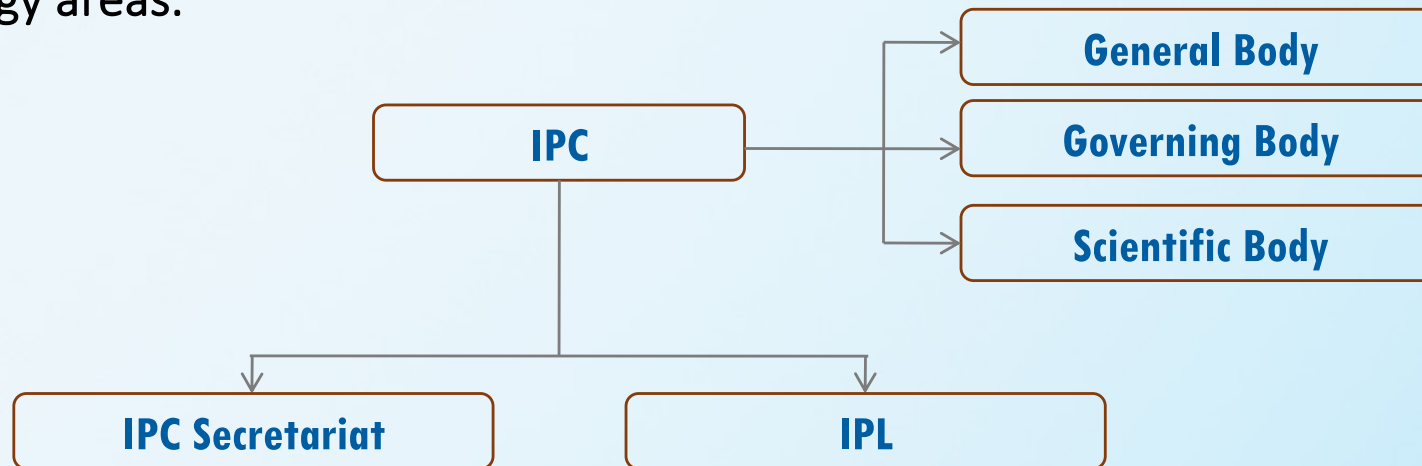


National Coordination Centre-Pharmacovigilance Programme of India



Indian Pharmacopoeia Commission

- The Govt. of India has created a separate, dedicated, autonomous institution-Indian Pharmacopoeia Commission (IPC)-to deal with matters relating to timely publication of the Indian Pharmacopoeia (IP) which is the official book of standards for drug included therein, in terms of the Second Schedule to the Drugs and Cosmetics Act, 1940.
- IP specifies the Standards of Quality (identify, purity and strength) of the drugs imported, manufactured for sale, stocked or exhibited for sale or distributed in India.
- IPC become fully operational from 1st January 2009.
- IPC has a three-tier policy formulation and execution setup comprising of the General Body, Governing Body and Scientific Body with experts drawn from various Science & Technology areas.



Indian Pharmacopoeia Commission

Vision

To promote the highest standards of drugs for use in humans and animals within practical limits of the technologies available for manufacturing and analysis.

Mission

To promote public health 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.

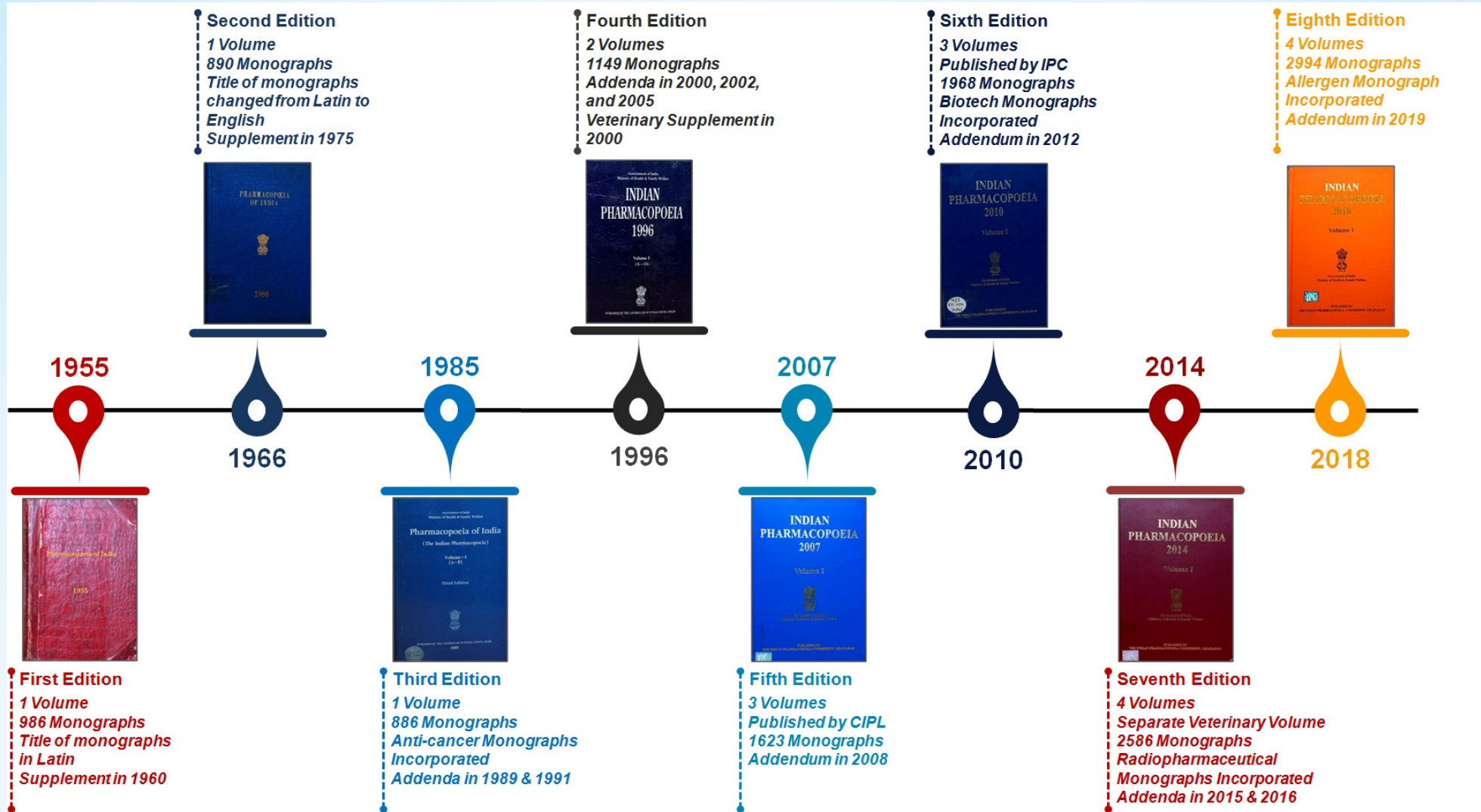


Mandates of IPC

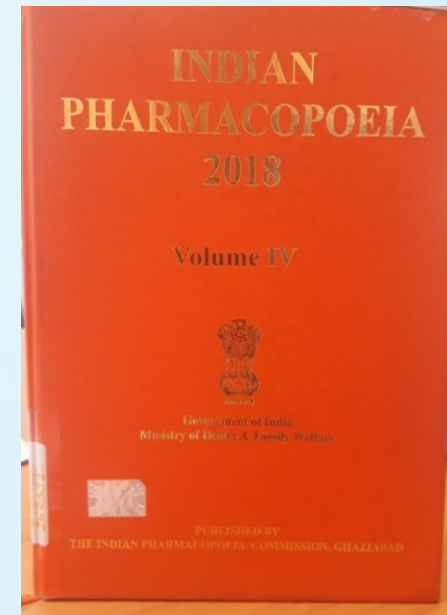
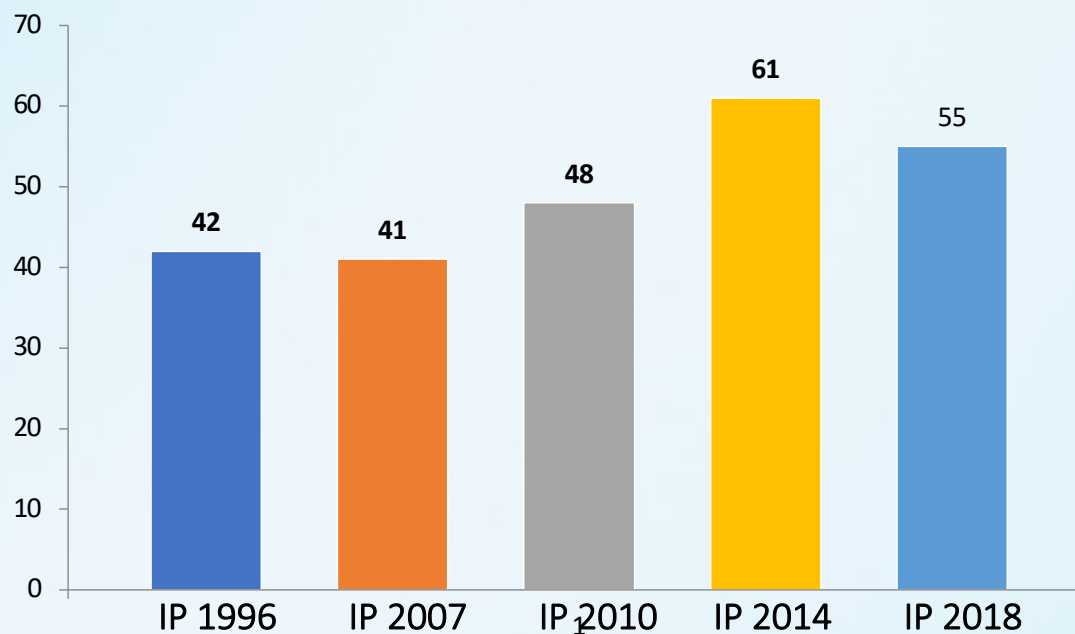
- To publish new edition and addenda of the IP at regular intervals.
- To publish the National Formulary of India (NFI).
- Certification and distribution of IP Reference Substances (IPRS) and Impurity Standards.
- National Coordination Centre (NCC) for Pharmacovigilance Programme of India (PvPI)
- To establish working relations with National and International Institutes.
- To organize educational programs, skill development and research activities.



Journey of IP Editions

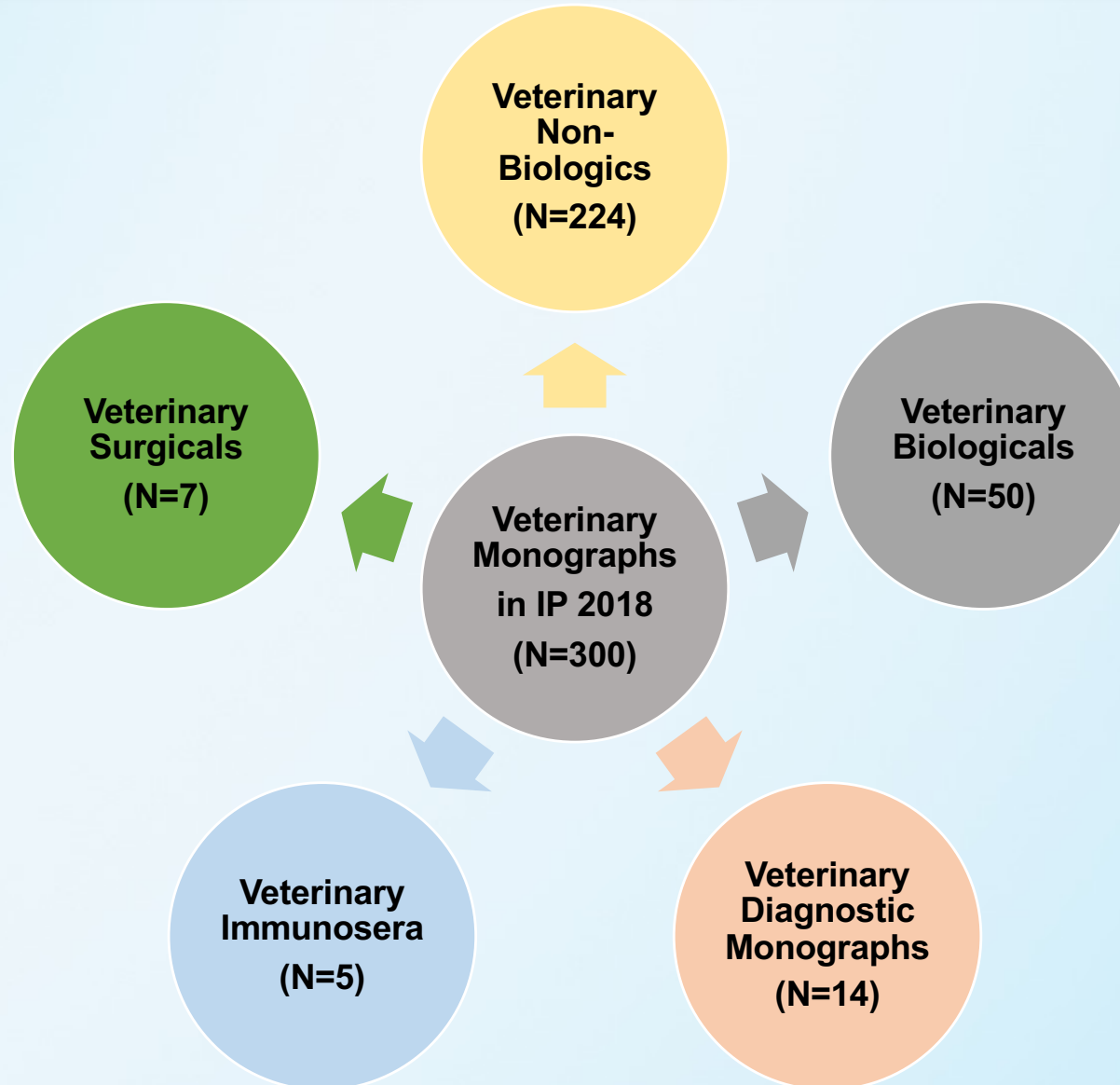


Veterinary Biological Monographs in IP



Separate IP Volume for Veterinary products- **IP 2014** & **IP 2018** (Current edition),
IP 2022 (Next Edition) will be effective from 1st December, 2022

Veterinary Biologicals Monographs in IP 2018



IPC's approach to adopt Alternatives to Animal Methods

IPC adopts any one or all of the following strategy

- **Comparability and applicability of suitable non-animal method/test** in place of current *in vivo* method/test
- **Alternative approaches** based on scientific literature, retrospective data (ex: ATT), GMP and Pharmacovigilance in place etc
- Implementation of **consistency approach**
- **International harmonization** of regulatory requirements-WHO TRS and other pharmacopoeia
- **Expert opinion:** IPC has constituted a separate expert working group for 'Alternatives to Animal Methods'



Target animal safety test (TABST) in Veterinary vaccine monographs

- Reference:
 - ✓ VICH GL 41 and 44
- Challenges:
 - ✓ Potential safety risk involved not only to animals but also to Human
 - ✓ Safety of target animals
 - ✓ No suitable data from domestic manufacturer
 - ✓ Only scientific literatures available



Target animal safety test (TABST) in Veterinary vaccine monographs

Action taken:

- ✓ Scientific discussion in EWG-Veterinary products, EWG-Alternatives to animal methods
- ✓ workshop on 'Future of TABST and LABST in the Indian Pharmacopoeia Monographs' Organized by Humane Society International (HSI), India on 11 Feb 2021
- ✓ Stakeholders were asked to submit
 - Retrospective analysis of data showing no negative result for TABST
 - Demonstration of consistent production through at least 10 consecutive batches passed (or at least 5 if only 10 batches are produces in 3 years)
 - Any failure to TABST (reported, reason investigated/explained, Risk management)
 - Pharmacovigilance data/post marketing surveillance data, if available



3R opportunities in IP veterinary vaccine monograph

➤ New General chapters for next edition of IP

1. Substitution of *In Vivo* Method(s) by *In Vitro* Method(s) for the Quality Control of Vaccines
2. General requirements- For inactivated vaccines- **development of *in-vitro* methods is recommended**, provided that:-key in-process parameters are defined and monitored
3. Test for bacterial endotoxins (2.2.3) is prescribed in place of Pyrogen (2.2.8)

➤ New General Requirements for next edition of IP

On a case-by-case basis, with the agreement of the competent authority, the choice of and need for certain final product tests may be reconsidered, where in-process tests are able to demonstrate that the finished product meets the requirements of the monograph or where alternative tests validated with respect to the Pharmacopoeia method have been carried out.





Thank You

*USE OF IP & IPRS IS SOCIAL AND LEGAL OBLIGATION FOR "IP"
PRODUCTS*

**Indian Pharmacopoeia Reference
Standards &
Impurity Standards**



Indian Pharmacopoeia (IP)



National Formulary of India (NFI)



**National Coordination Centre-
Pharmacovigilance Programme
of India**

