INTERNATIONAL MEETING OF WORLD PHARMACOPOEIAS
29 February to 2 March 2012
WHO, Geneva

By
Dr G N Singh
Secretary-cum-Scientific Director
and
Drugs Controller General (India)
Indian Pharmacopoeia Commission

- The Indian Pharmacopoeia Commission is the Standards Setting Institution for Drugs in India.
- It is an autonomous body under the Ministry of Health & Family Welfare, Govt. of India, New Delhi.
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 in India by bringing out authoritative and officially accepted standards for quality of drugs including APIs, excipients and dosage forms, used by health professionals, patients and consumers.
Mandates of the Commission

• Publication of Indian Pharmacopoeia the book of standards for Drugs in India
• Bringing out the National Formulary of India, the reference book for healthcare professionals
• Providing IP Reference Substances
• Nodal agency for establishing national/international collaboration with similarly placed bodies
Highlights of 6th Edition IP 2010

- Total monographs ~2000
- New monographs – 287
- Updated monographs > 600
- Special emphasis on
  - Herbals
  - Biologicals
  - Veterinary Products
IP Herbal Monographs

- Monographs on herbs and herbal products in IP 2010 include color photograph of crude drugs and TLC/ HPLC/HPTLC chromatogram
- IP also provided the specifications /details:
  - Foreign organic matter
  - Ethanol soluble extractive
  - Water soluble extractive
  - Total ash and Acid-insoluble ash,
  - Heavy metal content
  - Loss on drying,
  - Microbial limits/contamination,
  - Assay method by HPLC/HPTLC/TLC
Trends of Herbs and Herbal Products Monographs in IP

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<td>9</td>
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<td>Extracts</td>
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<td>21</td>
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<td>Finished formulations</td>
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<td>Pharmaceutical aid</td>
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<td>17</td>
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# Trends of Biopharmaceuticals Monographs in IP

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<td>Vaccines &amp; immunosera for Human use</td>
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Government Initiatives

- Establishment of Autonomous Standard Setting Institution for Drugs
- Transparent and Accountable Regulatory System
- Trained and Talented Manpower
- Special Economic Zones for Pharma Sector
Industry Perspective

- Global ranking-
  3rd - Volume
  14th - Value

- India is a recognized for supplying quality medicines
  ✓ Anti TB segment
  ✓ Antiretroviral
  ✓ Vaccines
  ✓ Herbal drugs

- Manufacturing Capability for conventional and current drugs delivery systems
  ✓ 20,000 Formulations in 30 categories
Challenges

• Sharing of information among Pharmacopoeias?
  o Resources
  o Working in pockets where there is need for sharing information
  o Commitment
    ▪ Let’s begin top 20 selling molecules to service humanity
    ▪ Monitoring
    ▪ Harmonization with leading pharmacopoeias
Way Forward

To provide ‘Quality Medicines’ through harmonized ‘Drug Standards’ and monitoring quality of medicines through effective ‘Regulatory System’
International vision with an approach to make IP Standards globally recognized