

Development of Pharmacoeconomic Guidelines for India



PE Guidelines Development: Background

- ISPOR India Chapter came up with the concept of developing PE guidelines for India in year 2013
- Prof (Dr.) S. K Gupta appointed a core committee under his leadership for developing the first draft of the PE Guidelines for India
- Core committee comprised of experts in Health Economics and Outcomes Research (HEOR) from academics and industry
- Core committee that developed the first draft of the PE Guidelines for India included following members:
 - Dr. S.K.Gupta
 - Mahendra Kumar Rai
 - Dr. Divya Mishra
 - Richa Goyal
 - Javed Shaikh
 - Munish Duvedi

PE Guidelines Development: Methods

- All existing guidelines in other countries were reviewed for their content, methodology and key messages
- Guidelines for Canada were followed closely and adapted to develop the guidelines for India
- A framework for guideline was created and subsequently first draft was developed and distributed within the peer group in India
- Second draft version of PE guidelines was presented in the annual conference of ISPOR India in year 2014.
- Second draft version of the PE guidelines underwent changes as suggested by contributors from other ISPOR regional chapters within India.
- Third draft version of the guidelines was created with major changes as per suggestions from peer reviewer in India as well as global ISPOR chapters in March 2016.



PE Guidelines for India: Current Status



PE Guidelines for India: Current Status

Guideline Development

- Third draft version of the guideline is ready and is posted on ISPOR HealthNet India website at http://www.ispor.org/consortiums/asia/PE_Guidelines_India_March2016.pdf
- Contribution from Industry and academic experts in field of health economics
- Guideline will be finalized after incorporating comments from peer-reviewers, if any

Panel Discussion

- Panel discussions been conducted for these guidelines in various forums
- These guidelines have been discussed in all annual conferences of ISPOR India chapter
- The development of PE Guidelines has been presented in similar forums in other ISPOR meetings in the USA and Asia-Pacific



7

TATA CONSULTANCY SERVICES

PEOR Guidelines for India: Content

PE Guidelines

- Clearly defined research question or objectives of analysis
- Audience of the evaluation
- Analysis methods
- Cost determination
- Viewpoint of the analysis
- Analytic horizon
- Intervention to be specified
- Choice of therapeutic alternatives for comparison should be specified
- Target population

Outcome Research Guidelines

- Evaluation of a PRO Instrument
- Endpoint Model
- Choice of PRO Instrument
- Conceptual Framework of a PRO Instrument
- Content Validity
- Reliability, Other Validity, and Ability to Detect Change
- Instrument Modification
- PRO Instruments Intended for Specific Populations



8

TATA CONSULTANCY SERVICES

Applications of PE Guideline in India



Applications of PE Guidelines in India

- Health Technology Assessment (HTA): PE guideline will be an important step in order to establish HTA in India (MTAB- Medical Technology Assessment Board)
- National Pharmaceutical Pricing Authority (NPPA) – National Pharma Pricing Policy: Prioritization and identification of drugs/products in India, which are pharmaco-economically more important and beneficial.
- Central/State Governments can be guided on reimbursement under various mandatory sponsored insurance schemes
- Health Insurance - estimate the costing of health services for evolving benefit packages and to determine the premium to be levied and subsidies to be given
- Guide government on subsidy to be provided on Health technologies
- Prescription advice to practitioners in various therapeutic domains.

Challenges and Way Forward



PE Guidelines: Challenges & Way Forward

Challenges

- Multiple ISPOR chapters in India leading to divergent views and multiple iterations in the PE guideline drafts
- Multiple government agencies and stakeholders involved for approval and adoption of PE guidelines at national level
- Limited support from Ministry of Health (MoH) on PE guidelines development and implementation
- Limited engagement of Key Opinion Leaders (KOLs) and advocacy groups in guideline development process

Way Forward

- Panel of PE experts created from all ISPOR chapters in India to contribute on current guidelines
- Engaging with specific stakeholders in various ministries for adopting these guidelines in national healthcare system
- ISPOR India chapter to engage continuously with MoH to have support from MoH on implementation of these guidelines
- Engaging actively with KOLs and advocacy groups to create awareness on need of PE Guidelines and timely implementations of these guidelines

Thank you



PE Guidelines for India: Contributors

Prof (Dr.) S. K. Gupta

- **Mahendra Kumar Rai**
- **Dixon Thomas**
- **A.N. Nagappa**
- **N. Udupa**
- **Munish Duvedi**
- **Divya Mishra**
- **Richa Goyal**
- **Javed Shaikh**

- **Jitendar Sharma**
- **Denny John**
- **David Danko**
- **Y. Padmanabha Reddy**
- **Subhash C. Mandal**
- **J.S. Bapna**
- **Uday Venkat Mateti**
- **Asim Priyendu**