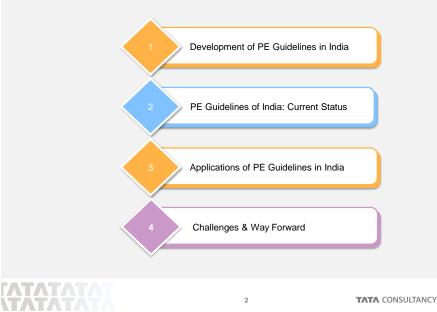


Pharmacoeconomic and Outcomes Research Guidelines of India

Presented by: Mahendra Kumar Rai **Delivery Head- Market Access** (HEOR, PRMA & Real World Evidence) Tata Consultancy Services, Mumbai President (Elect)- ISPOR India Mumbai Chapter

2016

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Development of Pharmacoeconomic Guidelines for India



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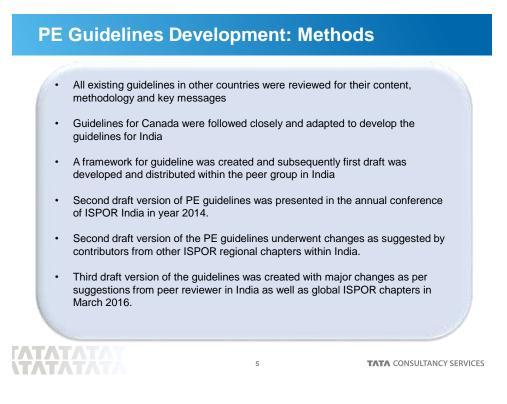
PE Guidelines Development: Background

- 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:

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- Dr. S.K.Gupta
- Mahendra Kumar Rai
- Dr. Divya Mishra
- Richa Goyal
- Javed Shaikh
- Munish Duvedi







PE Guidelines for India: Current Status

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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 <u>http://www.ispor.org/consortiums/asia/PE</u>

Guidelines_India_March2016.pdf

- Contribution from Industry and academic experts in field of health economics
- Guideline will be finalized after incorporating comments from peerreviewers, 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



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PEOR Guidelines for India: Content

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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





Applications of PE Guideline in India



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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



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PE Guidelines: Challenges & Way Forward

| Challenges | Way Forward |
|--|---|
| Multiple ISPOR chapters in India leading to divergent views and multiple iterations in the PE guideline drafts | Panel of PE experts created from all ISPOR chapters in India to contribute on current guidelines |
| Multiple government agencies and stakeholders involved for approval and adoption of PE guidelines at national level | Engaging with specific stakeholders in various ministries for adopting these guidelines in national healthcare system |
| Limited support from Ministry of Health (MoH) on PE guidelines development and implementation | ISPOR India chapter to engage continuously with MoH to have support from MoH on implementation of these guidelines |
| Limited engagement of Key Opinion Leaders (KOLs) and advocacy groups in guideline development process | Engaging actively with KOLs and advocacy groups to create awareness on need of PE Guidelines and timely implementations of these guidelines |

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Thank you

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PE Guidelines for India: Contributors

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