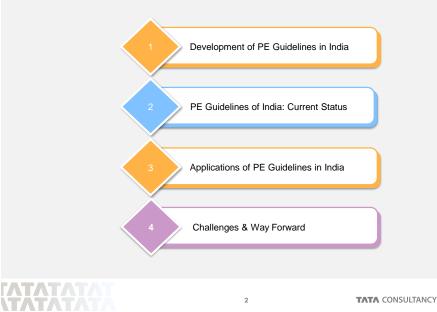


Pharmacoeconomic and Outcomes Research Guidelines of India

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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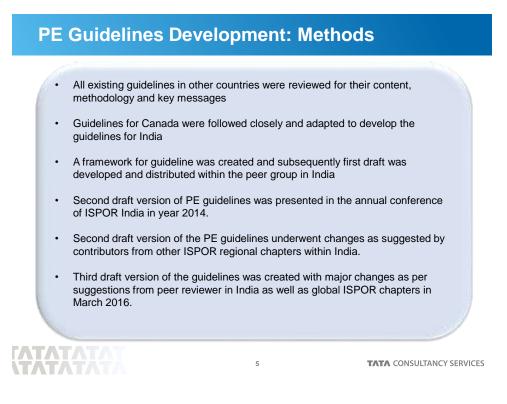
PE Guidelines Development: Background

- 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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