A Policy Perspective on Real World Evidence & Role of HTA

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https://www.thelancet.com/gbd
https://vizhub.healthdata.org/gbd-compare/india
DISEASE BURDEN


Summary

Background Monitoring levels and trends in premature mortality is crucial to understanding how societies can address prominent sources of early death. The Global Burden of Disease 2016 Study (GBD 2016) provides a comprehensive assessment of cause-specific mortality for 264 causes in 195 locations from 1990 to 2016. This assessment includes evaluation of the expected epidemiological transition with changes in development and where local patterns deviate from these trends.


List of Diseases
List of Different categories of interventions

Non Communicable Disease

Communicable Diseases

Export Data

Import Data

Local Evidence Generation Through Global Parameters
Market Intelligence and Trade

Indigenous Sales Vs Imports: Financial Year 2016-17

STAKEHOLDERS CONSULTATION

Formative Industry leaders Research institutes Start-up Partners Technology Meet (FIRST)

Core Technological Links (CTLs) Core Scientific Facilities (CSFs)

Multi Criteria Decision Analysis (MCDA)
Government Policy In Research Grant Allotment
E-AUCTION PROCESS FLOW

Start → e-Auction Item Creation → e-Auction Authorization → Live e-Auction → e-Auction Bidder participation request

Bidder and Seller to proceed further on their Terms

Bidder to Pay 10% to Seller

KIHT to share information of Seller

Service charges to KIHT → LoA → Winners → Bidding Process

Clarification

Enabling /disqualifying

Refunding

TESTING AND CERTIFICATION

SERVICES OFFERED

Business Plan Reality Check
Scrub the plans from every angle to ensure the product will meet the end-user's needs.

Quality compliance
To complete the design, development, manufacture and certification of medical devices.

Market Access Avenues
- Health Technology Assessment
- Systematic Review/Meta Analysis
- Program efficiency model
- Uptake model.

Testing
Helps in testing to comply with applicable standards
- Electro Magnetic Interference (IEC 60400-1 series)
- Electrical Magnetic Compatibility (IEC 801-5 series)
- Electrical Safety testing
- Biocompatibility
- Good Manufacturing Practices (ISO 13485)
- Software testing (IEC 42410)
- Material testing (Relevant ASTM standards)
- Radiation protection
- IEC 60601-1-2

Rapid Prototyping
Supports clients in manufacturing
- Low Volume
- High Complexity
Prototype/Innovation

(Sign an agreement /MOU with the owner of the innovation for examining and reviewing the innovation)

Perform a technical classification of each component of the innovation. Perform a compliance study of each component with the respective regulatory standard.

Material Testing
a. Approval of biomaterials
   i. Drug/Device combination product
   ii. Medical devices incorporating materials of animal/human origin
   iii. Testing of Biomaterials
      i. Chemical analysis
      ii. Physical evaluation
      iii. Biological evaluation (ISO 10993)
      iv. Biocompatibility
   a. Sterilization practices control and validation for medical devices
   b. Cleanroom environments for medical devices (ISO 14698)

Electrical (EMI/EMC) Testing (IEC 60601)
   i. Risk Management: All hazards associated with medical device
   ii. Performance testing: Functionality and tolerances in normal and fault conditions
   iii. Operator’s protection: Check for intended level of protection
   iv. Electrical safety
   v. Mechanical safety
   vi. Radiation safety (IEC 60601-1-3)
   vii. Other hazards
   viii. Markings/Labeling
   ix. Wireless Testing (ANSI C63.10-2013)
   x. Acoustics

Software (IEC 62304)
   Dynamic
   Environmental
testing

Other relevant scientific facilities with whom AMTZ/KIHT have an MoU/MoA

If the innovation complies with the standard, approach the relevant agency for assessment; testing & validation.

Failure Analysis
1. Chemical testing
2. Finite Element Analysis
3. Failure Mode Effect Analysis
4. Mechanical/Physical Testing
5. Fatigue testing
6. Microscopic analysis
7. Compound Analysis
8. Formula Reconstruction
9. Impact testing
10. Ultra-High-strain rate analysis
11. Gap Analysis

Failure
1. Technical
2. Marking
3. Packaging
4. Environmental
5. Translational

YES

Certification & Market Authorization
Certification by National and/or International agency

Market Access
1. Health Technology Assessment (HTA)
2. Value based pricing
3. Reimbursement compared to competition
4. Preferential Market Access
5. Value proposition and Dossier
6. Innovative Programs Integration

Product Success

NO

Criteria's adopted to undertake Medical Devices in India through Health Technology Assessment

Availability

Acceptability

Affordability
Components of HTA

- Safety
- Clinical Effectiveness
- Economic Evaluation
- Budgetary Consideration
- Ethics
- Legal & Regulatory
- Feasibility

Research and Development and Manufacturing Support
State-of-the-art Scientific Facilities

INNOVATION ➔ MARKET ➔ ACCEPTANCE BY PROVIDERS
HEALTH TECHNOLOGY ASSESSMENT ACT AS A IMPORTANT EVIDENCE BASED TOOL