

Regulatory Framework for Healthcare Technologies

Level I: Global

Level II: Societal

Level III: Service Provision

PROVISION

ADOPTION

UTILISATION

(industry / market)

(healthcare planners)

(healthcare providers)

CRITERIA:

**SAFETY
PERFORMANCE**

Activities:

- Innovation
- Distribution
- Post-Market Surveillance

Instruments:

- Good Manufacturing Practice
- Quality Management System
- Risk Classification
- International Standards
- Post-Market Surveillance

**ACCESS, EQUITY & AFFORDABILITY
COST-EFFECTIVENESS
SOCIETAL IMPACT
APPLICATION ENVIRONMENT**

- Needs Assessment
- Strategic Service Planning
- Technology Scanning
- HTA (for selected technologies)

- National Policies & Regulations
- HT Planning System
- HT Assessment System
- HT Procurement System

**SAFETY
EFFECTIVENESS / EFFICIENCY
COST / AFFORDABILITY
SUSTAINABILITY**

- Needs Assessment
- Planning & Budgeting
- Evaluation & Selection
- Procurement & Commissioning
- Asset- & Risk-Management
- Replacement Planning & Decommissioning

- HT Utilisation System
- Performance Monitoring
- Competent Users/Maintainers
- IPM / Corrective Maintenance
- Guidelines / Procedures
- Training & Support
- Information Systems
- Hazard Alert System

Poluta (2006)

The 4 sub-systems of the proposed South African **Health Technology Management System** (as per SA DoH HT Policy Framework) are *indicated thus*