An Overview of IM Pharmaceutical Sector in Sri Lanka

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VISION

A healthy and prosperous nation for contributing to the development of the country through Indigenous Systems of Medicine (ISM)
MISSION

To achieve the quality of life by contributing to physical, mental, social, economic and spiritual well-being of the people of Sri Lanka by adopting professional excellence in Indigenous Systems of Medicine (ISM)
GOAL

Improving the health status of the Sri Lankan people through best practices of traditional, indigenous and other knowledge systems while preserving the identity and strengthening the role and contribution of the Indigenous Systems of Medicine (ISM) in the National Healthcare System.
What brought us here?

- Misinformation
- Adulterants
- Substitutes
- Spurious products
- Misbranding
- Quasi-Ayurvedic products
- Unhygienic implications
- Unethical promotions
- Illegal involvements
- Injurious products
National Policies Related to IM Pharmaceutical Sector

- Research and development outcomes in IM sector will be utilized and channeled through a scientific manner
- Quality of service delivery in IM healthcare providing institutes will be improved and maintained
- Entrepreneurship and stewardship of private sector will be systematically streamlined into IM sector
- Availability of quality, safe and efficacious IM medicines will be increased at affordable cost
- Traditional resources in IM sector well-preserved and materialized in a sustainable manner
- Functional capacity of MIM and IM institutes will be updated and upgraded
**Policy:** Accreditation and certification of quality standards for IM pharmaceutical products

**Objective:** Institutionalize a functional mechanism in order to assure quality, safety and efficacy of IM pharmaceuticals

**Programme:** Quality, safety and efficacy of IM Pharmaceuticals

**Project 1:** Legal Reforms in IM Pharmaceutical industry
**Project 2:** Establishment of a National Authority (NADCDCA)
**Project 3:** Introducing harmonized standards with India
**Project 4:** Upgrading the National IM Pharmacopeia and Formulary

**Output:** Availability of quality, safe and efficacious IM medicines increased at an affordable cost
Policy: Encouragement of agro-communities in medicinal plants cultivation for poverty alleviation and continuous supply of raw materials in environmentally friendly manner

Objective: Establish a farmer-community cultivating medicinal plants at commercial scale in order to increase the availability of quality raw materials for IM pharmaceutical industry

Programme: Medicinal plants for poverty alleviation

Project 1: Commercial scale cultivation of medicinal plants
Project 2: Establishment of herbal gardens for MP germ-plasm conservation of endangered and threatened MP species
Project 3: Joint research ventures in MP agronomical technologies
Project 4: Development of quality standards for raw material

Output: Availability of quality raw materials ensured and economical returns to the farmer-community sustained
National Scheme Towards
Standardization and Quality Control

Government Policy Holder
Ministry of Indigenous Medicine
Department of Ayurveda
Ayurvedic Formulary Committee
National Ayurveda Research Institute
State Ayurveda Drugs Corporation

Other Government Agencies
Ministries of Export Development &
International Trade, Enterprise
Development & Investment Promotion,
Tourism, Health & Nutrition,
BOI, EDB, and WB, WHO, JICA,

INTERNATIONAL COLLABORATION

Private Sector
Eg: Investors, Trade Associations, NCCSL,
Exporters, Importers, Distributors, Cultivators,
Farmer Clusters, Professional Associations

Academia & Technical Institutes
Eg. Ayurveda Universities, PGRC, ITI,
NSF, NERD, NASTEC, IDB, SLAAS,
Botanical / Herb Gardens
(Foreign) Universities
Diversity of Market Presentation

- Herbal medicine
- Herbal healthcare products
- Nutraceuticals
- Phytoceuticals / Botanical medicines
- Functional foods / Health foods / Medical foods
- Natural dietary supplements
- Herbal supplements
- Bioactive foods
- Prebiotics / Probiotics / Symbiotics
- Cosmeceuticals / Beauty care products
- Natural products
- Personal care products
- Ayurvedic medicine
Imported Products

- Country of Origin
- Product Category
- Company Profile
- Sri Lankan Counterpart
- Quality, Safety, and Efficacy
- Authenticity of Information
- Technical Documents
- Restrictions and Limitations
- Promotion and Marketing
- Registration Guidelines
- Random Market Screening
- Local investments under BOI
National Initiatives for Future Developments

- Legal reforms
- Strengthening R & D capacity
- Revising Certification System
- Encouraging GMP
- Upgrading and Updating National IM Pharmacopeia
- Expanding and Furthering R & D on Traditional Formula
- Uplifting Sri Lankan Image in International Market
- Special Programme for promotion of “PPP”
- Enhancing Institutional Capacity and Functionality
  - eg: NQCL / NADCDA / BMARI
- Harmonized Standards
- Promotion of Regional (SAARC) Collaboration
- Pharmacovigilance Programme
- Post Market Surveillance
Scope of a Regulatory System

- Registration and accreditation
- Infrastructure and facilities
- Human resources and skilled manpower
- Technical capacity and technology
- Manufacturing process
- Machineries and equipment
- Standard operating procedures
- Product development
- Research and analysis
- Clinical trials and toxicity studies
- Environmental impact
- Raw materials and pharmaceutical inputs
- Licensing of products
- Marketing and promotion
- Testing and certification
- Intellectual Property Rights
Legal Reforms Introduced for Accreditation, Recognition and Registration Process in the Sector

- **Human Resource Sector**
  - Practitioners / Scholars / Researchers / Scientists / Pharmacists / Dispensers / Skilled Labour

- **Institutions**
  - Factories / Pharmacies / Exporters / Importers / Distributors / Franchised agents / NGOs

- **Investment Projects**
  - BOI, EDB

- **Research Interventions**
  - TK based research, Foreign Funded R & D Programmes

- **Technical Publications**
  - MP Monographs, Formula, PDR, Agronomical guides

- **Agreements with Other Agencies**
  - DWLC, DoFC, DoAg. ITI
Quality Assurance

Every Product doesn’t bear the same quality.
Everybody has the same right to be protected.
Appropriate Technology

Best way to provide Affordability
Public Confidence

Efficacy and Safety will enhance the acceptability
The Mechanism to Interlink Local Market with Global Demand

- **Local Market**
  - Industry
  - Private Sector
  - Local Suppliers

- **International Market**

- **Legal Instruments**
  - Technical Support

- **R & D, GMP, SOPs, standards, Quality Control**

- **Certification, Monitoring and Assessment**

- **Marketing & Promotion**

- **Infrastructure**
  - Trade Plan
  - Export Trade
  - Trade Links
  - Market Info-net
  - Quality Certificate

- **Remove Impediments / Coordinate National Policy Formation**

- **Quality Assurance**

- **MIM / Other Ministries / Line Agencies / Private Sector**

- **Quality Assured Products**

- **Technological Inputs**
MAY LONG LIVE ALL HUMUN BEINGS!