Regulatory Paradigms for Change: A Singapore Perspective

Dr John Lim
Chief Executive Officer
HEALTH SCIENCES AUTHORITY
Scope

- Introduction To Singapore
- Overview Of HSA
- Regulators’ Challenges
- Regulatory Paradigms For Change
- Conclusion
Singapore
- An Introduction
Singapore

- **Total land area:** 697.1 sq km
- **Population:**
  - 4.5 million
  - Ethnic groups

<table>
<thead>
<tr>
<th>Ethnic Group</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chinese</td>
<td>76.2%</td>
</tr>
<tr>
<td>Malays</td>
<td>13.8%</td>
</tr>
<tr>
<td>Indians</td>
<td>8.3%</td>
</tr>
<tr>
<td>Others</td>
<td>1.7%</td>
</tr>
</tbody>
</table>
Overview of HSA
A Statutory Board of the Ministry of Health

The Singapore Public Service
Vision
To be the LEADING INNOVATIVE AUTHORITY protecting and advancing NATIONAL HEALTH and SAFETY

Mission
- To wisely regulate health products
- To serve the administration of justice
- To secure the nation’s blood supply
- To safeguard public health

Health Products Regulation Group • Blood Services Group • Applied Sciences Group

A Statutory Board of the Ministry of Health | The Singapore Public Service: Integrity • Service • Excellence
HSA Functions & Roles

Drugs & Devices
- Product Risk Assessment
- Quality Systems Audit
- Clinical Trials Regulation
- Licensing
- Vigilance & Surveillance
- Enforcement

Health Products Regulation

Applied Sciences
- Health Products
- Quality Analysis
- Chemical Metrology

Blood Services
- Bloodbanking & Transfusion Services
- Haemovigilance

Options for new & greater synergies across Groups
Health Products Regulation Group

- Health Products Control
  - Medicinal products
  - Chinese Proprietary Medicines
  - Medical Devices
  - Cosmetic Products

- Others
  - Smoking and Tobacco Products
Key Functional Areas of Health Products Regulation

Health Products Regulation Group

Pre-market
- Clinical Trials
- Product Evaluation & Registration

Post-market
- Manufacturing & Quality Audit
- Pharmacovigilance
- Enforcement & Prosecution
- Strategy & Policy Devt

Innovative Therapeutics
Pharmaceuticals
Medical Devices
Chinese Proprietary Medicines
Regulators’ Challenges
Key Challenges (1)

Globally…

- Increasing pressure on regulators & industry
  - Public & political expectations
  - Shifting of risk appetite

- Resource constraints

- Scope of issues extending beyond routine drug approval paradigm
  - Counterfeits and illegal drugs
Key Challenges (2)

Globally…

- Emerging diseases
  - Avian flu

- New types of health products
  - Gene therapy, nanotechnology

- World is now a smaller place
  - Advance in transportation & communications
Key Challenges (3)

In Singapore...

- Relative smallness of agency
  - Need to apply innovative approaches

- Biomedical Sciences Initiative in Singapore
  - Being an enabling regulator

- Talent attraction and retention
  - Opportunities from HSA’s unique structure and for research and collaborative development
Evolving Role of the Regulator

- Rapid development in translational research
  - Need to enhance research & clinical trials infrastructure
  - Emergence of new products

- Development & enhancement of regulatory frameworks for
  - Medical devices
  - Biologics & Biotech products
  - Human Cell & Tissue Therapy
  - Complementary medicines

- Implementation of Health Products Act
- Strengthen Post-marketing Compliance Surveillance & Safety Monitoring
  - Towards a networked Regulator to enhance public health & safety
HSA

Regulatory Paradigms For Change
Determining Regulatory Balance

Regulator

Protect Public

Enable & Facilitate

Relevant, Responsive & Ready

All Rights Reserved 2008
No health product is 100% safe
“Registered” does not = risk-free product

Constant balance needed: Role, Policy & Resources

Need for Effective Communication & Trusted Spokespersons
Regulatory Philosophy (1)

- Judicious adapting of good international regulatory principles & practices to meet Singapore's unique situation, without:
  - Over-regulating
  - Simplistically adopting systems of reference agencies
  - Blindly approving products already approved elsewhere

- Wise use of regulatory tools & risk-based regulation

- Tap on expertise of external experts and researchers
Regulatory Philosophy (2)

- Engage in research to advance regulatory knowledge

- Rationalise risk management framework with clarifications of roles of risk managers at various levels

- Life-cycle approach to health products regulation (concept under development)
Foster strategic partnerships internationally and regionally
- Information sharing and collaborations through MOUs & MRAs
- Leverage on expertise and work of more advanced agencies
- Work-sharing with like-minded agencies

Proactive communications strategy
- Inspiring trust
Legislative Restructuring

Health Products Act

- To consolidate medicines control laws
- Modular approach – more responsive & flexible to deal with different degrees of risk
  - Tighter control for higher-risk products
  - Lighter control for lower-risk products
- More efficient process to adjust legislation
- Covers regulation of health products, dealers’ obligations and more appropriate penalties
<table>
<thead>
<tr>
<th>Phases of Product Development</th>
<th>Pre-Marketing</th>
<th>Post-Marketing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescription Drugs &amp; Devices</td>
<td>Non-Clinical</td>
<td>Clinical</td>
</tr>
<tr>
<td>OTC Drugs &amp; Devices Complementary Health Products</td>
<td>Manufacturing</td>
<td>Marketing Application</td>
</tr>
<tr>
<td>Cosmetic Products</td>
<td>Marketing</td>
<td></td>
</tr>
</tbody>
</table>

**Relative Risk**

- Higher
- Lower
New Drug Evaluation – Risk-based Approach

Pre-submission consultation

No prior approval by any country

Full

Product approved by one drug regulatory agency

Full quality, non-clinical, & clinical data. Requires internal & external evaluation.

Abridged

Product approved by two reference agencies

Full quality data and Phase II & III clinical data. Requires internal & external evaluation.

Verification

Verification based on full assessment report by reference regulatory agency. Internal evaluation only.

Full quality, non-clinical, & clinical data. Requires internal & external evaluation.
Inspiring Trust

Proactive Communications Strategy

- Trust needs time to build up
- Long-term communication strategy needed
- Proactively engage stakeholders
  - Ongoing education and information sharing
- Effective spokesperson
- This Trust will serve the Regulator well in times of crisis
Conclusion
Conclusion

- Challenges and role of Regulators evolving
- Regulatory paradigms must stay relevant
- Legislative Restructuring when needed
- Risk-based approach to regulation
- Need to enhance communication strategies and skills
- Global partnership is a key success factor
Thank You!

visit us again: www.hsa.gov.sg