Regulatory Systems Strengthening for Health Products in Asia Pacific

4 November 2020

Prof John LIM
Executive Director
Centre of Regulatory Excellence,
Duke-NUS Medical School, Singapore

Core Lead (Policy),
SingHealth Duke-NUS Global Health Institute
The views and opinions expressed in the following PowerPoint slides are those of the individual presenter and should not be attributed to IFPMA, its directors, officers, employees, volunteers, members, chapters, councils, communities or affiliates, or any organization with which the presenter is employed or affiliated.
### Need for Strong Regulatory Systems

#### Area of Regulatory Weakness

<table>
<thead>
<tr>
<th>2010</th>
<th>2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Circulation of low-quality medicines and inconsistent enforcement of manufacturing standards</td>
<td><strong>Potential Systemic Effect</strong></td>
</tr>
<tr>
<td>Weak licensing process for businesses and products</td>
<td>Lack of confidence in medicine quality and preference for more expensive branded or imported medicines</td>
</tr>
<tr>
<td>Inadequate reporting of adverse events and inadequate recall mechanism</td>
<td>Fewer products on the market, potential delays in access to medicines</td>
</tr>
<tr>
<td>Sale of prescription medicines over the counter</td>
<td>Reliance on adverse event data from developed countries, with potentially disastrous health impacts</td>
</tr>
<tr>
<td>Inadequate information provided with medicines</td>
<td>Risk of irrational use of a medicine or use in cases where it is contraindicated, with negative impacts on individual’s and public’s health e.g. drug resistance, adverse reactions</td>
</tr>
<tr>
<td>Unethical marketing practices</td>
<td>Overuse and inappropriate use of certain medicines</td>
</tr>
<tr>
<td>Lack of oversight for clinical trials</td>
<td>Reduction of in-country clinical trials by pharmaceutical companies and trial data that is unacceptable to regulatory authorities; harm to patients</td>
</tr>
</tbody>
</table>

#### Adapted from Selter A. A Practical Approach to Pharmaceutical Policy. 2010, World Bank.


---

2010: Poor quality of health products, Inappropriate use, Lack of suitable clinical data.
Gaps in Regulatory Systems

Findings from a Duke-NUS CoRE project supported by the Asian Development Bank on regulatory systems strengthening in the Greater Mekong Subregion
Key principles for RSS as identified by international regulatory and industry organisations:

- Promote regulatory convergence through implementing global technical guidances and sharing similar requirements
- Implement regulatory reliance to enhance regulatory efficiency and effectiveness
- Commit to relevant capacity building to build competence and skills for effective regulatory outcomes
Regulatory Agility

Regulatory framework
- Flexibility to accommodate urgent public health emergencies
- Ability to adopt new regulatory approaches and innovation

Regulatory processes and requirements
- Regulatory convergence
- Regulatory cooperation
- Rolling submissions
- Use of Real World Evidence

- Timeliness of response
- Support scientific rigor of regulatory decisions
- Efficient use of resources

Impactful healthcare intervention
Advancing Regulatory Systems Strengthening in Asia Pacific

Strengthen Regional Collaboration Initiatives
- Build trust among regulators in the region

Commit to Regulatory Capability building
- Coordinate activities and use of resources
- Account for outcomes and measures of development plans
- Sustain efforts for long-term gains
To enhance the success of regulatory systems strengthening for health products, the wider context of the overall healthcare ecosystem needs to be considered and factored into regulatory frameworks and decision-making.
Towards the Success of Regulatory Systems Strengthening

**Enabling Factors**

- Expand goals of regulatory systems strengthening to health systems
- Incorporate multiple stakeholder perspectives into decision-making
- Develop frameworks for novel health products and regulatory science
Regulatory Systems Strengthening for Health Products in Asia-Pacific

https://youtu.be/ydV9UWAC16g
Thank you!

10th Asia Regulatory Conference 2020
Building Trust & Partnership to Deliver UHC in Asia