Comprehensive Measures to Increase Access to Medicines & research and development

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Food and Drug Administration, Thailand

PMAC Side Meeting: Ensuring Effective Access to Essential Medicines in Thailand
29 Jan 2020 @ Centara Grand Central World
Comprehensive Measures

- Targeted List of Priority Medicines
- Herbal Medicinal Products with Local Capacities to R&D and Production
- Medicines with the export potential or revenue generation
- Essential medicines with high cost

- Fast-track Drug Approvals & fee reduction
- Support R&D and Local Manufacturing
- NLEM + Reference Prices

Food and Drug Administration

Drug System Challenge 1
Comprehensive Measures: Results

**Output/Outcome**

<table>
<thead>
<tr>
<th>License</th>
<th>Estimate Saving (Million Baht)</th>
</tr>
</thead>
<tbody>
<tr>
<td>21 Generics (106 Licenses)</td>
<td>4,400</td>
</tr>
<tr>
<td>18 Generics (33 Licenses)</td>
<td>1,500</td>
</tr>
</tbody>
</table>

**Goal**

<table>
<thead>
<tr>
<th>2020</th>
<th>2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 Generics</td>
<td>50 Generics</td>
</tr>
<tr>
<td>2,500</td>
<td>4,000</td>
</tr>
</tbody>
</table>

**Phase I**

**Phase II**

**License**

**Result**

<table>
<thead>
<tr>
<th>2016-2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016-2018</td>
<td>2019</td>
</tr>
</tbody>
</table>

**Targeted Medicine License**

<table>
<thead>
<tr>
<th>Licenses</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>13</td>
<td>18</td>
<td>23</td>
</tr>
<tr>
<td>Local</td>
<td>8</td>
<td>8</td>
<td>23</td>
</tr>
<tr>
<td>Import</td>
<td>5</td>
<td>10</td>
<td>0</td>
</tr>
</tbody>
</table>

**Cumulative Saving from Std. Price Setting**

<table>
<thead>
<tr>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>126</td>
<td>1,268</td>
<td>2,430</td>
<td>4,963</td>
<td>13,255</td>
</tr>
</tbody>
</table>

**Total 959 Items**

<table>
<thead>
<tr>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>38</td>
<td>29</td>
<td>13</td>
<td>452</td>
<td>427</td>
</tr>
</tbody>
</table>
Innovative & Fast-track Licensing Strategy

Benefit-Risk Balance

Risk-based

Proactive concurrent consultation
- Work sharing with Stringent Regulatory Authority
- Internal Reviewer supported by University & External expert

Information, Communication, Transparency (COI, Assessment report)
Registration System Model implemented since 2016

1. Product classification
2. Scientific Advice/Protocol assistant
3. Stepwise registration

Pilot Office for assessment

Working group for product assessment /scientific advice

Herbal products
Biological products
Chemical products

Development of policy, law and regulation

Development of Technical guidelines and process guidelines

Service

Product classification
Quality consultation
Non-clinical consultation
Clinical trial consultation
Prior assessment consultation
Pre-Application consultation
Review application & Re-evaluation

Service evaluation

Technical & process guideline

Biologics
Herbals
Chemical

Quality
Non clinical
Clinical study

Drug development

Pre & Post- Marketing

Financing
Advisory Expert Panels
Human Resources: Evaluators & staffs

Infrastructure/Organization
Policy, Legislation, Regulation
The regulatory consideration model

**Application types**

- **IND**
  - Risk-based Products
  - Application type
  - Data requirement
  - Process
  - Technical guideline

**Product type**

- Drug product
  - Modern drug
  - New drug
  - Generic drug
  - Generic with BE/Bio-waiver
  - Low risk product
  - Herbal products
    - Traditional medicine
    - Herbal medicine

- Biological Drug
- Radioactive product
- Chemical Drug

**Pre-submission consultation**

- E-Submission
  - Standalone & Mix application
  - Fixed combination application
  - Well-established use application
  - Hybrid application
  - Biosimilar application
  - Generics with BE application
  - Generics without BE application

**Assessment**

- Benefit-Risk Analysis

- **IND**
  - Expert panel
  - Consultation System

- **Pre-submission consultation**
  - Application types
    - Variation Application
      - Major Variation - MaV
      - Minor Variation–MiV
        - Minor Variation Prior Approval – MiV-PA
        - Minor Variation Notification – MiV-N

- **Application Review**
  - Type of Review
    - Full
    - Abbreviated
      - Fee

- **Assessment**
  - GMP GDP/GSP
  - CMC
  - Labelling
  - BE/NC/C/CE
  - RMP surveillances

Assessment report (AR) / Public assessment report (PAR) / Information sharing
Lot/Batch release for vaccine, certain biological products
Registration Pathway of Herbal Medicinal Product

Herbal product

- Medicinal product
  - Herbal medicine
    - Modified Herbal Medicines using modern technology
    - Scientifically established herbal medicines
  - Modern herbal medicines
- Traditional medicine
  - Thai traditional medicine
  - Chinese traditional medicines
  - Thai folk medicines or modified product accepted within the system of Thai/Chinese traditional medicine
- Food supplements
  - Others Traditional medicine

Modern drug
Thank you