Malaysia’s Experience and Challenges in Implementing GDP

Centre of Compliance and Licensing
National Pharmaceutical Regulatory Agency (NPRA)
Ministry of Health Malaysia
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“The measures that need to be considered in the storage, transportation and distribution of any registered product/notified cosmetic and such that the nature and quality intended is preserved when it reaches the consumer.”
Evolvement of GDP Requirement

GSP
1995 – 2003 (1st Ed.)
2004 – 2010 (2nd Ed.)

GDP
2011 – 2012 (1st Ed.)
2013 - 2017 (2nd Ed.)
2018 - present (3rd Ed.)*

* with Annexes
### Evolvement of GDP Requirement

<table>
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<tr>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
<th>Phase 4</th>
<th>Phase 5</th>
<th>Phase 6</th>
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<tbody>
<tr>
<td>Licensing May 1987</td>
<td>Licensing 1992</td>
<td>Licensing Manufacturer Importers Jan 1999</td>
<td>Licensing Jan 2004</td>
<td>Licensing 1 Jan 2012*</td>
<td>No licensing Requirements as registration of API is linked to products</td>
</tr>
</tbody>
</table>
Directive on GDP

Issued by Senior Director of Pharmaceutical Services

*under Regulation 29*

*Control of Drugs and Cosmetics Regulation 1984*

- Compliance towards Good Distribution Practice (GDP) Guideline requirements
- Enforced since 1st January 2012
- For all local manufacturers/importers/wholesalers of registered products/notified cosmetic
01 How do we regulate GDP in Malaysia?

Challenges faced by NPRA in implementing GDP

02 Challenges faced by the industry to comply with GDP requirement

03 Impact of GDP implementation

04 Way forward ...
How do we regulate GDP in Malaysia??

- Involving manufacturers, importers and wholesalers of registered products/notified cosmetics
  - Manufacturers – subjected to GMP and GDP requirements, inspection performs by NPRA officers
  - Importers and wholesalers – subjected to GDP requirements *
How do we regulate GDP in Malaysia??

• GDP inspection performs by NPRA officers in collaboration with States Pharmacy Enforcement Division *

• Initial and Routine
  ➢ Consideration for issuance of Import License and Wholesaler License

• Special
  ➢ Inspection to verify the cold chain facility of the importer/wholesaler
How do we regulate GDP in Malaysia?

Challenges faced by NPRA in implementing GDP

Challenges faced by the industry to comply with GDP requirement

Impact of GDP implementation

Way forward...
Challenges faced by NPRA in implementing GDP

- Distribution network involves many parties and getting more complicated (multiple distribution levels & channels)
  - Lack of awareness among stakeholders
  - Understanding of GDP requirement among stakeholders are varies
<table>
<thead>
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<th>Ranking</th>
<th>Criterion</th>
<th>Deficiencies</th>
<th>Non-compliance Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>8.1</td>
<td>Procedure of Handling Substandard and Falsified Products/Cosmetics was not established.</td>
<td>76.83</td>
</tr>
<tr>
<td>2</td>
<td>3.15</td>
<td>Temperature mapping exercise was not carried out on the storage area.</td>
<td>65.85</td>
</tr>
<tr>
<td>3</td>
<td>2.6</td>
<td>Training effectiveness evaluation was not conducted.</td>
<td>53.05</td>
</tr>
<tr>
<td>4</td>
<td>10.1</td>
<td>Self-inspection procedure was not established.</td>
<td>48.78</td>
</tr>
<tr>
<td>5</td>
<td>3.13</td>
<td>Equipment used for monitoring conditions was not calibrated.</td>
<td>46.98</td>
</tr>
<tr>
<td>6</td>
<td>2.4</td>
<td>Training records were not established.</td>
<td>45.12</td>
</tr>
<tr>
<td>7</td>
<td>11.1</td>
<td>Written procedures used were not approved and not indicated with any approval date.</td>
<td>43.90</td>
</tr>
<tr>
<td>8</td>
<td>2.3</td>
<td>Training procedure / Training programme was not established.</td>
<td>43.29</td>
</tr>
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<td>Ranking</td>
<td>Criterion</td>
<td>Deficiencies</td>
<td>Non-compliance Percentage (%)</td>
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<td>---------</td>
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<td>------------------------------------------------------------------------------</td>
<td>-------------------------------</td>
</tr>
<tr>
<td>9</td>
<td>10.3</td>
<td>Self-inspection report was not established.</td>
<td>35.98</td>
</tr>
<tr>
<td>10</td>
<td>3.16</td>
<td>The maintenance schedule of equipment and premises was not established.</td>
<td>35.37</td>
</tr>
<tr>
<td>11</td>
<td>4.9</td>
<td>Procedure of Handling Returned Product/Cosmetics was not established and its records were not kept.</td>
<td>34.76</td>
</tr>
<tr>
<td>12</td>
<td>9.2</td>
<td>Contract Giver did not assess the competency of Contract Acceptor accordingly.</td>
<td>33.54</td>
</tr>
<tr>
<td>13</td>
<td>4.13</td>
<td>Product/cosmetic disposal procedure was not established and disposal record was not kept.</td>
<td>32.93</td>
</tr>
<tr>
<td>14</td>
<td>10.2</td>
<td>Self-inspections should be conducted in an independent way by a designated, competent person.</td>
<td>32.32</td>
</tr>
<tr>
<td>15</td>
<td>9.1</td>
<td>There must be a written contract between the Contract Giver and the Contract Acceptor which clearly established the duties of each party.</td>
<td>31.71</td>
</tr>
</tbody>
</table>
Challenges faced by NPRA in implementing GDP

- Emerging of E-commerce
  - Transportation by courier company, online platform shipper, delivery sharing platform
  - Direct shipping from oversea
  - Unauthorized online seller without proper storage and transportation
  - Counterfeit product
  - Track & Trace issue
Challenges faced by NPRA in implementing GDP

• To ensure all importers and wholesalers of TTSPs comply to TTSP requirement
  ➢ Stringent requirement
  ➢ Difficulties in identifying hidden TTSP wholesalers especially brokers or middle man
Challenges faced by NPRA in implementing GDP

- Different GDP requirements among countries
  - Country specific requirements – security label (hologram)
  - Labeling requirements – may involved repacking activities
- Readiness of stakeholders to comply with current GDP requirement
- Standardization in interpretation of guideline by different agencies
Challenges faced by NPRA in implementing GDP

• Language barrier
  ➢ Multi racial and multi lingual society: interpretation of guideline and communication barrier during inspection
How do we regulate GDP in Malaysia?

Challenges faced by NPRA in implementing GDP

Challenges faced by the industry to comply with GDP requirement

Impact of GDP implementation

Way forward ...
Challenges faced by the industry to comply with GDP requirement

- Financial shortage (cost vs. compliance)
  - Cost of equipment/premises maintenance, pest control, temperature mapping, upgrading of premises, etc.

- Lack of human resource, knowledgeable/qualified/competent personnel
  - Small-medium/family-oriented companies which operate small businesses
  - Difficulties to implement GDP requirements within company such as independency of internal audit, training, documentation, etc.
Challenges faced by the industry to comply with GDP requirement

• Different/Lack of GDP understanding
  ➢ Different background e.g. SMEs vs. MNCs, company owner vs. knowledgeable/qualified personnel, company handling pharmaceuticals vs. company handling cosmetics

• Regulatory compliance
  ➢ Handling various type of products (pharmaceutical, medical device, food, etc.) – need to adhere to different guideline requirement imposed by different agencies
Challenges faced by the industry to comply with GDP requirement

- Inability in information accessing
  - Geographical restriction - inconvenient to approach RA in person
  - Lack of training opportunity
  - Lack of knowledgeable/competent workers especially in remote area
Challenges faced by the industry to comply with GDP requirement

- Inappropriate government/RA policies
- Customer attitudes and behaviors
- Rivals’ influences
How do we regulate GDP in Malaysia?

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Impact of GDP implementation

Way forward ...
Impact of GDP implementation

The quality, safety and efficacy of products can be preserved along the distribution chain

Helps company save cost with the quality principle of ‘do it right at the first time’

Improve traceability of product

Helps securing the distribution system from counterfeits, unapproved, illegally imported, stolen, substandard, adulterated, and/or misbranded medicinal products/cosmetics
Impact of GDP implementation

Requires company to invest largely at the initial stage (financial & personnel resources) - increase in operation cost

Deepens the gap between ‘big’ player and ‘small’ player which have limitation in both financial & human resources

Closure of business
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Way forward ..... 

• Challenges in finding balance between regulatory compliance and business/marketing plan

• Work hand in hand (industry & RA) to improve GDP compliance
  ➢ having dialogues with relevant stakeholders
  ➢ organizing training events – reaching out to the industry/counterparts to enhance understanding
  ➢ organizing public engagement before implementation of new policy or guideline requirements