



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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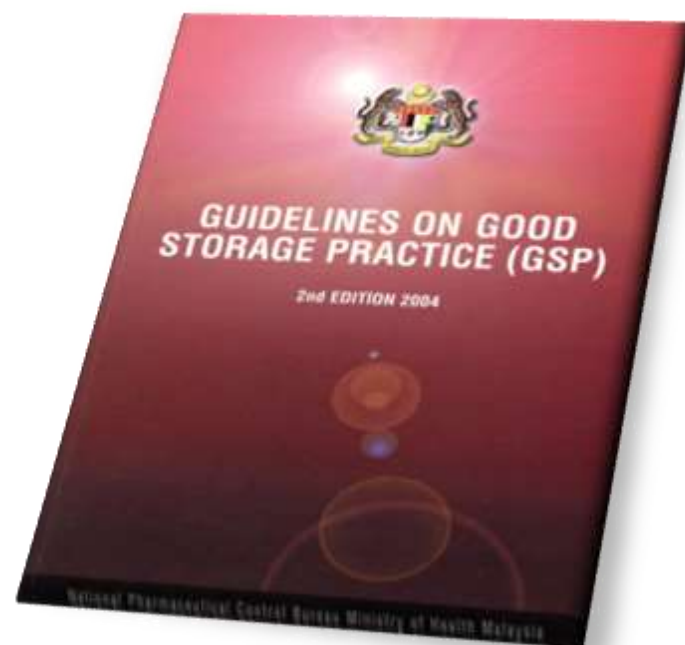
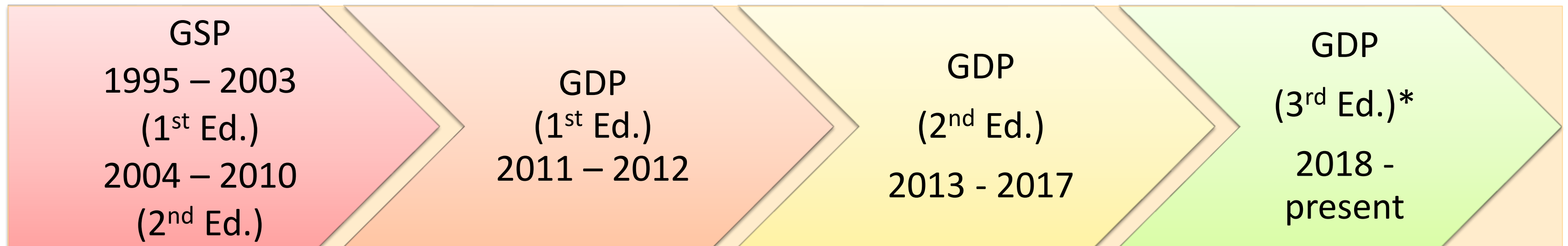


Good Distribution Practice (GDP)

“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.”



Evolution of GDP Requirement



* with Annexes



Evolution of GDP Requirement

Phase 1	Phase 2	Phase 3	Phase 4	Phase 5	Phase 6
Registration Aug 1985 (Prescription Drugs)	Registration 1988 (OTC)	Registration Jan 1992 (Traditional Medicine)	Registration Feb 2002 (Cosmetics)	Registration Aug 2007 (Veterinary)	Regulatory control of Active Pharmaceutic al Ingredient (API)**
Licensing May 1987	Licensing 1992	Licensing Manufacturer Importers Jan 1999	Licensing Jan 2004	Licensing 1 Jan 2012*	No licensing Requirements as registration of API is linked to products



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



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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



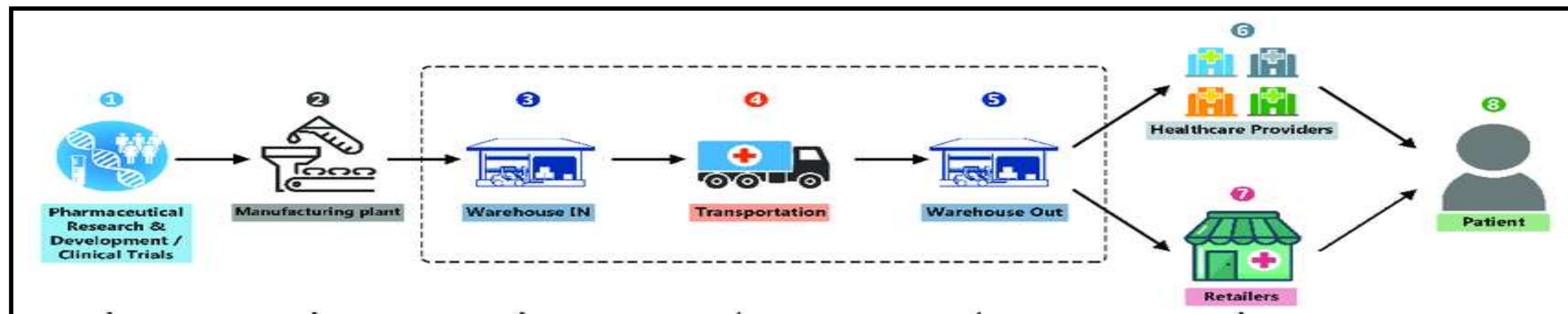
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Challenges faced by NPRA in implementing GDP

- 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





Ranking	Criterion	Deficiencies	Non-compliance Percentage (%)
1	8.1	Procedure of Handling Substandard and Falsified Products/Cosmetics was not established.	76.83
2	3.15	Temperature mapping exercise was not carried out on the storage area.	65.85
3	2.6	Training effectiveness evaluation was not conducted.	53.05
4	10.1	Self-inspection procedure was not established.	48.78
5	3.13	Equipment used for monitoring conditions was not calibrated.	46.95
6	2.4	Training records were not established.	45.12
7	11.1	Written procedures used were not approved and not indicated with any approval date.	43.90
8	2.3	Training procedure / Training programme was not established.	43.29



Ranking	Criterion	Deficiencies	Non-compliance Percentage (%)
9	10.3	Self-inspection report was not established.	35.98
10	3.16	The maintenance schedule of equipment and premises was not established.	35.37
11	4.9	Procedure of Handling Returned Product/Cosmetics was not established and its records were not kept.	34.76
12	9.2	Contract Giver did not assess the competency of Contract Acceptor accordingly.	33.54
13	4.13	Product/cosmetic disposal procedure was not established and disposal record was not kept.	32.93
14	10.2	Self-inspections should be conducted in an independent way by a designated, competent person.	32.32
15	9.1	There must be a written contract between the Contract Giver and the Contract Acceptor which clearly established the duties of each party.	31.71



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





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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



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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

