



Licensing of Drug Packaging Manufacturers

Review Committee's recommendation

- The Administration should require both primary and secondary packaging be carried out by a licensed manufacturer

Primary and Secondary packaging

PIC/S GMP definition:

- Packaging: “All operations, including filling and labelling, which a bulk product has to undergo in order to become a finished product.”
- Packaging material: “Any material employed in the packaging of a medicinal products, excluding any outer packaging used for transportation or shipment. ***Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.***”

Licensing of drug packaging manufacturers

- “No person shall manufacture any pharmaceutical product on any premises unless he is the holder of a licence to manufacture pharmaceutical products on those premises”

[Pharmacy and Poisons Regulations, Cap 138A Reg. 29(1)]

- “manufacture” means “the preparation of pharmaceutical products for sale or distribution...”

[Pharmacy and Poisons Ordinance, Cap 138 section 2]

Licensing of drug packaging manufacturers

- To implement the Review Committee's recommendation and to fulfill the legal requirements, all manufacturers involved in packaging activities, both primary and secondary included, should be duly licensed

Licensing of drug packaging manufacturers

- It is proposed that secondary packaging, which may affect the quality and safety of pharmaceutical products, should only be performed by holders of the “**licence for manufacturer**”
- With a condition limiting the licence holder to conduct secondary packaging operations only

Current situation

- Currently, manufacturers involved in primary packaging are all licensed GMP manufacturers
- Among the licensed wholesalers and importers/exporters, about 160 reported they are involved in secondary packaging

Implementation Proposal

- Consultation with the trade (early 2013)
- Licensing of secondary packaging manufacturers (2013)
- Issuance of guidance notes on implementing PIC/S GMP (2013)
- Impose licensing condition to prohibit WPL and I/E of pharmaceutical products from conducting secondary packaging activities (2014)
- Implementation of PIC/S GMP (2014)
- Full compliance of PIC/S GMP (2015)

Consultation with the trade (2013)

- Consultation with trade associations (HKAPI, HKPDA & HKPMA)
- Consultation with major players (DKSH, LF Asia & Zuellig)
- Consultation with dealers

Licensing of drug packaging manufacturers (2013)

- Fulfill all the legal requirements for manufacturers (Reg. 30 - 35 of PPR)

Legal requirements for manufacturers

- Manufacture under supervision of a registered pharmacist or a person approved by the PPB
- Labelling
- Personnel hygiene
- Testing of bulk material
- Testing of products in finished form
- Keep control sample for each batch (retain samples)
- Appropriate premises
- Record keeping

Issuance of guidance notes on implementing PIC/S GMP (2013)

- Preparation with assistance from DH consultant
- Abridged version of the PIC/S GMP guideline that are applicable to manufacturers only involved in secondary packaging activities
- To facilitate traders on transition to PIC/S GMP standards
- To unify inspection and licensing standards

Prohibit WPL and I/E from conducting secondary packaging (2014)

- Impose licensing condition to prohibit WPL and I/E of pharmaceutical products from conducting secondary packaging activities

Implementation of PIC/S GMP (2014)

- License with condition: to comply fully with the PIC/S GMP **by 2015**
- Allow key personnel to accumulate the required GMP experience
- Drug Office will issue guidance notes to facilitate traders to implement PIC/S GMP

Full compliance of PIC/S GMP (2015)

- Mandatory compliance of PIC/S GMP for renewal or issuance of new licence **by 2015**



Thank you