Overview of Legislation for Manufacturers

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Pharmacy and Poisons Board

1 Under the Pharmacy and Poisons Ordinance, Cap.138 of the Laws of Hong Kong, "manufacture" means (a)(i) the preparation of pharmaceutical products, from purchase or acquisition of materials, through processing and packaging, to their completion as finished products for clinical trial, sale or distribution; or (ii) the repackaging of pharmaceutical products as finished products for clinical trial, sale or distribution; but (b) does not include the individual dispensing on a prescription or otherwise of the product if the product (i) is not an advanced therapy product; or (ii) is an advanced therapy product the dispensing of which does not involve substantial manipulation of cells or tissues. "Manufacturer", in relation to a pharmaceutical product, means a person who manufactures the product.

2 Part 7 of the Pharmacy and Poisons Regulations ("the Regulations") relates to the licensing of pharmaceutical manufacturers. A person must not manufacture any pharmaceutical product on any premises unless he is the holder of a licence to manufacture pharmaceutical products on those premises.

3 A person is not regarded as manufacturing a pharmaceutical product only by affixing to the container of the product a label—

(a) that does not state any of the following particulars—

(i) particulars regarding—

(A) designation and quantitative particulars of the ingredient(s),

(B) batch number,

(C) expiry date of the pharmaceutical product,

(D) for an advanced therapy product—

(i) the product code, and the unique donation identifier, assigned in accordance with the codes of practice issued by the Board; and

(ii) if the product is for autologous use only—

- the unique recipient identifier assigned in accordance with the codes of practice issued by the Board; and
- the English words "For autologous use only" or the Chinese characters "只供自體使用";

(ii) particulars regarding the dosage, route or frequency of administration of the product;

(iii) the name of the product; and

(b) that does not obscure, change or obliterate any of the following particulars labelled on the container—

(i) particulars mentioned in subparagraph (a) above;

(ii) name and address of the manufacturer.

4 The licensing authority is the Pharmacy & Poisons (Manufacturers Licensing) Committee, an Executive Committee established under the Pharmacy and Poisons Board ("the Board"). The licensing requirements to be met in awarding a manufacturer licence and during licence renewal include—

(a) pharmaceutical products are manufactured by or under the supervision of a registered pharmacist or person approved by the Board;

(b) at least one authorized person is employed to be responsible for ensuring and certifying that each batch of the pharmaceutical products has been manufactured and checked in accordance with the Good Manufacturing Practice Guide ("the GMP Guide"); and the registrable particulars of each batch of the pharmaceutical products correspond exactly with the registered particulars of the products;

(c) proper labelling of pharmaceutical products manufactured;

(d) premises used in the manufacturing, testing and dispatch of pharmaceutical products being suitable for the purpose;

(e) adequate hygiene control of personnel and premises to avoid contamination of pharmaceutical products;

(f) quality assurance of raw materials and finished products with retention of control sample and all related records;

(g) compliance with the GMP Guide issued by the Board;

(h) results of inspection, which is conducted to evaluate whether the premises under application are fit for the licence purposes;

(i) previous drug-related conviction(s), in particular those have significant impact to the public interest, of the applicant or his key personnel, if applicable; and

(j) previous disciplinary action(s) against the applicant or his key personnel, if applicable.

5 A licensed manufacturer selling his own products by way of wholesale dealing does not require a wholesale dealer licence, but he shall comply with the requirements under Part 6 of the Regulations in the same way as a wholesale dealer. Manufacture of dangerous drugs is required to hold an additional licence issued by the Director of Health under the Dangerous Drugs Ordinance, Cap. 134.