Inspection of Manufacturers of Pharmaceutical Products

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Pharmacy and Poisons Board

Introduction

1. According to regulation 29 of the Pharmacy and Poisons Regulations, Cap. 138A, Laws of Hong Kong ("the Regulations"), 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. The Pharmacy and Poisons (Manufacturers Licensing) Committee ("the Committee") is responsible for the licensing of manufacturers under the Regulations. The Manufacturers Regulatory Unit and the Wholesalers Regulatory Unit of the Drug Office, Department of Health, are responsible for conduction inspections on manufacturers and making recommendations to the Committee regarding the licensing of these manufacturers.

Purpose of Inspection

2. The purpose of the inspections on manufacturers is to assess their compliance to the Good Manufacturing Practice ("GMP") Guide issued by the Pharmacy and Poisons Board ("the Board") and the relevant regulatory requirement.

Scheduling of Inspection

3. The frequency of inspection is based on the concept of rating manufacturing sites on the basis of an estimated risk that they may pose to patients, consumer and users of medicines, taking into account the complexity of the site, the manufacturing processes, the criticality of the products as well as the GMP compliance level of the manufacturer, etc.

Inspection Duration

4. Depending on the complexity of the company's operations and the purpose of the inspection, an inspection generally takes two to five days.

Inspection Team

5. An inspection team generally consists of one lead inspector and assisting inspector(s). Where appropriate, one or more technical specialists may be included. The lead inspector is responsible for leading the inspection and compiling the inspection report. The inspection team may also include inspector trainees or observers. All inspection team members are bounded by obligations of confidentiality.

Inspection Steps

6. The major stages of inspection processes are:

- Opening meeting
- Site inspection
- Closing meeting

Opening meeting

7. In the opening meeting, inspectors shall meet the management and key personnel from the manufacturer to discuss the arrangements for inspection. The lead inspector will typically explain the purpose and scope of inspection, the inspection plan and schedule. Representative of the manufacturer is required to brief the inspection team on any significant changes since last inspection.

Site inspection

8. The scope of inspection includes inspecting the manufacturing, quality control and storage facilities, interview with personnel and a review of system, documentation and procedures of the manufacturer. Inspectors may take samples during inspection for analysis by the Government Laboratory when necessary.

Closing meeting

9. The inspection team will provide a verbal summary of inspection findings and allow the manufacturer to clarify any deficiencies. The priorities and timelines for corrective and preventive actions may be discussed. The manufacturer's representatives attending the closing meeting normally include the key personnel and the senior management.

Inspection Report

10. The lead inspector shall prepare an inspection report describing findings, observations and deficiencies. The report will be reviewed by a senior pharmacist before sending to the manufacturer. The manufacturer shall normally rectify the deficiencies within the timeframe specified in the covering letter to the report. Follow-up inspection may be conducted to verify the effectiveness of the manufacturer's rectification measures.

Power of the Pharmacy and Poisons (Manufacturers Licensing) Committee

11. According to regulation 29 of the Regulations, the Committee has the power to revoke a licence to manufacture pharmaceutical products or suspend it for a period it thinks fit, issue a warning letter, or vary a condition of the licence, if, in the Committee's opinion, the licensed manufacturer has contravened a condition of the licence or any of the Regulations, a code of practice applicable to the licensed manufacturer or the GMP Guide issued by the Board, or has been convicted of a drug-related offence.

12. Any person aggrieved by a decision of the Committee under the regulation may appeal to the Pharmacy and Poisons Appeal Tribunal against that decision.