

## LCQ5: Handling an incident of suspected drug contamination by Department of Health

Following is a question by the Dr Hon Helena Wong and a reply by the Secretary for Food and Health, Professor Sophia Chan, in the Legislative Council today (July 11):

Question:

On the 21st of last month, the Department of Health (DH) received a report from the Queen Mary Hospital that Enzyplex, a commonly used drug for treatment of digestive disorders, was suspected of having been contaminated by mould. On the following day, the supplier of that drug requested all its clients to suspend the supply and sale of the drug to patients or customers, and the Hospital Authority also immediately ceased dispensing the drug in public hospitals. On the 26th of last month, DH endorsed the supplier's recall of all batches of the drug from the market due to a quality issue, and called on members of the public to stop taking the drug. In this connection, will the Government inform this Council:

(1) since when the clinics under DH have ceased dispensing the drug concerned;

(2) of the reasons why not until five days after the receipt of the report did DH call on members of the public to stop taking the drug; whether DH has reviewed if such a response was too slow; if DH has reviewed and the outcome is in the affirmative, of the improvement measures to be put in place; and

(3) whether it will establish a system under which sampling checks will be conducted on imported pharmaceutical products at import, wholesale and retail levels, in order to better protect public health; if so, of the details; if not, the reasons for that?

Reply:

President,

In consultation with the Department of Health (DH), my reply to the three parts of the question is as follows:

(1) and (2) In accordance with the Pharmacy and Poisons Regulations (Cap. 138A) and the Code of Practice for Holder of Wholesale Dealer Licence, the DH has to take into account various factors in exercise of the powers (including the order to recall products) vested in the department by the legislation and licensing conditions, or before calling on the public to stop taking a registered pharmaceutical product. In general, the DH is required to make a preliminary assessment as to whether the incident poses a significant public health risk, and may order suppliers to recall the product or call on the

public to stop taking the product after obtaining the analysis results.

As regards the subject incident, the DH received a report from the Queen Mary Hospital (QMH) on June 21, 2018 that a pharmaceutical product named Enzyplex was suspected of having been contaminated by Monascus. The DH's Drug Office immediately started an investigation and collected a total of 13 samples from the local suppliers, the QMH and the dispensaries of DH clinics for analysis. These samples were taken from ten different batches of Enzyplex, including two batches involved in the report made by the QMH.

In the afternoon on the same day, the Drug Office delivered all the samples to the laboratory of the Centre for Health Protection for analysis. An analysis was conducted in accordance with the requirements specified by pharmacopoeias (Note) to ascertain whether the product had exceeded the pharmacopoeial standards for the total mould and yeast count and the total bacterial count of non-sterile oral products. According to the pharmacopoeial methods and requirements, an analysis of the total bacterial count takes five full days while that of the total mould and yeast count needs seven full days.

On the same day (i.e. June 21), the DH made the incident public and instructed the local supplier to ask the Indonesian manufacturer of the product to conduct an investigation.

On June 22, the supplier submitted to the DH the results of a preliminary assessment of the drug conducted by the Indonesian manufacturer, which stated that the raw materials and the production environment met the pharmacopoeial standards or its in-house specifications. However, as a precaution, the supplier asked its clients on the same day to stop supplying the drug to the public pending the completion of the DH's investigation. DH clinics and the Hospital Authority also stopped dispensing the drug with immediate effect.

The analysis of the bacterial content was completed on the afternoon of June 26 as scheduled. The analysis results showed that all the samples complied with the pharmacopoeial standards. However, as the bacterial content was found to have exceeded the in-house specifications set by the manufacturer, the supplier recalled the relevant batches of the drug on their own initiative. The DH announced the update on the same day and asked the public to stop taking the drug. DH clinics proactively contacted the patients concerned and called on them to stop taking the drug. The DH also asked the manufacturer to conduct a further investigation based on the latest analysis results.

The analysis of the total mould and yeast content was completed on the afternoon of June 28 as scheduled. The analysis results showed that all the samples complied with both the pharmacopoeial requirements and the in-house specifications set by the manufacturer. The DH also announced the analysis results on the same day.

In sum, the DH conducted an investigation of the product in accordance with the legal requirements and made public the results timely. The 13

samples collected for the investigation complied with the pharmacopoeial requirements on the total mould and yeast count and the total bacterial count of non-sterile oral products.

Note: In respect of the microbiological standards for non-sterile pharmaceutical products, the mainstream pharmacopoeias worldwide (e.g. European Pharmacopoeia, US Pharmacopoeia and Chinese Pharmacopoeia) have established the same standards, i.e. the total mould and yeast count and the total bacterial count of non-sterile oral solid pharmaceutical products should not exceed 200 cfu/g and 2 000 cfu/g respectively.

(3) Under the Pharmacy and Poisons Ordinance (Cap. 138), pharmaceutical products must satisfy the criteria of safety, efficacy and quality, and must be registered with the Pharmacy and Poisons Board before they can be supplied in Hong Kong. For manufacturers, the most important and effective way to ensure the quality and safety of their products is to strictly comply with the Good Manufacturing Practices (GMP) for medicines. As regards the pharmaceutical products registered in Hong Kong, be they locally produced or imported, their manufacturers must meet the GMP requirements of the Pharmaceutical Inspection Co-operation Scheme (PIC/S).

In addition, the DH has an established mechanism where samples of pharmaceutical products (including locally produced and imported products) are collected from suppliers and the market for regular analysis according to risk assessment. Items for analysis include the content of the active ingredients of a product and other requirements of the pharmacopoeia (e.g. testing for microbiological quality and dissolution test for tablets, and sterility test for sterile preparations) on different dose forms. When a product is found to be non-compliant with the relevant specifications or requirements, the DH will conduct an investigation immediately and, where necessary, require the supplier to recall the products and make a public announcement. The above sampling mechanism and the regulatory measures for pharmaceutical products have been working effectively over the years.