

The Department of Health (DH) reviews the medicines containing red yeast rice in Hong Kong

The DH, in response to the incident of red yeast rice products produced by Kobayashi Pharmaceutical Co. Ltd. (Kobayashi Pharmaceutical) of Japan, has reviewed and taken the following actions on medicines containing red yeast rice in Hong Kong.

They are:

1. Red yeast rice (also known as red fermented rice) is artificial culture of the fungus *Monascus purpureus* Went, inoculated in rice. It contains chemical substance lovastatin. Red yeast rice has all along been used as food colourant, flavour enhancer, for meat preservation and wine brewing in Asia.
2. The DH immediately contacted the Hong Kong branch of Kobayashi Pharmaceutical and learnt that the concerned products are not registered medicines, nor are they regulated as pharmaceutical products in Japan. The products have not been marketed by the company in Hong Kong.
3. The DH notes that in 2019, the Pharmacy and Poisons Board of Hong Kong (the Board) established under the Pharmacy and Poisons Ordinance (Cap. 138) (PPO) had deliberated the sales control of red yeast rice containing the ingredient of lovastatin. Considering red yeast rice is widely used in food and the amount of lovastatin contained is generally not more than 0.6 per cent, and with reference to the practice of other drug regulatory authorities, the Board decided that only products containing lovastatin with a daily dose of 10mg or more would be regarded as pharmaceutical product, which shall be registered as prescription only medicine by the Board before they could be sold or distributed in Hong Kong. According to the record, there is no registered pharmaceutical product in Hong Kong containing red yeast rice as active ingredient currently. The DH noted from the local manufacturers of pharmaceutical products that they had not used red yeast rice as raw materials for their registered pharmaceutical products. In addition, the DH has not received any adverse reaction reports in connection with pharmaceutical products containing red yeast rice.
4. On the other hand, when red yeast rice is used as Chinese medicine and the product concerned fulfils the definition of proprietary Chinese medicine (pCm) under the Chinese Medicine Ordinance (Cap. 549) (CMO), it must be registered with the Chinese Medicines Board (CMB) of the Chinese Medicine Council of Hong Kong

before it can be sold or possessed in Hong Kong. Currently, there are three pCm containing red yeast rice as active ingredient registered in Hong Kong. None of them is produced by Kobayashi Pharmaceutical in Japan. The DH has contacted the registration holders and confirmed that the raw material of red yeast rice used in the three registered pCm were not manufactured by Kobayashi Pharmaceutical in Japan. The DH has not received any adverse reaction report in connection with the products.

5. Considering that red yeast rice contains lovastatin, if people taking pCm containing red yeast rice also consume other statin-like medicines or other products containing red yeast rice at the same time, the risk of adverse reactions may increase. The CMB decided to enhance relevant regulation in 2020 such that registered pCm containing red yeast rice as active ingredient must list out the ingredient of red yeast rice on the product labels and package inserts, as well as include a precautionary statement "Should avoid using this product concurrently with statin drugs or other products containing red yeast rice, or consult medical professionals before use" to ensure the use of medicine by the public safely.
6. In Hong Kong, products that fall within the definition of "pharmaceutical products" under the PPO and "pCm" under the CMO must comply with the respective regulatory requirements for safety, quality and efficacy and be registered before they can be sold and supplied. The PPO and the CMO also stipulate the licensing and practicing requirements for drug dealers. In addition, according to the Import and Export Ordinance (Cap. 60), the importation and exportation of pharmaceutical products, pCm and 36 types of controlled Chinese herbal medicines must be covered by relevant import and export licences issued by the DH with the authority delegated by the Trade and Industry Department.
7. The DH has a market surveillance mechanism in place to monitor the safety, efficacy and quality of medicines. The DH collects products in the market from different channels (including the Internet) for medicine-related testing. If a product fails to comply with relevant statutory requirements (such as being unregistered, or found to have quality defects or adulterated with harmful substances), the DH will make public announcement as soon as possible to safeguard public health. When report about suspected contravention of medicine-related offences, including suspected illegal sale or possession of unregistered pharmaceutical products or pCm, is received, the DH will follow up immediately and take enforcement action against any contravention of drug-related offences. The DH will conduct joint enforcement

operations with the Hong Kong Customs or the Hong Kong Police Force, or refer the cases to other law enforcement departments for follow-up actions.

8. The DH has been strongly urging the public to refrain from purchasing products with unknown or dubious ingredients, or consuming products from unknown sources, as their safety, quality and efficacy are not guaranteed. The DH also urges members of the public who have purchased unregistered medicines to stop consuming them immediately. If they feel unwell after consuming them, they should seek advice from medical professionals.
9. The DH has also compiled safety information for consumers on the purchase and use of drugs, including "Be Cautious when Buying Medicines on Internet", "General Knowledge on Registered Medicines", and points to note for purchasing pCm. Relevant documents are available on website of the Drug Office (www.drugoffice.gov.hk/eps/do/en/consumer/consumer_safety_advisories/index.html) or the Chinese Medicine Regulatory Office (www.cmro.gov.hk/html/eng/useful_information/public_health/notes_for_purchasing_cm.html#purchasing_proprietary_cm) for public reference.

Department of Health
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