

## CONTAMINATED SYRUP AND LIQUID-BASED MEDICINES DETECTED OVERSEAS NOT REGISTERED NOR DISTRIBUTED IN SINGAPORE

The Health Sciences Authority (HSA) is aware of overseas reports of kidney injury or deaths in children that are associated with the consumption of syrup and liquid-based medicines. These incidents were suspected to be caused by the contamination of the medicines with ethylene glycol or diethylene glycol, which are toxic chemicals.

HSA would like to inform the public that the affected medicines comprising cough, cold, flu and fever medicines (Annex A) are not registered in Singapore. Based on our surveillance, these medicines have not been detected locally so far. We have also not received any serious adverse events reports of acute kidney injury or deaths in children related to the consumption of contaminated syrup and liquid-based medicines from our healthcare professionals. As such, HSA has not stopped the sale or supply of syrup or liquid-based medicines in Singapore.

### HSA's Regulation of Medicines

3 All syrup and liquid-based medicines are required to meet the stipulated international standards of quality, safety and efficacy before they are approved by HSA for sale in Singapore. HSA assesses the clinical studies data, manufacturing and quality control processes, and conducts checks to ensure that manufacturers conform to international Good Manufacturing Practice standards.

4 After these medicines are allowed for sale in Singapore, HSA assures the safety of the products through the following:

- Manufacturers are required to test all batches of these medicines including for levels of contaminants before selling them in Singapore;
- HSA regularly inspects local licensed manufacturers, importers and distributors to ensure compliance with the required standards; and
- HSA monitors adverse events and conducts risk-based product testing, including for contaminants in medicines.

#### **Public Advisory**

5 Although the contaminated medicines on Annex A are not registered in Singapore, some members of the public may have obtained them from overseas or unfamiliar sources. In such instances, they should monitor their health and consult a doctor if they feel unwell. The signs and symptoms of acute kidney injury include:

- Decreased urine output
- Swelling in legs, ankles and around the eyes due to fluid retention
- Fatigue or tiredness
- Nausea
- Shortness of breath
- Confusion

6 Members of the public are strongly advised to exercise caution when buying health products online or from unfamiliar overseas sources, as there is no knowing where and how these products were made and whether they have been contaminated with harmful ingredients. If buying online, members of the public are encouraged to buy them from reputable retailers' websites or those with an established retail presence in Singapore.

7 HSA will continue to monitor the situation closely and will also step up our surveillance checks to ensure that medicines available locally continue to be safe for use. Should there be any safety concerns detected locally, HSA will alert members of the public soonest possible and take the necessary actions such as recalling the affected medicines or stopping the sale or supply of such medicines.

# HEALTH SCIENCES AUTHORITY SINGAPORE

#### 22 OCTOBER 2022

#### About the Health Sciences Authority (HSA)

The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services and Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and

efficacy. As the national blood service, it is responsible for providing a safe and adequate blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit <a href="http://www.hsa.gov.sg/">http://www.hsa.gov.sg/</a>.

For more updates on public health and safety matters, follow us on Twitter at <u>www.twitter.com/HSAsg</u>.

#### About HSA's Health Products Regulation Group

The Health Products Regulation Group (HPRG) of HSA ensures that medicines, innovative therapeutics, medical devices and health-related products are wisely regulated and meet appropriate safety, quality and efficacy standards. It contributes to the development of biomedical sciences in Singapore by administering a robust, scientific and responsive regulatory framework.

## ANNEX A

No.	Name of affected products	Produced by /Manufacturer
1.	Termorex Fever	PT Konimex
2.	Flurin DMP Sirup	PT Yarindo Farmatama
3.	Unibebi Cough Sirup	Universal Pharmaceutical Industries
4.	Unibebi Sirup Fever	Universal Pharmaceutical Industries
5.	Unibebi Fever Drops	Universal Pharmaceutical Industries
6.	Promethazine Oral Solution	Maiden Pharmaceuticals Ltd
7.	Kofexmalin Baby Cough Syrup	
8.	Makoff Baby Cough Syrup	
9.	Magrip N Cold Syrup	

## Table of affected medicines and their manufacturers