

**Annex G**

**Chronology of Drug Incidents since March 2009**

<b>Date</b>	<b>Details of Incident</b>
6 March	The University of Hong Kong announced that four batches of Allopurinol tablets produced by a local manufacturer, Europharm Laboratoires Co. Ltd. were contaminated with Rhizopus microsporus. HA announced replacement of the drug for affected patients from 8 March 2009. On 9 March, DH ordered Europharm to recall all Allopurinol tablets from the market as laboratory analysis of the samples of the affected four batches of Allopurinol confirmed the presence of Rhizopus. DH investigation revealed that during the production process, there was prolonged storage of granules prior to tabletting. Europharm voluntarily stopped production and distribution of all products.
11 March	DH instructed Marching Pharmaceutical Ltd., a local manufacturer, to recall a total of 216 pharmaceutical products as the label expiry dates of these products were not substantiated by laboratory data. On 12 March, the Manufacturers Licensing Committee of the Pharmacy and Poisons Board suspended the licence of the company for one month. The case had also been reported to the police as during the course of DH investigations, certain irregularities in the documents submitted by the company were found.
16 March	DH investigation found that part of the pharmaceutical products, metformin tablets packed in 50x10's blister, supplied to HA by a local manufacturer, Christro Pharmaceuticals Ltd., was not registered with DH. HA announced replacement of the drug for affected patients from 17 March 2009.
19 March	DH investigation found that Unipharm Trading Company, a licenced wholesaler with no drug manufacturing licence, conducted unlicensed packaging of Amitriptyline tablets. DH ordered the company to recall the product.

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20 March	DH investigation found that the expiry dates of two batches of Cosalgesic tablets imported by Unipharm Trading Company had been tampered. The correct expiry dates of the concerned batches should be May 2009 and June 2009 respectively, but they had been changed to June 2010. DH would report the case to the police for investigation. Unipharm initiated product recall at consumer level.
22 March	HA announced that staff of Yaumatei Jockey Club General Out-patient Clinic dispensed expired cough medicine, Promethazine Co Linctus, to around 10 out of 250 patients prescribed with this drug during 1 February to 20 March. HA made arrangements for replacement of the drug for affected patients.
	DH received report from HA that the actual volume of two batches of "Water for injections" imported by Luen Cheong Hong Ltd., a licenced wholesaler, exceeded the volume of 100 ml on the product label by 30 ml. The product was manufactured by the Indonesian subsidiary of a Japanese company, Otsuka. Luen Cheong Hong initiated product recall from HA. The product was not available in private market.
27 March	In response to media enquiries, HA replied that a leukemia female patient in Prince of Wales Hospital received two doses of 4 grams of Cytarabine instead of the correct quantity of 2 grams on 24 March on the first day of a five-day chemotherapy treatment. Staff later became aware of the mistake and doctor immediately assessed the patient; the patient was in stable condition.
2 April	DH investigation found that Mentholatum Pain Patch supplied by Mentholatum (Asia Pacific) Ltd., a licensed wholesaler, was unregistered. Mentholatum applied for registration of the product in 2005 but the application was yet to be approved. DH instructed Mentholatum to recall the product at retail level. There was however no immediate safety or quality concern over the use of the product.

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4 April	DH investigation found that a product named Viscotears supplied by Novartis Pharmaceuticals (Hong Kong) Ltd., a licenced wholesaler, was not yet registered. DH instructed Novartis to recall the product from the market. There was however no immediate safety or quality concern over the use of the product.
6 April	DH investigation found that the registration of a product named Cortipheno H Eye ointment 2.5g supplied by Novartis Pharmaceuticals (Hong Kong) Ltd. had been expired in December 2007. DH instructed Novartis to recall the product from the market. There was however no immediate safety or quality concern over the use of the product.
	Hind Wing Company Ltd., a licensed wholesaler, initiated a consumer-level recall of two batches of Dithrasal ointment, Dithrasal ointment and Dithrasal ointment 2%, as they were found containing a higher than permitted level of 1,8 dihydroxyanthraquinone (DHAQ) by the Australian drug authority.
	DH investigation found that five pharmaceutical products supplied by Main Life Corporation Ltd., a licensed wholesaler, were unregistered. DH instructed Main Life to recall the products from the market. There was however no immediate safety or quality concern over the use of the product.
11 April	Tung Wah Hospital announced that during a routine check of Phenobarbitone tablets before issuing to the ward on 8 April, it was discovered that Phenobarbitone 60 mg tablets were pre-packaged instead of the intended Phenobarbitone 30 mg tablets on 17 March, resulting in the intake of double dosage of the medication by 6 in-patients. One of the concerned patients passed away on 10 April while the remaining 5 patients were in stable condition.
18 April	In response to media enquiries, HA replied that staff of Lady Trench General Out-patient Clinic mixed up diabetes tablets with drugs for controlling high blood pressure for

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	at least 63 diabetes patients on 17 April.
21 April	DH investigation found that the product insert of Funginox Solution imported by Deltpharm Ltd., a licenced wholesaler, contained unregistered indications and treatment duration. DH instructed Deltpharm to recall the product from the market. There was however no immediate safety or quality concern over the use of the product.
22 April	The pharmacy of Kennedy Town Jockey Club Clinic found black spots on some tablets in a bottle of diuretic drug (Frusemide 40 mg) supplied by Vickmans Laboratories Ltd., a licensed wholesaler, on 15 April. HA Head Office carried out a random check on other batches of Frusemide 40mg and found out that some tablets of another batch also had black spots. According to initial findings, the black spots were confirmed as contamination by fungal species asperigillus. HA announced replacement of the drug for affected patients from 8 March 2009. The Manufacturers Licensing Committee suspended the license of Vickmans with immediate effect for non-compliance with GMP standards on 22 April. DH also instructed Vickmans to conduct a consumer level recall of the product.
28 April	Pfizer Corporation Hong Kong Ltd., a licenced wholesaler, recalled a product Lignocaine HCl Injection 1% from the market as one bottle in a ten-bottle pack of the product was found to be labeled as Sodium Chloride Intravenous Infusion 0.9%. The product was manufactured and packed in Australia, without further repackaging after import into Hong Kong.
6 May	In an internal review, Zuellig Pharma Ltd., a licensed wholesaler, found that Milupa GES 45 Oral Rehydration Salts Sachet was not registered. The product was manufactured in Germany and was once registered in Hong Kong from 1989 to 2004. However, the registration holder did not renew the product registration

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	after its expiry in 2004. Zuellig initiated a recall of the product.
7 May	DH investigation found that the registration of a drug Povidone-iodine Prep Pad imported by Luen Cheong Hing Ltd., a licenced wholesaler, had expired in October 2008, but Luen Cheong Hong was still selling the product. DH instructed Luen Cheong Hong to recall the product from the market. There was however no immediate safety or quality concern over the use of the product.
	During a DH investigation, Hitpharm Pharmaceutical Company Ltd., a licensed wholesaler, was found selling 46 pharmaceutical products in unapproved sales packages with unapproved label information. DH instructed Hitpharm to recall the unregistered products from the market.
2 September	DH investigation found that Jacobson Medical (Hong Kong) Ltd., a licensed wholesaler, had sold the product Tylenol in unapproved sales packages with unapproved label information. Jacobson initiated a recall of the product. There was however no immediate safety or quality concern over the use of the product.
28 September	DH investigation found that a series of 17 pharmaceutical products imported by Dragon Link (International) Trading Company Ltd., a licensed wholesaler, contained 10mg of the mineral manganese instead of 5mg as per the product label. Dragon Link initiated a recall of the affected products.