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(來函請敍明此檔案號碼)
(IN REPLY PLEASE QUOTE THIS FILE REF.)

7 July 2023

Dear Healthcare Professionals,

De-registration of Pharmaceutical Products containing Pholcodine

Your attention is drawn to the de-registration of pharmaceutical products containing pholcodine. On 6 July 2023, the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/Medicinal Test) Committee (the Committee) has decided to, in the public interest as stipulated by the Pharmacy and Poisons Regulations (Cap. 138A), de-register pharmaceutical products containing pholcodine **with effect from 1 January 2024** owing to their benefits no longer outweigh the risks.

The Committee's decision has been made after taking into consideration the latest recommendations on pholcodine by overseas regulatory authorities including the European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC), the Therapeutic Goods Administration (TGA) and the Medicines and Healthcare products Regulatory Agency (MHRA), the decisions by the European Commission, TGA and MHRA, and the advice given by local experts. The Committee noted that the available data showed the use of pholcodine in the 12 months before general anaesthesia with neuromuscular blocking agents (NMBAs) is a risk for developing NMBA anaphylaxis and there is a lack of identifiable effective measures to minimize this risk, and the European Commission, TGA and MHRA had decided to cancel the registration of pholcodine-containing medicines in the European Union, Australia and the United Kingdom respectively. The Committee has also noted from the advice given by local experts that there is evidence supporting NMBAs remain the most common cause in perioperative anaphylaxis and pholcodine consumption has been shown to be a risk factor for NMBA anaphylaxis. After consideration of the above, the Committee decided to de-register pharmaceutical products containing pholcodine with effect from 1 January 2024.

In Hong Kong, there are currently 27 registered pharmaceutical products containing pholcodine and these products are listed in the Annex.

Healthcare professionals should stop prescribing or dispensing pharmaceutical products containing pholcodine and review the treatment plans of their patients as soon as possible. There are other medicines for cough treatment available in local market. Please also report any adverse events caused by these products to the Adverse Drug Reaction Unit of the DH (tel. no.: 2319 2920, fax no.: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": http://www.drugoffice.gov.hk/adr.html. You may also wish to visit the Drug Office's website for subscription and browsing the "Drug News" which is a monthly digest of drug safety news and information issued by DH Drug Office.

Please note that this letter serves as a means for the DH to communicate important new safety information about registered pharmaceutical products with healthcare professionals in Hong Kong and is not intended to serve as guidelines or to replace professional clinical judgement. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Yours faithfully,

(Raccoon CHUNG)
for Assistant Director (Drug)

Annex

List of Registered Pharmaceutical Products containing Pholcodine

	HK-Registration No.	Name of Product	Name of Registration Certificate Holder
1	HK-05445	PHOLCODINE SYRUP 4MG/5ML	NEOCHEM PHARMACEUTICAL LABORATORIES LTD.
2	HK-08768	RICON BABY COUGH SYRUP	JEAN-MARIE PHARMACAL CO LTD
3	HK-12701	TRIPLE 'P' COUGH SYRUP	UNIVERSAL PHARMACEUTICAL LABORATORIES, LIMITED
4	HK-12858	BABYSED COUGH SYRUP	JEAN-MARIE PHARMACAL CO LTD
5	HK-16048	PHOLCODINE CITRATE SYRUP 0.2%	VICKMANS LABORATORIES LTD
6	HK-17890	PHOLEPHAMINE COUGH SYRUP	ADVANCE PHARMACEUTICAL COMPANY LIMITED
7	HK-19749	PHOLCOLIN COUGH SYRUP	VICKMANS LABORATORIES LTD
8	HK-23525	PHOLCODINE LINCTUS 0.1%	QUALITY PHARM LAB LTD
9	HK-32223	FARCOLIN COUGH SYRUP	MEYER PHARMACEUTICALS LTD
10	HK-33745	UNI-PHOLCO LIQUID 10MG/5ML	UNIVERSAL PHARMACEUTICAL LABORATORIES, LIMITED
11	HK-38753	DURO-TUSS FORTE COUGH LINCTUS 15MG/5ML	INOVA PHARMACEUTICALS (HONG KONG) LIMITED
12	HK-38857	DURO-TUSS EXPECTORANT COUGH LINCTUS	INOVA PHARMACEUTICALS (HONG KONG) LIMITED
13	HK-38888	DURO-TUSS REGULAR COUGH LINCTUS 1MG/ML	INOVA PHARMACEUTICALS (HONG KONG) LIMITED
14	HK-41358	EUROPHOLDINE SYRUP 0.1%	EUROPHARM LAB CO LTD
15	HK-46509	CP-PHOLCODINE ELIXIR 10MG/5ML	CHRISTO PHARM LTD
16	HK-47461	NEO-PHOLCODINE SYRUP 5MG/5ML	NEOCHEM PHARMACEUTICAL LABORATORIES LTD.
17	HK-47610	NEO-PHOLCO SYRUP 10MG/5ML	NEOCHEM PHARMACEUTICAL LABORATORIES LTD.
18	HK-56517	PHOLCODINE ELIXIR 10MG/5ML	VICKMANS LABORATORIES LTD
19	HK-57260	PHOTIFED-M CHILDREN COUGH SYRUP	BRIGHT FUTURE PHARMACEUTICALS FACTORY O/B BRIGHT FUTURE

			PHARMACEUTICAL LABORATORIES LIMITED
20	HK-59070	MITON CHILDREN COUGH SYRUP	JEAN-MARIE PHARMACAL CO LTD
21	HK-59712	YESON CHILDREN COUGH SYRUP	JEAN-MARIE PHARMACAL CO LTD
22	HK-59713	ZIBON CHILDREN COUGH SYRUP	JEAN-MARIE PHARMACAL CO LTD
23	HK-60456	COMPOUND PHOLCODINE ORAL SOLUTION (10ML/SACHET)	BRIGHT FUTURE PHARMACEUTICALS FACTORY O/B BRIGHT FUTURE PHARMACEUTICAL LABORATORIES LIMITED
24	HK-60820	COMPOUND PHOLCODINE ORAL SOLUTION (BRIGHT FUTURE)	BRIGHT FUTURE PHARMACEUTICALS FACTORY O/B BRIGHT FUTURE PHARMACEUTICAL LABORATORIES LIMITED
25	HK-64367	PHOLCODINE LIQUID 5MG/5ML	UNIVERSAL PHARMACEUTICAL LABORATORIES, LIMITED
26	HK-65159	PHOLCODINE ELIXIR 10MG/5ML	SYNCO (H.K.) LIMITED
27	HK-65233	PHOLCODINE ELIXIR 0.1% W/V	SYNCO (H.K.) LIMITED