



**PHARMACY AND POISONS BOARD
HONG KONG**
香港藥劑業及毒藥管理局

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衛生署藥物辦公室

7th July 2023

To: All holders of licences and certificates issued under the Pharmacy and Poisons Ordinance

Dear Sir / Madam,

De-registration of Pharmaceutical Product(s) containing Pholcodine

I write to inform you about 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) decided to de-register pharmaceutical products containing pholcodine under regulation 36(8) of the Pharmacy and Poisons Regulations (Cap. 138A) with effect from 1 January 2024 because the benefits of the products no longer outweigh their 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.

Please note that when the Committee's decision takes effect on 1 January 2024, the products will become unregistered pharmaceutical product. All licensed manufacturers, licensed wholesale dealers and authorized sellers of poisons must stop selling or supplying pharmaceutical products containing pholcodine. Licensed manufacturers and wholesale dealers are also required to recall all products concerned from the market by 31 December 2023. Under the Pharmacy and Poisons Ordinance (Cap. 138), sale, offer for sale, distribution or possession of unregistered pharmaceutical products are criminal offences. The maximum penalty for each offence is a fine of \$100,000 and two years' imprisonment.

For further enquiries, please contact Mr. Albert CHUNG at 3974 4148.

Yours faithfully,



(Y. F. YEUNG)

Secretary,

Pharmacy and Poisons (Registration of Pharmaceutical
Products and Substances: Certification of Clinical
Trial/Medicinal Test) Committee

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

	HK-Registration No.	Name of Product	Name of Registration Certificate Holder
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