

PHARMACY AND POISONS BOARD

HONG KONG

香港藥劑業及毒藥管理局

Your Ref. :
貴處檔號

Our Ref. : DH DO PRIE/1-55/1
本局檔號

Tel. No. : 2319 8468
電 話

Fax No. : 2803 4962
圖文傳真

C/O Drug Office
3/F., Public Health Laboratory Centre,
382 Nam Cheong Street,
Kowloon, Hong Kong.
香港九龍南昌街382號
公共衛生 檢 測中心三樓

20 January 2017

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

Dear Sirs/Madams,

Strengthening the Sales Control of Pharmaceutical Products

(i) for Human Parenteral Administration and (ii) containing Designated Vitamins

The Pharmacy and Poisons (Registration of Pharmaceutical Products & Substances: Certification of Clinical Trial/Medicinal Test) Committee (the Committee) under the Pharmacy and Poisons Board has recently reviewed the sales control of two categories of pharmaceutical products, including those (i) for human parenteral administration, and (ii) containing designated vitamins, which are currently sold as non-prescription drugs in Hong Kong.

The Committee considered that there are potential risks when these products are sold without prescriptions to the patients. With reference to the sales restriction of these products in some overseas countries (e.g. the United States, the United Kingdom, Australia, Canada, and Singapore) and based on the available scientific information, the Committee decided that the sales control of these products should be strengthened (i.e. to be sold under prescription) for protection of public health.

In this regard, the gazette of amendment to the Pharmacy and Poisons Regulations (the Regulations) (Cap. 138A) for the above is published on 20 January 2017.

According to the gazette, at the expiry of six months from the date of gazette, the pharmaceutical products for human parenteral administration containing the substances listed at Appendix I or their salts, as active ingredient, except when they are in mixture with insulin; and the pharmaceutical products containing the designated vitamins at Appendix II, will be added to Schedule 1, Schedule 3, and Part 1 of Schedule 10 (i.e. prescription-only medicines) of the Regulations. In addition, at the expiry of 12 months from the date of gazette, the pharmaceutical products for human parenteral administration containing sodium chloride 0.9% or water as active ingredient will also be added to Schedule 1, Schedule 3, and Part 1 of Schedule 10 of the Regulations.

The registration certificate holders of the above affected products should review their products and comply with the labelling requirements by including the bilingual statement of “Prescription Drug 處方藥物” on the sales pack of the products. Any illegal sale of Part 1, First and Third Schedule poisons without a prescription, and the sale of medicine not complying with the above labelling requirements are offences under the Pharmacy and Poisons Ordinance and Regulations, of which the maximum penalty for each offence is a fine of \$100,000 and two years’ imprisonment.

For further enquiries on the registration of pharmaceutical products, please contact the Drug Office at 2319 8458.

Yours faithfully,



(T. K. YIM)

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

Appendix I: Pharmaceutical products containing the following substances or their salts as active ingredient for human parenteral administration

- | | | |
|---|-------------------------|------------------------|
| 1. Acetic acid | 25. Ephedrine | 61. Paracetamol |
| 2. Acetylcholine | 26. Exametazime | 62. Patent blue V |
| 3. Acetylcysteine | 27. Fish Oil | 63. Pentetic acid |
| 4. Adenosine | 28. Fluorescein | 64. Pentoxifylline |
| 5. Adrenaline | 29. Gallium | 65. Phenol |
| 6. Ambroxol | 30. Gelatin | 66. Phenylephrine |
| 7. Amino acids | 31. Glucosamine | 67. Piracetam |
| 8. Aminophylline | 32. Glucose | 68. Procaine |
| 9. Anti-D (rho) immunoglobulins | 33. Glycerol | 69. Protamine |
| 10. Anti-histamine substances | 34. Glyceryl trinitrate | 70. Ranitidine |
| 11. Atropine | 35. Guaifenesin | 71. Rhenium |
| 12. Betiatide | 36. Heparin | 72. Sodium |
| 13. Bicisate | 37. Hyaluronic acid | pyrophosphate |
| 14. Butetamate | 38. Hyaluronidase | 73. Sodium tetradecyl |
| 15. Caffeine | 39. Hydroxyethyl starch | sulfate |
| 16. Carnitine | 40. Hyoscine | 74. Sodium thiosulfate |
| 17. Cations, the following, except in
preparations containing any substance
to which the Antibiotics Ordinance
(Cap. 137) applies: | 41. Icodextrin | 75. Sorbitol |
| Calcium, | 42. Indocyanine green | 76. Soya oil |
| Chromium, | 43. Iodine | 77. Stonefish |
| Copper, | norcholesterol | antivenom |
| Iron, | 44. Isosorbide | 78. Succimer |
| Magnesium, | 45. Lactic acid | 79. Terbutaline |
| Manganese, | 46. Lecithin | 80. Tetrakis copper |
| Potassium, | 47. Lignocaine | tetrafluoroborate |
| Selenium, | 48. Mannitol | 81. Tetrofosmin |
| Sodium(except sodium chloride 0.9%) | 49. Mebrofenin | 82. Thallium |
| Zinc | 50. Medronic acid | 83. Tin |
| 18. Choline | 51. Mesna | 84. Triglycerides |
| 19. Cimetidine | 52. Methoxyphenamine | 85. Tubercullin |
| 20. Dextromethorphan | 53. Methylene blue | 86. Vitamins |
| 21. Dicycloverine | 54. Methylephedrine | 87. Xantinol |
| 22. Difenidol | 55. Metronidazole | nicotinate |
| 23. Diprophylline | 56. Noradrenaline | |
| 24. Disofenin | 57. Olive oil | |
| | 58. Omeprazole | |
| | 59. Oxidronate | |
| | 60. Papaverine | |

Appendix II: Designated Vitamins

1. Alfacalcidol; its salts
2. Calcitriol, its salts
3. Vitamin D and its salts when contained in pharmaceutical products the recommended daily dose of which contains more than 1,000 international units of vitamin D
4. Vitamin K and its salts when contained in pharmaceutical products, except products with recommended daily dose of 120mcg or less of vitamin K1 or K2 or its salts