

L.N. 228 of 2018

**Pharmacy and Poisons (Amendment) (No. 7) Regulation
2018**

(Made by the Pharmacy and Poisons Board under section 29(1B) of the Pharmacy and Poisons Ordinance (Cap. 138) subject to the approval of the Secretary for Food and Health)

1. Pharmacy and Poisons Regulations amended

The Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) are amended as set out in sections 2, 3 and 4.

2. Schedule 1 amended (substances to which certain restrictions with respect to the sale, supply, labelling and storage apply under regulations 3, 5, 6, 22 and 24)

Schedule 1, Division A, after item “Antithymocyte Immunoglobulin”—

Add

“Apalutamide; its salts”.

3. Schedule 3 amended (substances required by regulation 9 to be sold by retail only upon a prescription given by a registered medical practitioner, registered dentist or registered veterinary surgeon)

Schedule 3, Division A, after item “Antithymocyte Immunoglobulin”—

Add

“Apalutamide; its salts”.

4. Schedule 10 amended (Poisons List)

Schedule 10, section 2, Table, Part 1, Division A, after item
“Antithymocyte Immunoglobulin”—

Add

“Apalutamide; its salts”.

Dr. Constance CHAN
Chairman,
Pharmacy and Poisons Board

6 November 2018

Explanatory Note

This Regulation amends the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) to add Apalutamide and its salts (*Apalutamide*) to—

- (a) Division A of Schedule 1;
- (b) Division A of Schedule 3; and
- (c) Division A of Part 1 of the Poisons List set out in Schedule 10.

2. The amendments relate to requirements concerning sale, supply, labelling and storage. Main effects of the amendments include—

- (a) that the sale, by retail, of Apalutamide—
 - (i) may only be effected on registered premises of an authorized seller of poisons by a registered pharmacist or in the presence and under the supervision of a registered pharmacist; and
 - (ii) may only be effected on and in accordance with a prescription by a registered medical practitioner, registered dentist or registered veterinary surgeon; and
- (b) that Apalutamide, if stored in retail premises, must be stored in a part of the premises to which customers are not permitted access.