

POISONS AND DRUGS ACT 1978

MODIFICATION

INSTRUMENT NO. 254 OF 2001

EXPLANATORY STATEMENT

The *Poisons and Drugs Act 1978* (the Act) is an act relating to poisons and drugs.

Section 2 of the Act gives effect to the Standard for the Uniform Scheduling of Drugs and Poisons (the Standard). The Standard is referred to as the drugs and poisons standard in the Act. This adoption of the Standard by reference is the basis of the Territory's commitment to harmonisation of drugs and poisons legislation made at the Australian Health Ministers' Conference in June 1990.

The Standard is the decisions of the National Drugs and Poisons Schedule Committee (the Committee) regarding the classification of drugs and poisons into schedules for inclusion in the relevant legislation of the states and territories of Australia.

The Committee is a statutory body under the Commonwealth *Therapeutic Goods Act 1989* and meets four times a year to revise and update the Standard.

At its meeting on 21-23 August 2001, the Committee withdrew a number of entries relating to solanaceous plants and alkaloids from the Standard effective from 1 September 2001.

Solanaceous alkaloids include the naturally occurring alkaloids atropine, hyoscyamine and hyoscyamine which may be obtained from solanaceous plants or by synthesis. The solanaceous plants include Belladonna, Datura, Duboisia, Hyoscyamus and Stramonium.

Low strength preparations of solanaceous plants and alkaloids for the treatment of irritable bowel syndrome and other minor gastric upsets have been available without prescription from pharmacies for many years in over-the-counter (OTC) medicines. The Committee's decision at its 20-22 February 2001 meeting results in these preparations being available only on prescription from 1 September 2001.

The complexity of the change was such that some errors in relation to the cut-offs in concentrations of solanaceous alkaloids were only recently brought to the attention of the Committee. The Committee felt it prudent to review all the entries relating to solanaceous plants and alkaloids.

As it was too late to amend the Standard, the Committee asked that all jurisdictions take the necessary action to ensure that scheduling changes to the solanaceous related entries were not implemented on 1 September 2001. The aim of the Committee is to ensure that these products remain available as OTC medicines.

Section 46 of the Act enables the Minister to modify, by disallowable instrument, the drugs and poisons standard. This instrument ensures that the entries relating to solanaceous plants and alkaloids are withdrawn from the drugs and poisons standard effective from 1 September 2001.

This will maintain the status quo regarding the availability of OTC medicines containing low concentrations of solanaceous plants and alkaloids. This will ensure that these OTC products remain available to consumers in the Territory and assist in fulfilling the Territory's continuing commitment to harmonisation of drugs and poisons legislation throughout Australia.