

Supply of Product Starter packs by Wholesalers

NOTE The information below has been updated to reflect the release of Edition 16 of the Medicines Australia Code of Conduct. Existing licences that include a reference to Edition 15 are still valid and will be amended at renewal.

The possession for demonstration purposes of samples of each Schedule 4 poison by representatives or agents of manufacturers and/or wholesalers holding a Victorian licence is not directly authorised by the Drugs, Poisons and Controlled Substances Regulations 2006.

Section 7 *Product starter packs* of the Medicines Australia Code of Conduct Edition 16, effective date 1 January 2010, covers the supply, size, quantities carried and supplied, record keeping, labelling and product information, transport and storage, security and returns and disposal of product starter packs.

The Glossary in the Code states that a starter pack "*means a quantity of a product supplied without cost to medical practitioners, dentists and hospital pharmacists. Starter packs are also referred to as "samples" by healthcare professionals.*"

Recommendation 12 of the National Competition Policy Review of Drugs, Poisons and Controlled Substances Legislation 2001 (the Galbally Review) recommended that the Medicines Australia Code of Conduct be amended to provide more comprehensively for the supply of clinical samples and that States and Territories require compliance of manufacturers and wholesalers with the amended code through a condition on their licences.

In accordance with the agreement of the Council of Australian Governments on the recommendations from the Galbally Review, holders of licences to manufacture and sell or supply by wholesale and licences to sell or supply by wholesale Schedule 2, 3, or 4 poisons are regulated in Victoria by the addition of a licence condition, to the effect that the licence holder is to adhere to the current edition of the Medicines Australia Code of Conduct with respect to the supply of product starter packs.

The standard condition for all manufacture/wholesale and wholesale licence holders for Schedule 2, 3 or 4 poisons is as follows:

The holder of this licence must ensure that the supply of starter packs of Schedule 4 poisons is in accordance with the current edition of the Medicines Australia Code of Conduct (the Code). The term "starter packs" has the same meaning here as in the Code.

Supply of starter packs of Schedule 8 and Schedule 9 poisons is not authorised in Victoria.

See the Medicines Australia Code of Conduct Edition 16 on <http://www.medicinesaustralia.com.au>

Drugs and Poisons Regulation Group
Updated 24 February 2010