

Application for a Licence to Deal in Controlled Drugs Responsible Persons Guidance Notes

From 1 August 2009 the Ministry of Health will be including a list of responsible persons on all Licences to Deal in Controlled Drugs. (If you also hold a Licence to Sell Medicines by Wholesale you may have noticed that the responsible persons are already a feature on that licence). This information will be requested on the licence application form.

Regulation 3(4) of the Misuse of Drugs Regulations 1977 references the "propriety of the application" for a licence application. In this regard the Licensing Authority determines a "responsible person", in relation to a licensee corporation, to mean an agent or employee of that corporation who is approved by the Licensing Authority as a responsible person for the purposes of the licence.

The expectation of a person listed as a responsible person on a Licence to Deal in Controlled Drugs is that they:

- have sufficient knowledge of the obligations of a licensee, the legislative requirements and the hazards associated with dealing in the controlled drugs concerned
- have knowledge of the day to day running of the business with respect to controlled drugs
- are required to ensure the business operates within all legislative requirements and according to the Standard Operating Procedures of the business
- are usually key-holders to the Controlled Drugs safe.

In addition it is expected that the responsible persons listed on a Licence to Deal in Controlled Drugs collectively:

- are responsible for all activities undertaken by the business in relation to the licence (e.g. director(s) of board or major shareholders or CEO)
- are accountable for ensuring that all legislative requirements relating to the licence are met, which include but are not limited to:
 - *the controlled drug register (or approved recording system) is maintained accurately, with all transactions of controlled drugs recorded within one business day (Misuse of Drugs Regulations 1977 regulation 40)*
 - *performing a physical stocktake as at the close of business on 30 June and 31 December annually, and a quantity stock account within 14 days of these dates (regulation 43)*
 - *submitting the returns of wholesale transactions of controlled drugs to the Advisor, Controlled Drugs, Medicines Control within 7 days after the end of each month (regulation 47)*
 - *notifying Medicines Control in writing of aberrant ordering, missing consignments or other incidents involving controlled drugs.*

The applicant must list the responsible persons on the enclosed application form. Please note that responsible persons must include one who is a New Zealand resident and at least one of the following: owner(s)/ manager(s)/ director(s).

It is the responsibility of the applicant to ensure that all individuals listed as responsible persons on the application form are aware of their responsibilities. Individuals are not to be listed as responsible persons without their consent.

Should you have any questions regarding the listing of responsible persons on a Licence to Deal in Controlled Drugs please contact the Licensing Co-ordinator, Medicines Control on (04) 496 2444.