

APPENDIX A

GUIDELINES FOR IMPORTERS OF THERAPEUTIC SUBSTANCES

INTO AUSTRALIA

The Department of Community Services and Health controls the importation and distribution of therapeutic substances into Australia. This control is administered under the legislative provisions of the Customs (Prohibited Imports) Regulations and the Therapeutic Goods Act.

"Therapeutic Substance" means a substance, including a mixture or compound of substances, that has a therapeutic use and includes a surgical ligature, suture or dressing.

"Therapeutic Use" means a use for the purpose of:

- A. Preventing, diagnosing, curing or alleviating of a disease, ailment, defect or injury in persons or in animals;
- B. The influencing, inhibiting or modifying of a physiological process in persons or animals; or
- C. The testing of the susceptibility of persons or animals to a disease or ailment.

For the purpose of the Therapeutic Goods Act, "goods for therapeutic use" means goods that are, whether in writing or otherwise, represented to be, or are likely to be taken to be, for therapeutic use, and includes goods for use in contraception and testing for pregnancy.

Persons or companies wishing to import therapeutic substances into Australia must make an application in writing to this Department. Applicants should allow a minimum of 28 days for their application to be considered and NO "into-store" permits will be issued within this 28 day period. Before a permit or permission to import is granted the Secretary to the Department may require such information as is necessary to establish that the substance proposed for importation conforms to acceptable standards of quality, safety and efficacy.