

must retain records of such reports for a period of not less than 18 months from the day the Director - Adverse Drug Reactions Unit is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

Where a listed medicine is distributed overseas as well as in Australia - product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality - safety or efficacy of the goods distributed in Australia - must be notified to the Director - Non-prescription Medicines Branch - Therapeutic Goods Administration - immediately the action or information is known to the sponsor.

Export Alias Name

**CERTIFIED ORIGINAL
CERTIFICATE**