

ADVISORY NO. RADR&MDP - 1

[Please file in your ACO Practitioner Manual in the “Advisories” Section.]

Date: April 1, 2005

**Subject: REPORTING ADVERSE DRUG REACTIONS
AND MEDICAL DEVICE PROBLEMS**

All marketed health products and devices have benefits and risks. Although, health products and devices are carefully tested for safety and efficacy before they are licensed and marketed, some adverse drug reactions or medical device problems may not become evident until the general population uses a health product or device under “real life” circumstances. Albeit that submitting an adverse reaction or device problem report is strictly voluntary, by submitting a report you are contributing to the ongoing collection of safety and effectiveness information that occurs once health products and medical devices are licensed and marketed.

It is the opinion of the Alberta College of Optometrists that participation by optometrists in the Canadian Medication Incident Reporting and Prevention System (CMIRPS) and the Health Products and Food Branch Inspectorate (HPFBI) will strengthen the Canadian health care system’s capacity to report, analyze and manage data about adverse drug reactions and medical device problems.

Even though participation by optometrists is voluntary, it is recommended that optometrists report all suspected adverse drug reactions or medical device problems to Health Canada, particularly if they are:

- [a] Unexpected adverse reactions (side effects) that are not consistent with product information or labeling – regardless of their severity.
- [b] Serious adverse reactions that require hospitalization, significant medical intervention, congenital malformation, significant disability or incapacity, is life threatening or results in death.
- [c] Adverse reactions related to recently marketed health products (anything on the market for less than 5 years).

Reporting Adverse Drug Reactions and Medical Device Problems.....page 2

A sample report form, guidelines for reporting, and contact information is included in the attached Canadian Adverse Drug Reaction Monitoring Program Report Form (re: adverse drug reactions) and the Health Products and Food Branch Inspectorate Medical Devices Problem Report Form (re: medical device problems). Additional forms may be downloaded from www.hc-sc.gc.ca under the Health Protection Section.