Balance

The Official Publication of the College of Traditional Chinese Medicine Practitioners and Acupuncturists of British Columbia

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Adverse Event Reporting for Herbal Medicines

Adverse Event Reporting for Herbal Medicines: Protecting Patients

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The World Health Organization (WHO) defines adverse drug reactions (ADRs) as unintended consequences suspected to be related to the use of medicinal products, including herbal medicines. Adverse reactions may be a result of herb-drug, herb-herb and/or herb-food interactions from herbal medicines and other natural health products (NHPs) that are available over the counter from community pharmacies, grocery outlets and health food stores, as well as online.

Despite the worldwide availability of herbal medicines and NHPs, it is suspected that ADRs are significantly underreported.

Privacy - Terms

In Canada, in addition to reporting directly to the manufacturer of a product of concern, physicians, pharmacists, TCM practitioners other healthcare providers should also submit reports of product or herbal safety concerns to the Canada Vigilance Program.

"The Canada Vigilance Program is Health Canada's post-market surveillance program that collects and assesses reports of suspected adverse reactions to health products marketed in Canada.

The Canada Vigilance Program provides a variety of tools for health professionals and consumers to report suspected adverse reactions. Reporting is simple and can be done online, by phone or by submitting the Side Effect Reporting Form by fax or mail."

Here are some excerpted definitions from Canada Vigilance Program's Side Effect Reporting Form.

A **side effect** (also known as adverse reaction) is a harmful and unintended response to a health product.

A **serious side effect** is one that requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death. Side effects that result in significant medical intervention to prevent one of these listed outcomes are also considered to be serious.

Health products include prescription and non-prescription medications; natural health products; biologics (includes biotechnology products, vaccines, fractionated blood products, human blood and blood components, as well as human cells, tissues, and organs) radiopharmaceuticals; and disinfectants and sanitizers with disinfectant claims.

Types of side effects that should be reported. All suspected side effects should be reported, especially those that are:

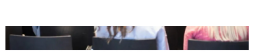
- unexpected, regardless of their severity (i.e., not consistent with product information or labelling;
- serious, whether expected or not;
- reactions to recently marketed health products (on the market less than five years), regardless of their nature or severity.

This includes any undesirable patient effect suspected to be associated with health product use. An unintended effect, health product abuse, overdose, interaction (including drug-drug and drug-food interactions) and unusual lack of therapeutic efficacy are all considered to be reportable side effects.

It is imperative to ensure that TCM practitioners licensed to prescribe and dispense TCM herbal medicines (R.TCM.H, Dr.TCM, R.TCM.P classes) maintain excellent herbal inventory records including TCM herbal name, herbal medicine name and/or natural product number (NPN), lot number, date of purchase, date of expiry, and service notes (if applicable). Well-maintained records will help practitioners inform and protect patients in the event of a manufacturer or distributor recall.

IC Statistics

Inquiry Committee Quarterly Caseload Report and Statistics



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The Inquiry Committee is established under section 19(1)(t) of the *Health Professions Act* (the "Act") and is comprised of CTCMA registrants and public representatives. The Inquiry Committee investigates and disposes of complaints received from the public regarding the conduct and competence of CTCMA registrants and former registrants in accordance with the College mandate to protect the public and Part 3 of the Act.

The following figures reflect matters before the Inquiry Committee for investigation and disposition in the third quarter of the 2020/21 fiscal year:

Inquiry Caseload: November 1, 2020 to January 31, 2021	**Total**	**By Type**	**By %**
New Files	20		
Complaints		8	
Own Motion Investigations		12	
Files Closed	12		
Complaints		3	
Own Motion Investigations		9	
Total Files Pending Disposition by Primary Allegation Type	43		
Clinical Records		1	2%
Criminal Record Check Compliance		7	16%
Misbilling		4	9%
Practice Incompetency		4	9%
Professional Misconduct		1	2%
Professional Misconduct of a Sexual Nature		4	9%
Unauthorized Practice		20	47%

	Unauthorized Title	1	2%
	Unprofessional Conduct/Behaviour	1	2%
Files Carried Over		9	

Planning for CTCMA Election 2021

Registrants, the College has started planning for Board Nominations and Elections for the 2022-2024 term and wanted to give you early notice in case you wish to run for office yourself or might know someone you would like to nominate。

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The Board is responsible for leading the College in its capacity as regulator, setting strategy and making policy designed to ensure the public receives ethical, competent care. It receives its authority from the *Health Professions Act* and ensures that the College meets public safety interests and duties as specified. The Board Nominations and Election period is always an important part of the College's annual calendar.

There are three positions up for election for the 2022-2024 term. The positions are open to registrants in the following electoral districts:

- District 1 (Lower Mainland): up to two candidates
- District 2 (the province of British Columbia outside of Lower Mainland): at least one candidate.

By voting in the 2021 CTCMA Board election, you make your voice heard and register your opinion as to how *your* CTCMA Board should operate. As an eligible registrant, you have the right to vote, so make sure your vote is counted!

The election is scheduled for December 2021. Further information and important dates will follow.

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