Participant information sheet

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Participant Information Sheet- for participants (Qualtrics-online)

This Participant Information Sheet will help you decide if you would like to take part in this study. Please make sure you have read and understood all the pages.

Project Title:

Pharmacovigilance for natural health products (NHPs): an international perspective on industry contributions.

Research team:

Principal investigator
Professor Jo Barnes, School of Pharmacy, University of Auckland

Co-investigators
Associate Professor Shane Scahill, School of Pharmacy, University of Auckland
Dr Sanya Ram, School of Pharmacy, University of Auckland

PhD student researcher
Xin Yi Lim, School of Pharmacy, University of Auckland

Advisor
Phil Rasmussen, Honorary Professional Teaching Fellow, School of Pharmacy, University of Auckland

This participant information sheet will help you decide if you would like to take part in this study. It explains why we are doing the study, what is involved if you decide to take part, the potential risks and benefits of taking part, and what will happen when the study ends.

If you have any questions, please contact the study researchers (the contact information is available at the end of this document). You may wish to discuss whether you want to take part in this study with family members or friends.

Background

Broadly, natural health products (NHPs) (also referred to as complementary medicines and dietary supplements, among other terms) includes, but is not limited to, herbal remedies, vitamins, minerals, traditional medicines (e.g., Traditional Chinese Medicine, Traditional Indian (Ayurveda) Medicine, Japanese (Kampo) Medicine, Traditional Korean Medicine (Hanbang), rongoā Māori, etc.), pre/pro/post-biotics, amino acids, food supplements, nutraceuticals, and animal-based products (e.g., fish oil, bee products). This study focuses on manufactured NHPs in dose forms. It does not include cosmetics and fortified foods (e.g., drinks, bars).

There is considerable variation in regulatory frameworks for pharmacovigilance for NHPs across jurisdictions, ranging from structured frameworks similar to those for pharmaceuticals (conventional medicines) in some countries to limited or minimal oversight in others. This study seeks to explore key international stakeholders' views on the current contributions of the NHPs industry towards pharmacovigilance of NHPs, views on regulatory requirements across different jurisdictions (i.e., countries/regions), and on what resources/support the NHPs industry needs to help it meet pharmacovigilance regulatory requirements. The study also seeks stakeholders' views on active surveillance and other methods for monitoring the safety of NHPs. The study intends to capture viewpoints from across the NHPs industry and regulatory stakeholders to build a broad understanding of the topic.

About this study

This study involves completing an **online survey.** This survey takes about 15 minutes to complete. Responses will be submitted anonymously.

The key stakeholders that we are inviting to participate are:

- Industry professionals from national, regional, and global NHPs industry associations
- Industry professionals from private pharmacovigilance service/ consultancy providers
- Regulators/ competent authorities regulating NHPs/ complementary medicines/ dietary supplements/ food supplements and/or medicines*
- Pharmacovigilance professionals working at government pharmacovigilance centres (national/regional)

*Here, the terms 'regulators/ competent authorities regulating NHPs/ complementary medicines/ dietary supplements/ food supplements and/or medicines' are employed in their broadest sense to account for the diverse terminology used and scope of legislative requirements across jurisdictions. We understand that regulatory responsibility for NHPs varies significantly by region: in some jurisdictions, a single authority oversees pharmacovigilance for both conventional medicines and NHPs, whereas in others, NHPs (sometimes further divided into subcategories) are regulated by distinct competent authorities, or within food authorities. For this study, we are inviting all relevant regulators in the broadest scope of any NHP categories across countries/regions.

The questionnaire will ask about:

- your professional experiences in pharmacovigilance
- your views on regulations pharmacovigilance for NHPs
- your views on active surveillance and other methods for monitoring the safety of NHPs.

The questionnaire development was informed by feedback from individuals with NHPs industry and/or regulatory expertise.

This study is an independent study. It is a student doctoral research project at the University of Auckland.

Study procedures

This study aims to recruit up to 650 participants across various countries and regions of the world.

By submitting the survey anonymously, you are providing consent to participate in this study. This study will not ask for any personally identifiable information about you, your organisation, and country. You are not expected to speak on behalf of your organisation, unless you choose to do so. Your responses will be treated as your individual views and not those of your organisation.

You can access the survey on the next page. The first and second questions are screening questions required to confirm your eligibility to participate in this study and to ensure that appropriate subsequent questions are displayed based on your responses. Otherwise, you can choose whether or not to answer any of the remaining questions. You will be able to download a copy of your responses after submitting the questionnaire.

The survey is optimised for completion on a desktop or laptop, though it is also accessible on tablets and mobile devices. Please complete the survey in one sitting as it will not save partial responses.

Invitation to participate

You are invited to participate in this study if you meet the following criteria:

- Aged 18 years or older
- You are currently employed as one or more of the following:
    - An industry professional affiliated with a national, regional, or global industry association of NHPs, complementary medicines, dietary supplements, or food supplements
    - An industry professional providing pharmacovigilance services, including consultancy, specifically related to NHPs
    - A regulator/competent authority regulating NHPs, complementary medicines, dietary supplements, food supplements, and/or medicines
    - A pharmacovigilance professional working at a government pharmacovigilance centre (national/regional)
- You are based in one of the following countries:
    - Australia, Austria, Belgium, Brazil, Canada, China (including Hong Kong and Macao), Denmark, France, Germany, India, Italy, Ireland, Japan, the Republic of Korea, Netherlands, Poland, South Africa, Spain, Sweden, Switzerland, UK, USA.

Participation in the study is entirely voluntary, and you are free to decline to participate without experiencing any disadvantage.

Right to withdraw from participation

You can withdraw your participation from the study at any time before and during the completion of the online questionnaire, by closing the web browser. Data will be submitted at the end of the survey. Because no personally identifying information is collected, we will not be able to link responses back to individuals. For this reason, once your survey has been submitted, it will not be possible to withdraw your participation or remove your data.

Possible risks and benefits of taking part in the study

There are no direct expected risks or benefits to you, your business, company, or organisation for participating in this study. By participating in this study, you will be able to express your views on the contributions of the NHPs industry towards pharmacovigilance for NHPs, related regulations, and methods for safety monitoring of NHPs. Findings from this study will provide insights on this topic, which was not previously well explored.

Reimbursement

Unfortunately, we are unable to offer reimbursement that is financially and logistically viable to our study team because the study involves international participants.

Anonymity and confidentiality
This survey is submitted anonymously. We will not be collecting any personally identifiable information from you. Similarly, we are not collecting names of organisations. We will not be able to link responses to individuals or organisations. Names of invited organisations will not be shared in any results dissemination.

Data storage and retention
All study data will be stored securely on a University of Auckland research drive, with restricted access through a secured username and password-controlled network. This research drive is only accessible by the research team listed above (not including the advisor).

Study data will be stored for a minimum of six years or until the publication process is complete, whichever is longer. After that, data will then be deleted (electronic documents) or shredded (paper documents).

Study results
To enhance accessibility and maximise the impact of this research to participants and the wider public, study findings is intended to be published in peer-reviewed, Open Access academic journals. Findings from this study will also be reported in the student researcher's doctoral thesis and may be presented to the wider, relevant stakeholder community at meetings and conferences.

Because we are not collecting any personally identifiable information (including contact information), a summary of findings and a link to an Open Access article (once published) will be shared with national, regional, and global industry associations for NHPs, competent authorities responsible for regulating NHPs and/or medicines, and national/regional pharmacovigilance centres who have been invited directly to participate in this study.

As the research team is based in New Zealand, a summary of findings will also be disseminated to various organisations within New Zealand such as the Pharmaceutical Society of New Zealand (PSNZ), Pharmacy Council of New Zealand (PCNZ), Ngā Kaitiaki o Te Puna Rongoā o Aotearoa (Māori Pharmacists Association - MPA), Pacific Pharmacists' Association (PPA), New Zealand Pharmacovigilance Centre, Ngā Pae o te Māramatanga (New Zealand's Māori Centre of Research Excellence), Iwi United Engaged Ltd., Whakauae Research for Māori Health & Development, Natural Health Products New Zealand, the New Zealand Ministry for Primary Industries, and the New Zealand Ministry of Health.

Project funding

This study funded by the Auckland Medical Research Foundation, Maclaurin & Barham Doctoral Scholarship. The funder has no involvement in the study design and will not provide input to the analysis or interpretation of the findings.

Contact details

For queries or concerns about the study, you may contact the research team at the following:

1. Principal investigator: Professor Jo Barnes (email: j.barnes@auckland.ac.nz).
2. Co-investigators:
    a. Associate Professor Shane Scahill (s.scahill@auckland.ac.nz)
    b. Dr Sanya Ram (email: sanya.ram@auckland.ac.nz)
3. PhD student researcher: Xin Yi Lim (email: xin.yi.lim@auckland.ac.nz).

Alternatively, you can contact the Head of School, Associate Professor Amy Chan (a.chan@auckland.ac.nz).

For concerns of an ethical nature, you can contact the Chair of the Auckland Health Research Ethics Committee at ahrec@auckland.ac.nz or at 373 7599 ext 83711, or at Auckland Health Research Ethics Committee, The University of Auckland, Private Bag 92019, Auckland 1142.

Thank you.

Approved by The Auckland Health Research Ethics Committee (AHREC) on 17/10/2025 for three years. Reference number AH29964.