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Towards consensus - defining and supporting a professional role for pharmacists associated with traditional and complementary medicines – a protocol of implementing an international e-survey

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Abstract

Introduction - Traditional and complementary medicines (T&CM) are predominantly self-selected from retail outlets including pharmacies as part of self-care practices. Concerns about the appropriate and safe use of T&CM products raises questions about 'should' and 'how' pharmacists could adopt professional responsibilities. There lacks a consensus about the scope of these responsibilities, or the initiatives required to execute them. The aim of this study is to identify an international set of core responsibilities that support pharmacists' contribution to ensuring the quality and safe use of T&CMs to promote public health.

Methods and analysis - An international cross-sectional e-survey of pharmacists representing the six World Health Organisation regions will be conducted over a twelve-month period. Pharmacists will be invited via representative organisations and professional networks within their respective country. Survey responses to statements about the relevance of T&CM to day-to-day practice; opinions about the bioethical and practice responsibilities; and support required to build their scope of practice associated with T&CM will be collected centrally via the online survey platform Qualtrics and analysed using the Statistical Package for Social Sciences version 27 software for Windows. Bivariate statistical analysis will be conducted to examine the associations between agreement to statements within each section with key demographic variables, country of practice, pharmacy type, age, gender, qualification, and years in practice. Cronbach's alpha will be used to test the internal consistency of items from certain sections of the survey and evince their clarity to respondents of the questionnaire.

Ethics and Dissemination - Ethics approval has been obtained from the University of Macau and pending University of Sydney Human Research Ethics Committee approval. The results of this survey will be used to inform key discussion points in a consensus process and a step towards developing an agreed and defined professional role for pharmacists in T&CMs.

Strengths and limitations of this study

- We will conduct an international web-based, cross-sectional survey of pharmacists utilising the Checklist for Reporting the Results of Internet E-Surveys and STROBE guidelines.
- We have undertaken a comprehensive and iterative process to develop and pilot the survey instrument with pharmacists.
- Dissemination of the survey in different countries over the same time will capture similarities and differences between the socio-demographic contexts.
- Using convenience sampling of pharmacist professional associations and networks may introduce selection bias.
- Use of the same core survey questions translated from English may have compromised some of the cultural nuances specific to a country or region.

Introduction

Safe and appropriate use of traditional & complementary medicines – a public health matter

The use of traditional and complementary medicines (T&CM) use is highly prevalent around the world.[1] Ensuring the safe and appropriate of T&CM to minimize risks and optimize benefits is an important area of public health that is yet to be fully addressed. While the terms "traditional medicine (TM)" and "complementary medicine (CM)" are often used interchangeably or combined, there are fundamental differences between the two.[1] TM refers 'the sum of the knowledge, skill and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness' and have a long history of use.[1] Whereas, CM is described as a broad set of healthcare practices that are not part of a country's own traditional or conventional medicine and are not fully integrated into the dominant healthcare system.[1] The terms TM and CM encompasses products, practices, and practitioners.[1] For the purposes of this

study, T&CM products will refer to natural products that are used for medicinal purposes including herbal products, nutritional supplements, vitamin and minerals, essential oils, and homeopathic products.[2]

T&CM products are an increasingly prevalent component of healthcare and self-care practices across the world. People choose T&CM products for health maintenance as well as disease prevention and treatment, with varying prevalence rates across regions.[1] As new evidence emerges regarding the safety and effectiveness of some T&CM products, knowledge about their contribution to health outcomes across world regions will become clearer. However, many consumers consider T&CM products as "natural and therefore safe" and thus may not extend the same caution towards their use as they would for prescription medicines.[3] Further, decisions about T&CM products use amongst people with serious conditions such as cancer maybe un-/mis-informed.[4] Indeed, there are safety risks related to the quality of products,[5] potential adverse events including drug-herb/nutrient interactions,[6] and delays in initiating known effective treatments, all of which can easily be overlooked.[7] This is particularly the case for special population groups such as children, the elderly, and people living with chronic or other complex health issues, among whom the risk of experiencing adverse drug reactions and drug-herb interactions may be increased.[8] Some of these risks are potentially confounded by integrative approaches (the use of T&CM products in conjunction with conventional medicines)[9] and poor inter-professional communication between conventional and complementary medicine practitioners.[10]

Collectively, there is a public health need to harness the potential benefits and minimize risk associated with T&CM products around the world. The evidence base evaluating the use of T&CM products is growing, which can help resolve uncertainty on safety and effectiveness and should be used to guide decisions about their use.[11] The Cochrane Complementary Medicine group critically evaluate and synthesise the evidence originated from meta-analyses and randomized clinical trials about the effectiveness of a range of T&CM products and practices for the treatment of various conditions, and accounts for 10% of Cochrane reviews.[12] Indeed, the research on T&CM herbal ingredients is growing exponentially. It is apparent that identifying large-scale high-quality evidence is challenging due to heterogenous study designs (populations studied, formulations and doses used, lack of detailed reporting) and risk of bias. Therefore, for the average consumer, access to a health professional who can help identify, evaluate, and translate the available evidence to inform and guide their decisions about using T&CM products is important.

Pharmacists' role in addressing the concerns about the use of T&CM products

The pharmacist's role in contributing to public health by ensuring the safe and appropriate use of medicines is well established. Discussion regarding broadening the scope of pharmacists' professional practice to include T&CM products began over two decades ago.[5] International and national professional pharmacist organizations also advocate the inclusion of T&CM products into pharmacists' scope of practice. In general, pharmacists recognize the relevance of T&CM products s to their daily practice, the needs of consumers, and are keen on stepping up their professional role in the delivery of more responsible pharmaceutical services.[13-15] Further, an argument proposing pharmacists provide professional advice in this area should not be limited to those T&CM products accessed only through pharmacies. Indeed, encouraging disclosure about all T&CM products including those purchased through other retail stores and online outlets needs to be considered by pharmacists as part of the pharmaceutical care they provide. Despite this, pharmacists still do not engage and are professionally underperforming in this area.[16] Such observations have been reported in US[15] Australia[16], China[14] and many other countries.[17]

Lack of an international consensus on pharmacists' responsibilities in T&CM products

No international consensus has been reached about the practicalities and processes required to engage pharmacists in caring for people who use T&CM products. A systematic review published in 2017 identified pharmacists' practical responsibilities most commonly reported in the literature and called for actions to reach a consensus on how pharmacists should be involved in safeguarding the proper use of T&CM.[17] The seven responsibilities proposed were for pharmacists to acknowledge the use of T&CM products in the communities they serve; be knowledgeable about the evidence-base for T&CM products; ensure patients are using T&CM products safely; document the use of T&CM products on patient records; report adverse drug reactions associated with T&CM products; educate patients about T&CM products; and communicate with other health care professionals about the use of T&CM products.

These findings were raised again in a more recent systematic review[18] that informed the development of a bioethical framework for pharmacists' responsibilities when selling T&CMs[19]. The framework supported and built on the aforementioned pharmacists responsibilities to propose that both pharmacists and their staff should be trained in the provision of evidence-based T&CM recommendations; pharmacy staff should know when to refer to a pharmacist about T&CM products; pharmacists should be able to provide T&CM product information for people to make

informed decisions; the layout and business model of the pharmacy should be conducive to consumers receiving T&CM product advice from a pharmacist when purchasing the products; and pharmacists should intervene if there is a risk of harm is significant. Despite these individual and collective research efforts, a substantial gap remains between the responsibilities and ethical framework that have been proposed in relation to T&CM products and what takes place in day-to-day pharmacy practice.[16,20] This may be related to the fact that internationally and nationally in most countries, the legal and professional expectations associated with this role are still not clearly defined.[13]

Changes to the legal and professional expectations of pharmacists associated with T&CM products is complex and involves multiple stakeholders including professional pharmacy organizations, universities, government, pharmacy owners, and pharmacists to develop education and training, build the T&CM evidence base and reliable and accessible T&CM resources and imbed a workplace culture that supports best practice in T&CM.[21] This requires a strategic and coordinated effort driven by pharmacists and their representative organisations around the world towards a consensus that translates the last two decades of research into implementable global practice behaviours that support public health and safety. According to a strategic model developed by Ung et al, among other actions, translating a set of responsibilities into practice standards and implementing those standards is critical to improving pharmacists' professional practice associated with T&CM products.[21] As such, a clear description of pharmacist professional involvement in T&CM products serves two main purposes. Firstly, it raises the public's attention about the need for health professional's involvement when making decisions about the use of T&CM products and drives the standardization of pharmacists' practice behaviors. More importantly, it forms the foundation for developing competency standards that inform learning outcomes in undergraduate and postgraduate pharmacy education. The need for T&CM education in pharmacy training programs is well established to facilitate competent and confident communications between pharmacists and the public they serve.

Aims/goals

The overarching aim of this international study is to identify a set of core responsibilities that support pharmacists' contribution to ensuring the quality and safe use of T&CM products and promote of public health.

The objectives are (1) to develop, pilot and disseminate a cross-country e-survey through an international collaborative effort via professional associations and representative organisations; and

(2) provide an international perspective of pharmacists' opinions about their professional responsibilities associated with T&CMs, and the steps and support required to formalize such a role; and (3) use these perspectives and key points of agreement to inform the next project – a consensus process.

Methods and analysis

A cross-sectional online survey with convenience sampling in each of the participating countries will be employed. This study protocol outlined here is developed in accordance with the STrengthening the Reporting of OBservational studies in Epidemiology (STROBE)guideline[22] and the Checklist for Reporting Results of Internet E-Surveys (CHERRIES).[23]

This international collaboration is led by researchers from The University of Sydney School of Pharmacy, Faculty of Medicine and Health in New South Wales Australia, and the Institute of Chinese Medical Sciences, University of Macau. A web-based cross-sectional open survey will be disseminated across countries representing pharmacists from the six designated World Health Organisation regions: African Region (AFR), Region of the Americas (AMR), South-East Asian Region (SEAR), European Region (EUR), Eastern Mediterranean Region (EMR) and Western Pacific Region (WPR) over a twelve-month period. Countries to be surveyed will be recruited via purposive sampling and snowballing. To identify researchers to lead the survey in individual countries, a search of published studies on the topic of pharmacists and T&CM published within the last 5 years will be conducted. Email addresses of the corresponding author/s available in each publication will be used to initiate contact. Authors who respond to the email will be invited to a research team discussion (online) and encouraged to extend the invitation to researchers in the field. To date, the recruitment method for building an international research team has attracted commitment from researchers located across the six designated WHO regions AFR (Cabo Verde and Angola), AMR (United States of America and Brazil), SEAR (Thailand and Indonesia), EUR (Croatia, Unite Kingdom and Portugal), EMR (United Arab Emirates and Lebanon), and the WPR (Australia, China and Malaysia) who have confirmed their participation. The researcher/team based in each country will be responsible for leading the study in their respective country. The link to the e-survey will be open for a maximum of 4 weeks.

Population and recruitment

Pharmacists across the participating countries will be eligible to participate. People who are not pharmacists or pharmacists from outside of the participating countries will not be eligible to

participate. No incentives for participation will be offered. The research team in each of the participating countries having effective contact with the national or local pharmacists' representative organisations and professional networks will be responsible for recruitment. In accordance with the size of pharmacist workforce which may vary considerably from a few hundred to several hundred thousand,[24] varying degrees of access to the lists of registered pharmacists and the differences in the organizational structures of pharmacy organizations, a combination of sampling approaches including probability sampling (when the entire pharmacist workforce in the country is reachable), purposive sampling (when only a subset of pharmacist workforce in the country is reachable) and snowball sampling will be employed. The minimum sample size for each country will be targeted to obtain a confidence level 95%, with a margin of error 5% for the survey results.

In each country, the local research team member will select the pharmacist professional networks through which to disseminate the link to the survey. In accordance with the ethical requirements of each country, an invitation to participate in the open survey will be circulated via pharmacists' representative organisations within the respective country. The invitation with the survey link will be distributed through professional newsletters, email correspondence, local supporting professional organization, pharmacist professional networks and/or social media links. The recruitment rate will be calculated by the ratio of people who agreed to participate on the first page of the survey divided by the number how visited the survey but did not agree to participate.

Survey development and pretesting

Following a systematic review of the literature reporting on the topic of pharmacists and T&CM products, the research team has undertaken a comprehensive and iterative process to develop and pilot the survey instrument (with pharmacist co-investigators). To ensure the face validity of the questionnaire, the initial instrument was first assessed by four researchers experienced in quantitative studies and pharmacy practice (including a full professor, 1 postdoctoral fellow and 2 PhD students who specialize in the discipline of medicinal administration and research experiences related to the objectives of this study) through a focus group. They were also asked to evaluate if the statements in the questionnaire would allow reasonable and operational measurements of each key item and to elaborate further on how to improve the validity of the questionnaire design. Based on their feedback, revisions were made to improve the comprehensibility of items. The revised instrument was then pilot tested on a convenience sample of 20 pharmacists in Macau who received their pharmacy training in the United States (n=2), the United Kingdom (n=3), Australia (n=3), Portugal (n=2), Mainland China (n=5), and Taiwan (n=5), and had a minimum of three years of

professional pharmacy practice experience within the community, hospital and/or regulation sectors. Two pharmacists held leadership positions in pharmacist professional organizations. They were asked to specifically evaluate whether the items encapsulated pharmacists practice related to T&CM products. They all agreed that the questions were comprehendible thus confirming the face and content validity of the survey instrument. No removal or addition of the original items was suggested.

The research team member based in each region/country will organise translation of the survey instrument if required, local field testing and any additional ethical review required within that country. Whenever applicable, translation will ensure that the survey is available in the national language of the country and other relevant languages. For survey questionnaires translated from English, a third step is undertaken translating the items back to English to ensure the intent of questions have not be lost in translation. To finalise the survey instrument structure used in each country, field testing using a print form of the survey to five to ten individuals will be conducted to have them provide feedback about translations. Three rounds of iteration per country survey are expected to finalise the content. Further field testing in digital form will be conducted with another five to ten individuals per country to examine errors in skip logic.

Inclusion criteria for the survey include adults (≥18 years of age), currently practicing as pharmacist in the participating countries, and able to provide online informed consent. A completeness check is embedded via a forced response with all items providing a non-response option "neutral". Participants are able select a back button to allow respondents to review and change their answers. Completion rate will be the ratio of people who finished the survey who agreed to participate i.e., the number of people submitting the last questionnaire page, divided by the number of people who agreed to participate. A setting in Qualtrics will be activated to prevent users' access to the survey from a single IP address (in countries where this is available) twice. IP addresses will not be used to identify participants' computers and ensure complete privacy. The average time to complete the survey is nine to eleven minutes.

Questionnaire design

The survey instrument starts with a brief overview about the research topic, a link to a participant information statement and a question confirming consent. Overall, the survey consists of five sections involving 43 items relevant to T&CM products in pharmacy practice: Section 1 – participants' sociodemographic characteristics (seven items), Section 2 – participants' perception

about T&CM (five items), Section 3 - opinions about bioethical responsibilities related to T&CM products (three items), Section 4 - opinions about practice responsibilities related to T&CM products (15 items), and Section 5 - the support they need to build their scope of practice related to T&CM products (13 items). The survey ends with an open question to draw participants' additional comments regarding professional pharmacy practice regarding T&CM products. The full survey instrument is included as a supplementary file (insert link here).

In Section one, participants will be asked to confirm their eligibility of being a pharmacist in the first question. Questions about basic demographic characteristics such as gender and age will follow. The In the subsequent five questions, sociodemographic information which has been suggested to have an impact on how pharmacists perceive their professional practice related to T&CM products will be sought. These include education background,[25] practice setting,[14] status of employment,[21] and history of T&CM education.[15]

In section two, the level of agreement to three items capturing pharmacists' perception about T&CM products are sought. Perceptions about evidence, safety and efficacy are thought to influence pharmacists' approach to providing advice area in day-to-day practice. [14] An additional two items will identify what types of T&CM products participants consider should (or shouldn't) be within the scope of their professional practice.

In section three, the level of agreement to three items designed to capture opinions about a set of proposed bioethical responsibilities,[18] and a framework for pharmacists managing T&CM products are requested.[19]

In section four, participants will be asked to rate their level of agreement to 15 responsibilities that have been proposed in earlier literature associated with pharmacists and T&CM products.[17,26, 27]

In section five, level of agreement to 13 items related to the factors thought to enable pharmacists to effectively engage and build their scope of practice related to T&CM products will be sought.[13,20,28] These items correspond to six domains: (1) clarifying pharmacist role related to T&CM products, (2) a need for T&CM related education, (3) fostering workplace support, (4) facilitating more non-biased research of T&CM products, (5) promoting effective inter-professional communication, and (6) improving regulation standards of T&CM products.

Data protection and consent

This research study will present no greater than minimal risk to participants. The participants will be allowed to stop the survey at any point of time. No participant names or other identifiers will be collected. While research team members will coordinate the study in each country, and analyse the survey data for their country, decisions about data sharing across countries will be agreed on and data sharing agreements for cross-country analyses will be signed between the research team and the leading research team member in each country.

All survey data will be collected via University of Sydney licensed access to Qualtrics in Australia. Qualtrics is an online data capture tool that stores data on secure servers within New South Wales Australia. A survey link specific to each country will be created. The data will be collected centrally via the online survey platform Qualtrics in accordance with the user agreements licenced to The University of Sydney Australia. Participation in the study is voluntary, and the survey completed anonymously. A question at the start of the survey will confirm participants have read and understood the participation information statement and agree to the use of their responses in the analysis.

Data analysis plan

Individual country anonymous survey data will be provided to the external co-investigators (research team members) in an excel spreadsheet once the survey data for their country/region is completed. The meta-data (all country/ regions survey results) will be held by the CIs (XX and XX) and analysed using the Statistical Package for Social Sciences (SPSS) version 27 software for Windows.

This statistical analysis plan focuses on the cross-county comparison component of the analysis. Only survey data that meet the following criteria will be included in the international comparison: completed surveys of at least 200 participants (unless the pharmacist workface is less than 200 in the participating country), Human Research Ethics Committee/Institutional Review Board (IRB) approval from the local authority if required in addition to the University of Macau and University of Sydney approval, description of sampling methodology, and local instrument translated whenever applicable, and field tested.

The demographic data of the respondents and the ratings of the item statements will be analysed using descriptive statistics (frequencies, means, and standard deviations). In addition to descriptive analysis for responses to sections 2 to 5, various bivariate statistical procedures will be used to evaluate the association between the ratings of item statements and the demographic variables. The international analysis will use multiple linear regression to examine individual-level and country-level

variables associated with primary measurements: pharmacist's opinions about their professional responsibilities associated with T&CMs, and the steps and support required to formalise such a role. This is to identify the respondents' demographic characteristics worth considering when deciding on the strategies that promote the implementation of the practice behaviours. Data from different countries will also be combined to conduct subgroup analyses on the following groups of individuals: age groups, education level, seniority, practice setting, and previous education about T&CM. ` A *p* value of less than 0.05 will be accepted as statistically significant. Data from Sections 3, 4 and 5 of the survey will be placed into an exploratory factor analysis procedure to help identify overarching domains of pharmacists' responsibilities related to T&CM products. Cronbach's alpha will be calculated on the combination of these items to help assess their internal consistency and as a check to help assess the sincerity of the respondent's engagement during the survey process. In lacking a gold standard to measure pharmacists' perceptions, the exploratory factor analysis will help affirm at least some degree of validity as to the construct of pharmacists' responsibilities.

Patient and Public Involvement

No patient/s were involved in the development of this study protocol.

Dissemination of results

Results will be disseminated in scientific papers and made available to professional audience during professional events. All participating countries will be encouraged to communicate research findings to relevant key stakeholders and to use the findings as a foundation to extend more in-depth research in the country. Based on the collaborative work in this project, all the participating investigators will form a consortium which will take a lead in developing a universal set of pharmacists' primary responsibilities in T&CMs for academic and professional interests.

Ethics

The study has been approved by the University of Macau (approval number SHRE21-APP068-ICMS) and pending review and approval from the University of Sydney Human Research Ethics Committee (approval number TBC). All potential participants will be provided a participant information statement outlining the background, purpose, and details of the study; how their data will be stored during and after the study; and contact details of the lead investigator. The results of this study will be submitted for publication in peer-reviewed journals and conference proceedings. To ensure a comprehensive insight into each country/region results, both country, and region specific, and a collective report will be reported.

Implications of this research

Evidence suggests that use of T&CMs by the public all over the world will continue to proliferate.[1] While the benefits and risks of many T&CMs are yet to be fully evaluated, the prevalent use without consistent oversight, has not been fully addressed by the public health sector. Pharmacists play an integral role in contributing to public health through their expertise in medicines management. However, T&CMs continue to be self-selected and purchased as 'retail products' rather than medicines and are not routinely integrated into pharmaceutical care and practice. While some isolated measures towards integration have been proposed, there remains no consensus on how to deliver pharmaceutical care in a coordinated, systematic manner.

To date, no research examining pharmacist's role in T&CMs across world regions during a single period has been conducted. It is critical that pharmacist professions opinions are represented strongly in the development of a consensus process about their professional role in T&CMs. This study is an important step towards ensuring the credibility and applicability of a consensus discussion. The results of this survey will be used to inform key discussion points in a consensus process and a step towards developing an agreed and defined professional role for pharmacists in T&CMs; and the support required for them to enact that role effectively. This will have implications to the quality and safe use of T&CMs and therefore public health.

Contributor statement

JH and CU conceptualise the study protocol design. JH and CU drafted the manuscript and SD critically reviewed the draft and final manuscript.

Competing interests

The authors have no completing interests to declare

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Towards consensus - defining and supporting a professional role for pharmacists associated with traditional and complementary medicines

Section 1 - Background and consent

Globally, a substantial portion of traditional and complementary medicine products (T&CMs) are accessed by the public through pharmacies. Pharmacists are trained to be “the gate-keepers” of drug safety and are trusted by the public. Therefore, it has been proposed that pharmacists are well-positioned to extend their scope of practice and assume a role in ensuring the safe and appropriate use of T&CMs. Currently, professional performance in this area has been reported as suboptimal due to; deficits in pharmacy education, limited or no access to reliable information resources, concerns about the regulation, quality, and safety of T&CMs, and a lack of time to engage with consumers about T&CMs use. Further, in most countries, the legal and professional expectations associated with this role are not clearly defined.

The aim of this study is to gather pharmacists’ perspectives from around the world to better define and support pharmacists in this important professional role. It is critical that pharmacist opinions are represented strongly in the development of a consensus process about their professional role in T&CMs. This study is an important step towards ensuring the credibility and applicability of a consensus discussion.

The results of this survey will be used to inform key discussion points in a consensus process and a step towards developing an agreed and defined professional role for pharmacists in T&CMs; and the support required for them to enact that role effectively. This will have implications to the quality and safe use of T&CMs and therefore public health.

The findings of this international study will contribute to the development of an international consensus about the:

- professional role of pharmacists regarding T&CM products.
- support required to enact the role effectively and safely.

Please download and read the Participant Information Statement for further details about this study.

Participant information statement survey australia

By completing the survey, we assume that you:

- understand what you have read in the Participant Information Statement.
- agree to take part in the research study as outlined above.
- agree to the use of your personal information as described.
- are providing consent to take part in the study

☐ I agree and consent to my responses being used in this study

Section 2 - Demographics

Are you a registered pharmacist?

◯ Yes
◯ No

What is your gender?

◯ Male

- ◯ Female
- ◯ Non-binary / third gender
- ◯ Prefer not to say

Please choose the age group you belong to.

- ◯ 18-30
- ◯ 31-40
- ◯ 41-50
- ◯ 51-60
- ◯ 61-70
- ◯ > 71 years of age

What is your highest level of pharmacy qualification?

- ◯ Diploma
- ◯ Advanced Diploma
- ◯ Bachelors degree
- ◯ Masters degree
- ◯ Professional doctorate
- ◯ PhD

Which of the following best describes your current role as a pharmacist? (more than one may apply)

- ☐ I am a community pharmacist
- ☐ I am a hospital pharmacist
- ☐ I am clinical pharmacist (consultant)
- ☐ I work in the pharmaceutical industry
- ☐ I work as an academic
- ☐ I work in a regulatory body

What best describes your current employment?

- ◯ Employed as a pharmacist
- ◯ Self-employed pharmacist/business owner
- ◯ Currently not employed

Was education about traditional and complementary medicine included in your undergraduate pharmacy training?

- ◯ Yes and it was comprehensive enough for me to inform my practice
- ◯ Yes but it was not comprehensive enough to inform my practice
- ◯ No it was not included in my undergraduate pharmacy training

Section 3 - Perceptions about traditional and complementary medicine products

Traditional and complementary medicine product use is common in the community I serve

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree nor disagree
- ◯ Somewhat disagree
- ◯ Strongly disagree

There is evidence to support the efficacy of some traditional and complementary medicine products in specific conditions.

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree nor disagree
- ◯ Somewhat disagree

- ◯ Strongly disagree

There are known and unknown safety risks associated with the use of traditional and complementary medicine products.

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree nor disagree
- ◯ Somewhat disagree
- ◯ Strongly disagree

Traditional and complementary medicine products should be considered within the scope of professional pharmacy practice.

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree nor disagree
- ◯ Somewhat disagree
- ◯ Strongly disagree

Which of the following traditional and complementary medicine products do you believe should be integrated into the professional practice of pharmacy? (choose as many options as apply)

- ☐ Products containing herbal or botanical ingredients (e.g. ginseng, gingko biloba, garlic, pine bark extract)
- ☐ Nutritional products containing vitamins and/or minerals and amino acids (e.g. single and multivitamin formulations)
- ☐ Non-vitamin and mineral supplements (e.g. fish oils, Coenzyme Q10, glucosamine, bee pollen etc.
- ☐ Probiotic and prebiotic formulations
- ☐ Homoeopathic products
- ☐ No traditional and complementary medicines should be included in the professional practice of pharmacy

Section 4 - Pharmacists bioethical responsibilities in relation to T&CM

Pharmacists are in a position to prevent harm associated with the inappropriate use of traditional and complementary medicine products.

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree nor disagree
- ◯ Somewhat disagree
- ◯ Strongly disagree

Pharmacists are in a position to provide evidence-based advice about traditional/complementary medicine products to optimize patient outcomes.

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree nor disagree
- ◯ Somewhat disagree
- ◯ Strongly disagree

Pharmacists should respect consumer's autonomy regarding their choice to use traditional and complementary medicine products.

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree nor disagree
- ◯ Somewhat disagree
- ◯ Strongly disagree

Section 5 - Pharmacist's practice responsibilities regarding T&CM products

Pharmacists should routinely ask about of the use of traditional and complementary medicine products by those taking pharmaceutical medicines.

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree nor disagree
- ◯ Somewhat disagree
- ◯ Strongly disagree

Pharmacists should routinely document the use of traditional and complementary medicine products on patients' records.

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree nor disagree
- ◯ Somewhat disagree
- ◯ Strongly disagree

Pharmacists should be able to source and provide consumer medicine information (CMI) about traditional and complementary medicine products.

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree nor disagree
- ◯ Somewhat disagree
- ◯ Strongly disagree

Pharmacists should be able to inform consumers about the potential risks associated with the use of a traditional and complementary medicine product (e.g. side effects, drug-herb interactions)

- ◯ Strongly agree

- ◯ Somewhat agree
- ◯ Neither agree nor disagree
- ◯ Somewhat disagree
- ◯ Strongly disagree

Pharmacists should be able to inform consumers about the current evidence-base for the effectiveness of a traditional and complementary medicine product.

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree nor disagree
- ◯ Somewhat disagree
- ◯ Strongly disagree

Pharmacists should be able to provide their patients personalised advice about the use of traditional and complementary medicine products.

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree nor disagree
- ◯ Somewhat disagree
- ◯ Strongly disagree

Pharmacists should be able to guide consumers in making an informed decision about the use of traditional and complementary medicine products.

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree nor disagree
- ◯ Somewhat disagree
- ◯ Strongly disagree

Pharmacists should monitor for any the adverse events associated with the use of traditional and complementary medicine products

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree nor disagree
- ◯ Somewhat disagree
- ◯ Strongly disagree

Pharmacists should be able to provide guidance on the management of adverse events associated with the use of traditional and complementary medicine products when they occur.

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree nor disagree
- ◯ Somewhat disagree
- ◯ Strongly disagree

Pharmacists should report suspected adverse adverse events associated with the use of traditional and complementary medicine products to the relevant medicines regulatory authority.

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree nor disagree
- ◯ Somewhat disagree
- ◯ Strongly disagree

Pharmacists should refer consumers to qualified T&CM practitioners for advice about traditional and complementary medicine product use.

- ◯ Strongly agree

- ◯ Somewhat agree
- ◯ Neither agree nor disagree
- ◯ Somewhat disagree
- ◯ Strongly disagree

Pharmacists should only stock traditional and complementary medicine products approved by the local regulatory authority eg. Federal Drug Authority, Therapeutic Goods Administration

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree nor disagree
- ◯ Somewhat disagree
- ◯ Strongly disagree

Business owners should setup the pharmacy so advice from a pharmacist can be easily accessed by those purchasing traditional and complementary medicine products.

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree nor disagree
- ◯ Somewhat disagree
- ◯ Strongly disagree

Pharmacists should provide training for their staff about traditional and complementary medicine products

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree nor disagree
- ◯ Somewhat disagree
- ◯ Strongly disagree

Pharmacists should communicate with other healthcare professionals (e.g. doctors, T&CM practitioners) regarding a patients use of traditional and complementary medicine products to ensure appropriate and safe use.

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree nor disagree
- ◯ Somewhat disagree
- ◯ Strongly disagree

Section 6 - Support for pharmacists professional practice in T&CM products

There is a need to clearly define pharmacists' professional responsibilities associated with traditional and complementary medicine products.

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree or disagree
- ◯ Somewhat disagree
- ◯ Strongly disagree

There is a need to develop traditional and complementary medicine product practice standards for pharmacists.

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree nor disagree
- ◯ Somewhat disagree
- ◯ Strongly disagree

There is a need to develop an accreditation system for pharmacists traditional and complementary medicine competency.

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree nor disagree
- ◯ Somewhat disagree
- ◯ Strongly disagree

There is a need to include traditional and complementary medicine product education in undergraduate professional pharmacy practice.

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree nor disagree
- ◯ Somewhat disagree
- ◯ Strongly disagree

There is a need to provide traditional and complementary medicine product education as continuing professional development.

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree nor disagree
- ◯ Somewhat disagree
- ◯ Strongly disagree

In the workplace, there is an need to improve access to evidence based traditional and complementary medicine information.

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree nor disagree

- ◯ Somewhat disagree
- ◯ Strongly disagree

In the workplace, there is a need to provide support for pharmacists to undertake training in traditional and complementary medicine.

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree nor disagree
- ◯ Somewhat disagree
- ◯ Strongly disagree

In the workplace, pharmacy business owners should employ accredited practitioners (e.g. naturopath - herbalist - nutritionist) to provide advice to consumers about traditional and complementary medicine products.

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree nor disagree
- ◯ Somewhat disagree
- ◯ Strongly disagree

More support is required to facilitate non-biased research about the efficacy and safety of traditional and complementary medicine products.

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree nor disagree
- ◯ Somewhat disagree
- ◯ Strongly disagree

There is a need to develop effective interprofessional communication processes regarding traditional and complementary medicine product use.

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree nor disagree
- ◯ Somewhat disagree
- ◯ Strongly disagree

Improvements in the regulatory standards of traditional and complementary medicine product quality, safety and efficacy are required.

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree nor disagree
- ◯ Somewhat disagree
- ◯ Strongly disagree

Improvements in the regulatory standards of traditional and complementary medicine product labelling and advertising are required.

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree nor disagree
- ◯ Somewhat disagree
- ◯ Strongly disagree

Regulatory bodies should consider scheduling of traditional and complementary medicine products as 'pharmacy only' medicines.

- ◯ Strongly agree
- ◯ Somewhat agree
- ◯ Neither agree nor disagree

- ◯ Somewhat disagree
- ◯ Strongly disagree

Please make any additional comments regarding traditional and complementary medicine products and professional pharmacy practice.

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Checklist for Reporting Results of Internet E-Surveys (CHERRIES)

Item Category / Checklist Item	*Explanation*	*Location in paper (pg)*
Design		
Describe survey design	Describe target population, sample frame. Is the sample a convenience sample? (In "open" surveys this is most likely.)	8 – 9
IRB (Institutional Review Board) approval and informed consent process		
IRB approval	Mention whether the study has been approved by an IRB.	11
Informed consent	Describe the informed consent process. Where were the participants told the length of time of the survey, which data were stored and where and for how long, who the investigator was, and the purpose of the study?	9
Data protection	If any personal information was collected or stored, describe what mechanisms were used to protect unauthorized access.	8
Development and pre-testing		
Development and testing	State how the survey was developed, including whether the usability and technical functionality of the electronic questionnaire had been tested before fielding the questionnaire.	8
Recruitment process and description of the sample having access to the questionnaire		
Open survey versus closed survey	An "open survey" is a survey open for each visitor of a site, while a closed survey is only open to a sample which the investigator knows (password-protected survey).	8
Contact mode	Indicate whether or not the initial contact with the potential participants was made on the Internet. (Investigators may also send out questionnaires by mail and allow for Web-based data entry.)	8
Advertising the survey	How/where was the survey announced or advertised? Some examples are offline media (newspapers), or online (mailing lists – If yes, which ones?) or banner ads (Where were these banner ads posted and what did they look like?). It is important to know the wording of the announcement as it will heavily influence who chooses to participate. Ideally the survey announcement should be published as an appendix.	9
Survey administration		
Web/E-mail	State the type of e-survey (eg, one posted on a Web site, or one sent out through e-mail). If it is an e-mail survey, were the responses entered manually into a database, or was there an automatic method for capturing responses?	8
Context	Describe the Web site (for mailing list/newsgroup) in which the survey was posted. What is the Web site about, who is visiting it, what are visitors normally looking for? Discuss to what degree the content of the Web site could pre-select the sample or influence the results. For example, a survey about vaccination on a anti-immunization Web site will have different results from a Web survey conducted on a government Web site	8
Mandatory/voluntary	Was it a mandatory survey to be filled in by every visitor who wanted to enter the Web site, or was it a voluntary survey?	9

Incentives	Were any incentives offered (eg, monetary, prizes, or non-monetary incentives such as an offer to provide the survey results)?	N/A
Time/Date	In what timeframe were the data collected?	8 - 9
Randomization of items or questionnaires	To prevent biases items can be randomized or alternated.	N/A
Adaptive questioning	Use adaptive questioning (certain items, or only conditionally displayed based on responses to other items) to reduce number and complexity of the questions.	9
Number of Items	What was the number of questionnaire items per page? The number of items is an important factor for the completion rate.	9
Number of screens (pages)	Over how many pages was the questionnaire distributed? The number of items is an important factor for the completion rate.	8
Completeness check	It is technically possible to do consistency or completeness checks before the questionnaire is submitted. Was this done, and if "yes", how (usually JAVAScript)? An alternative is to check for completeness after the questionnaire has been submitted (and highlight mandatory items). If this has been done, it should be reported. All items should provide a non-response option such as "not applicable" or "rather not say", and selection of one response option should be enforced.	9
Review step	State whether respondents were able to review and change their answers (eg, through a Back button or a Review step which displays a summary of the responses and asks the respondents if they are correct).	N/A
Response rates		
Unique site visitor	If you provide view rates or participation rates, you need to define how you determined a unique visitor. There are different techniques available, based on IP addresses or cookies or both.	N/A
View rate (Ratio of unique survey visitors/unique site visitors)	Requires counting unique visitors to the first page of the survey, divided by the number of unique site visitors (not page views!). It is not unusual to have view rates of less than 0.1 % if the survey is voluntary.	N/A
Participation rate (Ratio of unique visitors who agreed to participate/unique first survey page visitors)	Count the unique number of people who filled in the first survey page (or agreed to participate, for example by checking a checkbox), divided by visitors who visit the first page of the survey (or the informed consents page, if present). This can also be called "recruitment" rate.	N/A
Completion rate (Ratio of users who finished the survey/users who agreed to participate)	The number of people submitting the last questionnaire page, divided by the number of people who agreed to participate (or submitted the first survey page). This is only relevant if there is a separate "informed consent" page or if the survey goes over several pages. This is a measure for attrition. Note that "completion" can involve leaving questionnaire items blank. This is not a measure for how completely questionnaires were filled in. (If you need a measure for this, use the word "completeness rate".)	N/A
Preventing multiple entries from the same individual		
Cookies used	Indicate whether cookies were used to assign a unique user identifier to each client computer. If so, mention the page on which the cookie was set and read, and how long the cookie was valid. Were duplicate	Not used

	entries avoided by preventing users access to the survey twice; or were duplicate database entries having the same user ID eliminated before analysis? In the latter case, which entries were kept for analysis (eg, the first entry or the most recent)?	
IP check	Indicate whether the IP address of the client computer was used to identify potential duplicate entries from the same user. If so, mention the period of time for which no two entries from the same IP address were allowed (eg, 24 hours). Were duplicate entries avoided by preventing users with the same IP address access to the survey twice; or were duplicate database entries having the same IP address within a given period of time eliminated before analysis? If the latter, which entries were kept for analysis (eg, the first entry or the most recent)?	Not used
Log file analysis	Indicate whether other techniques to analyze the log file for identification of multiple entries were used. If so, please describe.	Not used
Registration	In "closed" (non-open) surveys, users need to login first and it is easier to prevent duplicate entries from the same user. Describe how this was done. For example, was the survey never displayed a second time once the user had filled it in, or was the username stored together with the survey results and later eliminated? If the latter, which entries were kept for analysis (eg, the first entry or the most recent)?	N/A
Analysis		
Handling of incomplete questionnaires	Were only completed questionnaires analyzed? Were questionnaires which terminated early (where, for example, users did not go through all questionnaire pages) also analyzed?	9
Questionnaires submitted with an atypical timestamp	Some investigators may measure the time people needed to fill in a questionnaire and exclude questionnaires that were submitted too soon. Specify the timeframe that was used as a cut-off point, and describe how this point was determined.	N/A
Statistical correction	Indicate whether any methods such as weighting of items or propensity scores have been used to adjust for the non-representative sample; if so, please describe the methods.	N/A

BMJ Open

Towards consensus - defining and supporting a professional role for pharmacists associated with traditional and complementary medicines – a protocol of implementing an international e-survey

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Towards consensus - defining and supporting a professional role for pharmacists associated with traditional and complementary medicines – a protocol of implementing an international e-survey

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Abstract

Introduction - Traditional and complementary medicines (T&CM) are predominantly self-selected from retail outlets including pharmacies as part of self-care practices. Concerns about the appropriate and safe use of T&CM products raises questions about 'should' and 'how' pharmacists could adopt professional responsibilities. There lacks a consensus about the scope of these responsibilities, or the initiatives required to execute them. The aim of this study is to identify an international set of core responsibilities that support pharmacists' contribution to ensuring the quality and safe use of T&CMs to promote public health.

Methods and analysis - An international cross-sectional e-survey of pharmacists representing the six World Health Organisation regions will be conducted over a twelve-month period. Pharmacists will be invited via representative organisations and professional networks within their respective country. Survey responses to statements about the relevance of T&CM to day-to-day practice; opinions about the bioethical and practice responsibilities; and support required to build their scope of practice associated with T&CM will be collected centrally via the online survey platform Survey Monkey and analysed using the Statistical Package for Social Sciences version 27 software for Windows. Bivariate statistical analysis will be conducted to examine the associations between agreement to statements within each section with key demographic variables, country of practice, pharmacy type, age, gender, qualification, and years in practice. Cronbach's alpha will be used to test the internal consistency of items from certain sections of the survey and evince their clarity to respondents of the questionnaire.

Ethics and Dissemination - Ethics approval has been obtained from the University of Macau (approval number SSHRE21-APP068-ICMS-01). The results of this survey will be used to inform key discussion points in a consensus process and a step towards developing an agreed and defined professional role for pharmacists in T&CMs.

Strengths and limitations of this study

- We will conduct an international web-based, cross-sectional survey of pharmacists utilising the Checklist for Reporting the Results of Internet E-Surveys and STROBE guidelines.
- We have undertaken a comprehensive and iterative process to develop and pilot the survey instrument with pharmacists.
- Dissemination of the survey in different countries over the same time will capture similarities and differences between the socio-demographic contexts.
- Using convenience sampling of pharmacist professional associations and networks may introduce selection bias.
- Use of the same core survey questions translated from English may have compromised some of the cultural nuances specific to a country or region.

Introduction

Safe and appropriate use of traditional & complementary medicines – a public health matter

The use of traditional and complementary medicines (T&CM) use is highly prevalent around the world.[1] Ensuring the safe and appropriate of T&CM to minimize risks and optimize benefits is an important area of public health that is yet to be fully addressed. While the terms "traditional medicine (TM)" and "complementary medicine (CM)" are often used interchangeably or combined, there are fundamental differences between the two.[1] Traditional Medicine is defined as "*the sum total of the knowledge, skill, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness*".[1] Whereas, CM is described as a broad set of healthcare practices that are not part of a country's own traditional or conventional medicine and are not fully integrated into the dominant healthcare system.[1] The terms TM and CM encompasses products, practices, and practitioners.[1] For the purposes of this study, T&CM products

will refer to natural products that are used for medicinal purposes including herbal products, nutritional supplements, vitamin and minerals, essential oils, and homeopathic products.[2]

Traditional and Complementary medicine products are an increasingly prevalent component of healthcare and self-care practices across the world. People choose T&CM products for health maintenance as well as disease prevention and treatment, with varying prevalence rates across regions.[1] As new evidence emerges regarding the safety and effectiveness of some T&CM products, knowledge about their contribution to health outcomes across world regions will become clearer. However, many consumers consider T&CM products as "natural and therefore safe" and thus may not extend the same caution towards their use as they would for prescription medicines.[3] Further, decisions about T&CM products use amongst people with serious conditions such as cancer maybe un-/mis-informed.[4] Indeed, there are safety risks related to the quality of products,[5] potential adverse events including drug-herb/nutrient interactions,[6] and delays in initiating known effective treatments, all of which can easily be overlooked.[7] This is particularly the case for special population groups such as children, the elderly, and people living with chronic or other complex health issues, among whom the risk of experiencing adverse drug reactions and drug-herb interactions may be increased.[8] Some of these risks are potentially confounded by integrative approaches (the use of T&CM products in conjunction with conventional medicines)[9] and poor inter-professional communication between conventional and complementary medicine practitioners.[10]

Collectively, there is a public health need to harness the potential benefits and minimize risk associated with T&CM products around the world. The evidence base evaluating the use of T&CM products is growing, which can help resolve uncertainty on safety and effectiveness and should be used to guide decisions about their use.[11] The Cochrane Complementary Medicine group critically evaluate and synthesise the evidence originated from meta-analyses and randomized clinical trials about the effectiveness of a range of T&CM products and practices for the treatment of various conditions, and accounts for 10% of Cochrane reviews.[12] Indeed, the research on T&CM herbal ingredients is growing exponentially. It is apparent that identifying large-scale high-quality evidence is challenging due to heterogenous study designs (populations studied, formulations and doses used, lack of detailed reporting) and risk of bias. Therefore, for the average consumer, access to a health professional who can help identify, evaluate, and translate the available evidence to inform and guide their decisions about using T&CM products is important.

Pharmacists' role in addressing the concerns about the use of T&CM products

The pharmacist's role in contributing to public health by ensuring the safe and appropriate use of medicines is well established. Discussion regarding broadening the scope of pharmacists' professional

practice to include T&CM products began over two decades ago.[5] International and national professional pharmacist organizations also advocate the inclusion of T&CM products into pharmacists' scope of practice. In general, pharmacists recognize the relevance of T&CM products to their daily practice, the needs of consumers, and are keen on stepping up their professional role in the delivery of more responsible pharmaceutical services.[13-15] Further, an argument proposing pharmacists provide professional advice in this area should not be limited to those T&CM products accessed only through pharmacies. Indeed, encouraging disclosure about all T&CM products including those purchased through other retail stores and online outlets needs to be considered by pharmacists as part of the pharmaceutical care they provide. Despite this, pharmacists still do not engage and are professionally underperforming in this area.[16] Such observations have been reported in US[15] Australia[16], China[14] and many other countries.[17]

Lack of an international consensus on pharmacists' responsibilities in T&CM products

No international consensus has been reached about the practicalities and processes required to engage pharmacists in caring for people who use T&CM products. A systematic review published in 2017 identified pharmacists' practical responsibilities most commonly reported in the literature and called for actions to reach a consensus on how pharmacists should be involved in safeguarding the proper use of T&CM.[17] The seven responsibilities proposed were for pharmacists to acknowledge the use of T&CM products in the communities they serve; be knowledgeable about the evidence-base for T&CM products; ensure patients are using T&CM products safely; document the use of T&CM products on patient records; report adverse drug reactions associated with T&CM products; educate patients about T&CM products; and communicate with other health care professionals about the use of T&CM products.

These findings were raised again in a more recent systematic review[18] that informed the development of a bioethical framework for pharmacists' responsibilities when selling T&CMs[19]. The framework supported and built on the aforementioned pharmacists responsibilities to propose that both pharmacists and their staff should be trained in the provision of evidence-based T&CM recommendations; pharmacy staff should know when to refer to a pharmacist about T&CM products; pharmacists should be able to provide T&CM product information for people to make informed decisions; the layout and business model of the pharmacy should be conducive to consumers receiving T&CM product advice from a pharmacist when purchasing the products; and pharmacists should intervene if the risk of harm is significant. Despite these individual and collective research efforts, a

substantial gap remains between the responsibilities and ethical framework that have been proposed in relation to T&CM products and what takes place in day-to-day pharmacy practice.[16,20] This may be related to the fact that internationally and nationally in most countries, the legal and professional expectations associated with this role are still not clearly defined.[13]

Changes to the legal and professional expectations of pharmacists associated with T&CM products is complex and involves multiple stakeholders including professional pharmacy organizations, universities, government, pharmacy owners, and pharmacists to develop education and training, build the T&CM evidence base and reliable and accessible T&CM resources and imbed a workplace culture that supports best practice in T&CM.[21] This requires a strategic and coordinated effort driven by pharmacists and their representative organisations around the world towards a consensus that translates the last two decades of research into implementable global practice behaviours that support public health and safety. According to a strategic model developed by Ung et al, among other actions, translating a set of responsibilities into practice standards and implementing those standards is critical to improving pharmacists' professional practice associated with T&CM products.[21] As such, a clear description of pharmacist professional involvement in T&CM products serves two main purposes. Firstly, it raises the public's attention about the need for health professional's involvement when making decisions about the use of T&CM products and drives the standardization of pharmacists' practice behaviors. More importantly, it forms the foundation for developing competency standards that inform learning outcomes in undergraduate and postgraduate pharmacy education. The need for T&CM education in pharmacy training programs is well established to facilitate competent and confident communications between pharmacists and the public they serve.

Aims/goals

The overarching aim of this international study is to identify a set of core responsibilities that support pharmacists' contribution to ensuring the quality and safe use of T&CM products and promote of public health.

The objectives are (1) to develop, pilot and disseminate a cross-country e-survey through an international collaborative effort via professional associations and representative organisations; and (2) provide an international perspective of pharmacists' opinions about their professional responsibilities associated with T&CMs, and the steps and support required to formalize such a role; and (3) use these perspectives and key points of agreement to inform the next project – a consensus process.

Methods and analysis

A cross-sectional online survey with convenience sampling in each of the participating countries will be employed. This study protocol outlined here is developed in accordance with the STrengthening the Reporting of OBservational studies in Epidemiology (STROBE)guideline[22] and the Checklist for Reporting Results of Internet E-Surveys (CHERRIES).[23]

This international collaboration is led by researchers from the Institute of Chinese Medical Sciences, University of Macau and The University of Sydney School of Pharmacy, Faculty of Medicine and Health in New South Wales Australia. A web-based cross-sectional open survey will be disseminated across countries representing pharmacists from the six designated World Health Organisation regions: African Region (AFR), Region of the Americas (AMR), South-East Asian Region (SEAR), European Region (EUR), Eastern Mediterranean Region (EMR) and Western Pacific Region (WPR) over a twelve-month period. Countries to be surveyed will be recruited via purposive sampling and snowballing. To identify researchers to lead the survey in individual countries, a search of published studies on the topic of pharmacists and T&CM published within the last 5 years will be conducted. Email addresses of the corresponding author/s available in each publication will be used to initiate contact. Authors who respond to the email will be invited to a research team discussion (online) and encouraged to extend the invitation to researchers in the field. To date, the recruitment method for building an international research team has attracted commitment from researchers located across the six designated WHO regions AFR (Cabo Verde and Angola), AMR (United States of America and Brazil), SEAR (Thailand and Indonesia), EUR (Croatia, Unite Kingdom and Portugal), EMR (United Arab Emirates and Lebanon), and the WPR (Australia, China, and Malaysia) who have confirmed their participation. The researcher/team based in each country will be responsible for leading the study in their respective country. The link to the e-survey will be open for a maximum of 4 weeks.

Population and recruitment

Pharmacists engaged in a range of practice settings (both in the past and present) including community pharmacy, hospital pharmacy, clinical/consultancy, the pharmaceutical industry, academia, and regulatory bodies across the participating countries will be eligible to participate. People who are not pharmacists or pharmacists from outside of the participating countries will not be eligible to participate. No incentives for participation will be offered. The research team within each country will be required to engage with national or local pharmacists' representative organisations and professional networks to recruit participants. In accordance with the size of the pharmacist workforce - which may vary considerably from a few hundred to several hundred thousand,[24] varying

degrees of access to the lists of registered pharmacists and the differences in the organizational structures of pharmacy organizations, a combination of sampling approaches including probability sampling (when the entire pharmacist workforce in the country is reachable), purposive sampling (when only a subset of pharmacist workforce in the country is reachable) and snowball sampling will be employed. The minimum sample size for each country will be targeted to obtain a confidence level 95%, with a margin of error 5% for the survey results.

In each country, the local research team member will select the pharmacist professional networks through which to disseminate the link to the survey. In accordance with the ethical requirements of each country, an invitation to participate in the open survey will be circulated via pharmacists' representative organisations within the respective country. The invitation with the survey link will be distributed through professional newsletters, email correspondence, local supporting professional organization, pharmacist professional networks and/or social media links. The recruitment rate will be calculated by the ratio of people who agreed to participate on the first page of the survey divided by the number who visited the survey but did not agree to participate.

Survey development and pretesting

Following a systematic review of the literature reporting on the topic of pharmacists and T&CM products[17], the research team has undertaken a comprehensive and iterative process to develop and pilot the survey instrument (with pharmacist co-investigators). To ensure the face validity of the questionnaire, the initial instrument was first assessed by four researchers experienced in quantitative studies and pharmacy practice (including a full professor, 1 postdoctoral fellow and 2 PhD students who specialize in the discipline of medicinal administration and research experiences related to the objectives of this study) through a focus group. They were also asked to evaluate if the statements in the questionnaire would allow reasonable and operational measurements of each key item and to elaborate further on how to improve the validity of the questionnaire design. Based on their feedback, revisions were made to improve the comprehensibility of items. The revised instrument was then pilot tested on a convenience sample of 20 pharmacists in Macau who received their pharmacy training in the United States (n=2), the United Kingdom (n=3), Australia (n=3), Portugal (n=2), Mainland China (n=5), and Taiwan (n=5), and had a minimum of three years of professional pharmacy practice experience within the community, hospital and/or regulation sectors. Two pharmacists held leadership positions in pharmacist professional organizations. They were asked to specifically evaluate whether the items encapsulated pharmacists practice related to T&CM products. They all agreed that the questions were comprehendible thus confirming the face and content validity of the survey instrument. No removal or addition of the original items was suggested.

The research team member based in each region/country will organise translation of the survey instrument if required, local field testing and any additional ethical review required within that country. Whenever applicable, translation will ensure that the survey is available in the national language of the country and other relevant languages. For survey questionnaires translated from English, a third step is undertaken translating the items back to English to ensure the intent of questions have not be lost in translation. To finalise the survey instrument structure used in each country, field testing using a print form of the survey to five to ten individuals will be conducted to have them provide feedback about translations. Three rounds of iteration per country survey are expected to finalise the content. Further field testing in digital form will be conducted with another five to ten individuals per country to examine errors in skip logic.

Inclusion criteria for the survey include adults (≥18 years of age), currently practicing as pharmacist in the participating countries, and able to provide online informed consent. A completeness check is embedded via a forced response with all items providing a non-response option "neutral". Participants are able select a back button to allow respondents to review and change their answers. Completion rate will be the ratio of people who finished the survey who agreed to participate i.e., the number of people submitting the last questionnaire page, divided by the number of people who agreed to participate. A setting in Survey Monkey will be activated to prevent users' access to the survey from a single IP address (in countries where this is available) twice. IP addresses will not be used to identify participants' computers and ensure complete privacy. The average time to complete the survey is nine to eleven minutes.

Questionnaire design

The survey instrument starts with a brief overview about the research topic, a link to a participant information statement and a question confirming consent. Overall, the survey consists of five sections involving 43 items relevant to T&CM products in pharmacy practice: Section 1 – participants' sociodemographic characteristics (seven items), Section 2 – participants' perception about T&CM (five items), Section 3 - opinions about bioethical responsibilities related to T&CM products (three items), Section 4 - opinions about practice responsibilities related to T&CM products (15 items), and Section 5 - the support they need to build their scope of practice related to T&CM products (13 items). The survey ends with an open question to draw participants' additional comments regarding professional pharmacy practice regarding T&CM products. The full survey instrument is included as a supplementary file (insert link here).

In Section one, participants will be asked to confirm their eligibility of being a pharmacist in the first question. Questions about basic demographic characteristics such as gender and age will follow. The In the subsequent five questions, sociodemographic information which has been suggested to have an impact on how pharmacists perceive their professional practice related to T&CM products will be sought. These include education background,[25] practice setting,[14] status of employment,[21] and history of T&CM education.[15]

In section two, the level of agreement to three items capturing pharmacists' perception about T&CM products are sought. Perceptions about evidence, safety and efficacy are thought to influence pharmacists' approach to providing advice area in day-to-day practice. [14] An additional two items will identify what types of T&CM products participants consider should (or shouldn't) be within the scope of their professional practice.

In section three, the level of agreement to three items designed to capture opinions about a set of proposed bioethical responsibilities,[18] and a framework for pharmacists managing T&CM products are requested.[19]

In section four, participants will be asked to rate their level of agreement to 15 responsibilities that have been proposed in earlier literature associated with pharmacists and T&CM products.[17,26, 27]

In section five, level of agreement to 13 items related to the factors thought to enable pharmacists to effectively engage and build their scope of practice related to T&CM products will be sought.[13,20,28] These items correspond to six domains: (1) clarifying pharmacist role related to T&CM products, (2) a need for T&CM related education, (3) fostering workplace support, (4) facilitating more non-biased research of T&CM products, (5) promoting effective inter-professional communication, and (6) improving regulation standards of T&CM products.

Level of agreement scores will be obtained by coding the 5-point Likert scale i.e. 1 = low level of agreement and 5= high level of agreement.

Data protection and consent

This research study will present no greater than minimal risk to participants. The participants will be allowed to stop the survey at any point of time. No participant names or other identifiers will be collected. While research team members will coordinate the study in each country, and analyse the survey data for their country, decisions about data sharing across countries will be agreed on and data

sharing agreements for cross-country analyses will be signed between the research team and the leading research team member in each country.

All survey data will be collected via the author's licensed access to Survey Monkey in Macau. Survey Monkey is an online data capture tool that stores data on secure servers. A survey link specific to each country will be created. The data will be collected centrally via the online survey platform Survey Monkey in accordance with the user agreements licenced to The University of Macau. Participation in the study is voluntary, and the survey completed anonymously. A question at the start of the survey will confirm participants have read and understood the participation information statement and agree to the use of their responses in the analysis.

Data analysis plan

Individual country anonymous survey data will be provided to the external co-investigators (research team members) in an excel spreadsheet once the survey data for their country/region is completed. The meta-data (all country/ regions survey results) will be held by the CIs (JH and CU) and analysed using the Statistical Package for Social Sciences (SPSS) version 27 software for Windows.

This statistical analysis plan focuses on the cross-county comparison component of the analysis. Only survey data that meet the following criteria will be included in the international comparison: completed surveys of at least 200 participants (unless the pharmacist workface is less than 200 in the participating country), Human Research Ethics Committee/Institutional Review Board (IRB) approval from the local authority if required in addition to the University of Macau approval, description of sampling methodology, and local instrument translated whenever applicable, and field tested.

The demographic data of the respondents and the ratings of the item statements will be analysed using descriptive statistics (frequencies, means, and standard deviations). In addition to descriptive analysis for responses to sections 2 to 5, various bivariate statistical procedures will be used to evaluate the association between the ratings of item statements and the demographic variables. The international analysis will use multiple linear regression to examine individual-level and country-level variables associated with primary measurements: pharmacist's opinions about their professional responsibilities associated with T&CMs, and the steps and support required to formalise such a role. This is to identify the respondents' demographic characteristics worth considering when deciding on the strategies that promote the implementation of the practice behaviours. Data from different countries will also be combined to conduct subgroup analyses on the following groups of individuals: age groups, education level, seniority, practice setting, and previous education about T&CM. ` A *p* value of less than 0.05 will be accepted as statistically significant. Data from Sections 3, 4 and 5 of the

survey will be placed into an exploratory factor analysis procedure to help identify overarching domains of pharmacists' responsibilities related to T&CM products. Cronbach's alpha will be calculated on the combination of these items to help assess their internal consistency and as a check to help assess the sincerity of the respondent's engagement during the survey process. In lacking a gold standard to measure pharmacists' perceptions, the exploratory factor analysis will help affirm at least some degree of validity as to the construct of pharmacists' responsibilities.

Patient and Public Involvement

No patient/s were involved in the development of this study protocol.

Ethics and dissemination

The study has been approved by the University of Macau (approval number SSHRE21-APP068-ICMS-01). All potential participants will be provided a participant information statement outlining the background, purpose, and details of the study; how their data will be stored during and after the study; and contact details of the lead investigator. The results of this study will be submitted for publication in peer-reviewed journals and conference proceedings. To ensure a comprehensive insight into each country/region results, both country, and region specific, and a collective report will be reported.

Results will be disseminated in scientific papers and made available to professional audience during professional events. All participating countries will be encouraged to communicate research findings to relevant key stakeholders and to use the findings as a foundation to extend more in-depth research in the country. Based on the collaborative work in this project, all the participating investigators will form a consortium which will take a lead in developing a universal set of pharmacists' primary responsibilities in T&CMs for academic and professional interests.

Implications of this research

Evidence suggests that use of T&CMs by the public all over the world will continue to proliferate.[1] While the benefits and risks of many T&CMs are yet to be fully evaluated, the prevalent use without consistent oversight, has not been fully addressed by the public health sector. Pharmacists play an integral role in contributing to public health through their expertise in medicines management. However, T&CMs continue to be self-selected and purchased as 'retail products' rather than medicines and are not routinely integrated into pharmaceutical care and practice. While some isolated measures towards integration have been proposed, there remains no consensus on how to deliver pharmaceutical care in a coordinated, systematic manner.

To date, no research examining pharmacist's role in T&CMs across world regions during a single period has been conducted. It is critical that pharmacist professions opinions are represented strongly in the development of a consensus process about their professional role in T&CMs. This study is an important step towards ensuring the credibility and applicability of a consensus discussion. The results of this survey will be used to inform key discussion points in a consensus process and a step towards developing an agreed and defined professional role for pharmacists in T&CMs; and the support required for them to enact that role effectively. This will have implications to the quality and safe use of T&CMs and therefore public health.

Contributor statement

JH and CU conceptualise the study protocol design. JH and CU drafted the manuscript and SD critically reviewed the draft and final manuscript.

Competing interests

The authors have no completing interests to declare

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Name of the country

Towards consensus - defining and supporting a professional role for pharmacists associated with traditional and complementary medicine products

Participant Information Statement

1. What is this study about?

Globally, a substantial portion of traditional and complementary medicine (T&CM) products are accessed by the public through pharmacies. Pharmacists are trained to be "the gate-keepers" of drug safety and are trusted by the public. Therefore, it has been proposed that pharmacists are well-positioned to extend their scope of practice and assume a role in ensuring the safe and appropriate use of T&CM products. Currently, professional performance in this area has been reported as suboptimal due to deficits in pharmacy education, limited or no access to reliable information resources, concerns about the regulation, quality, and safety of T&CM products and a lack of time to engage with consumers about the use of T&CM products. Further, in most countries, the legal and professional expectations associated with this role are not clearly defined.

The aim of this study is to gather pharmacists' perspectives in (name of the country) to better define and support pharmacists in this important professional role. It is critical that pharmacist opinions are represented strongly in the development of a consensus process about their professional role in T&CM products. This study is an important step towards ensuring the credibility and applicability of a consensus discussion.

The results of this survey will be used to inform key discussion points in a consensus process and a step towards developing an agreed and defined professional role for pharmacists in T&CM products; and the support required for them to enact that role effectively. This will have implications to the quality and safe use of T&CM products and therefore public health. The findings of this study will contribute to the development of an international consensus about the:

- **professional role of pharmacists regarding T&CM products.**
- **support required to enact the role effectively and safely.**

You have been invited to participate in this study because you are a registered pharmacist.

This Participant Information Statement tells you about the research study. Knowing what is involved will help you decide if you want to take part in the research. Please read this sheet carefully and ask questions about anything that you do not understand or want to know more about.

By completing the survey we assume that you:

- **§ understand what you have read.**
- **§ agree to take part in the research study as outlined above.**

§ agree to the use of your personal information as described.
§ are providing consent to take part in the study.

2. Who is running the study?
The study has been granted ethics approval by The Panel on Research Ethics, University of Macau (approval number SSHRE21-APP068-ICMS-01) and is being carried out by the following researchers:

Dr Carolina Ung, Assistant Professor, Institute of Chinese Medical Sciences, University of Macau; Department of Public Health and Medicinal Administration, Faculty of Health Sciences, University of Macau

Dr. Joanna Harnett, Senior lecturer, The University of Sydney, Faculty of Medicine and Health, School of Pharmacy, Sydney, New South Wales, Australia

3. What will the study involve for me?
To be a participant, you will be invited to complete an online survey which is hosted by the online host Survey Monkey.

4. How much time will this study take me?
It takes about 15 minutes to complete the survey in this study.

Name of the country

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Participant Information Statement (continued)

5. Who can participate in this study?
Registered pharmacists in participating countries/regions.

6. Do I have to be in the study? Can I withdraw from the study once I've started?
Participating in this survey is completely voluntary and you do not have to take part. Your participation is completely anonymous. You can withdraw from the study at any-time. However, if you decide to take part in the survey and then change your mind later, any data collected from the survey is unidentifiable and therefore once completed and submitted cannot be withdrawn from the analysis.

7. Are there any risks or costs associated with being in the study?
Aside from giving up your time, we do not expect that there will be any risks or costs associated with taking part in this study.

8. Are there any benefits associated with being in the study?
By participating in this survey you are contributing to developing the body of about pharmacist's professional role in T&CM products. However, there will be no other benefits associated with your support and participation.

9. What will happen to data I provide during the study?
The data collected will be stored securely and you cannot be identified from your survey responses. The results will be kept strictly confidential. Study findings may be published or presented, but you will not be individually identifiable in these publications or presentations. Electronic files will be kept in a laptop with a key-in password only the lead researcher knows. All data will be retained for five years after the study and then all the electronic files will be removed from the hard drive and memory card permanently and all the hard copies, if any, will be shredded before disposal.

10. Can I tell other people about the study?
Yes, you are welcome to tell other people about the study.

11. What if I would like further information about the study?
When you have read this information, Dr Carolina Ung will be available to discuss it with you further and answer any questions you may have. If you would like to know more at any stage during the study, please feel free to contact Dr Ung by phone (+853-8822-4672) or email carolinaung@um.edu.mo.

* 1. By completing the survey, we assume that you:
- understand what you have read in the Participant Information Statement.
- agree to take part in the research study as outlined above.
- agree to the use of your personal information as described.
- are providing consent to take part in the study

◯ I agree and consent to my responses being used in this study.

Name of the country

Towards consensus - defining and supporting a professional role for pharmacists associated with traditional and complementary medicine products

Section 1 – Participants' sociodemographic characteristics / Demographics

* 2. Are you a registered pharmacist?

- ◯ Yes
- ◯ No

* 3. What is your gender?

- ◯ Male
- ◯ Female
- ◯ Prefer not to say

* 4. What is you age? (years)

* 5. What is your highest level of pharmacy qualification?

- ◯ Diploma
- ◯ Advanced Diploma
- ◯ Bachelors degree
- ◯ Masters degree
- ◯ Professional doctorate
- ◯ PhD

* 6. Which of the following best describes your current role as a pharmacist?(more than one may apply)

- [ ] I am a community pharmacist
- [ ] I am a hospital pharmacist
- [ ] I am clinical pharmacist (consultant)
- [ ] I work in the pharmaceutical industry
- [ ] I work as an academic
- [ ] I work in a regulatory body
- [ ] If other areas are applicable, please provide further information.

* 7. What best describes your current employment?

- ( ) Employed as a pharmacist
- ( ) Self-employed pharmacist/business owner
- ( ) Currently not employed
- ( ) Retired

* 8. Was education about traditional and complementary medicine included in your undergraduate pharmacy training?

- ( ) Yes and it was comprehensive enough for me to inform my practice
- ( ) Yes but it was not comprehensive enough to inform my practice
- ( ) No it was not included in my undergraduate pharmacy training

Name of the country

Towards consensus - defining and supporting a professional role for pharmacists associated with traditional and complementary medicine products

Section 2 – Participants' perception about T&CM products

For Questions 9-12, to state your level of agreement to the following statements, please use:
1 star for "Strongly disagree"
2 stars for "Somewhat disagree"
3 start for "Neither agree nor disagree"
4 stars for "Somewhat agree"
5 stars for "Strongly agree"

* 9. Traditional and complementary medicine product use is common in the community I serve.

Strongly disagree Strongly agree

* 10. There is evidence to support the efficacy of some traditional and complementary medicine products in specific conditions.

Strongly disagree Strongly agree

* 11. There are known and unknown safety risks associated with the use of traditional and complementary medicine products.

Strongly disagree Strongly agree

* 12. Traditional and complementary medicine products should be considered within the scope of professional pharmacy practice.

Strongly disagree Strongly agree

* 13. Which of the following traditional and complementary medicine products do you believe should be integrated into the professional practice of pharmacy? (choose as many options as apply)

- [ ] Products containing herbal or botanical ingredients (e.g. ginseng, gingko biloba, garlic, Tongkat Ali)
- [ ] Nutritional products containing vitamins and/or minerals and amino acids (e.g. single and multivitamin formulations)
- [ ] Non-vitamin and mineral supplements (e.g. fish oils, Coenzyme Q10, glucosamine, bee pollen etc)
- [ ] Probiotic and prebiotic formulations
- [ ] Homoeopathic products
- [ ] No traditional and complementary medicines should be included in the professional practice of pharmacy

Name of the country

Towards consensus - defining and supporting a professional role for pharmacists associated with traditional and complementary medicine products

Section 3 - Participants' opinions about bioethical responsibilities related to T&CM products

To state your level of agreement to the following statements, please use:
1 star for "Strongly disagree"
2 stars for "Somewhat disagree"
3 start for "Neither agree nor disagree"
4 stars for "Somewhat agree"
5 stars for "Strongly agree"

* 14. Pharmacists are in a position to prevent harm associated with the inappropriate use of traditional and complementary medicine products.

Strongly disagree Strongly agree

* 15. Pharmacists are in a position to provide evidence-based advice about traditional and complementary medicine products to optimize patient outcomes.

Strongly disagree Strongly agree

* 16. Pharmacists should respect consumer's autonomy regarding their choice to use traditional and complementary medicine products.

Strongly disagree Strongly agree

Name of the country

Towards consensus - defining and supporting a professional role for pharmacists associated with traditional and complementary medicine products

Section 4 - Participants' opinions about practice responsibilities related to T&CM products

To state your level of agreement to the following statements, please use:
1 star for "Strongly disagree"
2 stars for "Somewhat disagree"
3 start for "Neither agree nor disagree"
4 stars for "Somewhat agree"
5 stars for "Strongly agree"

* 17. Pharmacists should routinely ask about of the use of traditional and complementary medicine products by those taking pharmaceutical medicines.

Strongly disagree Strongly agree

* 18. Pharmacists should routinely document the use of traditional and complementary medicine products on patients' records.

Strongly disagree Strongly agree

* 19. Pharmacists should be able to source and provide consumer medicine information (CMI) about traditional and complementary medicine products.

Strongly disagree Strongly agree

* 20. Pharmacists should be able to inform consumers about the potential risks associated with the use of a traditional and complementary medicine products (e.g. side effects, drug-herb interactions).

Strongly disagree Strongly agree

* 21. Pharmacists must be able to provide advice based on accurate information (eg scientific studies) on the effectiveness of traditional and complementary medicine products.

Strongly disagree Strongly agree

* 22. Pharmacists should be able to provide their patients personalised advice about the use of traditional and complementary medicine products.

Strongly disagree Strongly agree

* 23. Pharmacists should be able to guide consumers (including patients) in making an informed decision about the use of traditional and complementary medicine products.

Strongly disagree Strongly agree

* 24. Pharmacists should monitor for any the adverse events associated with the use of traditional and complementary medicine products.

Strongly disagree Strongly agree

* 25. Pharmacists should be able to provide guidance on the management of adverse events associated with the use of traditional and complementary medicine products when they occur.

Strongly disagree Strongly agree

* 26. Pharmacists should report suspected adverse adverse events associated with the use of traditional and complementary medicine products to the relevant medicines regulatory authority.

Strongly disagree Strongly agree

* 27. Pharmacists should refer consumers (including patients) to qualified T&CM practitioners for advice about traditional and complementary medicine product use.

Strongly disagree Strongly agree

* 28. Pharmacists should only stock traditional and complementary medicine products approved by the local regulatory authority such as the drug regulatory authorities.

Strongly disagree Strongly agree

* 29. Business owners should set up the pharmacy so advice from a pharmacist can be easily accessed by those purchasing traditional and complementary medicine products.

Strongly disagree Strongly agree

* 30. Pharmacists should provide training for their staff about traditional and complementary medicine products.

Strongly disagree Strongly agree

* 31. Pharmacists should communicate with other healthcare professionals (e.g. doctors, T&CM practitioners) regarding a patient's use of traditional and complementary medicine products to ensure appropriate and safe use.

Strongly disagree Strongly agree

Name of the country

Towards consensus - defining and supporting a professional role for pharmacists associated with traditional and complementary medicine products

Section 5 - The support participants need to build their scope of practice related to T&CM products

For Questions 32-44, to state your level of agreement to the following statements, please use:
1 star for "Strongly disagree"
2 stars for "Somewhat disagree"
3 start for "Neither agree nor disagree"
4 stars for "Somewhat agree"
5 stars for "Strongly agree"

* 32. There is a need to clearly define pharmacists' professional responsibilities associated with traditional and complementary medicine products.

Strongly disagree — Strongly agree

* 33. There is a need to develop traditional and complementary medicine product practice standards for pharmacists.

Strongly disagree — Strongly agree

* 34. There is a need to develop an accreditation system for pharmacists' traditional and complementary medicine competency.

Strongly disagree — Strongly agree

* 35. There is a need to include traditional and complementary medicine product education in undergraduate pharmacy curricula/studies.

Strongly disagree — Strongly agree

* 36. There is a need to provide traditional and complementary medicine product education as continuing professional development.

Strongly disagree — Strongly agree

* 37. In the workplace, there is a need to improve access to evidence-based traditional and complementary medicine information.

Strongly disagree Strongly agree

* 38. In the workplace, there is a need to provide support for pharmacists to undertake training in traditional and complementary medicine.

Strongly disagree Strongly agree

* 39. In the workplace, pharmacy business owners should employ accredited practitioners (e.g. naturopath - herbalist - nutritionist) to provide advice to consumers about traditional and complementary medicine products.

Strongly disagree Strongly agree

* 40. More support is required to facilitate non-biased research about the efficacy and safety of traditional and complementary medicine products.

Strongly disagree Strongly agree

* 41. There is a need to develop effective interprofessional communication processes regarding traditional and complementary medicine product use.

Strongly disagree Strongly agree

* 42. Improvements in the regulatory standards of traditional and complementary medicine product quality, safety and efficacy are required.

Strongly disagree Strongly agree

* 43. Improvements in the regulatory standards of traditional and complementary medicine product labelling and advertising are required

Strongly disagree Strongly agree

* 44. Regulatory bodies should consider scheduling of traditional and complementary medicine products as 'pharmacy only' medicines.

Strongly disagree Strongly agree

45. Please make any additional comments regarding traditional and complementary medicine products and professional pharmacy practice.

Checklist for Reporting Results of Internet E-Surveys (CHERRIES)

Item Category / Checklist Item	*Explanation*	*Location in paper (pg)*
Design		
Describe survey design	Describe target population, sample frame. Is the sample a convenience sample? (In "open" surveys this is most likely.)	8 – 9
IRB (Institutional Review Board) approval and informed consent process		
IRB approval	Mention whether the study has been approved by an IRB.	11
Informed consent	Describe the informed consent process. Where were the participants told the length of time of the survey, which data were stored and where and for how long, who the investigator was, and the purpose of the study?	9
Data protection	If any personal information was collected or stored, describe what mechanisms were used to protect unauthorized access.	8
Development and pre-testing		
Development and testing	State how the survey was developed, including whether the usability and technical functionality of the electronic questionnaire had been tested before fielding the questionnaire.	8
Recruitment process and description of the sample having access to the questionnaire		
Open survey versus closed survey	An "open survey" is a survey open for each visitor of a site, while a closed survey is only open to a sample which the investigator knows (password-protected survey).	8
Contact mode	Indicate whether or not the initial contact with the potential participants was made on the Internet. (Investigators may also send out questionnaires by mail and allow for Web-based data entry.)	8
Advertising the survey	How/where was the survey announced or advertised? Some examples are offline media (newspapers), or online (mailing lists – If yes, which ones?) or banner ads (Where were these banner ads posted and what did they look like?). It is important to know the wording of the announcement as it will heavily influence who chooses to participate. Ideally the survey announcement should be published as an appendix.	9
Survey administration		
Web/E-mail	State the type of e-survey (eg, one posted on a Web site, or one sent out through e-mail). If it is an e-mail survey, were the responses entered manually into a database, or was there an automatic method for capturing responses?	8
Context	Describe the Web site (for mailing list/newsgroup) in which the survey was posted. What is the Web site about, who is visiting it, what are visitors normally looking for? Discuss to what degree the content of the Web site could pre-select the sample or influence the results. For example, a survey about vaccination on a anti-immunization Web site will have different results from a Web survey conducted on a government Web site	8
Mandatory/voluntary	Was it a mandatory survey to be filled in by every visitor who wanted to enter the Web site, or was it a voluntary survey?	9

Incentives	Were any incentives offered (eg, monetary, prizes, or non-monetary incentives such as an offer to provide the survey results)?	N/A
Time/Date	In what timeframe were the data collected?	8 - 9
Randomization of items or questionnaires	To prevent biases items can be randomized or alternated.	N/A
Adaptive questioning	Use adaptive questioning (certain items, or only conditionally displayed based on responses to other items) to reduce number and complexity of the questions.	9
Number of Items	What was the number of questionnaire items per page? The number of items is an important factor for the completion rate.	9
Number of screens (pages)	Over how many pages was the questionnaire distributed? The number of items is an important factor for the completion rate.	8
Completeness check	It is technically possible to do consistency or completeness checks before the questionnaire is submitted. Was this done, and if "yes", how (usually JAVAScript)? An alternative is to check for completeness after the questionnaire has been submitted (and highlight mandatory items). If this has been done, it should be reported. All items should provide a non-response option such as "not applicable" or "rather not say", and selection of one response option should be enforced.	9
Review step	State whether respondents were able to review and change their answers (eg, through a Back button or a Review step which displays a summary of the responses and asks the respondents if they are correct).	N/A
Response rates		
Unique site visitor	If you provide view rates or participation rates, you need to define how you determined a unique visitor. There are different techniques available, based on IP addresses or cookies or both.	N/A
View rate (Ratio of unique survey visitors/unique site visitors)	Requires counting unique visitors to the first page of the survey, divided by the number of unique site visitors (not page views!). It is not unusual to have view rates of less than 0.1 % if the survey is voluntary.	N/A
Participation rate (Ratio of unique visitors who agreed to participate/unique first survey page visitors)	Count the unique number of people who filled in the first survey page (or agreed to participate, for example by checking a checkbox), divided by visitors who visit the first page of the survey (or the informed consents page, if present). This can also be called "recruitment" rate.	N/A
Completion rate (Ratio of users who finished the survey/users who agreed to participate)	The number of people submitting the last questionnaire page, divided by the number of people who agreed to participate (or submitted the first survey page). This is only relevant if there is a separate "informed consent" page or if the survey goes over several pages. This is a measure for attrition. Note that "completion" can involve leaving questionnaire items blank. This is not a measure for how completely questionnaires were filled in. (If you need a measure for this, use the word "completeness rate".)	N/A
Preventing multiple entries from the same individual		
Cookies used	Indicate whether cookies were used to assign a unique user identifier to each client computer. If so, mention the page on which the cookie was set and read, and how long the cookie was valid. Were duplicate	Not used

	entries avoided by preventing users access to the survey twice; or were duplicate database entries having the same user ID eliminated before analysis? In the latter case, which entries were kept for analysis (eg, the first entry or the most recent)?	
IP check	Indicate whether the IP address of the client computer was used to identify potential duplicate entries from the same user. If so, mention the period of time for which no two entries from the same IP address were allowed (eg, 24 hours). Were duplicate entries avoided by preventing users with the same IP address access to the survey twice; or were duplicate database entries having the same IP address within a given period of time eliminated before analysis? If the latter, which entries were kept for analysis (eg, the first entry or the most recent)?	Not used
Log file analysis	Indicate whether other techniques to analyze the log file for identification of multiple entries were used. If so, please describe.	Not used
Registration	In "closed" (non-open) surveys, users need to login first and it is easier to prevent duplicate entries from the same user. Describe how this was done. For example, was the survey never displayed a second time once the user had filled it in, or was the username stored together with the survey results and later eliminated? If the latter, which entries were kept for analysis (eg, the first entry or the most recent)?	N/A
Analysis		
Handling of incomplete questionnaires	Were only completed questionnaires analyzed? Were questionnaires which terminated early (where, for example, users did not go through all questionnaire pages) also analyzed?	9
Questionnaires submitted with an atypical timestamp	Some investigators may measure the time people needed to fill in a questionnaire and exclude questionnaires that were submitted too soon. Specify the timeframe that was used as a cut-off point, and describe how this point was determined.	N/A
Statistical correction	Indicate whether any methods such as weighting of items or propensity scores have been used to adjust for the non-representative sample; if so, please describe the methods.	N/A