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Reporting guidelines for medicinal plant extracts used in pharmacological and toxicological research: ConPhyMP

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SUMMARY

Every year, the number of studies that evaluate the pharmacological effects, (clinical) efficacy or the toxicity of medicinal plant extracts is constantly increasing, but reporting quality remains unsatisfactory. One of the main reasons is the lack of detailed reporting guidelines. In response to this challenge, a core group of nine experts, including editors-in-chief of leading specialist journals, and based in different research settings globally, developed the Consensus based reporting guidelines for Phytochemical Characterisation of Medicinal Plant extracts (ConPhyMP) through a multi-staged development process. This incorporated a) a global survey among medicinal plant researchers, b) a core group, who developed the guidelines through a Delphi process, and c) an advisory group of 20 experts, including editors of leading journals and scientific societies in medicinal plants research, who provided feedback and sanctioned the final guidelines. The ConPhyMP guidelines comprise two tables with accompanying explanatory figures. The first table provides recommendations for reporting the plant material, and the second table presents recommendations for conducting and reporting the analytical methods for defining the chemical profile based on the type of extracts used in the research. ConPhyMP will support authors as well as peer reviewers and editors assessing these studies for publication and assist the production of evidence-based guidance of studies utilising plant extracts.

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INTRODUCTION

Medicinal plant extracts [phyto-pharmaceuticals] are different from their pharmaceutical counterparts in that they are complex mixtures, where the identities, and quantities of the active ingredients/marker compounds cannot be fully known. The compositions could also vary depending on the methods of

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preparation and source material used. This creates a unique set of challenges for researchers (Sticher, 2008) and impacts the interpretation of pharmacological, toxicological and clinical studies using plant extracts. As an attempt to help rectify this situation, we have recently provided some perspective on what may be viewed as 'best practice' in early stage phytopharmacological research (Heinrich et al., 2020).

PROCESS AND METHODS

The statement which is a part of a manuscript currently under review (Heinrich et al. n.d.) provides a multi-stakeholder, Consensus based reporting guidelines for Phytochemical Characterisation of Medicinal Plant extracts (ConPhyMP). We conducted a survey to gather global perspectives, and overarching challenges faced in characterising plant extracts under different laboratory infrastructures. A core group, consisting of 9 experts, met monthly to develop the guidelines through a Delphi process; then, the final draft guidelines, endorsed by the core group, were distributed for feedback and endorsement by an extended advisory group consisting of 20 experts.

RESULTS AND DISCUSSION

ConPhyMP statement is the main outcome (Heinrich et al. n.d.). It comprises key items that should be reported concerning plant materials, and the chemical methods utilised for defining the chemical compositions of the plant extracts used in these studies. Plant extracts are classified into one of three types (the initial distinction was developed by the lead author (MH)), capturing species importance and regulatory status. Therefore, rather than chemical criteria alone, the guidelines are based on the importance of a plant as a medicine (as defined by its inclusion in a pharmacopoeia) and, its importance in international trade (e.g., as a food supplement). For each extract type, a different level of phytochemical characterisation is required. To date, the ConPhyMP project was presented in many national and international conferences.

It's widely recognised by researchers, where it sparked global debates supporting the importance, uniqueness, and need for the ConPhyMP statement. The ConPhyMP is also endorsed by several scientific societies and many leading specialist journals in medicinal plant research. The statement is under consideration for inclusion as a part of author guidelines, taking into account ConPhyMP limitations and feasibility within the guidelines of respective journals.

CONCLUSIONS

The guidelines (the consensus statement) are a 'first of its kind'. The treatise does not suggest a standard way of reporting but defines core requirements for what needs to be reported. We look forward not only to implementation of ConPhyMP but also to further development based on global use and robust debate, leading to further refinement of the proposed methods and classifications. By providing an actionable checklist of reporting key items, the ConPhyMP guidelines will facilitate the appraisal of studies using plant extracts and help to assure the reproducibility of findings.

CONFLICT OF INTEREST

ZK is an employee of Dr. Willmar Schwabe GmbH & Co. KG, Germany, and his specific input into this project relates to the analytical techniques and their use in the industry focusing on technical and analytical aspects.

FUNDING

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