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Future development of global regulations of Chinese herbal products â˜†

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Abstract

Ethnopharmacological relevance

GP-TCM is the first EU-funded Coordination Action consortium dedicated to traditional Chinese medicine (TCM) research. One of the key deliverables of the Work Package 7 in GP-TCM was to investigate information of the existing requirements for registration of TCM products listed by global regulatory bodies. The paper aims to collate data and draw comparison of these regulations. Case studies are also presented to illustrate the problems involved in registering TCM products in different regions worldwide.

Materials and methods

A collaborative network task force was established during the early stage of the GP-TCM project and operated through exchanges, teleconferences and focused discussions

at annual meetings. The task force involved coordinators, academics who are actively involved with R&D of Chinese herbal medicines, experts on monographic standards of Chinese materia medica, representatives from regulatory agencies, experts from industries in marketing Chinese medicines/herbal medicines and natural products. The co-ordinators took turns to chair teleconferences, led discussions on specific issues at AGM discussion sessions, at joint workshops with other work-packages such as WP1 (quality issues), WP3 (toxicology issues) and WP6 (clinical trial issues). Collectively the authors were responsible for collating discussion outcomes and updating written information.

Results

A global overview of regulations on herbal registration has been compiled during the three years of the consortium. The regulatory requirements for registration of herbal products in the EU and China were compared, and this is extended to other regions/countries: Africa, Australia, Brazil, Canada, Japan, Russia, South Korea, Taiwan, and the United States. A wide variation of the regulations for the categories of herbal products exists: food (functional food, novel foods, dietary food for special medical purpose, foods for particular nutritional use, food supplement); cosmetic, traditional herbal medicine products; herbal medicines for human use and veterinary use.

Conclusion

The regulatory issues for registration of herbal products are complicated among the countries and regions worldwide. The information summarised in the text is for reference only. Some regulations which are presented in this review are still in legislation process and may change in due course. Before taking any regulatory action, readers are advised to consult current official legislation and guidance and/or to seek appropriate professional advice. The lessons learnt from global regulation of TCM will provide valuable insights for regulation of other traditional medicine such as Ayurveda and Unani medicine, as well as other forms of indigenous medicine. The WHO is well placed to co-ordinate a consultation process with the aim of putting forward suggestions for harmonisation to key regulatory agencies.

Graphical abstract

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Abbreviations

CHM, Chinese herbal medicine; CMM, Chinese materia medica or Chinese medicinal material; CHP, complex herbal products; EDQM, European Directorate for Quality Medicines & Healthcare; EMA, European Medicines Agency; EU, European Union; FDA, Food and Drug Administration (USA); FP7, 7th Framework Programme; GP-TCM, Good Practice in Traditional Chinese Medicine Research in the Post-genomic Era; GxP, good practice guidelines; MHRA, Medicines and Healthcare products Regulatory Agency (UK); R&D, Research and development; SFDA, State Food and Drug Administration (P.R. China); TCM, Traditional Chinese medicine; TGA, Therapeutic Goods Administration (Australia); THMP, traditional herbal medicinal product; WP, work package

Keywords

Country regulatory guidelines; Categories of herbal products; Comparison of regulatory requirements for registration

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â˜† The authors and editors of this GP-TCM Work Package deliverable are engaged to create accurate and up to date content reflecting reliable research evidence, guidance and best practice in TCM research and development. They are free from any commercial conflicts of interest. Reference herein to any specific commercial product, process or service, whether by trade name, trade mark, manufacturer or otherwise does not imply its endorsement, recommendation or favouring by the members of GP-TCM, and is not hereby endorsed, recommended or favoured by GP-TCM. The

examples of TCM-derived products quoted are solely intended as case-studies of successful registration of herbals, their particular route to market and lessons learnt to date.

[1] These authors contributed equally to the manuscript.

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