Safety issues in the preparation of homeopathic medicines



World Health Organization

Safety issues in the preparation of homeopathic medicines



WHO Library Cataloguing-in-Publication Data:

Safety issues in the preparation of homeopathic medicines.

1.Homeopathy - standards. 2.Homeopathy - trends. 3.Drug compounding - standards. 4.Medicine, Herbal. 5.Medicine, Traditional. I.World Health Organization.

ISBN 978 92 4 159884 2

(NLM classification: WB 930)

© World Health Organization 2009

All rights reserved. Publications of the World Health Organization can be obtained from WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland (tel.: +41 22 791 3264; fax: +41 22 791 4857; e-mail: <u>bookorders@who.int</u>). Requests for permission to reproduce or translate WHO publications – whether for sale or for noncommercial distribution – should be addressed to WHO Press, at the above address (fax: +41 22 791 4806; e-mail: permissions@who.int).

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

Printed in Spain

Contents

Contents iii
Acknowledgementsv
Foreword vii
Prefaceix
1 Introduction
2 Challenges for quality control of homeopathic medicines
2.1 Homeopathy and homeopathic medicines
2.2 Potential safety issues
2.3 Quality control challenges
3 Quality control issues for homeopathic medicines
3.1 Plant material
3.2 Animal or human derived source material
3.3 Mineral and chemical material
3.4 Mother tincture
3.5 Finished product
3.6 Diluents and excipients
3.7 Impurities and contaminants
4 Regulation regarding homeopathic medicines
4.1 Regulations relating to manufacturing and marketing
4.2 Consumer information
4.3 Regulatory frameworks
References
Annex 1: List of participants in the WHO consultation on quality of
homeopathic medicines, Milan, Italy, 25-27 June 2007 23
Annex 2: Glossary 25
Annex 3: Points to consider on safety of homeopathic medicines from biological origin
Annex 4: Examples of national labelling requirements for homeopathic medicines in selected countries
Annex 5: Examples of national regulatory requirements for homeopathic medicines in selected countries

Acknowledgements

The World Health Organization wishes to express its appreciation for the generous financial support provided by the Regional Government of Lombardy for the development and publication of this document, including financial support for the organization of a WHO consultation during the development process.

WHO further wishes to express its thanks to the Regional Government of Lombardy and the WHO Collaborating Centre for Traditional Medicine at the State University of Milan, Italy, for kindly hosting the WHO consultation on quality of homeopathic medicines held in Milan, Italy, in June 2007.

WHO also acknowledges its indebtedness to approximately 400 reviewers from more than 105 countries, including experts and national regulatory authorities in more than 101 countries who provided national information, comments and advice on the draft texts, members of the WHO Expert Advisory Panel on Traditional Medicine, members of the WHO Expert Advisory Panel on International Pharmacopoeia and Pharmaceutical Preparations, and members of the WHO Collaborating Centres for Traditional Medicine. The preparation of this document benefited, in addition, from technical support received from relevant professional organizations and nongovernmental organizations in the field of homeopathic medicines.

Special acknowledgement for the preparation of the revised draft document, by reviewing and technically assessing the comments received, is also due to Professor Tamas Paal, Hungary and, for preparation of the original text, thanks are due to Dr Hermann Garden, Basel, Switzerland.

Special thanks are also due to participants at the June 2007 WHO consultation on quality of homeopathic medicines in Milan, Italy, who reviewed and finalized the draft document (Annex 1).

Foreword

Homeopathy is a system of medicine born in Europe in the last part of the eighteenth century. The homeopathic doctors use homeopathic medicines, which are prepared following a well-defined procedure, starting from substances derived from the mineral, herbal and animal worlds. The techniques of preparation of these drugs include the dilution of the raw material, in hydroalcoholic solutions or in other excipients, and the potentization of the product into different grades. In some cases, the dilution is so high that it is almost impossible to find one molecule of the original raw material. Of course this fact has created an intense debate between, on one side, people who have experienced positive effects from homeopathic therapy and strongly believe in it and, on the other side, people who criticize these products, as being contrary to all the requirements of modern pharmacology.

The use of homeopathic medicines has spread more and more, and nowadays it is widespread not only in the European region but also in south Asian countries and North and South American countries. With the worldwide increase in the use of homeopathic medicines and the rapid expansion of the global market, the safety and the quality of homeopathic medicines has become a major concern for health authorities, pharmaceutical industries and consumers. The safety of the homeopathic medicines largely depends on their quality. Requirements and methods for the quality control of finished homeopathic medicines are far more complex than for chemical drugs, particularly for the combined or mixed homeopathic medicines. Furthermore, the quality of the homeopathic medicines is influenced both by the quality of the procedure used during their production and the quality of the raw material. Products which meet high quality standards are needed to allow the patient to make safe use of the homeopathic medicines. Nowadays, this is more and more important because, as a consequence of market globalization, many of the raw materials and medicines used in the homeopathic systems come from different countries.

In the Lombardy region about 20% of the population regularly uses homeopathic medicines, but almost 60% of the population use them occasionally for their

预览已结束, 完整报告链接和二维码如下:



https://www.yunbaogao.cn/report/index/report?reportId=5 29234