

INTERNATIONAL COMPARISON OF FIVE HERBAL MEDICINE REGISTRATION SYSTEMS TO INFORM REGULATION DEVELOPMENT IN KUWAIT

¹AZHAR H. ALOSTAD, ²DOUGLAS T. STEINKE, ³ELLEN I. SCHAFHEUTLE

¹MPharm MSc, ²BSc (Pharm) MSc PhD,

^{1,2,3}Division of Pharmacy and Optometry, School of Health Sciences, Faculty of Biology, Medicine and Health, The University of Manchester, Manchester M13 9PT, UK

E-mail: ¹azhar.alostad@postgrad.manchester.ac.uk, ²douglas.steinke@manchester.ac.uk,

³ellen.schafheutle@manchester.ac.uk

Abstract- Aim In order to inform the design of a registration system for herbal medicines (HMs) in Kuwait, a country, which does not manufacture but imports all HMs from abroad, this study aimed to compare current HM registration systems of five countries that are either major source countries for Kuwait with well-established HM registration processes (Germany, United Kingdom (UK), United States (US)) or countries similar to Kuwait in size, location and scope (United Arab Emirates (UAE), Kingdom of Bahrain). Methods A systematic documentary analysis of HM classification systems was performed by reviewing the regulatory and pre-marketing registration documents of the five countries' Drug Regulatory Authorities' (DRAs) websites. This was achieved by extracting and analysing data on HM definition, classification and main requirements for registration. Data were analysed by coding and presenting them in a table allowing comparison of similarities and differences. Results Analysis showed diversity in how countries classify HMs showing differences in terms used, definitions, requirements, restrictions and type of preparation. One of the classification pathways in Germany, UK, UAE and Bahrain allow for a simplified registration of HMs, mainly requiring reasonable evidence of traditional use to determine medicine efficacy. This pathway does not exist in the US, where an alternative pathway is to regulate HMs as dietary supplements where products are not assessed for their quality, safety and efficacy before accessing the market. Conclusion In line with the findings, the study emphasises that it would be vital to propose a harmonised clear definition of HMs for the purpose of registration for all countries, and recommends that Kuwait must take steps to acknowledge imported HMs that escape scientific evaluation in the country of origin.

Keywords- Comparison, Herbal Medicines, Kuwait, Regulations.
