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Strengths and weaknesses of the herbal medicine registration system in Bahrain

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The primary goal of a country's Drug Regulatory Authority (DRA) is to ensure that all products on the market are safe, effective and meet the approved quality standards. Kuwait however, lacks appropriate herbal medicines (HMs) regulations causing consumer safety issues. An important part of informing effective policy formation is to understand strengths and weaknesses in more advanced systems. As part of a wider research programme to inform a registration system for HMs in Kuwait, this study aimed to highlight the main strengths and weaknesses of the HMs registration system in Bahrain, a country similar to Kuwait, which does not manufacture but import all HMs and has a HM registration system. With ethics and Bahrain DRA approval, eight face-to-face semi-structured interviews were conducted with key officials involved in the registration of HMs in Bahrain. Interview data were analysed using thematic framework analysis. Participants perceived the major strengths of the current registration system as: having appropriate registration guidelines in place which are continuously updated, having an increased level of transparency by publishing registration activities and sharing these publicly, being a trusted reference source for other countries in the region and being an independent entity not influenced by governmental higher powers providing full autonomy of introducing new policies. Some of the major perceived weaknesses of the current system were the lack in the organisational structure and hierarchy which is causing communication difficulties between departments, the restraint in financial resources to invest in continuous staff training, the significant lack of human resources causing workload and delay in submission to deadlines, and absence of important regulatory activities such as a pharmacovigilance system. It is anticipated that this study will provide evidencebased lessons for Kuwait and other countries with unsophisticated drug regulatory systems to design effective HMs regulation.

Speaker Biography

Azhar Alostad is a pharmacist with qualifications in MPharm and MSc. She has expertise in pharmaceutical and herbal regulations. Since her graduation, she worked as a scientific reviewer in the Kuwaiti Drug Regulatory Authority. In 2016, she started her PhD in Pharmacy and Pharmaceutical Sciences at the University of Manchester, United Kingdom supervised by the coauthors Ellen Schafheutle and Douglas Steinke. Her PhD research aims to introduce suitable guidelines for the registration of herbal medicines in Kuwait.

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