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## PHARMACEUTICAL REGULATORY AFFAIRS AND IPR

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### Herbal medicines pre-marketing registration process in the state of Kuwait: An up-to-date overview of the process

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 $extcircle{ au}$  uwait is a very rich country located at the top of the Arabian Gulf between Iraq and Kingdom of Saudi Arabia. Kuwait Wast is a very rich country located at the top of the Findship Can be buys all their herbal medicines (HMs) from other countries. It spent USD 1.02 billion on importing pharmaceuticals in 2016 only. Kuwait has a new and unsophisticated system of registering HMs, which could be improved. The registration system of HMs has some concerns and safety issues have been identified. In a survey conducted by Awad and Al-Shaye in 2011, HMs was the most common natural health products consumed by the Kuwaiti population. There are currently 270 HMs registered in Kuwait. In 1990, the Iraqi invasion of Kuwait caused a seven month long Iraqi occupation of Kuwait that led to the collapse of the entire healthcare and pharmaceutical regulatory system. In 1991, the war ended and the relations between the two neighboring countries turned friendly. Since then, the health system in Kuwait and the registration and regulation of all medicines, including herbals, were addressed and developed. All HMs imported into Kuwait are currently registered and regulated by Kuwait Drug and Food Control and Administration (KDFC), a division under the Ministry of Health. The Herbal Medicine Department under the KDFC was established only 18 years ago. Current literature related to HMs regulation in Kuwait is limited, as it only describes the regulations of the Centre for Islamic Medicine, which used to regulate HMs. KDFC's HMs registration process, documents needed for their registration and the decision process of registering are scarcely addressed in literature. There is a need to provide with descriptive information and familiarize the worldwide interested HMs stakeholders with the current HMs registration system. Therefore, the aim of this review is to illustrate the current most upto-date HMs pre-marketing required documents, the process and procedures carried out to assess the approval of HMs into the Kuwaiti market.

#### **Biography**

Azhar H Alostad is a Pharmacist graduated with Master of Pharmacy (MPharm) degree from the University of Bradford, UK in 2012 and obtianed her Master of Science (MSc) in Pharmaceutical Services and Medicines Control from the University of Bradford, UK in 2013. She has expertise in pharmaceutical regulations. Since her graduation, she worked as a Scientific Reviewer at the KDFC in Kuwait Ministry of Health (MOH). Her work as a Scientific Reviewer at the Registration Department in KDFC covered studying and assessing pharmaceutical applications with New Active Substance (NAS) and Existing Active Substance (EAS) for the purpose of registration and approval into the Kuwaiti market, monitoring and setting timelines for license variations and products renewal approvals, advising pharmaceutical manufacturers on regulatory requirements and undertaking pharmaceutical manufacturer regulatory inspections. In 2016, she started a 4-year PhD in Pharmacy and Pharmaceutical Sciences at the University of Manchester (UoM), UK. She is currently a PhD student at the UoM and her thesis is "Introducing suitable guidelines for the registration of herbal medicines in the State of Kuwait".

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