Evaluating the attitudes of pharmacy student in the University of Umm Al-qurah, Holy city of Makkah, Saudi Arabia towards their pharmacovigilance module

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Introduction: The increasing knowledge and awareness of adverse drug reactions (ADRs) has been reported throughout the world and therefore, teaching pharmacovigilance to pharmacy students will make them aware of their central responsibility to both understand and report ADRs, so as to fulfill their important role as pharmacists.

Aim: To assess the knowledge and attitudes of pharmacy students in Umm Al-qurah University, Holy city of Makkah, Saudi Arabia toward a pharmacovigilance module given as part of their undergraduate degree.

Materials & Method: 180 third and fourth year pharmacy students at the School of Pharmacy, Umm Al-Qura University, Makkah, KSA, were invited to participate in the study. They were divided into groups of 20 for formal tuition about pharmacovigilance. Following the training, two open questions were used to assess a) their views and attitudes towards the importance of Pharmacovigilance and b) did they consider that the topic should be included in their undergraduate curriculum as a discrete module. In both cases asking to explain their reasons for their suggestions. Two open questions were used: 1. How did you find the lesson – for example their scope, degree of interest, examples, and application about knowledge of pharmacovigilance and ADRs reporting. Comments as to how the material could be improved were also requested? 2. Do you think that the material you were provided will enhance your awareness of the topic and was it suitable to be taught as a separate module?

Results & Conclusions: Students completed the questions. The overall conclusion was that students found the sessions interesting, informative and at a suitable level for their existing knowledge. They suggested that it was important that pharmacovigilance should be provided as a basic requirement for undergraduate programs in medical schools generally, and in pharmacy schools, in particular.

Quality and bioequivalence of modified release products regulatory aspects

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The most recent position of the European Medicines Agency (EMA) concerning the quality and clinical evaluation of modified release dosage forms reflected by the publication of two separate guidelines is reviewed and the main points discussed in these two guidelines are highlighted. The definition and criteria of modified release products along with the objective behind their clinical use to differ from immediate release dosage forms is covered. Driven by popularity, focus on the quality and bioequivalence of oral modified release products is made. For quality, the development pharmaceutics and choice of composition leading to scaling up to commercial size batches is highlighted. In addition to achieving consistent quality, the importance of pharmaceutical development concept to establish the quality from pharmacokinetic parameters through in vivo drug release to in vitro dissolution is briefly overviewed. The dissolution method criteria being discriminatory, it’s in vivo implication or link to the quality of the finished product and how comparison between dissolution profiles after variation in order to justify biowaiver is carefully discussed. The effect of alcohol and food on the bioavailability of the drug substance and clinical implication is also discussed. Finally, the requirement for bioequivalence studies of generic modified release product versus the brand as per the SPC recommendation and posology to comply with requirements of the guideline under fast and fed states are covered.