LETTERS

The Need to Cover Generic Medications and Generic Substitution Practice in the Curricula of Pharmacy Colleges in Saudi Arabia

To the Editor. Generic medications are essentially the same as their counterpart brand medications. They can provide the same therapeutic outcomes, but at a much cheaper cost.[1,2] Because of this, they are promoted in many countries in order to confront the problem of escalating pharmaceutical expenditures. However, there are many challenges that hinder the promotion and use of generic medicines, including negative perceptions from healthcare professionals, misconceptions, and inadequate knowledge of the role of bioequivalence in the use of generic medications.[2]

In literature specifically written about pharmacy students and preregistration pharmacists, there is evidence from studies conducted in Australia and Bangladesh that highlighted the issue of negative perceptions regarding the quality, safety, and efficacy of generic medications, as well as a lack of adequate knowledge of bioequivalence.[3,4] Moreover, in an American study, Holmes and Dennison reported that pharmacy students' perceptions about effectiveness, harmful effects, and economic value can influence their recommendation of either generic medicines or brand medicines, both in general and for some specific diseases in particular.[5]

In Saudi Arabia, generic medications represented by value only 8.1% of the total medicine market and only 9.1% of the prescription medicines market in 2012. Moreover, it is forecasted to reach only approximately 11.5% in 2020.[6] In fact, successful promotion of generic medications requires all stakeholders and involved parties including educational institutions (colleges of pharmacy and colleges of medicines) to play active roles in this regard. Therefore, as part of the national efforts, colleges of pharmacy in Saudi Arabia need to ensure that future pharmacy practitioners are empowered with adequate knowledge regarding generic medications, generic substitution, and relevant concepts, such as bioequivalence.

From our experience and observations, we believe there are several important topics related to generic medications and generic substitution that need to be covered adequately in the curricula of pharmacy colleges so that following graduation, pharmacy students can play a pivotal role in the promotion of the appropriate use of generic medications. This education initiative could be done by designing a short module to include in the curricula of pharmacy colleges regarding safety, effectiveness, and quality of generic medications, generic substitution practice, and regulations related to generic substitution in Saudi Arabia.

It is also important to cover issues and aspects of the use of generic medications in a systematic and comprehensive way, taking a more clinical or practical approach. Therefore, the module needs to address the clinical and non-clinical considerations that should be taken into consideration when performing generic substitution, including the factors related to the medication, the patient, the prescriber and the regulations. It is also essential to fully cover the concept and science of bioequivalence including bioequivalence study design, its clinical importance, and the correct understanding and interpretation of the regulatory bioequivalence criteria. Another important topic includes the regulations related to generic substitution by pharmacists specifically addressed in the Health Professions Act,[7] including the act's executive regulations.[8] These regulations granted pharmacists the right to perform generic substitution in most cases, with the exception of NTI drugs. In this act, the permission from a prescriber is not a legal requirement for generic substitution. However, patient consent is required. Beside these scientific and legal aspects, pharmaceutical industry marketing and its potential influence on their practice need to be addressed adequately with emphasis on the professional and ethical standards that govern the relationship between the pharmacist as a healthcare professional and pharmaceutical industry.

The module also needs to provide the students with more detailed information about the procedural and registration requirements of generic medications by the nation's regulatory and registration authority, namely the Saudi Food and Drug Authority. The topics include the following:

- General requirements of medication registration in Saudi Arabia. [9,10]
- Registration requirements of generic medications in Saudi Arabia.[11]
- The concept and science of bioequivalence and bioequivalence requirements in Saudi Arabia.[12]
- Requirements for the renewal of marketing authorization in Saudi Arabia.[13]
- Current Good Manufacturing Practice (cGMP) requirements, quality assurance and quality control requirements, and inspection requirements.[14]
- Pharmaceutical equivalence requirements,[15] and chemistry and manufacturing quality requirements.[16]
- Requirements and registration system of drug manufacturers and companies in Saudi Arabia.[17]

- Additional related issues, such as product stability requirements.[18]

In summary, pharmacy students are the future pharmacy practitioners and will be a source of information for their colleagues in other healthcare professions regarding medications on the market. Because of this, we believe that it is essential to ensure that they are provided with an advanced knowledge during their undergraduate training regarding the appropriate use of generic medications. We also believe that designing an instructional module and covering the topics outlined in this letter would be useful and could help to prepare pharmacy students for their important role in the appropriate use of generic medications in the Saudi healthcare system.

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