Module 9: Generic Drugs and Therapeutic Equivalence

Educational Objectives

1. Identify terminology related to pharmaceutical and therapeutic equivalence;
2. Explain the pharmacist's and pharmacy technician’s responsibilities in generic substitution; and
3. Discuss how patients can be educated about generic substitution as part of MTM practice.

Post-test/Rationale

1. Differences between a pharmaceutical equivalent and a pharmaceutical alternative include:
   A. Pharmaceutical equivalents have the same active ingredients
   B. Pharmaceutical alternatives may contain a different salt
   C. Pharmaceutical alternatives may have a different dosage form (capsule/tablet)
   D. All of the above***

Correct Answer: D

Pharmaceutical equivalents are agents that have the same active ingredient, dosage form, route of administration, and strength or concentration. Pharmaceutical alternatives may have some of these differences (different salt, dosage form, etc).

2. To be considered therapeutically equivalent to a branded or reference drug, a generic must also be:
   A. A pharmaceutical equivalent***
   B. Biosimilar
   C. Deemed by the pharmacist to be an acceptable substitution
   D. A or B rated

Correct Answer: A

The FDA's criteria for therapeutic equivalence require that the drug be a pharmaceutical equivalent, meaning that it is bioequivalent and contains the same active ingredients and dosage
form. “Biosimilar” is a term used for biologic drugs—these agents are often not approved for direct substitution with a biologic, so (B) is incorrect. A “B” rating indicates that a drug is not therapeutically equivalent, so (D) is incorrect.

3. An AB rating means that:
   A. A drug is therapeutically equivalent to the reference drug, with no known bioequivalence problems
   B. A drug is therapeutically equivalent and is given as an oral tablet or capsule
   C. The drug is not therapeutically equivalent to the reference drug because of unresolved bioequivalence issues
   D. The drug is therapeutically equivalent to the reference product, but there are known or possible bioequivalence issues

Correct Answer: D
Answer (A) refers to an “A” rating; answer (B) would describe an “AA” rating, and answer (C) would describe a “B” rating. Agents with AB ratings can be used for substitution in many cases.

4. Joanne O. is a patient receiving MTM consultation. She says does not want to receive a generic version of one of her drugs because she has more nausea from it than she does with branded drug. A correct response would be:
   A. The generic drug is exactly the same as the branded one; it just has a different name
   B. There may be an inactive ingredient that is causing the nausea, or a difference in how the drug is absorbed. We can ask the pharmacist to look into this
   C. If you take the drug with more food instead of on an empty stomach probably won’t cause nausea
   D. You are probably imagining the nausea—there isn’t really any risk of that associated with this drug

Correct Answer: B
There is a small possibility that an inactive ingredient could be causing this issue, depending upon the drug. There is not enough information to determine whether (C) is correct. Negating the patient’s perceptions of nausea from the drug (Answers A and D) is unhelpful. If the pharmacist can verify that the inactive ingredients are the same or similar and unlikely to be the cause, the patient may be more accepting of the generic and then other possible causes of nausea can be explored and discussed.