ZVMS Policy Brief

GENERIC SUBSTITUTIONS

SUMMARY

Generic Substitution Laws are state laws that provide a legal pathway for the dispensing pharmacist to substitute a therapeutically equivalent but cheaper drug (e.g., generics) for a more expensive (e.g., pioneer drug), without having to obtain an affirmative authorization from the prescriber. These laws have led to a significant expansion of the generic market. However, they are deficient when dealing with combination medical products due to how "therapeutically equivalent" is determined under state law, including under Minnesota state law. Other states have already taken steps to address this shortcoming, and we ask the Minnesota legislature to amend the State's generic substitution law to allow for more seamless substitution.

BACKGROUND

Generic Substitution Laws are state laws adopted virtually by all states, including Minnesota, that provide a legal mechanism for a pharmacist to dispense a cheaper substitute product (e.g., generic drug, different brand, or formulation) for a more expensive one (e.g., pioneer drug or a brand/formulation not covered by patient's insurance), if the two are therapeutically equivalent without having to obtain an affirmative authorization from the prescriber. In practical terms, if a prescription is issued for Lipitor (the brand name drug for atorvastatin), the pharmacist may dispense the cheaper generic, atorvastatin, without needing affirmative authorization from the prescriber.

Generic substitution laws have been instrumental in expanding the generic drug market and reducing drug costs over the past few decades. However, these laws have significant shortcomings in dealing with the ever-expanding list of what FDA classifies as combination products. These are products that comprise of two or more different types of regulated components (i.e., some combination of drugs, biologics, and devices). The shortcoming is particularly acute in cases of drug-device combination products such as albuterol metered-dose-inhalers (MDIs) and epinephrine autoinjectors. The hindrance arises from how permissible substitution is defined; worded differently, how the state law defines "therapeutic equivalence" creates a special problem when dealing with drug-device combination products. This is especially problematic given the vast price differences between different brands and varying insurance coverage.

DISCUSSION

Issue: Generic Substitution for Combination Products

Some jurisdictions only allow substitution if the generic drug is recognized as a therapeutic equivalent in the FDA's "Orange Book[1]." Other jurisdictions allow some flexibility and defer to the professional judgment of the pharmacist, although the scope of such flexibility is usually very limited. Minnesota, being one of the states that does not reference the Orange Book, determination of therapeutic

[1] Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book and more recently with the online version the Electronic Orange Book). In addition to other eligible drug products, it lists every prescription drug that has been approved by the FDA as a new drug (both the pioneer drug and the generic drug); which with a few exceptions of older drugs, includes most drug products available in the US.

equivalence and interchangeable safety is deferred to the "pharmacist's professional judgment" [1]. However, the Minnesota Board of Pharmacy has interpreted "professional judgment" to be a limiting clause and requires "legitimate and documented basis" to justify the substitution decision [2]. Under this interpretation, the issue with drug-device combination products is that even though the "drug" element of the product is therapeutically equivalent since the "device" element does not operate exactly the same way, the combination product as a whole is no longer deemed to be "therapeutically equivalent." Consequently, pharmacists need to obtain affirmative authorization from prescribers to substitute a cheaper drug-device combination product for a more expensive one; even though from a clinical standpoint, there is very little difference between them as the drug part is therapeutically equivalent, leading to administrative waste, increased cost and/or delayed care. For example, if a prescription is issued for brand name EpiPen, the pharmacist is unable to substitute that for a potentially cheaper version of an epinephrine autoinjector, Adrenaclick, without affirmative authorization from the prescriber due to minor differences in operation of the device portion even though the drug element "epinephrine" is identical in both. Of note, under current law prescribers have always had the ability to restrict substitution if clinically indicated regardless of the product and patients can always decline the substitution if desired. Other states including Indiana, Ohio and Utah have already passed legislation to expand pharmacist's authority in substituting drug-device combination products.

RECOMMENDATIONS

We recommend that Minnesota's generic substitution law be amended to expand the authority of the pharmacist to substitute more expensive drug-device combination products with cheaper drug-device combination products as long as the drug element of the drug-device combination is therapeutically equivalent based on the pharmacist's judgment and substitution is not rescripted by the prescriber or declined by the patient.

REFERENCES

1. Minn. Stats. Section 151.21.
2. General FAQs / Minnesota Board of Pharmacy (mn.gov)