



*****Attention Medical Providers – Important Information Regarding Generic Formulations of Concerta® *****

On November 13, 2014, the FDA released a statement expressing concern that two approved generic versions of Concerta® tablets (methylphenidate hydrochloride extended-release tablets), may not be therapeutically equivalent to the brand-name drug. More information found here:

<http://www.fda.gov/Drugs/DrugSafety/ucm422568.htm>.

The FDA has not identified any serious safety concerns with these two generic products; however, Mallinckrodt and Kremers Urban (Kudco) products may deliver drug in the body at a slower rate and the diminished release rate may result in patients not having the desired effect. As a result, the FDA has changed the therapeutic equivalence rating for the Mallinckrodt and Kremers Urban products from AB to BX. This means the Mallinckrodt and Kremers Urban products are still approved and can be prescribed, but are no longer recommended by the FDA as automatically substitutable at the pharmacy for Concerta. Methylphenidate ER tablets, marketed by Actavis, are identical to Janssen's Concerta® and remain bioequivalent to, and substitutable for, Concerta®.

In terms of impact on the impending NC Medicaid and Health Choice Preferred Drug List (PDL) changes that will take effect Jan. 1, 2015, brand name Concerta® will become non-preferred and its generic equivalent, methylphenidate ER, will remain preferred. In light of the above FDA guidance, Actavis will be the only manufacturer of generic Concerta® that will be both an AB-rated therapeutic equivalent and have preferred status on the North Carolina Medicaid and Health Choice PDL. The other two manufacturers, Mallinckrodt and Kremers Urban, will remain preferred agents; however, the PDL will reflect that these agents are not considered therapeutically equivalent to Concerta®.

Your local CCNC Network Pharmacist can provide you with a list of your patients taking Concerta®, or one of its generics, along with the current manufacturer. If a patient is clinically stable on their current methylphenidate ER manufacturer, and you'd like them to stay on that manufacturer, please write future prescriptions for "methylphenidate ER tabs." This will allow the pharmacy to continue to dispense the same manufacturer's product to your patient if the pharmacy chooses to continue stocking that product. If future prescriptions are written for Concerta®, the pharmacy will most likely change the patient to the product marketed by Actavis.