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Ask The Pharmacist: Exploring Drug Market Exclusivity and Generic Availability

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When do drugs become generic?

When drugs are first introduced, they are made available as brand name only for differing lengths of time depending on the particular drug. Individuals often want to know when a generic will be released for the brand name medications to hopefully reduce the price of the medication. To better understand this, it is important to first know the process behind bringing a new drug to market.

When a drug manufacturer develops an idea for a new drug, one of the first steps they take is to file a patent for the compound or substance they will be using as the active ingredient in the medication. These patents are filed through and reviewed by the U.S Food and Drug Administration (FDA). Should the FDA approve the patent, companies are given 20 years of patent life. Over the next 20 years the manufacturing company will begin to develop all aspects of the medication and eventually begin clinical trials to prove both safety and efficacy. Once this is completed the FDA will review all the information and study results again. When the FDA believes the medication is safe and effective, they will approve it for use, and the manufacturing company is then permitted to sell their drug.

When a drug first comes to market, the FDA allows the company exclusive rights to sell their drug on a brand name basis while no other companies can produce a generic version for a certain amount of time. This is called market exclusivity. This is to allow time for the manufacturing companies to recover the costs from the years spent researching and developing the medication before others can introduce competing generics.

The timeframe for market exclusivity has a very wide range depending on numerous situations. Most of a drug's market exclusivity comes from the time remaining on its original 20-year patent. For example, if the company completes the development, research, and FDA approval and launches the drug to market in 12 years, they will

still have eight years left on the 20-year patent. During the eight-year timeframe no other company can produce or sell a generic version. Additional time may also be allotted to the drug if it meets certain criteria set by the FDA.

The Orphan Drug Act provides incentives for pharmaceutical companies to develop drugs for rare diseases, which affect a small population and might not be profitable otherwise. If a drug qualifies for orphan drug status, which includes treating diseases affecting fewer than 200,000 people in the U.S., it can receive seven years of market exclusivity. During this period, the manufacturer has the exclusive right to produce and sell the drug for the specific condition, allowing them to recoup their research and development costs. This provision encourages drug development for rare diseases and diseases with limited treatment options.

Market exclusivity can also be extended or shortened if companies challenge the FDA's decisions. Additionally, there are other ways to extend the market exclusivity of a drug. For example, OxyContin, which is branded oxycodone ER, has been around since the late 1990s, but it still doesn't have a true generic equivalent. OxyContin changed its formulation to be abuse deterrent in 2010, and in doing so, the oxycodone ER generic was no longer equivalent. Given this, OxyContin remains without a true authorized generic for the time being. A formulation change like this is one popular example of how drugs can extend their market exclusivity.

Once the market exclusion is over, other companies can produce generic versions of the medication and prices can sometimes drastically drop for individuals and insurers. The average market exclusivity period for newly approved drugs is more than 12 years. So, it may be quite a while before a newer innovative drug has a generic available. If you have a question regarding a specific medication and would like to know when a generic may be available, reach out to us at AskThePharmacist@mitchell.com and our team will do the research and gather the information needed to best answer your questions.

This information is meant to serve as a general overview, and any specific questions or concerns should be more fully reviewed with your health care professional such as the prescribing doctor or dispensing pharmacist.

Do you have a workers' compensation or auto related pharmacy question? Send us an email at AskThePharmacist@mitchell.com.

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