Clearing a Path for More Efficient Generic Drug Development

Branded drugs with expired patents but without generic competition may keep prices high and ultimately hurt patients.

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Statement from FDA Commissioner Scott Gottlieb, MD, on new policy to improve access and foster price competition for drugs that face inadequate generic competition

In too many cases, branded drugs that are no longer protected by patents or other exclusivities do not face expected competition. In fact, there are several hundred of such branded drugs that do not have any generic competition. Instances like these may keep prices high and ultimately hurt American patients.

We've been taking new policy steps at the FDA to support downward pressure on drug prices by helping to clear a path for more efficient generic development. In doing so, we know that various factors may influence a manufacturer's decision to develop and market a generic drug. For example, some drugs may not attract a high level of interest if there is a limited market for them. We also know that some drugs may be less desirable to genericize because they are complex drugs, which are more difficult to copy.

We're working to reduce barriers to generic development and to lower the cost of generic entry so that more of the generic medicines that the FDA approves are launched and reach patients. Over the next year, the FDA will advance additional policies to promote generic competition including for complex drugs.

Among other steps, we intend to issue additional guidance documents for developing specific complex generic medicines, as well as address categories of complex drugs that are hard to copy because of their complex formulation or mode of delivery. This will include the publication of a series of guidances to address regulatory and scientific challenges that make it generally more difficult to develop complex generics. As part of this, we intend to issue draft guidance with recommendations on establishing active ingredient sameness. In addition, we'll advance the development of new analytical tools and in vitro tests to provide additional accurate, sensitive and reproducible tools to support approval of complex generic drugs. Better tools for proving sameness can open up more complex drugs to generic competition.

Today, the FDA is taking another step to encourage generic entry for drugs that face inadequate

competition by laying out new, efficient guidelines for the use of a novel pathway that provides incentives for developing generic versions of drugs that currently face little or no competition.

This new pathway for Competitive Generic Therapies (CGTs) is a significant advancement in generic drug competition. Designation of a drug as a CGT can be granted to a company submitting an application for their generic drug when there's inadequate generic competition for that drug, meaning there is not more than one approved drug in the active section of the Orange Book. The designation, which was established by Congress when it granted the FDA new authorities in the FDA Reauthorization Act of 2017, provides certain incentives for industry to develop generics for drugs lacking competition that have been designated as CGTs.

Under this pathway, companies may submit requests to designate a drug as a CGT at the time of submitting an abbreviated new drug application (ANDA) or at any time before the original ANDA submission. At the request of the applicant, the FDA may expedite the development and review of an ANDA for a drug that is designated as a CGT. CGT designation can afford companies a number of early benefits, including product development meetings with the FDA to discuss specific scientific issues or questions they may have such as proposed study design or alternative approaches. These early benefits may also help to reduce the number of application review cycles ultimately decreasing the time it takes for the generic drug to receive approval.

If a CGT designation is granted, the application may be eligible for a 180-day period of marketing exclusivity provided the applicant is the first approved ANDA for that CGT and meets other conditions.

Since being granted these new authorities, the agency has moved quickly in designating drugs as CGTs. To date, the FDA has granted more than 100 CGT designation requests, and in 2018 between August and December, the FDA approved the first five ANDAs for generic drugs designated as CGTs, and when the drugs covered by those ANDAs were commercially marketed those ANDAs qualified for 180-day exclusivity. The successful implementation of these new authorities demonstrates that the competitive generic therapy pathway is efficient and effective at promoting new competition. It's also a key step in making safe and effective generic drugs available to patients quickly while helping to ensure there's adequate competition in the market place, so patients have access to the treatments they need.

But we know there are still many branded products on the market without generic competition. We must do more to encourage development of safe and effective generic competition to these sole source drugs.

In addition to taking action to enhance generic competition, the FDA is working to make generic drug development more efficient and predictable. We're working to reduce approval times and to enhance the efficiency of certain aspects of the submission process for generic drug applicants. And we're also working to provide the generic industry with increased transparency to provide greater certainty around timing of first possible generic entry and potential competition from other generic entrants, and to make the scale up of manufacturing more efficient, to enable more

informed decisions on how to prioritize their resources and come to market. We also recently announced a guidance providing application holders with clarity on information they are required to share with the FDA under another FDARA provision that will enable us to have more timely, accurate information about what drugs are being actively marketed to help provide transparency around circumstances where generic competition is lacking to inform our policy making.

Building on those efforts, today the FDA has issued the new draft guidance aptly titled, Competitive Generic Therapies, to help provide even greater clarity to industry about the CGT pathway. This new guidance provides robust information on how drug developers can apply for CGT designation and when they may be eligible for CGT exclusivity. The CGT pathway is intended to incentivize effective development, efficient review, and importantly the timely market entry of generic drugs.

The FDA's implementation of this new pathway is an important part of our broader effort to foster generic competition and help address the high cost of drugs and improve patient access to important medicines. Overall, addressing the challenges related to developing generics, and promoting more generic competition to these medicines, is a key part of our Drug Competition Action Plan, and the agency's efforts to help advance patient access to more affordable medicines.

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