Statement from FDA Commissioner Scott Gottlieb, M.D., on new policies to reduce the ability of brand drug makers to use REMS programs as a way to block timely generic drug entry, helping promote competition and access

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Statement

Our system for developing new drugs is based on a careful equilibrium enshrined in legislation by Congress that seeks to balance access with innovation.

That system enables market-based rewards for novel innovation as a way to create incentives for the time, risk and capital required to develop new medical advances. At the same time, the law allows for brisk competition from safe and effective generic medicines once the period of patent protection or exclusivity has lapsed on a new medicine.

But we know that there are situations where that expected competition isn't materializing in a timely manner. Sometimes this is the result of tactics that brand drug makers adopt.

For example, sponsors have sometimes been able to use our Risk Evaluation and Mitigation Strategy (REMS) requirements to block timely generic entry. For drugs that are associated with serious risks, the FDA can require drug makers to develop REMS to ensure that the benefits of the drug outweigh its risks to protect patient safety.

We have seen REMS requirements be exploited in two ways. One occurs at the front end of the drug development process, when generic drugs are being developed. The other occurs at the back end of the process, after necessary testing has been completed, when a generic drug seeks approval and market entry.

On the front end, brand drug makers sometimes use REMS as a way to restrict the sale of their drugs, keeping the drug out of the hands of generic firms. The generic drug makers typically need up to 5,000 doses of a brand drug in order to run bioequivalence and bioavailability studies to prove the generic medicine is the same as its brand drug.

Congress deliberately designed a regulatory process that minimized hurdles to generic market entry. In general, a generic applicant only has to show that its drug is bioequivalent to and the same as the brand drug. But even this standard is hard to achieve if generic drug makers can't get access to the doses of the brand drug that they require.

The other obstacle occurs at the back end, after a generic drug seeks FDA approval and market entry. This is the impediment we're seeking to address today, with the new policies that we're announcing.

Brand and generic drug makers are required to develop a single shared REMS program when a generic drug seeks approval and the brand drug has a REMS associated with it. This requirement applies when a generic drug applicant wants to market a generic version of a drug that has REMS with certain requirements or activities known as "Elements to Assure Safe Use" (ETASU). The current law requires that the brand and generic companies use a single, shared system REMS, unless the FDA waives that requirement and permits the generic drug to use a separate, comparable REMS program.

Bringing together multiple products under one REMS program can have real benefits for the health care system, including for providers. But, the generic drug maker has to negotiate with the brand firm to enter into a shared REMS programs before the generic drug can be approved. We know that these negotiations between a brand and generic company -- to reach agreement on shared system REMS -- can extend for long periods of time. This can delay market entry of a generic drug.

While the FDA recognizes that these negotiations are an important step in the formation of a shared system REMS, the agency is also committed to making sure that REMS programs maintain their role in serving public health. The REMS shouldn't become a tool that drug companies can use to delay or block competition from generic products or hinder their ability to enter the market.

Through the new policies that we're advancing today, our aim is to help generic drug makers get their products through the development and approval processes efficiently while maintaining the safety controls sought by the REMS. The first draft guidance being issued today, **Development of a Shared System REMS (/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM609045.pdf)**, describes general principles and recommendations to assist sponsors with developing these programs. The goal is to improve the clarity and efficiency for developing shared system REMS, which will enable timelier market entry for products that are part of these REMS.

The second draft guidance, **Waivers of the Single, Shared System REMS Requirement (/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM609048.pdf)**, describes when and how the FDA will consider waiving the single, shared system requirement, and how generic applicants can request a waiver. The FDA may waive the single, shared system REMS requirement and permit the generic company to use a "different, comparable" aspect of the ETASU if the agency finds that (1) the burden of forming a single shared system outweighs the benefits of having one, or (2) an aspect of the REMS is covered by a patent or is a trade secret and the generic applicant certifies that it sought a license for use of that aspect and was unable to obtain one. This draft guidance describes the factors the FDA will consider in evaluating a request for a waiver of the single, shared system REMS requirement. The guidance makes clear that while the FDA encourages companies to work together to form a single, shared system, the agency will consider a waiver at any time (either upon request of the applicant, or on the agency's own initiative). The draft guidance also provides recommendations to generic drug applicants regarding the submission and content of waiver requests.

We believe that by making the process for developing a shared system REMS more efficient, we'll discourage brand drug makers from using REMS as a way to block generic entry and help end some of the tactics that can delay access. We're also going to be clearer about the circumstances when we'll issue waivers to let the generic

firms develop their own REMS program. Our safety programs shouldn't be leveraged as a way to forestall generic entry after lawful IP has lapsed on a brand drug. Our market-based system for rewarding innovation is dependent on this kind of legal competition.

Related Information

- FDA Draft Guidance: Development of a Shared System REMS (/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM609045.pdf)
- FDA Draft Guidance: Waivers of the Single, Shared System REMS Requirement (/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM609048.pdf)
- FDA: Risk Evaluation and Mitigation Strategy (REMS) (/Drugs/DrugSafety/REMS/default.htm)
- Statement from FDA Commissioner Scott Gottlieb, M.D. on new steps to improve FDA review of shared Risk Evaluation and Mitigation Strategies to improve generic drug access (/NewsEvents/Newsroom/PressAnnouncements/ucm584259.htm)
- Statement from FDA Commissioner Scott Gottlieb, M.D., on new agency efforts to shine light on situations where drug makers may be pursuing gaming tactics to delay generic competition (/NewsEvents/Newsroom/PressAnnouncements/ucm607930.htm)
- HHS: Drug Pricing (http://www.hhs.gov/drugpricing)

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