Drug Manufacturing Innovations to Improve Quality and Lower Costs

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Statement from FDA Commissioner Scott Gottlieb, MD, on new programs to promote the adoption of innovations in drug manufacturing that can improve quality and lower drug costs

Ensuring the safety of our nation's drug supply is a cornerstone of our consumer protection mission. One of the fundamental elements of overseeing the quality and safety of pharmaceuticals is having a clear understanding of the specific processes and technologies used to manufacture drugs throughout their lifecycle. This starts before a product is even approved and brought to market, with the FDA's premarket (or pre-approval) review of drug applications. This includes a careful review of information about product and manufacturing quality, as well as, in many cases, premarket inspections of a company's intended manufacturing facility to ensure compliance with good manufacturing practices and other regulations. Overseeing how drugs are produced is a key component of ensuring the quality and safety of these products.

One way we can support efficiency in drug development and the FDA's oversight of drug quality is by recognizing a set of agreed-upon "voluntary consensus standards" related to pharmaceutical quality to take advantage of collaborative efforts between regulators, industry and academia that have resulted in nationally and internationally accepted standards for drug quality. That's why today we're announcing a new draft guidance, CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality. The guidance proposes a program in which stakeholders and FDA staff will have the opportunity to propose pharmaceutical quality standards for potential recognition by the FDA, providing industry with additional options for pharmaceutical development and manufacturing.

The overall goal of this program is to promote development and appropriate use of consensus standards to help expedite pharmaceutical development and streamline the review of drug product applications. By providing a list of recognized standards on our website, we will provide transparency regarding our thinking on a particular standard, which will help industry compile information for applications, can streamline the FDA's assessment and allow us to focus our efforts on developing guidance on other quality topics.

Our recognition of a standard may also reduce regulatory uncertainty, allowing applicants and manufacturers to utilize new or innovative approaches within their development programs. Once we've recognized a standard, applicants will generally not have to validate the approach outlined in the standard and can instead focus on appropriate use of the method and the acceptance criteria. We'll similarly be able to streamline assessment of applications that reference recognized standards. Our hope is that establishing this program will also encourage the development of standards for emerging technologies that can improve drug quality and reduce manufacturing costs. This includes continuous manufacturing. Informally recognized standards related to pharmaceutical quality will also be publicly available on our website.

It's important to understand this program doesn't change the requirements of the law – it does not apply to standards that are already legally binding, such as provisions of the Federal Food, Drug, and Cosmetic Act relating to the United States Pharmacopeia. But the proposed program will facilitate recognition of other standards concerning pharmaceutical quality to make the adoption of advances in drug manufacturing and application review more efficient; and encourage innovation in how drugs are manufactured.

While this program is intended for all drugs, brand and generics, we know that it will have a positive effect in supporting more efficient development and production of generic drugs, which often operate under small margins compared to brand drugs. Creating efficiencies in generic and biosimilar manufacturing is an important part of our work to streamline generic and biosimilar development overall, to help spur competition in the prescription drug market as part of our Drug Competition Action Plan (DCAP) and Biosimilar Action Plan.

It's also important to consider that the manufacturing of these products may evolve after they have come to market, as companies make updates and improvements to their processes. These updates can help improve quality and reduce costs. When these changes are made, it's the FDA's responsibility to review them to recognize and mitigate any risks that a manufacturing change might introduce. In doing so, the FDA is careful to strike the appropriate balance between understanding how these changes could impact product quality and ensuring that companies can swiftly and efficiently make changes to process that can increase production efficiency, bolster quality and ultimately, help increase competition in the marketplace.

Another way we can support efficiency of drug development and manufacturing is through greater transparency and clarity regarding the agency's thinking on quality standards from pre- to postmarket.

Last year, the FDA published a draft guidance for industry titled, "Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management." This guidance, developed under the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), provides a risk-based approach to regulatory oversight of post-approval manufacturing changes. The framework in this guidance provides a mechanism for applicants to gain agreement with the agency on the established conditions (ECs) necessary to ensure product quality, and to facilitate post-approval changes to those established conditions with a level of

regulatory oversight commensurate with the applicant's knowledge about their product and manufacturing process. Examples of ECs can include manufacturing and testing facilities, and certain process parameters and specifications. Tomorrow, we'll announce the details of a new pilot program to gain experience receiving, assessing, and engaging with applicants regarding proposed ECs (also referred to as "explicit" ECs). Once the ICH Q12 guideline is finalized and implemented, the use of ECs is intended to help reduce submissions of unnecessary postapproval supplement applications and encourage manufacturers to continually improve their processes using the agreed-upon ECs as their guardrails. This can help promote manufacturing innovations that can improve the quality and safety of drug manufacturing, and potentially lower the cost of finished drug products.

We'll continue to expand our efforts with established conditions and drug competition to help facilitate the development and marketing of safe and effective drugs for consumers.

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