Society of Gynecologic Oncology

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The Honorable Robert M. Califf, MD, MACC
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

SUBMITTED ELECTRONICALLY VIA http://www.regulations.gov

Re: Quality Management Maturity Program for Drug Manufacturing Establishments; Establishment of a Public Docket; Request for Comments

Dear Dr. Califf,

The Society of Gynecologic Oncology (SGO) appreciates the opportunity to provide comments on the Food and Drug Administration's (FDA) request for comments to assist the agency in developing a Quality Management Maturity (QMM) program for establishments manufacturing human drugs, including biological products, regulated by the Center for Drug Evaluation and Research.

The SGO is the premier medical specialty society for health care professionals trained in the comprehensive management of gynecologic cancers. Our 2,800 members, who include physicians, nurses, and advanced practice providers, represent the oncology team dedicated to the treatment and care of these patients. The society's purpose is to improve care by encouraging research and disseminating knowledge, raising the standards of practice in the prevention and treatment of gynecologic malignancies, and collaborating with other organizations interested in patient care, oncology, and related fields.

As you know, there are current shortages for chemotherapies, including cisplatin and carboplatin, which are used as first line therapies for ovarian, endometrial, and cervical cancers. Besides gynecologic cancers, these chemotherapies are also front-line therapies to treat certain breast and lung cancers. Chemotherapy drugs are often in the Top 5 class of drugs in shortage in the U.S., especially sterile injectable generic drugs. At one point this year, there were fifteen indispensable chemotherapy drugs in shortage, simultaneously, used in more than one hundred treatment indications for a variety of cancers in adults and children. Earlier this year, SGO estimated that over 500,000 patients were already being affected by these shortages. The American Society of Health-System Pharmacists also conducted a survey that found that 99% of hospital pharmacists reported shortages, which caused 85% to modify treatments and 84% to rely on different dosages. Although the data is not yet available, we believe that individuals in marginalized communities and rural areas have likely borne the brunt of the impact caused by drug shortages. We are concerned that patients have had curtailed access to the best standard of care cancer treatments due to the shortages, and we are currently evaluating if the chemotherapy shortages have negatively impacted survival outcomes for people with gynecologic cancers.

For these reasons, SGO believes that advancement of a robust QMM program is critical to supporting resilient supply chains and preventing future drug shortages, particularly for generic chemotherapies.

We agree with the FDA that the root cause for many drug shortages is the absence of incentives for manufacturers to strive for more than simply meeting current good manufacturing practice regulations and to develop mature quality management systems. Assessments should be conducted to support manufacturers' achieving higher levels of QMM by integrating high quality practices and technological advancements to optimize manufacturing process performance and product quality, enhance supply chain reliability, and foster proactive continual improvement. The QMM rating system will help incentivize manufacturers to attain higher levels of QMM at their facilities as hospitals will be more likely to purchase products from companies with greater QMM ratings. Currently, the only information available to purchasers is the price of drugs. Absent any additional information, purchasers do not have a rationale to purchase a drug with a higher price if the same drug is available from a different manufacturer at a lower price. A program such as a federal voluntary QMM program would provide purchasers with helpful information with which to guide their purchasing decisions. A purchaser could, for example, justify paying more for a drug if the manufacturer is part of a QMM program instead of paying less for a drug whose manufacturer is not part of a QMM program with the expectation that the product from the QMM manufacturer would be less likely to go into shortage or have history of contamination or recall.

Additionally, advancing the QMM program will continue to emphasize the importance of high-quality drug production and quality control measures, which would minimize the risk of shortages caused by operational inefficiencies or lapses in quality control. We believe that this is particularly important for the manufacture of generic drugs. Lack of transparency related to drug shortages also would be addressed by the QMM program. The FDA, hospitals, and providers would be able to better anticipate shortages and develop rapid guidelines to optimize drug supply, including strategies such as dose reduction, identification of alternative therapies with similar efficacy, and the initiation of pharmacy drug preservation protocols. This enhanced transparency would ensure a more agile response to potential shortages, mitigating the impact on patients. To ensure that the QMM program is aligned with the needs of gynecologic oncologists and patients undergoing cancer treatment, we encourage the FDA to improve communication channels between all stakeholders, including manufacturers, distributors, hospitals, and treating physicians. By including providers, including gynecologic oncologists, in the discussion, we can represent the perspectives of our cancer patients and the realities of oncology practice. With respect to the outcomes of a QMM assessment, the SGO recognizes the benefits of sharing outcomes publicly. The dissemination of information – both descriptive information and numerical ratings – to the public may incentivize manufacturers to produce higher quality products and utilizing quantitative data for outcomes would further enhance their robustness.

SGO joins other stakeholders in recommending that the FDA establish a permanent QMM program that initially focuses on a specific list of vulnerable, essential, multisource generic drugs, such as chemotherapy drugs, and the establishments that produce these drugs. We recognize that the FDA has limited resources and there are hundreds of manufacturers involved in the pharmaceutical supply chain. We support prioritizing drugs such as essential chemotherapies when deploying QMM programs, or prioritizing drugs that have been in the FDA shortage list in the last 5 years to make the most of limited resources. By focusing initially on preventing the most likely and impactful shortages, it will reduce administrative burden and cost while allowing the agency to determine best practices for the program's expansion. Additionally, we think the QMM program may be more effective if it remains a voluntary program rather than a mandatory program.

A QMM program holds the potential to significantly improve high-quality practices, leveraging technological advancements, enhancing supply chain reliability, and promoting a culture of continual improvement. The program's advancement will continue to address critical issues faced during drug shortages. Moreover, further innovative ideas are needed to ensure drug supply chain reliability beyond QMM practices. Ultimately, the bottom-line advantage of the QMM program is the ability to treat all patients with the best drugs at the right time, achieving cure and enhancing overall survival rates. Additionally, SGO recognizes that dedicated funding has not yet been appropriated for the QMM program; however, the FDA should continue to use all available resources to progress QMM program development and implementation until a reliable funding stream is available.

Thank you for the opportunity to provide these comments. We welcome the opportunity to work with you to implement a QMM program that protects patient access to necessary therapeutics. Should you have any questions, please contact Erika Miller at emiller@dc-crd.com.

Sincerely,

Angeles Alvarez Secord, MD, MHSc
President, 2023-2024