FDA Reorganizes Office That Reviews Cancer Treatments

The plan aims to streamline evaluation of increasingly complex therapies for these life-threatening diseases.

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FDA Office of Hematology Oncology Products Reorganizes, Renamed Office of Oncologic Diseases

The U.S. Food and Drug Administration's office responsible for reviewing applications for new and existing cancer therapies has reorganized and been renamed as part of modernization plans approved in September 2019.

The Center for Drug Evaluation and Research (CDER) Office of Hematology and Oncology Products (OHOP) has been reorganized and renamed the Office of Oncologic Diseases (OOD).

Richard Pazdur, MD, who joined the FDA in 1999 as director for the Division of Drug Oncology Products and became the OHOP director in 2005, is the acting director of OOD.

"As the practice of oncology and the treatments for these life-threatening diseases have become more complex, we recognized the need to flatten the organization with additional but smaller review divisions to enable more efficient drug review," Pazdur said. "Reorganizing the office in this manner will allow for greater stakeholder engagement in the various disease programs."

Pazdur also directs the FDA's Oncology Center of Excellence (OCE), established in 2017 to help expedite the development of oncology and hematology medical products and support an integrated approach in the clinical evaluation of drugs, biologics, and devices for the treatment of cancer. The OCE is not affected by the OHOP reorganization.

OHOP contained three clinical divisions and one nonclinical division: Division of Oncology Products 1 (DOP1), Division of Oncology Products 2 (DOP2), Division of Hematology Products (DHP), and Division of Hematology Oncology Toxicology (DHOT).

The new OOD structure consists of six divisions:

- DOP1 is re-named Division of Oncology 1 (DO1).
- DOP2 will be split into two divisions: Division of Oncology 2 (DO2) and Division of Oncology 3

(DO3).

- DHP will be split into two divisions to review products intended to treat hematologic malignancies: Division of Hematologic Malignancies 1 (DHM1) and Division of Hematologic Malignancies 2 (DHM2). DHP's review of products to treat non-malignant hematologic conditions will move to another office within CDER.
- DHOT remains the same.

DO1 will retain its responsibilities for products for breast, gynecologic, and genitourinary cancers as well as supportive care.

DO2 will review products for thoracic and head and neck cancers, central nervous system cancers, pediatric solid tumors, and rare cancers.

DO3 will review products for gastrointestinal malignancies, melanoma and other advanced skin cancers, and sarcomas.

DHM1 will be responsible for products for acute leukemia and myelodysplasia (includes myelodysplastic-myeloproliferative overlap syndromes), chronic myeloid leukemia and other myeloproliferative neoplasms with the term "leukemia," blastic plasmacytoid dendritic cell neoplasm (BPDCN), conditioning regimens for DHM1 indications, graft versus host disease, tumor lysis syndrome, cytokine release syndrome, and CAR-T neurotoxicity.

DHM2 will review for products for lymphoma, chronic lymphocytic leukemia, multiple myeloma, and other plasma cell malignancies.

Products for non-malignant hematologic diseases and conditions that DHP previously covered will be reviewed in the newly formed Division of Non-malignant Hematology (DNH) in the Office of Cardiology, Hematology, Endocrinology and Nephrology (OCHEN).

The Regulatory Project Management Staff are reorganized under the newly formed Office of Regulatory Operations (ORO) within the CDER Office of New Drugs (OND). Regulatory project management staff supporting OOD will be in the newly formed Division of Regulatory Operations–Oncologic Diseases (DRO-OD), with individual branches supporting each of the five clinical review divisions in OOD.

In addition, a centralized Safety Team has been created in the OOD to work with the review divisions to provide for consistent review, management, and communication of safety information across development programs and throughout the pre- and post-market life-cycle of oncology drugs. A centralized labeling team will standardize and harmonize labeling efforts across OOD.

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