Adverse effects of cancer therapies may occur more than three decades after drug administration. Continued vigilance in postmarketing use of oncology agents is necessary to accurately track adverse effects, update prescribing information, and alert healthcare providers in a timely manner. This article will define the processes involved in regulatory approval of oncology agents and discuss selected oncology drugs, labeling changes, and the role of oncology nurses in postmarketing surveillance by reviewing journal articles, governmental agency Web sites, federal regulatory documents, and pharmaceutical prescribing information. Oncology nurses administer and monitor cancer therapies in outpatient and inpatient settings and routinely assess patients for side effects of therapy; therefore, maintaining awareness of short- and long-term adverse effects after drug approval is important to patient safety. Nursing leadership should initiate, maintain, and manage an incident reporting system to effectively respond to changing needs. In addition, publication of case reports and articles on the emergence and management of postmarketing, treatment-related side effects in peer-reviewed nursing and medical journals may improve patient care and outcomes.

Postmarketing Surveillance for Oncology Drugs

At a Glance

- Patients with cancer have more treatment options than ever before, but therapies may have toxicities not yet identified by clinical trials.
- Postmarketing surveillance by healthcare professionals for toxicities related to cancer therapies and supportive care agents is essential to patient well-being.
- Oncology nurses should be vigilant in monitoring for and reporting unexpected side effects and adverse events related to therapy.