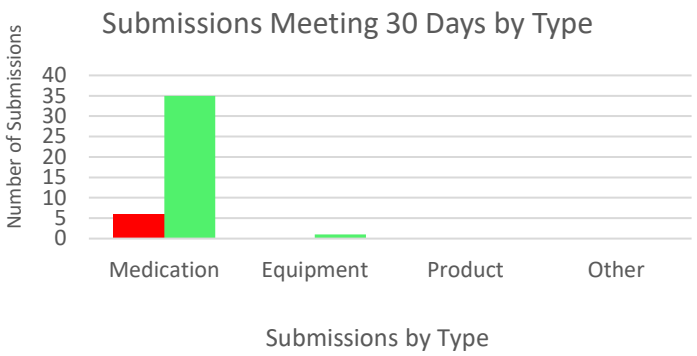
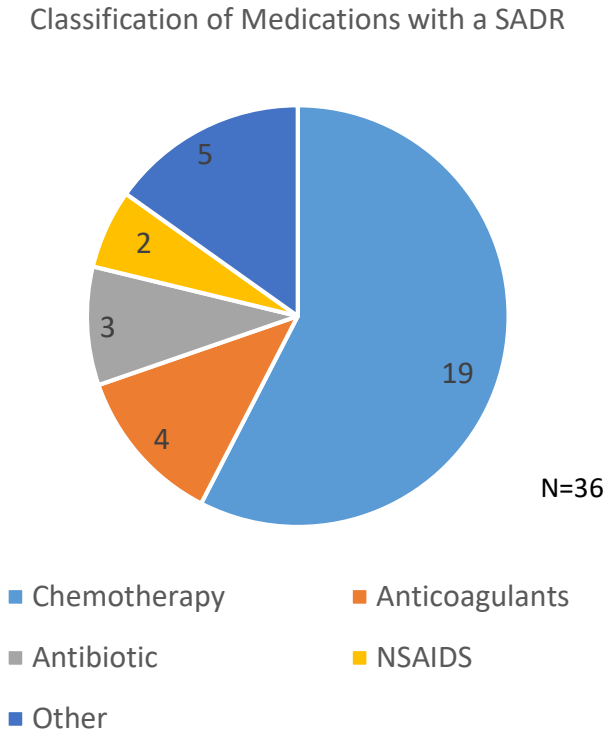
Annual Analysis 2023/24
Mandatory Reporting to Health Canada
Serious Adverse Drug Reaction (SADR)/ Medical Device Incident (MDI)



Submissions by Type



Summary

Thirty-five (35) reports were received for the fiscal year (April 1, 2023 – March 31, 2024). Of the 35 reports (34) were classified as SADRs and (1) MDI.

The following table to the left is a breakdown of submissions per category including the (30) day mandatory timeline from date of first documentation of event to date of submission to Health Canada. Of all the submissions, we are meeting the mandatory reporting requirements in a timely manner at 83%. The percentage of on-time submission ↓ from last year which = 93%.

The highest number of reports received are from the regional centers (34) with (1) under the category "Other" from a program/service voluntarily submission.

A monthly report of regional submissions for mandatory reporting of SADR and MDI are posted on the Secure Site.

Trends and Themes

There was a slight ↑ in reporting of 35 reports compared to the previous fiscal year of 31. The reporting has remained similar to the previous fiscal year.

An analysis of the 35 SADR reports received included a total of 38 medications. Some reports had multiple medications contributing to a SADR. The medications are listed according to drug classification and frequency of submissions.

SADR medications by drug classification & frequency of submissions:

1) Chemotherapy agents = 19 (54%)
2) Anticoagulants/Antiplatelet/Thrombolytic = 4 (11%)
3) Anitbiotic = 3 (9%)
4) NSAIDS (nonsteroidal anti-inflammatory drug) = 2 (6%)
5) Other (Antipsychotic drug, Iron Replacement, Biphosphonate (prevents bone density loss), Angiotensin Receptor Blocker, Seasonal Flu Vacccine = 5 (14%)

The most common theme of harm was hypersensitive reactions to chemotherapy i.e.) flushing, itchy rash, back pain, chest tightness, and shortness of breath. All symptoms presented within ~10 minutes of the infusion and required further actions i.e.) stopping of the infusion, administration of IV antihistamines/corticosteroids and restarting the infusion at a lower rate. There were 5 patients with GI Bleeds, 3 patients developing a bowel ilius, 1 patient having an anaphylactic reaction and 2 deaths.

MDI:

1) Equipment (A patient's condition deteriorated after an Ethicon circular ring stapler was used for a bowel resection. It was discovered that the anastomosis obliterated and was no longer attached resulting in a significant harm)

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