

**Safety Update on Dronedarone
July 25, 2011**

ICER's recent appraisal of management options for atrial fibrillation (AF) included dronedarone, which was the subject of recent safety alerts from both the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). A clinical trial of dronedarone in patients with permanent AF was halted prematurely due to twofold increases in death, stroke, and hospitalization for heart failure in patients receiving dronedarone as compared to those receiving placebo. While ICER's appraisal focused on paroxysmal and persistent AF, the two forms of the disease that represent dronedarone's approved indications, these new findings are clearly cause for concern. ICER will be monitoring the situation carefully, and will reconsider its findings, conclusions, and evidence ratings for dronedarone as further information is made available.

Link to FDA alert:

<http://www.fda.gov/Drugs/DrugSafety/ucm264059.htm>

Link to EMA alert:

http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2011/07/WC500109180.pdf