

Ms Moore

You kindly invited us on 23 March to comment on the appraisal consultation document on **dronedarone for atrial fibrillation**.

In section 1.1, the appraisal committee recommends that dronedarone as an option for the second-line treatment of patients who (amongst other possible factors) have left ventricular ejection fraction less than 40%; this probably reflects the population in one of the pivotal trials. However, the summary of product characteristics, in section 4.4 (Special warnings and precautions for use) states:

Because of limited experience in stable patients with recent (1 to 3 months) NYHA class III heart failure or with Left Ventricular Ejection Fraction (LVEF) <35%, the use of MULTAQ is not recommended.

The appraisal consultation document acknowledges this point in section 4.11

You may wish to consider how the statement from section 4.4 of the summary of product characteristics impinges on the committee's recommendations.