Summary: NICE GUIDANCE ON DRONEDARONE FOR THE TREATMENT OF NON-PERMANENT ATRIAL FIBRILLATION:

A PATIENTS GUIDE

NICE DECISION ON THE USE OF DRONEDARONE
The National Institute for Clinical Excellence (NICE) issued their original guidance on 24th December 2009 recommending that Dronedarone (Multaq) should not be approved for the treatment of non-permanent Atrial Fibrillation. The reason for this decision was on the grounds of cost.

Following this announcement there was widespread dismay from clinicians, AF patients and their carers who believed that Dronedarone's approval would be a useful alternative and addition to the few drug treatments which clinicians currently have available. Shortly after the initial guidance was published, organisations such as the Atrial Fibrillation Association and the Arrhythmia Alliance launched an appeal against the decision. Following an appeals process, the NICE Appraisal Committee recognised that Dronedarone can, and should, occupy a currently vacant place in the care pathway, and that for a large, and growing number of patients it could represent the only treatment option open to them.

GUIDANCE
NICE's final guidance was published on 25th August 2010. This states that Dronedarone is recommended as an option for the treatment of non-permanent Atrial Fibrillation if:

- You have already tried another type of drug (usually a drug called a beta-blocker) but this has not worked, and
- You have at least one of the following which means you are at a higher risk of developing disease of the heart or blood vessels:
  - You are taking at least two different types of drugs for high blood pressure
  - You have diabetes
  - You have had a type of stroke or a blood clot in the past
  - The left chamber of your heart is larger than normal
  - Your heart is pumping less blood around your body than normal, or
  - You are 70 or over, and
- You do not have a severe form of heart failure; that is, if you have been diagnosed as having heart failure, you are still able to carry out everyday tasks with either no symptoms, or symptoms that are mild (for example, you may experience mild chest pain or shortness of breath when walking or climbing the stairs).

The detailed guidance; quick reference guide; guidance written for patients and carers; audit support; and costing templates have been published.

DRONEDARONE
Dronedarone (Multaq) is an anti-arrhythmic drug belonging to the benzofuran class of anti-arrhythmic compounds. Its main mechanism of action, like that of Amiodarone and Sotalol, is achieved through the inhibition of potassium channels making heart cells less excitable and thereby making AF less likely.
**Side effects**

Dronedarone is generally well tolerated with no increase in serious adverse effects when compared with placebo. The most common side effects noted are: diarrhoea, abdominal discomfort, nausea and vomiting. There is an increased incidence of skin rash, bradycardia (slow heart rhythm) and prolonged QT intervals on electrocardiograms (ECGs) although the latter is rare. Most side effects resolve within the first two weeks of starting the drug, but it is thought that in a proportion of patients, Dronedarone will need to be discontinued because of intolerance.

**Guidelines for access**

The NHS Constitution states: “You have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are clinically appropriate for you”. This means that you have a right to receive an approved drug or treatment if your clinician says it is appropriate for you to receive it and it has have been recommended by NICE’s technology appraisal.

As a patient you also “have the right to expect local decisions on funding of other drugs and treatments to be made rationally following proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you.” Decision making on whether to fund a treatment is left to the local PCT in order for them to provide services they feel best fit the needs of their local population. If a PCT decides that a treatment will not be funded, then it needs to be able to consider whether to fund the treatment for an individual patient on an exceptional basis.

**Further information**

Further information on the NICE Guidance can be found on the NICE website (www.nice.org)

Further information on Atrial Fibrillation can be found on the AFA website (www.atrialfibrillation.org.uk)