In brief

US approval for dronedarone for AF patients

The US Food and Drug Administration (FDA) has approved dronedarone (Multaq®) 400 mg for patients with atrial fibrillation (AF) or atrial flutter (AFL) as a new treatment option to help improve current management of their disease. Dronedarone is the first drug to be approved in the US that has shown a clinical benefit to reduce cardiovascular hospitalisation in patients with AF/AFL.

The anti-arrhythmic agent is indicated to reduce the risk of cardiovascular hospitalisation in patients with paroxysmal or persistent AF or AFL, with a recent episode of AF/AFL and associated cardiovascular risk factors, who are in sinus rhythm or who will be cardioverted. Associated cardiovascular risk factors include age over 70 years, hypertension, diabetes, prior cerebrovascular accident, left atrial diameter ≥50 mm or left ventricular ejection fraction <40%.

The FDA approval is based on five international, multi-centre, randomised clinical trials involving nearly 6,300 patients, including the ATHENA study, which showed that dronedarone 400 mg twice daily, in addition to standard therapy, reduced the combined end point of cardiovascular hospitalisation or death from any cause by 24% ($p<0.001$) when compared to placebo, meeting the study's primary end point.

Clarification: NICE guidance on type 2 diabetes

The news item entitled 'New NICE guidelines on new treatments for type 2 diabetes' in the last issue (*Br J Cardiol* 2009;**16**:163) may have given the impression that the National Institute for Health and Clinical Excellence (NICE) only suggested DPP4-inhibitors be considered in the third-line position (as an add-on metformin and sulphonylurea) for the treatment of type 2 diabetes. In fact, the guideline also recommended consideration in the second-line position as an alternative to sulphonylurea in patients at significant risk of hypoglycaemia or its consequences, or in patients at significant risk of hypoglycaemia or its consequences, or in patients intolerant of or contraindicated to sulphonylureas. Additionally, of the two DPP4-inhibitors currently available, only sitagliptin is licensed for third-line use.

Full details of the guidance (NICE short clinical guides 87) are available on line at: www.nice.org.uk/CG87.

Hypertension tool available based on national guidance

Software is now available to help primary care professionals make hypertension treatment decisions according to National Institute of Health and Clinical Excellence (NICE)/British Hypertension Society (BHS) guidance.

Key features of the program, which has been developed by the Department of Medicines Management at Keele University with the support of an unrestricted educational grant from Takeda, include: treatment and lifestyle recommendations based on NICE/BHS algorithms and guidance; visual aids and personalised materials to support patient discussion, such as a cardiovascular risk assessment. Patients can also take away a personal report summarising their consultation and can be tracked over subsequent clinic visits.

The software will be kept up-to-date by automatic on-line update. Healthcare professionals who would like a free copy should contact Simon Thomas at Keele University by email: s.thomas@mema.keele.ac.uk or by phoning 01782 715458.

Prasugrel recommended by NICE for appropriate patients

The National Institute for Health and Clinical Excellence (NICE) has published a Final Appraisal Determination (FAD) for prasugrel (Efient®).

This states that prasugrel in combination with aspirin is recommended as an option for preventing atherothrombotic events in patients with acute coronary syndrome (ACS) having percutaneous coronary intervention (PCI) only when: immediate PCI for ST-segment-elevation myocardial infarction (STEMI) is necessary; or stent thrombosis has occurred during clopidogrel treatment; or the patient has diabetes mellitus. People currently receiving prasugrel for treatment of acute coronary syndromes whose circumstances do not meet these criteria should have the option to continue therapy until they and their clinicians consider it appropriate to stop.

Patients who have experienced the most severe form of ACS are among those who will benefit from prasugrel. The NICE committee evaluated the cost-effectiveness of prasugrel based on data from the TRITON-TIMI 38 trial. It concluded that the advantage of the new drug over clopidogrel "was plausible" in all patients with STEMI and in all patients with diabetes.

The committee acknowledged that formulations of generic clopidogrel were nearing the market, and the price of clopidogrel would change once generic formulations were made available. It recommended that the guidance on prasugrel should therefore be reviewed in one year's time when any substantial change to the nationally available price of clopidogrel could be considered.

Further information on the guidance can be found at www.nice.org.uk