Comment on NICE Appraisal of Ticagrelor Consultation from BCS/BCIS/RCP 21 July 2011

Comments from

- 1. Page 3, point 1.1, under "unstable angina" A comment should be added that benefit was only observed for ticagrelor in **troponin positive** patients
- 2. Page 7, 3.5: In relation to comments about bleeding, it should specifically stated that rates of major bleeding were significantly higher with ticagrelor compared to clopidogrel in the patients who did not undergo CABG. The rate of CABG in both groups was about 10% and therefore the risk of major bleeding was significantly greater in around 90% of potential candidates for ticagrelor.
- 3. Page 20, 4.2. The last 2 sentences are not accurate. (a) Patients with unstable angina are relatively uncommon and treated according to their clinical risk. Often they do not require revascularisation. Patients with unstable angina are unlikely to benefit from ticagrelor because subgroup analysis shows benefit only for troponin positive patients and unstable angina is troponin negative by definition. (b) I disagree that it is unusual for ACS patients in the UK to undergo CABG. It is unusual for **STEMI** patients to undergo CABG, but around 10% of **NSTEMI** patients do undergo CABG, as reflected in this study.
- 4. Page 22, 4.7 I think the issues raised in point 2 re major bleeding should be included again here under "safety concerns".

Comments from

- 1. as of this a.m. the FDA have approved Ticagrelor should NICE have a condition (as per their "blackbox" warning) re the need for a maximum dose of aspirin i.e. no > than 100 mg
- 2 We need to know something about minimum and maximum **timing** of recommended dose (the median time of the study was 9 months) and the curves (treated versus control) do not separate for a month
- 3 We need to emphasize there is a difference (excess + 22%) in non CABG bleeding