COMMENTS FOR BAUS SECTION OF URO-ONCOLOGY RE ABIRATARONE FOR CASTRATE-RESISTANT METASTATIC PROSTATE CANCER PREVIOUSLY TREATED WITH A DOCETAXEL CONTAINING REGIMEN

BAUS were disappointed with the committees' decision not to approve Abiraterone acetate for use in CRPC following prior chemotherapy. There is global consensus in the uro-oncology community that this agent is the first of a class of drugs which represent a paradigm shift in the management of advanced prostate cancer. The overall survival advantage offered by this agent is unparalleled and represents a major breakthrough in prostate cancer treatment.

In response to the preliminary report we would like to make the following comments:

1. NICE has rejected the manufacturer's economic model based on statistical modelling of data which the ERG conceded is associated with considerable uncertainties. While the committee accepted that the economic model submitted by the manufacturer closely adhered to the NICE reference for economic analysis, they concluded that an alternative model suggested by the ERG would be better applicable despite these uncertainties.

2. The next key issue relates to the manufacturer's preferred population for its base case, comprising of people who had received one prior chemotherapy only. Urologists and Oncologists in the United Kingdom would argue that this assumption is correct and accurately reflects the population of CRPC. Currently patients in only very exceptional circumstances would receive more than one type of chemotherapy prior to being considered for Abiratarone therapy. We would therefore disagree with the Committee's assumption that it was not appropriate to restrict the population considered in the basic analysis to the sub group with one prior chemotherapy. In fact the Expert Review Group also agreed with this in their report.

3. The third point relates to end of life criteria. While the Committee agrees that the criteria related to short life expectancy and extension of life were met, they argued that Abiratarone was not licensed for a small population. The definition of what constitutes a small population are obviously very variable and contentious and clinicians on the ground dealing with these patients would argue that the improvement in overall survival in patients with a limited life expectancy, should be the overall guiding principle. Survival improvements of this magnitude in this population of patients are unprecedented and therefore arguing on hypothetical grounds about relatively small numbers of patients and costs are not relevant.

4. I was personally disappointed to see that the Committee took into account factors in relation to the patient access scheme (PPRS). While the drug is available to patients

currently in England via the patient access scheme, it is not available to patients in Scotland and has recently been approved by the AWMSG for use in Wales. In my opinion this should have no bearing on the Committee's decision as to whether this drug should be approved or not, and again raises the issue of post code prescribing with geographical variations in access to these treatments.

5. It is disappointing that both Abiratarone Acetate and Cabazitaxel have been rejected in recent weeks, despite them both being able to offer patients with castrate-resistant prostate cancer improvement of overall survival. This therefore limits patient choice and limits physicians choice to offer the best available treatments.