Dear Jeremy,
we are aware of your formal process for comments on the guidance. Nevertheless, we would thake the opportunity to comment on the NICE draft proposal "*Total hip replacement and resurfacing arthroplasty for end-stage arthritis of the hip" (review of TA guidance 2 and 44).*

First of all Zimmer is concerned about the absence of members of the British Orthopaedic Association (BOA) or British Hip Society (BHS) at the TAC meeting on 18th September 2013.
Secondly, since patient reported experiences and outcomes (i.e. PROMs) have increased in importance in the UK we are wondering why patient groups were not present at the TAC meeting.

Specifically in regard to the draft proposal, and importantly in our view, two main factors have to be considered by NICE while defining success benchmark:

1- Non-linearity of revision in THA: given known revision rates early after the procedures that are non-device related (infection, dislocation).
2- Device vs. non-device-related revisions: benchmark should consider only device-related revisions, and those parameters should be well defined

Below is some additional information outlining our key concerns:.

- It is important to note that Hip and Knee arthroplasty survivorship is NOT entirely controlled by design of implant. One could argue that the majority of a permissible 5% ten-year revision rate will be consumed by issues/complications beyond the manufacturer's control.
- Reasons for failure of THA procedures are multifactorial. Most of the time the reasons in fact are not implant-related (infection, dislocation, intra-op fractures) and can also be due to surgical technique, surgeon's experience, comorbidities and/or patient incompliance. Globally, there persists more that 1% incidence of revision due to infection, which is not due to the implant itself. There is also more than 1.5% incidence of revision due to instability/dislocation. The majority of dislocation cases are due either to surgeon technique in mal-positioning of implants, patient soft tissue conditions or implant selection. Some facts and remarks:
    - **Indications**: different patient populations may have different risks and failure modes and rates after THA, examples:
        - Revision THA: especially difficult revisions with insufficient bone stock.
        - Dysplastic hips: some manufacturers have specific hip implants for this category of patients.
        - Fractured necks: different treatment modalities recommended with different success rates (unipolar, bipolar, THA, cemented, uncemented, hybrid).
        - Young active patients may have a higher revision rate.
    - **Surgeon's experience**: more experienced surgeons may have a lower rate of revision. This can be important in teaching hospitals where residents, who are less experienced, perform THAs.
    - **New hip implants**: as a revision is not linear with time and specific revisions occur shortly after the procedure (infection, dislocation), new implants when introduced will show a higher revision rate early after the product introduction. This could be interpreted as a failure as the implant will not meet the benchmark. This is the case already with the NICE 90% benchmark.
    - **Survival of a system (cup and stem) vs**. **a single component (cup or stem)**: in some circumstances during a revision surgery, there is a preference and/or an indication

to revise all components. This impacts the results of the non-loosened component and can result in artificially lowering the survival rate.

- There needs to be a strong definition of revision/survival rate:
    - The criteria used for the revision must be clearly defined. Survival rate must be defined according to a well-established methodology (i.e., survival rate according to Kaplan-Meier with mentioning of a confidence interval and the end-point).

Overall, we have a concern about setting this level of reduction in revision performance criteria, without having all of the other issues and questions outlined above addressed.

With regard to 1.2, we suggest that this language be amended. For many patient indications and disease states, as well as physician training and preference, there could be specific reasons why the lowest cost product would not be the appropriate choice. Mandating such could negatively impact patient outcomes.

Lastly, there does not appear to be a clear mechanism for how products with less than ten year performance or adequate time on the market would be able to be utilized if these are best for patient indications. This could potentially hamper the introduction or use of new technologies that could benefit patients.

Thank you for considering our comments.

Kind regards,