ABHI welcomes the opportunity to input into NICE proposals as laid out in its document "Charging for NICE technology appraisal and highly specialised technologies guidance"

Key Points

We do not support the proposal to introduce fees. Such a move could translate into limited patient access to innovative, cost-effective treatments within the UK market as companies redirect investment elsewhere. Given the decision for the UK to exit the EU the need to ensure that the UK is an attractive market for investment gains greater importance.

Topics for Technology Appraisals (TAs) are chosen by the Secretary of State based on potential patient value and health system benefit. As there is significant public benefit it is not appropriate that the cost burden falls to industry. Government should continue to provide sustainable funding for NICE to conduct its role.

We have specific concerns that SMEs could be particularly impacted by introduction of fees at

Fee Level

We have major concerns over the proposed amount and structure of charges. These are significantly more than other countries levy, for example, comparative HTA fees in Australia are £60,000, Canada £40,000 and France under £5,000.

For MedTech, where 98% of companies are SMEs, the introduction of charges may be prohibitive and risk dis-incentivising industry to engage with NICE and would result in the UK being a less desirable market to launch products.

The charges are based on costs and do not take into account the ability to pay or revenue opportunity which is likely to be smaller for both MedTech and Highly Specialised Technology (HST) compared to a pharmaceutical TA.

Clear and transparent methods and cost are absent for arriving at the suggested prices, although they do appear to include significant bureaucratic costs that could be avoided. Given the differences in resource needed, we do not consider that NICE should charge the same price for review and update compared with first TA guidance publication. Also, it is surprising to see the Decision Support Unit (DSU) costs included as core charge. This should not be included as a standard charge to industry given it is not a standard part of the process.

Any introduction of charges should be accompanied by safeguards to audit the level of fees and ensuring the revenue collected is used only for programme purposes.

We would welcome transparency in how these NICE fees have been calculated, by means of a more granular cost breakdown.

Charging Structure

The charges will be exacerbated by the proposed 100% upfront mechanism. Given that uptake of technologies is slow due to the tariff mechanism, the proposed commercial benefit to organisation may not be realised for some considerable time. We would recommend a staggered approach to funding with a significant portion triggered only when target uptake levels have been achieved. This aligns with recommendations within the AAR that NICE extends its role beyond evaluation.

We would seek clarification on the following points:

- There are no plans to extend charging to Interventional Procedure Guidance, Medical Technology or Medical Innovation Briefings
- If a company refused to pay as part of a Multiple TA will the appraisal still proceed? This could lead to a bias towards larger companies that may be more able to fund the charges
- In the above case will evidence related to the technology not included still utilize the evidence of that company in the appraisal?

Next Steps

We would be open to further discussion with NICE on how a fee for service arrangement could support an expanded NICE programme that has equity of access and mandate for MedTech and aligns with the recommendations of the anticipated report from the Accelerated Access Review.

Several areas would need to be considered before we could consider supporting fee arrangements:

- NICE proposes a more realistic fee level and structure
- Performance-related commitments are adopted by NICE with refunds offered if timelines are delayed
- Reform of NICE processes. Non-Pharmaceuticals are currently disadvantaged in selection for TAs given the alternative methods in the MTEP process, there needs to be a single topic selection process with equity of opportunity for MedTech into TA and Abbreviated TA programs.