

## **NICE Methods & Process and Topic Selection Changes: HealthTech Industry Concerns**

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### **1. HealthTech and Cost Saving**

We are concerned by the continued assumption that HealthTech must be cost saving to benefit from any substantive guidance. This is a legacy from the inception of the Medical Technology Evaluation Programme (MTEP) in 2010, and is a concern that was raised at the time. The same expectation to be cost saving to receive positive NICE guidance does not exist for pharmaceuticals, as without exception they are routed to Technology Appraisal (TA).

Whilst it is the case that much HealthTech is indeed cost saving, the narrative is that there is an expectation it will/must always be. This leads to processes such as Topic Selection driving HealthTech away from the TA route and leads to two key unintended consequences:

1. Savings claims are often at best tenuous, built on modest evidence and not plausible in a real-world setting.
2. Industry is incentivised to submit claims to satisfy the programme entry criteria when, in fact, the more plausible argument may indeed be increments in benefits and costs, and the topic should therefore be directed to other programmes.

### **2. Commercial and Managed Access Schemes (C&MA)**

The absence of any meaningful plan to adapt and modify the commercial and managed access programme to be fit for purpose for non-pharmaceutical technologies is a significant and persistent oversight. Such programmes are a valid way to de-risk product introduction and, via evidence generation, reduce uncertainty.

### **3. Topic Selection**

There is clear barrier to fair, equitable and open routing for HealthTech.

In dialogue it has been brought to our attention that MedTech Innovation Briefings (MIBs) are to be utilised for the Topic Selection process. As this was not their original intended use, they are not designed to realistically set out the case for routing a HealthTech innovation through to TA. Moreover, there is no process to re-route a technology from Medical Technology Guidance (MTG) to TA if, during the appraisal, the technology is found to be cost incurring, but could be cost effective, leading to a negative guidance conclusion from NICE.

Whilst, during the consultation webinars held by NICE, industry was reassured that MIBs would be adapted so that they were applicable to all programmes, and options such as re-routing technologies between programmes would be considered as part of the modular updates to the Methods and Process, there is no roadmap and timelines for this to occur.