Written comments prior to attendance at National Assembly for Wales' Health and Social Care Committee inquiry into access to medical technologies in Wales.

There are a number of parallels with this inquiry and the review of the appraisal of orphan and ultra-orphan medicines for the Minister that was produced in October 2013. A series of principles informed that review that would also be relevant for this inquiry. They were:

- Scientific rigour
- Inclusiveness
- Transparency
- Independence
- Challenge and review
- Support for implementation
- Timeliness
- Consistency
- Connectivity
- Equity

NICE undertakes health technology appraisals (HTA's) of selected new medical technologies (including devices and diagnostics) through its Medical Technologies Evaluation Programme (MTEP), using approaches that are regarded as being thorough and fit for the purpose of assessing the relative effectiveness and cost-effectiveness of these technologies. These approaches are employed by AWMSG in their appraisals of medicines for use in NHS Wales, and with slight modifications in other countries.

In many senses, the problem does not lie in the appraisal of these technologies but rather in the implementation of the recommendations emerging from such appraisals. In relation to medicines there is an 'obligation' to implement NICE/AWMSG recommendations within a finite time period, but this does not apply to technologies. In the review of orphan and ultra-orphan medicines the lack of connectivity in the processes surrounding therapeutic appraisal was clearly evident and it was recommended that, for example, the role of WHSCC should be amended to enable closer involvement and integration with the appraisal process.

The engagement of manufacturers with the appraisal process is likely to be key, as the commissioning of technologies is not currently related to any official appraisal process and is based on individual business cases, where degrees of rigour and detail would not adhere to the processes of AWMSG and NICE in their therapeutic appraisals. If manufacturers are to fully engage with an official appraisal process, then frustrations among manufacturers and clinicians evident in the review of orphan and ultra-orphan therapies due to implementation delays, cannot be allowed to be replicated.

There are an expanding number of manufacturers of such technologies within the life sciences sector in Wales, and conversations with some of them indicate their awareness of the need to increase the evidence relating to the effectiveness and cost-effectiveness of their products. Further,

there is a recognised NICE appraisal centre – CEDAR – based at University Hospital of Wales, that has a developing expertise in undertaking such appraisals and which would integrate well within the AWMSG framework.