EUnetHTA evidence submission template: Overview

- EUnetHTA evidence submission template is a flexible tool that reflects all national evidence requirements for reimbursement in Europe
  - Remit was to cover HTA CORE model domains: health condition and use of technology, description and characteristics of the technology, safety, clinical effectiveness
- The inclusion of all evidence requirements means it is broadly applicable to national and joint assessment
- An adaptation process is required to tailor the tool to either national processes or joint processes to reflect the methodology adopted and assessment processes of the agency or agencies involved

EUnetHTA evidence submission template: Analysis

- Template development was based on an analysis of national evidence requirements for reimbursement
- The analysis of evidence requirements showed greater variation in requirements for medical devices than for pharmaceuticals
  - Particularly around the information about the technology
  - Different purposes of submissions in different countries
- Evidence requirements for medical devices more likely to be less structured and less prescriptive than those of pharmaceuticals:
  - More freedom versus less clarity around expectation
- There is a set of commonly requested information across countries relating to: the description of the health condition, use of the technology, authorisation status, description of the technology, clinical effectiveness and safety.

EUnetHTA evidence submission template: Use in regional and national processes

- Two agencies approached us with a request to pilot the evidence submission template to support them to develop and update their tools for their medical devices HTA and reimbursement
  - Both agencies found that the tool provided them with a useful starting point for developing their own tools
  - Both simplified the tool including less methodological information for example removing the approach to synthesis and risk of bias
  - One commented that even with simplifications some companies found completing a submission of evidence challenging

EUnetHTA evidence submission template: Use in joint assessment

- WP5 piloted the draft version of the evidence submission template
  - Some adaptation was completed by WP5 to highlight questions of particular relevance to their assessment
- Following piloting, WP5 will be using a shorter version of the evidence submission template
- It is hoped further adaptation will take place during JA3 as part of finalising the joint assessment production process:
  - Clarity about the amount of methodology required, if there is a de novo assessment less methodology may be required from company
  - Incorporating further developments in EUnetHTA methods guidance
  - Clarity about scope: nationally specific vs cross European information
  - Notes for completion specifically for a EUnetHTA joint assessment

EUnetHTA evidence submission template: Finalisation

- Publication expected end of October
- Publically available
- Presented separately for pharmaceuticals and medical devices
- Presented as a ‘long’ form with all evidence requirements and as a ‘short’ form covering only those most frequently requested
  - Short form developed at request of agencies who use submission templates to obtain evidence for their own independent assessment or who currently have less HTA capacity but wanted support
  - Final documents will be available as templates in ‘Word’ and will be flexible allowing agencies to add, remove and adapt questions and provide further information to aid completion
  - A set of adaptation notes have been created to support agencies with the adaptation process

EUnetHTA evidence submission template: Opportunities and challenges

- HTA and reimbursement of med tech is less established and a concern for agencies – there may be more opportunities for development and change in med tech processes than in pharmaceutical processes
- Creating tools to support regional and national agencies in developing their processes appears to have been welcomed by agencies. Interest has been shown in:
  - Expanding the template to include diagnostic applications
  - Expanding the template to cost and organisational issues
- For joint assessment there may be challenges in creating a concise evidence submission with information relevant to large groups of agencies because of the variation in evidence requirements and variation in purpose of submissions of evidence