Summary results from WP7 research and implications for HTA cooperation

EUnetHTA Forum
September 14, 2017 - Amsterdam

Contents

- Overview of the aims and methods and data received
- Key findings of the research for pharmaceutical and other technologies:
  - Topic selection
  - Timing
  - Assessment production
- Key challenges to cooperation in each of these areas
- Recommendations to support implementation

Aims and methods

- The aim of the study was to analyse HTA and reimbursement processes in EUnetHTA partner countries and identify how within their existing processes agencies could:
  1. engage in EUnetHTA activities,
  2. use jointly produced EUnetHTA HTA information, and
  3. reuse national, regional and local HTA information from other jurisdictions.
- Study included pharmaceutical and non-pharmaceutical procedures for health technologies used in inpatient and outpatient settings

Methods

- Agencies were asked to provide documents that described their HTA and reimbursement processes.
- Information was then abstracted into a standardised template. Where information was missing or was not available agencies completed the template directly.
- The similarities and differences in the procedures were then analysed.

Data received

- Data were received from 59 agencies in 31 EUnetHTA partner countries.
  - Data include England, Scotland and Wales separately
  - Spain and Italy provided information about national and also regional HTA activities
- 94% of countries (29/31) reported assessment procedures for pharmaceuticals
- 71% of countries (22/31) reported assessment procedures for other technologies
- In general pharmaceutical activity is on a larger scale and is more established than activity for other technologies
- For pharmaceuticals, the procedures mainly described single technology assessment including relative effectiveness assessment and assessment of costs, budget impact or cost effectiveness that informed a reimbursement or pricing decision
- For other technologies, the procedures were more varied describing STA and MTA activity and including relative effectiveness assessment, costs and economics and also full HTA. The reason for completing the assessments were also varied.

Topic selection: key findings

	Pharmaceuticals	Other technologies
Who is involved?	Industry, HTA agency, Ministry of Health, payers	As pharma, but also providers, experts, regional authorities
Restrictions on assessment topic	Focus on new products or indications Inpatient products less likely	Rarely restricted by type Inpatient and outpatient products equally likely
Selection of topics for assessment	Often all submitted or all eligible	Selection of topics from those eligible more likely
Priority topics	Large economic impact Potential health benefits Severity of disease Timeliness	Large economic impact Potential health benefits Importance to healthcare Timeliness
Number of topics selected per year	No countries complete ≤10 and 64% (18/28) complete >50	18% (4/22) of countries ≤10 and 27% (6/22) >50
Advanced notice of assessments	In 78% (21/27*) of countries at least 1 agency may not know in advance	In 52% (11/21*) of countries at least 1 agency may not know in advance

*missing data for 1 country

Challenges to cooperation

- In most countries responsibility for topic selection includes multiple national and/or regional agencies, experts and stakeholders and may not include the agency carrying out the assessment or evaluation
- For both pharmaceuticals and other technologies topics for assessment may not be known very far in advance of an assessment being required
- Assessment of other technologies has particular challenges created by:
  - a large number of possible topics,
  - small number of topics considered, and;
  - low predictability and short advance notice within many countries about if and when an assessment will be required.

Recommendations to support implementation

- Build predictability into the model of HTA cooperation:
  - Publication of an annual work plan of topics and timelines for completion
  - Collaborative horizon scanning
  - Topic selection procedures that lead to agreement from all countries of priorities
  - Use of an agreed prioritisation tool to support the process
- Inclusion of a range of stakeholders in topic selection procedures
  - At a national level not only a European level
  - Consideration of launch plans across the EU to maximise timeliness
  - Possible cooperation with regulators to identify pharmaceutical products
- Recognising the low predictability, a facility whereby countries can request a collaborative assessment of priority topics that arise at short notice

Timing of assessments: key findings

	Pharmaceuticals	Other technologies
Scoping in advance of assessment	60% of countries (17/28) have an advance process, but in only 3 does scoping occur >90 days before assessment	77% (17/22) have an advance process, but in only 2 does scoping occur >90 days before assessment
Assessment start relative to marketing authorisation (MA) date	50% of countries (14/28) cannot start before MA 30% of countries (8/28) may start before MA 21% of countries (6/28) it varies	-
Timeframes for completion	35% of countries (6/17*) can have ≤60 days for an assessment 43% countries (9/21*) can have ≤60 days for an evaluation	17% of countries (3/18*) can have ≤60 days for an assessment 22% of countries (2/9*) can have ≤60 days for an evaluation
Timeframes set by the Transparency Directive (TD)	46% of countries (13/28) timeframe set by TD 21% of countries (6/28) timeframe not set by TD 32% of countries (9/28) timeframe for some agencies or procedures set by TD	-

*calculated from the total number of countries producing assessments or evaluations

Challenges to cooperation

- Agencies may not know the question that the assessment must address very far in advance of the assessment starting
- For pharmaceuticals:
  - a (large) minority of countries start work before marketing authorisation is granted to ensure guidance is published close to marketing authorisation
  - timing of initiation is often dependent on company application rather than factors within the agency, and can happen soon after authorisation
- For pharmaceuticals agencies often have a relatively small amount of time to complete their work and the timings are inflexible because the assessment fits into a larger pricing and/or reimbursement process
- For other technologies there is a particular issue to identify when an assessment should start to maximise timeliness for most agencies

Recommendations to support implementation

- Formal support for countries to become involved in earlier scoping activities, for example as part of topic selection procedures
- Incorporate explicit consideration of the best possible timing for the assessment into topic selection and prioritisation processes to maximise value of an assessment for the most countries
- For pharmaceuticals joint assessments need to be available at CHMP positive opinion before the vast majority of agencies have started work
  - however, implementation in the majority of countries could be achieved if a draft report was available at CHMP positive opinion and a final report available at marketing authorisation

Production of assessments: key findings

	Pharmaceuticals	Other technologies
Who is involved in defining the scope	Industry, HTA agency and Ministry of Health	As pharmaceuticals
Synthesis of evidence through assessment or evaluation	Most common approach is to evaluate industry submissions (75% (21/28 countries))	Most common approach is to produce own HTA (82% (18/22 countries))
Content of initial STA assessment	32% of countries (9/28) complete assessments including REA only; 89% (25/28) include REA and economics; 14% (4/28) full HTA*	41% (9/22) of countries complete assessments including REA only; 73% (16/22) include REA and economics; 41% (9/22) full HTA*
Type of assessment	Initial STA more common than initial MTA (100% vs 30% countries)	Initial STA and MTA more comparable (100% vs 70% countries)
Inclusion of full authorised population in assessment	75% of countries unnecessary (21/28)	90% of countries unnecessary (20/22)

*Countries and agencies may adopt more than 1 approach so totals do not add to 100%; economics includes primary and secondary health economic modelling, budget impact analysis and cost comparisons

Challenges to cooperation

- Question to be addressed in an HTA may not be defined by the HTA agency
- For pharmaceuticals the product created is most often an evaluation of a company submission not an HTA
- For countries using cost effectiveness analysis relying on relative effectiveness and economic data from different sources introduces risk to the assessment, even when decision making about relative effectiveness and cost effectiveness is separated, activity may still go on in parallel to be timely
- Companies and agencies may focus on a subgroup for assessment purposes rather than the full authorised population, subgroups may:
  - use different clinical evidence to the full population
  - be defined by local factors or characteristics not associated with differing relative effectiveness (e.g. economic impact, baseline risk)
- For other technologies no single approach to assessment predominates – varied evidence requirements across different countries

Recommendations to support implementation

- For pharmaceuticals reach agreement with countries about the most valued product (assessment vs evaluation) and end goal of HTA cooperation
  - Close work with people using the joint assessments in national processes, including decision makers to ensure the report meets their needs
  - If required, develop tools that support agencies to use joint assessment as part of evaluation and not only national adaptation
- Work with Industry to promote consistency of evidence between EUnetHTA REA and national cost effectiveness analysis
- Include a range of national organisations and stakeholders in the topic selection and planning stages to identify the issues to be addressed in the assessment and possible subgroups
- Topic selection processes for other technologies should include consideration of the HTA domains required in the assessment to maximise usefulness to the most countries

Questions