Manufacturer submission templates to support production of core health technology assessment (HTA) information (EUnetHTA Work Package 7 Subgroup 4)

Objectives

- Produce a manufacturer submission template for relative effectiveness assessment that includes all relevant evidence requirements from European agencies, and can therefore be used by any national agency for HTA and reimbursement decisions, and where appropriate for joint assessments by multiple agencies

- Produce a flexible template so agencies can use the questions and modules relevant to their criteria for decision making

Structure of the draft submission template

HTA CORE model domain: Description of health problem and current use of technology		
Module title	**Content of questions included in module**	**Use of module**
Overview of the disease or health condition	Description of disease, causes or risk factors, natural course, prevalence and incidence, symptoms and burden to patients, consequences to society, aspects of burden targeted by technology	Used for both pharmaceuticals and medical devices
Current clinical management	Current clinical management, issues in management	
Target population	Description and justification, comparators and justification, size of population, pathway of care with new technology	
Current use of technology and comparators	Experience of using the new technology, scale of current use, scale of use of comparators, variations in use of comparators	

HTA CORE model domain: description and technical characteristics of the technology		
Module title	**Content of questions included in module**	**Use of module**
Features of the technology and comparator	Names, active substance, galenic form, product codes, mechanism of action	Adapted for use with medical devices
Detailed characteristics	Description of the technology, diagram, how the technology is used, different models, package contents, history of development	Medical devices only
Administration and dosing	Packaging, volume in packaging, recommended course of treatment dosing, posology	Pharmaceuticals only
Investments, personnel and tools required for use	Context and level of care, concomitant therapies, who administers treatment, infrastructure, supplies and equipment required	Used for both pharmaceuticals and medical devices
Regulatory information	Approval status, wording of indication, other available indications, date of approval, launch date, conditions attached to authorisation	Adapted for use with medical devices
Reimbursement information	Reimbursement status in Europe, indications, restrictions and levels of reimbursement, date of decision, summary of recommendations	Used for both pharmaceuticals and medical devices
Details of manufacture and follow up	Location of manufacture, distribution mechanism, availability of spares and replacements, maintenance requirements, quality control requirements and medical surveillance requirements, statistics of repairs	Medical devices only
Procedures required to use the device	Type or procedure and approach, technical platform, anaesthesia requirements, whether the device is required to complete the procedure, similarities and differences where more than one procedure may be used	Medical devices only
Duration of life, guarantees and warranties	Life of the device and component parts, details of guarantees and warranties.	Medical devices only

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HTA CORE model domains: clinical effectiveness and safety		
Module title	**Content of questions included in module**	**Use of module**
Identification and selection of studies	Research question, databases and registries, search dates, search strategies, inclusion and exclusion criteria, flow chart, methods for identifying ongoing and unpublished studies, citation hits	Used for both pharmaceuticals and medical devices
List of relevant studies	Study reference, registration name/number, conflicts of interest, study dates, study location, source of identification, references to linked publications, status	
Details of the characteristics of studies	Study objective, design, population, intervention, comparator, follow up, primary and secondary outcome, randomisation methods, methods blinding, methods allocation concealment, methods of analysis	
Individual study results for clinical effectiveness	Sample size determination, patient withdrawal, baseline comparison, study results (including assessment measure, time point, n with event, n without event, mean, standard deviation, difference, confidence interval, p value)	
Individual study results for safety	Exposure, discontinuation and withdrawal of treatment, number of adverse events, susceptible patient groups	
Risk of bias study level (randomised studies)	Randomisation sequence, allocation concealment, blinding, complete outcome reporting, other aspects of bias	
Risk of bias study level (observational studies)	Determination of treatment group, baseline comparability, minimisation of bias, complete outcome reporting, intention to treat (ITT) implementation, other aspects of bias	
Risk of bias outcome level	Blinding of outcome assessor, ITT implementation, complete outcome reporting, other aspects of bias	
Methods of evidence synthesis	Type of synthesis, outcomes in synthesis, justifications, methods used for synthesis, heterogeneity, consistency, publication bias, sensitivity analyses	
Conclusions on clinical effectiveness	Relative effects on mortality, morbidity, management, quality of life, satisfaction	
Conclusions on safety	Harms (absolute and versus comparator), dose relationship, onset, changes over time, susceptible group data	
Subgroups	Characteristics, justification, plausibility, analysis methods, results	
Strengths and limitations	Internal validity, relevance of evidence base to scope, factors influencing external validity	
Manufacturer vigilance data	List of incidents, corrective measures, recalls, modifications, methods of optimising or limiting service to minimise risk	Medical devices only
Safety risk management	Methods of optimising or limiting service to minimise risk, changes to marketing authorisation as a result of safety, other harms appearing after granting of marketing authorisation	Pharmaceuticals only

Next steps

The first draft of the templates is being piloted in EUnetHTA relative effectiveness assessments and in one national process. A targeted consultation with national agencies and other stakeholders will take place from January 2015. Agencies will be asked to validate the information included in the data extraction for their agency and to comment on the draft template. Final templates will be available on the EUnetHTA website from October 2015 onwards.

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