An analysis of HTA and reimbursement procedures in EUnetHTA partner countries: Annex 1 Agency data

Disclaimer: EUnetHTA is supported by a grant from the European Commission. The sole responsibility for the content of this document lies with the authors and neither the European Commission nor EUnetHTA are responsible for any use that may be made of the information contained therein.

Contents

Annex table 1: Overview of the HTA processes described

National												
Country	**Agencies providing data**	**Health Technology**	**Assessment of evaluation[1]**	**Capacity (approx. per year)**	**Inpatient Outpatient**	**Informing a reimbursement process**	**Procedure for initial assessment[2]**					
							STA			**MTA**		
							REA	**REA + Ec**	**FULL**	**REA**	**REA + Ec**	**FULL**
Austria	GOEG	Both	Assessment	7	Both	No	Y	Y		Y		
Austria	HVB	Pharma[3]	Assessment	234-445	Outpatient	Yes		Y				
Austria	LBI-HTA	MedTech	Assessment	9	Inpatient	Yes	Y					Y
Belgium	RIZIV	Both	Assessment	P: 125 MT: 300	Both	Yes			Y			
Belgium	KCE	Both	Assessment	6	Both	No			Y			Y
Bulgaria	NCPHA	Pharma	Evaluation	40	Both	Yes		Y				
Croatia	AAZ	Both	Assessment	8	Both	Yes	Y (P)		Y[4] (MT)	Y (P)		Y (MT)
Croatia	CHIF	Both	Evaluation	P: 50-60 MT: <10	Both	Yes		Y[5]			Y[3]	
Czech Rep	SUKL	Pharma	Evaluation	90-100	Outpatient	Yes		Y				
Denmark	DEFACTUM	MedTech	Assessment	10	Both	Yes			Y			Y
Denmark	DMA	Pharma	Assessment	20	Outpatient	Yes		Y[3]		Y	Y	
Denmark	IRF	Pharma	Assessment	<10	Outpatient	No				Y		
Denmark	DMC	Pharma	Both	80	Inpatient [6]	Yes		Y			Y	
England	NICE	Both	Both	P: 73 MT: 84	Both	Yes[7]	Y[8]	Y			Y	
Estonia	EHIF	Pharma	Evaluation	Approximately 100	Both	Yes		Y				
Estonia	UT	Both	Assessment	4-6	Both	Yes		Y			Y	
Finland	FIMEA	Pharma	Assessment	<10	Inpatient	No		Y[3]				
Finland	HILA	Pharma	Evaluation	50	Outpatient	Yes		Y				
France	HAS	Both	Both	P: 100-120 MT: 231	Both	Yes	Y	Y[9]		Y		
Germany	GBA	Both	Assessment	P: 63 MT: 44	Both	Yes	Y					

[1] Assessment = production of an assessment; evaluation = evaluation of a submission of HTA information provided normally by Industry
[2] REA relative effectiveness assessment; REA + Ec relative effectiveness assessment and economic information; FULL full HTA
[3] Some MedTech outpatient assessment also completed but this is not routine
[4] But not economic
[5] Costs and budget impact analysis only
[6] MTAs may also include outpatient interventions as well as inpatient interventions
[7] but not Medical technologies innovation briefings and evidence summaries of new medicines
[8] REA only: interventional procedures, MTA as initial assessment usually only the diagnostics assessment programme
[9] Economic evaluation is required for certain claims of added clinical value

National													
Country	**Agencies providing data**	**Health Technology**	**Assessment of evaluation[1]**	**Capacity (approx. per year)**	**Inpatient Outpatient**	**Informing a reimbursement process**	**Procedure for initial assessment[2]**						
							STA			**MTA**			
							REA	**REA + Ec**	**FULL**	**REA**	**REA + Ec**	**FULL**
Hungary	NIPN	Both	Evaluation	P: 90-100 MT: 100-115	Both	Yes		Y	Y[10]			
Ireland	HIQA	Both	Assessment	5	Both	No			Y			Y
Ireland	NCPE	Pharma	Evaluation	20	Both	Yes		Y				
Italy	AGENAS	MedTech	Assessment	8	Both	No			Y			Y
Italy	AIFA	Pharma	Evaluation	51-75	Both	Yes		Y				
Latvia	NVD	Both	Evaluation	34	Outpatient	Yes		Y				
Lithuania	VASPVT	MedTech	Assessment	2-3	Both	No	Y[11]					
Lithuania	VVKT	Pharma	Assessment	62	Outpatient	Yes		Y[12]				
Malta	DPA/MFH	Pharma	Assessment	20	Both	Yes		Y			Y	
Netherlands	ZIN	Both	Assessment	P: 30-40 MD: 25-35	Both[13]	Yes	Y	Y	Y			
Norway	NIPHNO	Both	Assessment	30-50	Both	Yes		Y				Y
Norway	NOMA	Pharma	Evaluation	40-60	Both	Yes		Y				
Poland	AOTMiT	Both	Both	200	Both	Yes	Y[14]	Y				
Portugal	INFARMED	Pharma[15]	Evaluation	52	Both	Yes		Y				
Romania	NAMMD DA	Pharma	Evaluation	90	Both	Yes		Y[16]				
Scotland	SMC	Pharma	Evaluation	101	Both	Yes	Y[17]	Y				
Scotland	SHTG	MedTech	Assessment	35	Both	Yes		Y				Y
Slovakia	UNIBAFOF	Both	Evaluation	40	Outpatient	Yes		Y				
Slovenia	JAZMP	Pharma	Evaluation	500	Both	Yes		Y				
Slovenia	MoH/ HC	Both[18]	Evaluation	18	Both	No		Y				
Slovenia	HIIS[19]	Pharma	Evaluation	20-30	Both	Yes		Y				
Spain	AEMPS	Pharma	Assessment	44	Both	Yes		Y[20]				
Spain	ISCIII	MedTech	Assessment	19	Both	Yes	Y					
Spain	Spanish Network	MedTech	Assessment	63	Both	Yes		Y			Y	

[10] Assessments of healthcare technologies only not pharma or medical aids
[11] Budget impact analysis may be included if requested
[12] Assessments include both REA and economics, VVKT assess the REA only, economics is assessed by the MoH this is done in parallel
[13] Different processes apply to inpatient and outpatient pharma
[14] Theoretically all should include economic evidence, but many only include relative effectiveness assessment
[15] Procedures for MedTech are currently in development and not yet routine
[16] Scorecard approach including as criteria simplified budget impact analysis and evidence from a local real world data study
[17] 75 full assessments (REA+Ec), 26 abbreviated (REA only)
[18] New large health programmes of which a small number will include the assessment of a technology (product and/or service)
[19] Elements of HTA captured in pricing and reimbursement procedures
[20] Economic evaluation is performed in a second phase of the assessment in collaboration with the regions. This part of the assessment in not publicly available.

National												
Country	**Agencies providing data**	**Health Technology**	**Assessment of evaluation[1]**	**Capacity (approx. per year)**	**Inpatient Outpatient**	**Informing a reimbursement process**	**Procedure for initial assessment[2]**					
							STA			**MTA**		
							REA	**REA + Ec**	**FULL**	**REA**	**REA + Ec**	**FULL**
Sweden	SBU	Both	Assessment	60	Both	Yes	Y		Y		Y	Y
Sweden	TLV	Both	Evaluation	P: 56 MT: 55	Both	Yes		Y	Y			
Switzerland	BAG/FOPH	Both	Both	P: 140 MT: 40	Both[21]	Yes	Y	Y	Y	Y	Y	Y
Wales	AWTTC	Pharma	Evaluation	45	Both	Yes	Y[22]	Y				

Regional												
Country	**Agencies providing data**	**Health Technology**	**Assessment or evaluation**	**Capacity (per year)**	**Inpatient Outpatient**	**Informing a reimbursement process**	**Initial assessment**					
							STA			**MTA**		
							REA	**REA + Ec**	**FULL**	**REA**	**REA + Ec**	**FULL**
Italy	ASSR RER	MedTech	Assessment	10	Both	No				Y	Y	Y
Italy	VENETO	Both	Assessment	2-5	Both	No		Y[23]		Y		
Spain	AETSA	Both	Assessment	P: 2 MT: 15	Both	Yes	Y			Y	Y	
Spain	avalia-t	Both[24]	Assessment	P: <10 MT: 16	Both	Yes			Y		Y	Y
Spain	Madrid	MedTech	Assessment	MT: 10	Both	Yes		Y		Y	Y	
Spain	OSTEBA	Both[17]	Assessment	MT: 29 P: <10	Both	Yes[25]	Y	Y[26]		Y	Y[19]	
Spain	AQuAS	Both[27]	Assessment	MT: 15 P: 15	Both	No	Y		Y			Y
Spain	SCS	Both	Assessment	MT;16 P;<10	Both	No		Y			Y	

[21] The reimbursement track for pharmaceuticals are for outpatient technologies.
[22] Limited submission process only
[23] Cost information
[24] Pharmaceuticals as lifecycle technology assessments
[25] Lifecycle technology assessments only
[26] Approximately a third have economic analysis
[27] Pharmaceuticals as Low-value clinical practices recommendations (ESSENCIAL project)

Annex table 2: Horizon scanning and topic selection

National							
Country	**Agency**	**Health Technology**	**Horizon scanning procedure**	**Does the company initiate the initial process by application**	**Who chooses the topics for assessment**	**Are topic selection criteria used**	**How far in advance does the agency know they will have to assess topic**
Austria	HVB	Pharma	No	Yes	Company	No criteria	Not known in advance
Austria	GOEG	Both	No	No	Ministry of Health	No formal criteria	less than 6 months in advance
Austria	LBI-HTA	MedTech	No	No	Ministry of Health, Payer, Working group of representatives (mainly medical experts) from federal level, regional level and social insurance.	Informal criteria	Less than month
Belgium	RIZIV	Pharma	No (not officially or explicitly)	Partly	Company, HTA agency, Minister of Social Affairs	no criteria	Not known in advance
Belgium	RIZIV	MedTech	Yes (for invasive medical devices only)	Partly	Company, Ministry of Health, Other	no criteria	Not known in advance
Belgium	KCE	Both	No	No	HTA agency, Ministry of Health, National Insurance and stakeholders	Yes	less than 6 months in advance (around 4 months)
Bulgaria	NCPHA	Pharma	No	Yes	Company, Ministry of Health, Payer, HTA agency	Yes	Not known in advance
Croatia	AAZ	Both	No	No	Ministry of Health, Croatian Health Insurance Fund and hospital managements	No criteria[28]	Few days up to 1-2 weeks (Less than month)
Croatia	CHIF	Both	No	Yes	Company	no criteria	Not known in advance (3 weeks) but depends on number of submissions
Czech Rep	SUKL	Pharma	No	Yes	Company, HTA agency (for reviews), Payer	no criteria	Not known in advance; but reassessments are known less than 12 months in advance
Denmark	DMA	Pharma	No	Yes	Company, HTA agency (for reviews)	no criteria	Not known in advance
Denmark	DEFACTUM	MedTech	No	No	Hospital providers	no criteria	Not known in advance

[28] Assessment is carried out upon request from the decision maker and as such topic selection criteria don't apply in practise (Severity, economic and resource impact, policy importance, inappropriate use or variation)

National							
Country	**Agency**	**Health Technology**	**Horizon scanning procedure**	**Does the company initiate the initial process by application**	**Who chooses the topics for assessment**	**Are topic selection criteria used**	**How far in advance does the agency know they will have to assess topic**
Denmark	DMC	Pharma	No	Yes[29]	Company or anybody can propose that a therapeutic area should be assessed, The Danish Medicine Council determines which therapeutic area to develop joint regional treatment guideline for.	Yes	3 months
England	NICE	Pharma	Yes	No	NICE with the Department of Health, including consultation with Industry, patient, clinical and other health related groups	Yes	1 year or more
England	NICE	MedTech	No[30]	Partly	HTA agency: However, NICE can only choose from the topics for which it is notified usually by company sponsors, clinical and hospital managers	Yes	less than 6 months in advance
Estonia	EHIF	Pharma	No	Yes	Company	no criteria	Not known in advance
Estonia	UT	Both	Yes	No	HTA Council– the steering committee of HTA agency that includes representatives from the Estonian Health Insurance Fund, Ministry of Social Affairs, Estonian Hospitals Association, Union of General Practitioners, State Agency of Medicines, Tallinn University of Technology, and University of Tartu.	Yes	Less than 6 months ; new HTA topics are discussed and selected in HTA Council meetings
Finland	FIMEA	Pharma	No	No	HTA agency	Yes	less than a month (1-2 weeks)
Finland	HILA	Pharma	No	Yes	Company	no criteria	Not known in advance
France	HAS	Pharma	Yes	Yes (rapid assessment only)	For first assessment: company For reassessment: requests from institutions, professionals, patients organisations, Ministry of Health, or at HAS initiative	Yes (planned activity)	less than 12 months in advance (planned topics), not known in advance (submissions)
France	HAS	MedTech	Yes[31]	Yes[32]	Ministry of Health, Patient groups, Clinical or Medical Societies, HTA agency, Payer, Company For medical procedures: MoH, payer, HTA agency	Yes	less than 12 months in advance (planned topics), not known in advance (submissions)
Germany	GBA	Pharma	No	Yes (partly)	Company (but defined by market access)	no criteria	Not known in advance (except for extension of indication)

[29] Company initiates process when application is regarding new medicine and new indication, however anybody can make request regarding assessment of more than one medicine.
[30] Procedure currently being set up
[31, 30] No for medical procedures

National							
Country	**Agency**	**Health Technology**	**Horizon scanning procedure**	**Does the company initiate the initial process by application**	**Who chooses the topics for assessment**	**Are topic selection criteria used**	**How far in advance does the agency know they will have to assess topic**
Germany	GBA	MedTech	No	No	The G-BA impartials, Central Federal Association of Health Insurance Funds, the national and regional association(s) of Statutory Health Insurance Physicians and Dentists , the German Hospital Federation (DKG), or the patient representatives.	Yes	Less than a month
Hungary	NIPN	Both	No	Yes	Company, Payer	no criteria	Not known in advance
Ireland	NCPE	Pharma	Yes	Yes	Company, HTA agency, Payer	Yes	some months to a year before the assessment
Ireland	HIQA	Both	Yes	No	HTA agency	Yes	Variable
Italy	AIFA	Pharma	Yes[33]	Yes	Company	no criteria	Not known in advance
Italy	AGENAS	MedTech	Yes	No	Committee composed by AGENAS, Ministry of Health representatives and Regional Health Authorities representatives	Yes	less than a month
Latvia	NVD	Both	No	Yes	Company	no criteria	Not known in advance
Lithuania	VVKT	Pharma	No	Yes	Company	no criteria	Not known in advance
Lithuania	VASPVT	MedTech	No	It is possible	HTA agency, Committee (MoH), Applicants	Yes	Variable
Malta	DPA/MFH	Pharma	No	No	Ministry of Health	no criteria	Variable deadlines but could be very tight
Netherlands	ZIN	Pharma	Yes	Yes	For outpatient pharma company submits application, for inpatient pharma there is a topic selection process	Criteria for inpatient only	Not known in advance (6 months to 1 year in advance)
Netherlands	ZIN	MedTech	No	Partly	Payer, Company[34], Other: At any given time point, a patient organization, a manufacturer or an insurer	Yes (Not published)	Variable
Norway	NIPHNO	Both	Yes	It is possible	Regional Health Authorities Order Forum	Yes	Pharmaceuticals at day 120 during application process for MA. Other health technologies no specific timing or with CE approval
Norway	NOMA	Pharma	Yes	Yes (outpatient only)	HTA agency, company, Regional Health Authorities Order Forum (inpatient)	Yes	Pharmaceuticals at day 120 during application process for MA. (inpatient)

[33] Since 2016
[34] ZIN is involved in the process as well

National							
Country	**Agency**	**Health Technology**	**Horizon scanning procedure**	**Does the company initiate the initial process by application**	**Who chooses the topics for assessment**	**Are topic selection criteria used**	**How far in advance does the agency know they will have to assess topic**
							Not known in advance, but HTA + economic evaluation are mandatory in order to get reimbursement for outpatient
Poland	AOTMIT	Both	No	Yes	Company, Ministry of Health, Clinical or Medical Societies	no criteria	Not known in advance
Portugal	INFARMED	Pharma	No	Yes	Company, HTA agency, Ministry of Health	no criteria	Not known in advance (centralised products are known few days/months after the MA.)
Romania	NAMMD	Pharma	No	Yes	Company	Yes[35]	Not known in advance
Scotland	SMC	Pharma	Yes	No	Company, HTA agency	No[36]	Variable
Scotland	SHTG	MedTech	Yes	No	HTA agency	Yes	Less than 6 months in advance (3-6 months)
Slovakia	UNIBAFOF	Both	No	Yes	Company, Ministry of Health	no criteria	Not known in advance
Slovenia	JAZMP	Pharma	No	Yes	Company	no criteria	Not known in advance
Slovenia	MoH/HC	Both[37]	No	It is possible	Clinical or medical societies, health care providers, ministry of health, payer, other legal entities (company)	no criteria	Not known in advance
Slovenia	HIIS	Pharma	No	Yes	Company, health care provider, payer	no criteria	Not known in advance
Spain	AEMPS	Pharma	No	No	HTA agency, Ministry of Health, Payer	no criteria	Right after the CHMP decision
Spain	ISCIII	MedTech	Yes	No	Ministry of Health, HTA agency	Yes	Less than a month (2-4 weeks)
Spain	Spanish Network	MedTech	Yes	No	Ministry of Health, HTA agency	Yes	Less than a month

[35] NAMMD prioritize orphans, EMA fast-tracked and medicines that are national health priorities.
[36] Generally SMC assesses the majority of newly licensed medicines, including new formulations, new indications and line extensions of established products. For minor licence extensions population size may be taken into consideration.
[37] New large health programmes of which a small number will include the actual assessment of a technology (product and/or service)

National							
Country	**Agency**	**Health Technology**	**Horizon scanning procedure**	**Does the company initiate the initial process by application**	**Who chooses the topics for assessment**	**Are topic selection criteria used**	**How far in advance does the agency know they will have to assess topic**
Sweden	SBU	Both	No	No	HTA agency, Ministry of Health, the Council for Knowledge-Based Policy	Yes	Assessments commissioned by the government are known in advance
Sweden	TLV	Both	Yes	Yes	Company, Payer	Yes	Not known in advance
Switzerland	BAG/FOPH	Both[38]	No	No	Ministry of Health	Yes	less than 6 months in advance
Switzerland	BAG/FOPH	Pharma	No	Yes	Company	no criteria	Not known in advance
Switzerland	BAG/FOPH	MedTech	Yes	Yes	Company	no criteria	Not known in advance
Wales	AWTTC	Pharma	Yes	No	Company, HTA agency in conjunction with the AWMSG steering committee	Yes	Topics are identified during the horizon scanning stage

Regional							
Country	**Agencies providing data**	**Health Technology**	**Horizon scanning procedure**	**Does the company initiate the initial process by application**	**Who chooses the topics for assessment**	**Are topic selection criteria used**	**How far in advance does the agency know they will have to assess a topic**
Italy	ASSR	MedTech	Yes (for some)	No	HTA agency	Criteria not defined	Not defined
Italy	Veneto	Both	No	No	Regional commissions	Yes	Not defined
Spain	AETSA	Both	Yes[39]	No	HTA agency, Ministry of Health, Clinicians and health care managers, the Regional Andalusian Public Health System	Yes	3 weeks -2 months
Spain	avalia-t	Both	Yes	No	Ministry of Health, Regional Galician Public Health System; Clinical and Medical Societies and Health professionals.	Yes	Regional requirements not known in advance. National requirements 4 weeks
Spain	Madrid	MedTech	No	No	Ministry of Health	Yes	4 weeks

[38] HTA programme that includes topics for disinvestment and also topics where there is no sponsor
[39] emergent technology reports

Spain	OSTEBA	Both	Yes[40]	No	Ministry of Health, HTA agency	Yes	4 weeks
Spain	AQUAS	Both	No	No	Clinical or Medical Societies, HTA agency, Ministry of Health	Yes	1-2months
Spain	SCS	Both	No	No	Hospital managers, general directors and Ministry of Health	Yes	Around 4 weeks

[40] lifecycle technology reports

Annex table 2A: Topic selection criteria

National																
Country	**Agencies providing data**	**Health Technology**	**Severity**	**Population size**	**Health benefits**	**Economic and resource impact**	**Timely**	**Policy importance**	**Ethical and social importance**	**Importance to healthcare**	**Controversial**	**Uncertainty in benefits**	**Inappropriate use or variation**	**Innovative**	**Available alternatives**	**Implementation**
Austria	LBI-HTA	MedTech					Yes							Yes		
Belgium	KCE	Both	Yes	Yes		Yes	Yes	Yes	Yes	Yes						
Denmark	DMC[41]	Pharma		Yes		Yes		Yes								
England	NICE	Pharma	Yes	Yes	Yes	Yes	Yes						Yes			
England	NICE	MedTech			Yes	Yes	Yes			Yes				Yes		
Estonia	UT	Both	Yes	Yes	Yes	Yes		Yes		Yes					Yes	
Finland	FIMEA	Pharma	Yes	Yes		Yes	Yes									
France	HAS	Pharma		yes	Yes	Yes		yes		Yes		yes				
France	HAS	MedTech			Yes	Yes				Yes						
Germany	GBA	MedTech			Yes	Yes										
Ireland	NCPE	Pharma				Yes										
Ireland	HIQA	Both	Yes	Yes	Yes	Yes	Yes	Yes		Yes					Yes	Yes
Italy	AGENAS	MedTech	Yes	Yes		Yes						Yes	Yes			
Lithuania	VASPVT[42]	MedTech	Yes	Yes	Yes	Yes				Yes				Yes	Yes	
Netherlands	ZIN	Pharma (inpatient)		Yes	Yes	Yes		Yes		Yes						
Netherlands	ZIN	MedTech	Yes			Yes			Yes	Yes					Yes	
Norway	NIPHNO	Both	Yes		Yes	Yes										
Norway	NOMA	Pharma	Yes		Yes	Yes		Yes								
Romania	NAMMD	Pharma	Yes[43]			Yes		Yes								
Scotland	SHTG	MedTech			Yes	Yes	Yes			Yes		Yes	Yes			Yes

[41] Only for assessments of more than one medicine for a disease area
[42] Criteria are used but agency is not part of this process
[43] If no available alternative

National																
Country	**Agencies providing data**	**Health Technology**	**Severity**	**Population size**	**Health benefits**	**Economic and resource impact**	**Timely**	**Policy importance**	**Ethical and social importance**	**Importance to healthcare**	**Controversial**	**Uncertainty in benefits**	**Inappropriate use or variation**	**Innovative**	**Available alternatives**	**Implementation**
Spain	ISCIII	MedTech[44]			Yes	Yes				Yes				Yes		
Spain	Spanish Network	MedTech[45]			Yes	Yes				Yes				Yes		
Sweden	SBU	Both	Yes	Yes	Yes	Yes	Yes		Yes	Yes	Yes	Yes	Yes		Yes	
Sweden	TLV	Both	Yes	Yes	Yes	Yes	Yes		Yes	Yes	Yes					
Switzerland	BAG/FOPH	Both	Yes		Yes	Yes	Yes					Yes	Yes			
Wales	AWTTC	Pharma			Yes	Yes										

Regional																
Country	**Agencies providing data**	**Health Technology**	**Severity**	**Population size**	**Health benefits**	**Economic and resource impact**	**Timely**	**Policy importance**	**Ethical and social importance**	**Importance to healthcare**	**Controversial**	**Uncertainty in benefits**	**Inappropriate use or variation**	**Innovative**	**Available alternatives**	**Implementation**
Spain	AETSA	Both	Yes	Yes	Yes	Yes				Yes				Yes		
Spain	avalia-t	Both	Yes	Yes	Yes	Yes		Yes	Yes	Yes		Yes		Yes		Yes
Spain	Madrid	MedTech	Yes	Yes	Yes	Yes				Yes				Yes		
Spain	OSTEBA	Both	Yes	Yes	Yes	Yes				Yes				Yes		
Spain	AQUAS	Both	Yes	Yes	Yes	Yes				Yes				Yes		
Spain	SCS	Both	Yes	Yes	Yes	Yes				Yes				Yes		

[44] for early alert system only
[45] for early alert system only

Annex table 3: Overview of the HTA assessment processes

National									
Country	**Agencies providing data**	**Health Technology**	**Is there a scoping process occurring before the start of assessment**	**Who defines the scope of the assessment**	**Assessment process**	**Combined or separate REA and economic assessment**	**Time provided assessment (a) or evaluation (e)**	**Quality Assurance Process**	**Nature of quality assurance process**
Austria	GOEG	Both	Yes	HTA agency, Ministry of Health	Agency carries out its own HTA using evidence from company	Combined[46]	Up to 12 months (a)	Yes	Both
Austria	HVB	Pharma[47]	No	Company in its application with evaluation by HVB	Agency carries out its own HTA using evidence from company	Combined	4-6 weeks (e)	Yes	Internal
Austria	LBI-HTA	Medtech	Yes	HTA agency	Agency carries out its own HTA and identifies the evidence to use itself	N/A	5 months (a)	Yes	Both
Belgium	RIZIV	Both	Yes[48]	HTA agency	Agency carries out its own HTA using evidence from company	Combined [49]	60 days (pharma) 100 days (MT) (a)	Yes	Both
Belgium	KCE	Both	Yes	HTA agency	Agency carries out its own HTA and identifies the evidence to use itself	Combined	Up to 12 months (a)	Yes	Both
Bulgaria	NCPHA	Pharma	No	Ministry of Health, Payer	Company (MAH) provides the HTA that is used in the assessment	Combined	40 days (e)[50]	Yes	Internal
Croatia	AAZ	Both	Yes	HTA agency, Payer, Industry, MoH, CHIF or hospital managements	Agency carries out its own HTA and identifies the evidence to use itself	N/A	3 month[51] pharma; 4-9 months MT (a)	Yes	Internal
Croatia	CHIF	Both	No	Company in its application with evaluation by CHIF	Company (MAH) provides the HTA that is used in the assessment	Combined	15-60 days (e)	Yes	Internal

[46] Pharma: when Full HTA, assessment is combined, when Rapid assessment it is REA only.
[47] Some MedTech outpatient assessment also completed but this is not routine and uses different methods to pharmaceuticals
[48] Pharma only
[49] For non-invasive medical devices there is no formal assessment.
[50] 90 days is the length of the total procedure with 40 days provided to produce the draft HTA report from the receipt of the submission.
[51] By law it should take 1 month

National									
Country	**Agencies providing data**	**Health Technology**	**Is there a scoping process occurring before the start of assessment**	**Who defines the scope of the assessment**	**Assessment process**	**Combined or separate REA and economic assessment**	**Time provided assessment (a) or evaluation (e)**	**Quality Assurance Process**	**Nature of quality assurance process**
Czech Rep	SUKL	Pharma	No	Company, Payer	Company (MAH) provides the HTA that is used in the assessment	Combined	Not defined	Yes	Internal
Denmark	DEFACTUM	Medtech	Yes	HTA agency, decision makers, clinicians	Agency carries out its own HTA and identifies the evidence to use itself	Combined	Not defined	Yes	Both
Denmark	DMA	Pharma	No	Company, HTA agency	Company (MAH) provides the HTA that is used in the assessment	Combined	90 days (e)	No	NA
Denmark	DMC	Pharma	Yes	HTA agency	Company (that is the MAH or the MAH representative) provides the HTA that is used in the assessment process[52]	Separate	For new medicines: 12 weeks (e) For therapeutic areas: 6-8 months (a)	Yes	Both
England	NICE	Both	Yes	HTA agency, Ministry of Health with consultation	Company (MAH) provides the HTA that is used in the assessment[53]	Combined	10-24 weeks (a), 8-10 weeks (e)[54]	Yes	Both
Estonia	EHIF	Pharma	No	Company, HTA agency	Company (MAH) provides the HTA that is used in the assessment process	Separate	30 days (e) - REA	Yes	External
Estonia	UT	Both	Yes	Ministry of Health, Payer, HTA agency	Agency carries out its own HTA and identifies the evidence to use itself	Combined	Not defined	Yes	Both
Finland	FIMEA	Pharma	Yes	HTA agency, clinical experts	Agency carries out its own HTA and identifies	Combined	4-6 weeks (a)	Yes	External

[52] Assessment of more than one medicine: Agency carries out its own HTA and identifies the evidence to use itself (specify agency).
[53] Pharma can be placed in 3 different programmes, the agency carries out its own HTA using evidence from company in evidence summaries of new medicines (ESNM) programme. For MedTech there are 4 programmes in 2 (MIBs and DAP) a third party provides the HTA using evidence from company, in the IP programme the agency carries out its own synthesis of evidence and identifies the evidence to use itself.
[54] Depends on the programme

National									
Country	**Agencies providing data**	**Health Technology**	**Is there a scoping process occurring before the start of assessment**	**Who defines the scope of the assessment**	**Assessment process**	**Combined or separate REA and economic assessment**	**Time provided assessment (a) or evaluation (e)**	**Quality Assurance Process**	**Nature of quality assurance process**
					the evidence to use itself				
Finland	HILA	Pharma	No	Company, HTA agency	Company (MAH) provides the HTA that is used in the assessment	Combined	180 days total (e)	No	NA
France	HAS	Both	No[55]	HTA agency, Industry	Agency carries out its own HTA and uses evidence provided by the company after checking for completeness of the dossier [56]	Separate but in parallel[57]	90 days STA pharma, 180 days MTA and MT (a)	Yes	Both
Germany	GBA	Both	No (pharma)	Agency (Pharma)	Agency carries out its own HTA and identifies the evidence to use itself or uses evidence provided by the company	Combined[58]	3 months pharma 3-4.5 months MT (a)	Yes	Internal
Hungary	NIPN	Both	No	Ministry of Human Capacities (in Hungary healthcare belongs to this Ministry)	Company (MAH) provides the HTA that is used in the assessment	Combined	Up to 43 days pharma 15-30 days MT (e)	Yes	Internal
Ireland	HIQA	Both	Yes	HTA agency	Agency carries out its own HTA and identifies the evidence to use itself	Combined	Not defined	Yes	Both
Ireland	NCPE	Pharma	Yes	HTA agency	Company (MAH) provides the HTA that is used in the assessment	Combined	90 days (e)	Yes	Both
Italy	AGENAS	MedTech	Yes	HTA agency	Agency carries out its own HTA and identifies	Combined	Not defined	Yes	Both

[55] HAS doesn't have a proper scoping phase but the scope is usually defined at the beginning of our written appraisals
[56] Depending on the programme HAS may also evaluate company submissions and also carry out its own HTA and identify the evidence to use itself
[57] For assessments requiring submission of an economic evaluation
[58] Inpatient MedTech only

National									
Country	**Agencies providing data**	**Health Technology**	**Is there a scoping process occurring before the start of assessment**	**Who defines the scope of the assessment**	**Assessment process**	**Combined or separate REA and economic assessment**	**Time provided assessment (a) or evaluation (e)**	**Quality Assurance Process**	**Nature of quality assurance process**
					the evidence to use itself				
Italy	AIFA	Pharma	No	Industry	Company (MAH) provides the HTA that is used in the assessment	Combined	180 days total, 100 days total orphan (e)	Yes	Both
Latvia	NVD	Both	No	Industry	Company (MAH) provides the HTA that is used in the assessment	Combined	180 days total (e)	No	NA
Lithuania	VASPVT	MedTech	No	HTA agency and committee	Agency carries out its own HTA and identifies the evidence to use itself	Combined	90 days (a)	No	NA
Lithuania	VVKT	Pharma	No	Reimbursement committee	Agency carries out its own HTA using evidence from company	Separate but in parallel	90 days (a)	No	NA
Malta	DPA/MFH	Pharma	No	HTA agency	Agency carries out its own HTA and identifies the evidence to use itself[59]	Combined	12 weeks (a)	No	NA
Netherlands	ZIN	Both	Yes	HTA agency	Agency carries out its own HTA using evidence from company[60]	Combined	~70 days (P), 4 months MT (a)	Yes	Both
Norway	NIPHNO	Both	Yes	Clinical experts patient representatives and regional health authority representatives	Agency carries out its own HTA. For STAs we also use evidence from company	Combined	12 months (P) 180 days (MT)	Yes	Both
Norway	NOMA	Pharma	Yes	Industry, HTA agency	Company (MAH) provides the HTA that is used in the assessment	Combined	180 days total (e)	Yes	Both
Poland	AOTMiT	Both	No	Industry, Ministry of Health	Company (MAH) provides the HTA that is	Combined	Varies (a) 60 days (e)	Yes	Both

[59] MAH may also provide evidence when applying which is also taken into consideration
[60] MedTech only if supplied by the company

National									
Country	**Agencies providing data**	**Health Technology**	**Is there a scoping process occurring before the start of assessment**	**Who defines the scope of the assessment**	**Assessment process**	**Combined or separate REA and economic assessment**	**Time provided assessment (a) or evaluation (e)**	**Quality Assurance Process**	**Nature of quality assurance process**
					used in the assessment[61]				
Portugal	INFARMED	Pharma	No	Industry, HTA agency	Company (MAH) provides the HTA that is used in the assessment	Separate	75 days (e)	No	NA
Romania	NAMMD	Pharma	No	Industry	MAH provides the information needed for the scorecard based evaluation	Combined[62]	90 days total (e)	Yes	Internal
Scotland	SMC	Pharma	No	Industry	Company (MAH) provides the HTA that is used in the assessment	Combined	8 weeks (e)	Yes	Internal
Scotland	SHTG	MedTech	Yes	HTA agency, clinical or medical societies, evidence review committee	Agency carries out its own HTA and identifies the evidence to use itself[63]	Combined	13-26 weeks (a)	Yes	Both
Slovakia	UNIBAFOF	Both	No	Industry, ministry of health	Company (MAH) provides the HTA that is used in the assessment process	Combined	12 weeks (e)	No	NA
Slovenia	JAZMP[64]	Pharma	Yes	General scope: MoH in the pricing rule; Particular scope: the Company by its application whose eligibility is tested by JAZMP	Company (MAH) provides the HTA that is used in the assessment process	Combined	90 days total (e)	Yes	Internal

[61] AOTMiT may also carry out its own HTA at the request of the Ministry of Health
[62] Scorecard approach including as criteria simplified budget impact analysis
[63] SHTG also provides companies with an option to submit to SHTG in which case their submission will be evaluated (innovative medical technologies overview)
[64] Elements of HTA captured in pricing and reimbursement procedures

National									
Country	**Agencies providing data**	**Health Technology**	**Is there a scoping process occurring before the start of assessment**	**Who defines the scope of the assessment**	**Assessment process**	**Combined or separate REA and economic assessment**	**Time provided assessment (a) or evaluation (e)**	**Quality Assurance Process**	**Nature of quality assurance process**
Slovenia	MoH/ HC	Both[65]	No	The applicant[66]	Third party provides the HTA and identifies the evidence to use itself	Combined	Not defined	No	NA
Slovenia	HIIS	Pharma	No	Company in its application with evaluation by HIIS	Company (MAH) provides the HTA that is used in the assessment process	Combined	90 days (e)	Yes	Internal
Spain	AEMPS	Pharma	Yes	Committee including HTA agency, Ministry of Health and regional representatives	Agency carries out its own HTA and identifies the evidence to use itself	Separate	7 months (a)	Yes	Both
Spain	ISCIII	MedTech	Yes	Ministry of Health, HTA agency	Agency carries out its own HTA and identifies the evidence to use itself	Combined[67]	3-9 months (a)	Yes [68]	Both
Spain	Spanish Network	MedTech	Yes	Ministry of Health, HTA agency	Agency carries out its own HTA and identifies the evidence to use itself	Combined	6-9 months (a)	Yes[69]	Both
Sweden	SBU	Both	Yes	HTA agency, Patient groups, clinical of medical specialists, Ministry of Health	Agency carries out its own HTA and identifies the evidence to use itself	Combined	24 months (a)	Yes	Both
Sweden	TLV	Both	No	HTA agency, Industry, Payer	Company (MAH) provides the HTA that is used in the assessment process	Combined	3-6 months pharma; and MT (e)	Yes	Both
Switzerland	BAG/FOPH	Both	Yes	HTA agency, Industry, Ministry of Health	Company (MAH) provides the HTA that is	Combined	20 days (e pharma), 2-3	Yes	Both

[65] New large health programmes of which a small number will include the actual assessment of a technology (product and/or service)
[66] the Ministry of Health of the Republic of Slovenia, HIIS, health care providers, professional associations and societies in the field of health care in Slovenia, Medical Chamber of Slovenia, Pharmaceutical Chamber of Slovenia, Chamber of Nursing and Midwifery Services of Slovenia, other legal entities (could be a company)
[67] For both (ISCIII and Spanish network) run two programmes HTA and Early Awareness and Alert System, however Early Awareness and Alert System is REA only when completed by ISCIII.
[68] HTA programme yes, Early Awareness and Alert System does not have QA process
[69] Medical technology non-pharma appraisal programme follows QA process however Early Awareness and Alert System does not.

National									
Country	**Agencies providing data**	**Health Technology**	**Is there a scoping process occurring before the start of assessment**	**Who defines the scope of the assessment**	**Assessment process**	**Combined or separate REA and economic assessment**	**Time provided assessment (a) or evaluation (e)**	**Quality Assurance Process**	**Nature of quality assurance process**
					used in the assessment process[70]		months (e non-pharma)		
Wales	AWTTC	Pharma	Yes	Industry, HTA agency	Company (MAH) provides the HTA that is used in the assessment process	Combined	8 weeks (e)	Yes	Both

Regional									
Country	**Agencies providing data**	**Health Technology**	**Is there a scoping process occurring before the start of assessment**	**Who defines the scope**	**Assessment process**	**Combined or separate REA and economic assessment**	**Time provided for assessment (a) or evaluation (e)**	**Quality Assurance Process**	**Nature of the quality assurance process**
Italy	ASSR	MedTech	Yes[71]	HTA agency	Agency carries out its own HTA and identifies the evidence to use itself[72]	Combined	Not defined	No	NA
Italy	Veneto	Both	No	NA	Agency carries out its own HTA and identifies the evidence to use itself	NA	Not defined	No	NA
Spain	AETSA	Both	Yes	HTA agency, Ministry of Health, Clinical or Medical Societies, Payer, Hospital providers	Agency carries out its own HTA and identifies the evidence to use itself	Combined	20-40 weeks (a)	Yes	External
Spain	avalia-t	Both	Yes	HTA agency, hospital providers, Ministry of Health	Agency carries out its own HTA and identifies the evidence to use itself	Combined[73]	12-26 weeks (a)	Yes	External

[70] For the HTA programme the agency carries out its own assessments and identifies the evidence to use itself
[71] Within the programme high cost technologies the scope is produced but not for the medical devices programme.
[72] ASSR through high cost technology programme identifies evidence themselves, but through the medical devices programme agency uses evidence from the company
[73] Avalia T through TA programme produces combined assessment but through Lifecycle Technology Assessments (LTA) programme produces REA only

Regional									
Country	**Agencies providing data**	**Health Technology**	**Is there a scoping process occurring before the start of assessment**	**Who defines the scope**	**Assessment process**	**Combined or separate REA and economic assessment**	**Time provided for assessment (a) or evaluation (e)**	**Quality Assurance Process**	**Nature of the quality assurance process**
Spain	Madrid	MedTech	Yes	HTA agency, hospital providers, Ministry of Health	Agency carries out its own HTA and identifies the evidence to use itself	Combined	33 weeks (a)	Yes	External
Spain	OSTEBA	Both	Yes	HTA agency, hospital providers, Ministry of Health	Agency carries out its own HTA and identifies the evidence to use itself	Combined[74]	30-76 weeks (a)	Yes	External
Spain	AQUAS	Both	Yes	HTA agency, hospital providers, Ministry of Health, clinical or medical societies	Agency carries out its own HTA and identifies the evidence to use itself	Combined[75]	4-30 weeks (a)	Yes	External
Spain	SCS	Both	Yes	Patient groups, Hospital managers and providers, ministry of health	Agency carries out its own HTA and identifies the evidence to use itself besides using evidence from company	Combined	30 weeks (a)	Yes	Both

[74] OSTEBA through TA programme produces combined assessment but through Lifecycle Technology Assessments (LTA) programme produces REA only
[75] AQuAS through TA programme produces combined assessment but through Low-value clinical practices recommendations (ESSENCIAL project) programme produces REA only

Annex table 4: Advice and decision making

National												
Country	**Agency**	**Health Tech**	**Are recommendations and advice made to support decision maker**	**Who is making the recommendation**	**Additional documents provided to the decision maker**						**Who uses the advice for decision-making**	**What decision does the assessment inform**
					Company submission of evidence	**Full HTA Report**	**Summary of the HTA report**	**Critique of the HTA report**	**Clinical trial documents**	**Others**		
Austria	HVB	Pharma	Yes	Committee	Yes	Yes			Yes	Yes	Insurance funds or other reimbursement agencies; Payers	Reimbursement; pricing; quality standards
Austria	GOEG	Both	Yes	HTA agency; Other institutions		Yes					Insurance funds or other reimbursement agencies; Ministry of Health	Other
Austria	LBI-HTA	MedTech	Yes	Expert advisory groups						Full assessment is provided including recommendations	Federal Health Commission	Reimbursement
Belgium	KCE	Both	Yes	HTA agency		Yes	Yes				National policy makers or commissioners; Insurance funds or other reimbursement agencies; Pricing authorities; Ministry of Health; Payers	Reimbursement; pricing; Clinical guidelines; quality standards
Belgium	RIZIV	Pharma	Yes	Committee		Yes					Minister of Social Affairs	Reimbursement; pricing; Clinical guidelines
Belgium	RIZIV	Medtech	Yes	Committee	Yes	Yes					Minister of Social Affairs; Belgian King	Reimbursement; Pricing
Bulgaria	NCPHA	Pharma	Yes	Committee		Yes					National policy makers or commissioners; Insurance funds or other reimbursement agencies; Pricing authorities; Ministry of Health	Reimbursement; Pricing
Croatia	AAZ	Both	Yes	HTA agency		Yes					Insurance funds or CHIF, MoH, hospital management	Reimbursement; Clinical guidelines, Investment

National												
Country	**Agency**	**Health Tech**	**Are recommendations and advice made to support decision maker**	**Who is making the recommendation**	**Additional documents provided to the decision maker**						**Who uses the advice for decision-making**	**What decision does the assessment inform**
					Company submission of evidence	**Full HTA Report**	**Summary of the HTA report**	**Critique of the HTA report**	**Clinical trial documents**	**Others**		
Croatia	CHIF	Both	Yes	Committee		Yes [76]				Yes	Insurance fund	Price and guidelines for reimbursement, Budget decisions
Czech republic	SUKL	Pharma	No	N/A	Yes			Yes	Yes		National policy makers or commissioners	Reimbursement; Clinical guidelines
Denmark	DMA	Pharma	Yes	Committee	Yes	Yes			Yes		DMA	Reimbursement
Denmark	DMC	Pharma	Yes	HTA agency; Committee	Yes	Yes [77]		Yes			Pricing authorities; Regions	Reimbursement; Pricing; Clinical guidelines
Denmark	DEFACTUM	MedTech	Yes	HTA agency; expert advisory groups		Yes	Yes		Yes		National policy makers or commissioners; Hospital managers or hospital commissioners; Clinicians; Patient organisation and scientific societies	Reimbursement; Clinical guidelines; Quality standards; Budget decisions
England	NICE	Pharma	Yes	Committee	Yes			Yes			National policy makers or commissioners; Hospital managers or hospital commissioners	Reimbursement; Commissioning
England	NICE	MedTech	Yes	Committee	Yes	Yes	Yes	Yes			National policy makers or commissioners; Hospital managers or hospital commissioners; Clinicians	Reimbursement; Commissioning; Clinical guidelines
Estonia	EHIF	Pharma	Yes	Committee; HTA agency	Yes					A written opinion of the board of the Health Insurance Fund	The Minister of Social Affairs	Reimbursement; Pricing
Estonia	UT	Both	Yes	HTA agency; expert		Yes					National policy makers or commissioners; Insurance funds or other	Reimbursement; Clinical guidelines; Quality standards;

[76] If an HTA is requested to support the decision making
[77] Only Assessment of more than one medicine

National												
Country	**Agency**	**Health Tech**	**Are recommendations and advice made to support decision maker**	**Who is making the recommendation**	**Additional documents provided to the decision maker**						**Who uses the advice for decision-making**	**What decision does the assessment inform**
					Company submission of evidence	**Full HTA Report**	**Summary of the HTA report**	**Critique of the HTA report**	**Clinical trial documents**	**Others**		
				advisory groups;							reimbursement agencies; Ministry of Social Affairs	
Finland	FIMEA	Pharma(in patient)	No	NA							Hospital managers or hospital commissioners; Clinicians	uptake in hospital formulary
Finland	HILA	Pharma(outpatient)	Yes	HTA agency; expert advisory groups; other institutions	Yes	Yes	Yes	Yes	Yes	Yes	the Board of HILA	Reimbursement; Pricing,
France	HAS	Pharma	Yes	Committee;	Yes		Yes				National health insurance (level of co-payment); Ministry of Health (reimbursement and pricing)	Reimbursement level of co-payment pricing
France	HAS	MedTech	Yes	Committee; The board (for medical procedures	Yes	Yes				External experts opinion	Ministry of Health; Payers	Reimbursement; Pricing
Germany	GBA	Pharma	Yes	HTA agency; other institutions	Yes	Yes		Yes	Yes	stakeholders with their written and oral statements	Insurance funds or other reimbursement agencies; doctors	Pricing
Germany	GBA	MedTech	Yes	HTA agency		Yes			Yes	Yes	G-BA Directive	Reimbursement
Hungary	NIPN	Pharma	Yes	HTA agency; medical professional colleges; technology assessment committee			Yes	Yes			National policy makers or commissioners; Insurance funds or other reimbursement agencies; Ministry of Human Capacities	Reimbursement; Clinical guidelines

National												
Country	**Agency**	**Health Tech**	**Are recommendations and advice made to support decision maker**	**Who is making the recommendation**	**Additional documents provided to the decision maker**						**Who uses the advice for decision-making**	**What decision does the assessment inform**
					Company submission of evidence	**Full HTA Report**	**Summary of the HTA report**	**Critique of the HTA report**	**Clinical trial documents**	**Others**		
Hungary	NIPN	MedTech	Yes	HTA agency, clinical experts, technology assessment committee (in case of healthcare			Yes	Yes			National policy makers or commissioners; Insurance funds or other reimbursement agencies; Ministry of Human Capacities	Reimbursement
Ireland	NCPE	Pharma	Yes	HTA agency		Yes	Yes			Rapid Review Assessment	National policy makers or commissioners; Payers; Health Service Executive, National Cancer Control Programme	Reimbursement; Pricing; Clinical guidelines
Ireland	HIQA	Both	Yes	Expert advisory groups		Yes	Yes				Ministry of Health	Clinical guidelines; Commissioning
Italy	AIFA	Pharma	Yes	Committees (CTS and CPR)			Yes	Yes			The Italian Medicines Agency- Management board	Reimbursement; Pricing
Italy	AGENAS	MedTech	Yes	HTA agency		Yes					National policy makers or commissioners; Hospital managers or hospital commissioners; Clinicians; Regional Health Authorities	Clinical guidelines; Quality standards; Investments and tenders
Latvia	NVD	Both	Yes	HTA agency	Yes	Yes			Yes		Payers; Ministry of Health	Reimbursement; Pricing
Lithuania	VVKT	Pharma	Yes	Committee						Clinical value assessment report	National policy makers or commissioners; Reimbursement committee	Reimbursement

National												
Country	**Agency**	**Health Tech**	**Are recommendations and advice made to support decision maker**	**Who is making the recommendation**	**Additional documents provided to the decision maker**						**Who uses the advice for decision-making**	**What decision does the assessment inform**
					Company submission of evidence	**Full HTA Report**	**Summary of the HTA report**	**Critique of the HTA report**	**Clinical trial documents**	**Others**		
Lithuania	VASPVT	MedTech	Yes	Committee		Yes	Yes				Ministry of Health	The decision made by the committee does not influence the reimbursement
Malta	DPA/MFH	Pharma	Yes	Committee			Yes				Ministry of Health	Reimbursement; Pricing; Quality standards
Netherlands	ZIN	Both	Yes	HTA agency		Yes					Ministry of Health	Reimbursement; Pricing;
Norway	NIPHNO	Both	No[78]	Other institutions: Health authorities, regional and national	Yes	Yes	Yes	Yes			CEO at the four Regional Health Authorities in consensus	Reimbursement, introduction and disinvestment, Clinical guidelines
Norway	NOMA	Pharma	Yes	HTA agency		Yes		Yes			Ministry of Health; The Norwegian Medicines Agency	Reimbursement
Poland	AOTMIT	Both	Yes	HTA agency; Committee	Yes			Yes		clinical experts opinions, patients opinions	National policy makers or commissioners; Ministry of Health	Reimbursement; Pricing
Portugal	INFARMED	Pharma	Yes	HTA agency; expert advisory groups		Yes				Internal analyses, such as budget impacts and prioritisation framework	Ministry of Health	Reimbursement; Pricing
Romania	NAMMD	Pharma	Yes	HTA agency							Ministry of Health	Reimbursement Cost-volume agreements
Scotland	SMC	Pharma	Yes	Committee	Yes			Yes [79]			Payers	Reimbursement; Clinical guidelines

[78] Advice is not provided directly but decision maker can read the conclusions made.
[79] I.e. detailed advice document.

National												
Country	**Agency**	**Health Tech**	**Are recommendations and advice made to support decision maker**	**Who is making the recommendation**	**Additional documents provided to the decision maker**						**Who uses the advice for decision-making**	**What decision does the assessment inform**
					Company submission of evidence	**Full HTA Report**	**Summary of the HTA report**	**Critique of the HTA report**	**Clinical trial documents**	**Others**		
Scotland	SHTG	MedTech	Yes	Committee		Yes				External peer review comments	National policy makers or commissioners; Hospital managers or hospital commissioners; Clinicians; Payers	Reimbursement; Clinical guidelines
Slovakia	UNIBAFOF	Both	Yes	Committee	Yes						Ministry of Health	Reimbursement
Slovenia	JAZMP	Pharma	Yes	JAZMP pricing committee; payer, tertiary clinic; medical expert committee or 3 individual specialists	Yes					Yes	Pricing authority (JAZMP); Ministry of Health as the second-level (appeal) authority	Reimbursement ((indirectly) ; Pricing
Slovenia	MoH/HC	Both	Yes	Application assessment committee						Yes	Ministry of Health	Reimbursement
Slovenia	HIIS	Pharma	Yes	expert advisory groups	Yes				Yes		Insurance fund or other health insurance companies providing supplementary health insurance	Reimbursement
Spain	AEMPS	Pharma	Yes	HTA agency; GCPT [80]		Yes					Pricing authorities Healthcare providers Healthcare professionals	Reimbursement; Pricing Provision Clinical practice

[80] GCPT: Co-ordination Group for Therapeutic Positioning. GCPT includes representation from AEMPS and the 17 regional health authorities. The DG Pharmacy (part of the Ministry of Health), responsible for price and reimbursement decisions at national level, is also part of the GCPT although with no active role in the development of reports. The GCPT agree on the final recommendation of the assessment report.

National												
Country	**Agency**	**Health Tech**	**Are recommendations and advice made to support decision maker**	**Who is making the recommendation**	**Additional documents provided to the decision maker**						**Who uses the advice for decision-making**	**What decision does the assessment inform**
					Company submission of evidence	**Full HTA Report**	**Summary of the HTA report**	**Critique of the HTA report**	**Clinical trial documents**	**Others**		
Spain	ISCIII	MedTech	Yes	HTA agency		Yes				Horizon Scanning report	National policy makers or commissioners; Hospital managers or hospital commissioners; Clinicians; Ministry of Health	Reimbursement; Quality standards; Impacts
Spain	Spanish Network	MedTech	Yes	HTA agency		Yes				Horizon Scanning report	National policy makers or commissioners; Ministry of Health	Reimbursement; Quality standards; Impacts
Sweden	SBU	Both	No	NA							National policy makers or commissioners; Hospital managers or hospital commissioners; Clinicians; Insurance funds or other reimbursement agencies	Reimbursement; Clinical guidelines
Sweden	TLV	Both	Yes	HTA agency		Yes		Yes			Pricing authorities	Reimbursement; Pricing
Switzerland	BAG/FOPH	Both	Yes	Federal Commission			Yes				Ministry of Health; Pricing authorities	Reimbursement; Pricing
Switzerland	BAG/FOPH	Pharma	Yes	Federal Commission	Yes	Yes			Yes		Pricing authorities	Reimbursement; Pricing
Switzerland	BAG/FOPH	MedTech	Yes	Federal Commission						Yes	Ministry of Health	Reimbursement;
Wales	AWTTC	Pharma	Yes	HTA agency; Committee	Yes			Yes		Clinical expert questionnaires, patient organisation submissions and key references.	Welsh Government	Reimbursement

Regional												
Country	**Agency**	**Health Technology**	**Are recommendations and advice made to support decision maker**	**Who is making recommendation**	**Additional documents provided to the decision maker**						**Who uses the advice for decision-making**	**What decision does the assessment inform**
					Company submission of evidence	**Full HTA Report**	**Summary of the HTA report**	**Critique of the HTA report**	**Clinical trial documents**	**Others**		
Italy	ASSR	MedTech	No	N/A		Yes					National policy makers or commissioners; Hospital managers or hospital commissioners; Clinicians; Payers	Recommendations or criteria for appropriate use within prescription forms used locally
Italy	Veneto	Both	Yes	HTA agency and Regional committee						Varies between the type of assessment	Regional policy makers; Hospital managers or hospital commissioners	Use of health technologies in region
Spain	AETSA	MedTech	No	N/A		Yes					National policy makers or commissioners; Hospital managers or hospital commissioners; Clinicians; Ministry of Health	Reimbursement
Spain	AETSA	Pharma	Yes	HTA agency		Yes	Yes				Hospital managers or hospital commissioners; Clinicians; Andalusian Public Health System	Clinical guidelines; Quality standards; organizational issues; conditions of use
Spain	avalia-t	MedTech	Yes	HTA agency		Yes		Yes			National policy makers or commissioners; Ministry of Health; Hospital managers or hospital commissioners	Reimbursement
Spain	avalia-t	Pharma	Yes	HTA agency		Yes		Yes			National policy makers or commissioners; Hospital managers or hospital commissioners; Ministry of Health	Reimbursement
Spain	Madrid	MedTech	Yes	HTA agency		Yes					National policy makers or commissioners; Hospital managers or hospital commissioners; Clinicians; Ministry of Health	Reimbursement

Regional												
Country	**Agency**	**Health Technology**	**Are recommendations and advice made to support decision maker**	**Who is making recommendation**	**Additional documents provided to the decision maker**						**Who uses the advice for decision-making**	**What decision does the assessment inform**
					Company submission of evidence	**Full HTA Report**	**Summary of the HTA report**	**Critique of the HTA report**	**Clinical trial documents**	**Others**		
Spain	OSTEBA	MedTech	Yes	HTA agency		Yes					National policy makers or commissioners; Hospital managers or hospital commissioners; Clinicians; Ministry of Health	Reimbursement; Quality standards; Clinical guidelines
Spain	OSTEBA	Pharma	Yes	HTA agency		Yes					National policy makers or commissioners; Hospital managers or hospital commissioners	Reimbursement; Quality standards
Spain	AQUAS	MedTech	Yes	HTA agency		Yes	Yes				National policy makers or commissioners; Hospital managers or hospital commissioners; Clinicians; Ministry of Health	Reimbursement
Spain	AQUAS	Pharma	Yes	HTA agency; clinical experts		Yes	Yes			Yes	National policy makers or commissioners; Hospital managers or hospital commissioners; Clinicians; Patients and Caregivers; citizens	Quality standards; Clinical practice and organisational issues; Reimbursement
Spain	SCS	Both	Yes	HTA agency		Yes	Yes				National policy makers or commissioners; Hospital managers or hospital commissioners; Clinicians; Ministry of Health	Reimbursement

Annex table 5: Legal and procedural issues

National														
Country	**Agency**	**Health Technology**	**Agency work on the topic**			**Publication status of….[81]**			**Acceptable scope of the assessment**			**Acceptable population**		**Restrictions to choice of comparators**
			Can start before marketing authorisation	**Is determined by the Transparency Directive**	**Required in national language**	**Scope**	**Assessment**	**Advice**	**Unpublished data accepted**	**Acceptable study designs and evidence restricted**	**Clinical Study Report require**	**Inclusion of full indication**	**Inclusion of defined subgroup analyses**	
Austria	HVB	Pharma	No	Yes	Yes	NA	C (a)	C	Yes	Yes	No requirement	No	No	Yes
Austria	LBI-HTA	MedTech	NA	NA	No	C	P (a)	C	No	No	No requirement	Yes	No	No
Austria	GOEG	Both	No	No	No	P	P (a)	C	Yes	No	No requirement	No	No	No
Belgium	KCE	Both	No	No	Yes[82]	P	P (a)	P	Yes	Yes	Redacted	No	No[83]	No
Belgium	RIZIV	Pharma	Yes	Yes	Yes	C	C (a)	PC	Yes	No	Full required	No	No	Yes
Belgium	RIZIV	MedTech	NA	NA	Yes	NA	C (a)		Yes	No	Full required	No	No	Yes
Bulgaria	NCPHA	Pharma	No	Yes	Yes	PC	PC (e)	PC	Yes	No	No requirement	Yes	Yes	Yes
Croatia	AAZ	Both	No	Yes	Yes	P	P (a)	P	No	No	No requirement	Yes	Yes	No
Croatia	CHIF	Both	No	Yes	Yes	NA	C (e)	P	No	Yes	No requirement	No	Yes	Yes
Czech Rep	SUKL	Pharma	No	Yes	Yes	PC	PC (e)	NA	Yes	No	No requirement	No	No	Yes
Denmark	DMA	Pharma	Yes	Yes	No	NA	P (a)	P	Yes	No	No requirement	Yes	Yes	Yes
Denmark	DMC	Pharma	Yes[84]	Yes	Yes	P	P (e)	P	Yes	Yes	No requirement	No	No	Yes
Denmark	DEFACTUM	MedTech	NA	NA	No	P	P (a)	P	Yes	No	No requirement	No	Yes	No

[81] C = confidential; PC = public with confidential information removed; P = public; (a) agency carries out an assessment; (e) agency evaluates a company submission
[82] Only for the summary of the HTA report. The full HTA report is in English
[83] Subgroup analyses are also taken into account (with the necessary caution)
[84] Not when assessment of more than one medicine

National														
Country	**Agency**	**Health Technology**	**Agency work on the topic**			**Publication status of….[81]**			**Acceptable scope of the assessment**			**Acceptable population**		**Restrictions to choice of comparators**
			Can start before marketing authorisation	**Is determined by the Transparency Directive**	**Required in national language**	**Scope**	**Assessment**	**Advice**	**Unpublished data accepted**	**Acceptable study designs and evidence restricted**	**Clinical Study Report require**	**Inclusion of full indication**	**Inclusion of defined subgroup analyses**	
England	NICE	MedTech	NA	NA	Yes	P	PC (a, e)	PC	Yes	No	No requirement	No	No[85]	Yes[86]
England	NICE	Pharma	Yes	No	Yes	P	PC (a, e)	PC	Yes	No[87]	Full required	No	No	Yes
Estonia	UT	All	Yes	No	Yes	P	P (a)	P	No	No	No requirement	No	No	No
Estonia	EHIF	Pharma	No	Yes	Yes	Missing	PC (e)	Missing	Missing	Missing	Missing	Missing	Missing	Yes
Finland	FIMEA	Pharma	Yes	No	No	P	PC (a)	NA	Yes	No	No requirement	No	No	Yes
Finland	HILA	Pharma	No	Yes	No	NA	C (e)	PC	Yes	No	No requirement	No	No	Yes
France	HAS	Pharma	Yes	Yes	Yes	NA	P (a, e)	PC	Yes	Yes	Full required	No	No	Yes
France	HAS	MedTech	N/A	NA	Yes	P	P (a, e)	P	Yes	Yes	required	No	No	Yes
Germany	GBA	Pharma	No	No	Yes	P	P (a)	P	Yes	Yes	Full required	Yes	Yes	Yes
Germany	GBA	MedTech	N/A	NA	Yes	P	PC (a)	C	Yes	Yes	Redacted sufficient	Yes	Yes	Yes
Hungary	NIPN	Pharma	No	Yes	No	P	C (e)	C	Yes	No	Redacted sufficient	No	No	Yes
Ireland	NCPE	Pharma	No	Yes	Yes	C	C (e)	P	Yes	No	No requirement	No	No	Yes
Ireland	HIQA	Both	NA	No	Yes	PC	PC (a)	P	Yes	Yes	No requirement	No	No	Yes
Italy	AIFA	Pharma	Yes	Yes	Yes	NA	C (e)	PC	No	No	No requirement	No	No	No
Italy	AGENAS	MedTech	NA	NA	No	P	P (a)	P	No	Yes	No requirement	No	No	No
Latvia	NVD	Both	No	Yes	Yes	NA	PC (e)	P	Yes	Yes	No requirement	Yes	Yes	Yes

[85] N/A IP programme
[86] No MIBs
[87] Yes ESNM programme only

National														
Country	Agency	Health Technology	Agency work on the topic			Publication status of….[81]			Acceptable scope of the assessment			Acceptable population		Restrictions to choice of comparators
			Can start before marketing authorisation	Is determined by the Transparency Directive	Required in national language	Scope	Assessment	Advice	Unpublished data accepted	Acceptable study designs and evidence restricted	Clinical Study Report require	Inclusion of full indication	Inclusion of defined subgroup analyses	
Lithuania	VVKT	Pharma	No	Yes	Yes	NA	P (a)	P	Yes	No	No requirement	No	No	No
Lithuania	VASPVT	MedTech	NA	NA	No	NA	P (a)	P	No	No	No requirement	No	No	No
Malta	DPA/MFH	Pharma	No	Yes	Yes	NA	C (a)	C	Yes	No	No requirement	No	No	Yes
Netherlands	ZIN	Both	Yes	Yes	Yes	N/A	P (a)	P	Yes[88]	No	Full required	No	No	No
Norway	NIPHNO	Both	No	No	No	P	P	NA	No[89]	No	No requirement	Yes	Yes	No
Norway	NOMA	Pharma	Yes	Yes[90]	No	NA	PC (e)	PC	Yes	No	required	No	Yes	Yes
Poland	AOTMIT	Both	No[91]	Yes[92]	Yes	P	PC (a, e)	PC	Yes	No	No requirement	No	No	Yes[93]
Portugal	INFARMED	Pharma	No	Yes	Yes	C	PC (e)	PC	No	Yes	Full required	No	Yes	Yes
Romania	NAMMD	Pharma	No	Yes	Yes	NA	P (e)	P (e)	NA	NA	NA	NA	NA	Yes
Scotland	SMC	Pharma	No	No	No	NA	C	PC	Yes	No	No requirement[94]	No	No	No
Scotland	SHTG	MedTech	NA	NA	Yes	PC	PC (a, e)	PC	Yes	No	Full required	No	Yes	No
Slovakia	UNIBAFOF	All	No	Yes	Yes	P	P (e)	P	No[95]	No	No requirement	No	Yes	No

[88] Only cost effectiveness data
[89] There is no specific rules but normally only published data is included
[90] Transparency Directive mandatory for outpatient pharmaceuticals, but not yet mandatory for inpatient pharmaceuticals
[91] Yes if process triggered by MoH
[92] N/A if process triggered by MoH
[93] No if process triggered by MoH
[94] If data are only available in CSR (ie. not published elsewhere) then a full CSR is required.
[95] Yes for non-pharmaceutical health technologies.

National														
Country	**Agency**	**Health Technology**	**Agency work on the topic**			**Publication status of….[81]**			**Acceptable scope of the assessment**			**Acceptable population**		**Restrictions to choice of comparators**
			Can start before marketing authorisation	**Is determined by the Transparency Directive**	**Required in national language**	**Scope**	**Assessment**	**Advice**	**Unpublished data accepted**	**Acceptable study designs and evidence restricted**	**Clinical Study Report require**	**Inclusion of full indication**	**Inclusion of defined subgroup analyses**	
Slovenia	JAZMP	Pharma	No	Yes	Yes[96]	C[97]	C (e)	C	Yes	No	Redacted sufficient	No	No	Yes[98]
Slovenia	MoH/HC	Both	N/A	No	Yes[99]	NA	C (e)	C	Yes	No[100]	No requirement	No	No	No
Slovenia	HIIS	Pharma	No	Yes	Yes	NA	P (e)	C	No	No	No requirement	No	No	No
Spain	ISCIII	MedTech	NA	NA	No	P	P (a)	P	Yes	No	No requirement	No	No	No
Spain	Spanish Network	MedTech	NA	NA	No	P	P (a)	P	Yes	No	No requirement	No	No	No
Spain	AEMPS	Pharma	Yes	No	Yes	NA	P (a)	P	No[101]	No	No requirement	Yes	Yes	No
Sweden	SBU	All	Yes	No	Yes	P	P (a)	NA	No	Yes	No requirement	No	Yes	No
Sweden	TLV	All	Yes	Yes	Yes[102]	C	PC (e)	PC	Yes	No	No requirement	Yes	No	Yes
Switzerland	BAG/FOPH	All	Yes	No	No	P	P (a)	PC	No	No	No requirement	No	No	No
Switzerland	BAG/FOPH	Pharma	Yes	NA	Yes	C	PC (e)	C	No	No	Redacted sufficient	Yes	No	Yes
Switzerland	BAG/FOPH	MedTech	N/A	NA	No	PC	C (e)	P	Yes	No	No requirement	No	Yes	No
Wales	AWTTC	Pharma	Yes	No	Yes	C	PC (e)	P	Yes	No	No requirement	Yes	No	Yes

[97] »C« during the course of the pricing procedure, subsequently its disclosure depends on the provisions of the Public Character Data Disclosure Act (Note: same for Assessment and Advice columns)
[98] Answer »Yes« reflects regulatory practice of JAZMP rather than legal requirement
[99] technical documents in the application can be submitted in English, but that the decision must legally be written in the national language
[100] No upfront requirement in place, however there is a scoring mechanism for acknowledgement of the quality of studies
[101] AEMPS as a regulatory agency, has access to all the data contained in the marketing authorisation application. Therefore, no further information is required to be submitted by the applicant
[102] the company submission can be in English but documents TLV produce have to be in Swedish

Regional														
Country	**Agency**	**Health Technology**	**Assessment**			**Publication status of….**			**Acceptable scope of the assessment**			**Acceptable population**		**Restrictions to choice of comparators**
			Can start before marketing authorisation	**Timeframe determined by the Transparency**	**Required in national language**	**Scope**	**Assessment**	**Advice**	**Unpublished data accepted**	**Acceptable study designs and evidence restricted**	**CSR required**	**Inclusion of full indication**	**Inclusion of defined subgroup analyses**	
Italy	ASSR	MedTech	NA	NA	No	P	P (a)	NA	No	Yes	No requirement	No	No	No
Italy	Veneto	Both	No	No	No	NA	P (a)	P	No	No	No requirement	No	NA	No
Spain	AETSA	Both	Yes[103]	No	Yes	P	P (a)	P	No	No	No requirement	No	Yes (pharma)	Yes (pharma)
Spain	avalia t	Both	NA	No	Yes	P	P (a)	P	Yes	No	Full required	No	No	No
Spain	Madrid	MedTech	NA	NA	Yes	P	P (a)	P	No	No	Full required	No	No	No
Spain	OSTEBA	Both	Yes	No	Yes	P	P (a)	P	Yes	No	Full required	No	No	No
Spain	AQUAS	Both	Yes	Yes	Yes	P	P (a)	P	Yes	No	Full required	No	Yes (pharma)	Yes (primary care)
Spain	SCS	Both	Yes	No	Yes	P	P (a)	P	Yes	No	Full required	No	No	No

[103] Emergent technology reports only

Annex table 6: Reassessment

National									
Country	**Agencies providing data**	**Health Technology**	**Process of reassessment of initial decision**	**Approach to reassessment**					**Circumstances in which reassessment is completed**
				STA	**MTA**	**Full HTA**	**Effectiveness and economics**	**REA only**	
Austria	HVB	Pharma	Yes	Yes			Yes		Pharmaceuticals are reassessed, if for example - predefined criteria/conditions in the EKO change or - the package size changes or - the price increases or - pharmaceuticals are delisted from the EKO
Austria	LBI-HTA	MedTech	Yes	Yes				Yes	For reassessments and updates of earlier-performed assessments (such as repeated proposals for EMS rejected in earlier years, or technologies with preliminary status), an update of newly published literature is performed by using the same search strategy as in the primary assessment.
Austria	GOEG	Both	No						N/A
Belgium	RIZIV	Pharma	Yes	Yes	Yes	Yes			As 'standard' reassessments are completed (by regulation) for all class 1 drugs (added therapeutic value) and orphans between 18 months and 3 years. These individual revisions are also optional (if considered relevant) for other drugs and for modifications of indications. Group-wise revisions (class revisions) are done if substantial new medico/scientific insights (publications, guidelines, and consensus texts) are issued.
Belgium	KCE	Both	No						N/A
Belgium	RIZIV	MedTech	Yes	Yes	Yes	Yes			Re-assessment would be performed when important new evidence becomes available (e.g. results of trials that were still ongoing during the initial assessment), especially when the initial assessment did not allow a clear conclusion because of insufficient or weak evidence; or when a new alternative treatment for the same condition is introduced (could be a non-MedTech intervention); or when a stakeholder requests a re-assessment for another reason that is deemed appropriate after careful consideration.
Bulgaria	NCPHA	Pharma	Yes	Yes			Yes	Yes	
Croatia	AAZ	Both	No						N/A
Croatia	CHIF	Both	Yes	Yes			Yes		New evidence, new comparators, new treatment pathway, significant changes to the price of the product or the comparator.
Czech Rep	SUKL	Pharma	Yes	Yes	Yes		Yes	Yes	Every five years in order to maintain the product on the list of reimbursed pharmaceuticals.

National									
Country	**Agencies providing data**	**Health Technology**	**Process of reassessment of initial decision**	**Approach to reassessment**					**Circumstances in which reassessment is completed**
				STA	**MTA**	**Full HTA**	**Effectiveness and economics**	**REA only**	
Denmark	DMA	Pharma	Yes		Yes		Yes		Ongoing reassessment
Denmark	DMC	Pharma	No						N/A
Denmark	DEFACTUM	MedTech	Yes	Yes	Yes	Yes			Upon request from decision maker.
England	NICE	MedTech	Yes	Yes	Yes[104]		Yes	Yes[105]	New evidence, new comparators, new treatment pathway, significant changes to the price of the product or the comparator.
England	NICE	Pharma	Yes	Yes	Yes[106]		Yes		New evidence, new comparators, new treatment pathway, significant changes to the price of the product or the comparator.
Estonia	UT	All	Yes	Yes	Yes		Yes		New evidence on efficacy, costs, indications.
Finland	FIMEA	Pharma	No						N/A
Finland	HILA/PPB	Pharma	Yes	Yes			Yes		Decisions are made for a fixed time period (max 3/5 years) unless the product is in the reference price system with generic competition.
France	HAS	Both[107]	Yes	Yes	Yes	Yes (Not P)	Yes [108]	Yes[109]	Can occur at any time if requested by the company, institution, ministry of health, patients organisation or on HAS initiative. Otherwise, every five years in order to maintain the product on the (outpatient, in the case of drugs) list of reimbursed pharmaceuticals.
Germany	GBA	Both	Yes	Yes				Yes	When the issued resolution is time-restricted and expires after a certain amount of time.
Hungary	NIPN	Pharma	No[110]						N/A
Ireland	NCPE	Pharma	No						N/A
Ireland	HIQA	Both	Yes	Yes	Yes	Yes	Yes	Yes	When changes to methodology or practice impact on the content of the guidelines
Italy	AIFA	Pharma	Yes	Yes			Yes	Yes	Renegotiation process

[104] Diagnostic Assessment Programme (DAP) only
[105] Interventional Procedures (IP) only
[106] TA only
[107] But not for medical procedures
[108] Pharma only
[109] Pharma only
[110] Though a legal basis exists for completing reassessment

National									
Country	**Agencies providing data**	**Health Technology**	**Process of reassessment of initial decision**	**Approach to reassessment**					**Circumstances in which reassessment is completed**
				STA	**MTA**	**Full HTA**	**Effectiveness and economics**	**REA only**	
Italy	AGENAS	MedTech	No						N/A
Latvia	NVD	Both	Yes	Yes	Yes		Yes		New evidence, budget impact, price and level of reimbursement.
Lithuania	VVKT	Pharma	Yes	Yes			Yes		Request from appeal committee
Lithuania	VASPVT	MedTech	No						N/A
Malta	DPA/MFH	Pharma	No[111]	Yes	Yes		Yes		Possible upon request from MoH
Netherlands	ZIN	Both	Yes	Yes		Yes			New evidence, new comparators
Norway	NIPHNO	Both	No[112]	Yes	Yes	Yes	Yes	Yes	upon request
Norway	NOMA	Pharma	Yes	Yes			Yes		New evidence, the criteria for reimbursement are no longer fulfilled, Availability of a new comparator product, new evidence available on the efficacy.
Poland	AOTMIT	Both	No[113]						N/A
Portugal	INFARMED	Pharma	Yes	Yes	Yes		Yes	Yes	Availability of a new comparator product, new evidence available on the efficacy.
Romania	NAMMD	Pharma	Yes[114]	Yes			Yes		yearly
Scotland	SMC	Pharma	No						N/A
Scotland	SHTG	MedTech	Yes	Yes			Yes		2 yearly review or new evidence.
Slovakia	UNIBAFOF	All	Yes	Yes			Yes		New data and evidence and in case of conditional reimbursement, which is valid for 24 months.
Slovenia	JAZMP	Pharma	Yes	Yes			Yes		If the company/industry wants to extend the period of validity of exceptional higher allowed price for another 1-year period by submitting a new application. The same as initial assessment.
Slovenia	MoH/HC	Both	Yes[115]	Yes			Yes		The same as initial assessment.
Slovenia	HIIS	Pharma	Yes	Yes			Yes		The same as initial assessment.

[111] But may be carried out if requested by Ministry
[112] It's not an official process but it can be done upon request
[113] But may be requested to carry out reassessment by Ministry
[114] Reassessment possible using the same scorecard approach
[115] Reassessment is possible but does not differ from initial assessment (the same for HIIS and JAZMP)

National									
Country	**Agencies providing data**	**Health Technology**	**Process of reassessment of initial decision**	**Approach to reassessment**					**Circumstances in which reassessment is completed**
				STA	**MTA**	**Full HTA**	**Effectiveness and economics**	**REA only**	
Spain	ISCIII	MedTech	There is not a formal process	Yes			Yes	Yes	N/A
Spain	Spanish Network	MedTech	There is not a formal process						N/A
Spain	AEMPS	Pharma	There is not a formal process[116]	Yes				Yes	This is mainly due to new evidence on the pharmaceutical becoming available
Sweden	SBU	All	No defined process for reassessment[117]	Yes	Yes	Yes	Yes		N/A
Sweden	TLV	All	Yes	Yes	Yes	Yes	Yes		Mainly but not solely sales volume and budget impact
Switzerland	BAG/FOPH	All[118]	No						N/A
Switzerland	BAG/FOPH	Pharma	Yes	Yes	Yes		Yes		New evidence, new indication, re-evaluation of price after 3 years of first price-setting or if approved indications are extended.
Switzerland	BAG/FOPH	MedTech	Yes	Yes	Yes	Yes	Yes		if reimbursement was decided for a limited time only, on new indications, on new evidence
Wales	AWTTC	Pharma	Yes	Yes			Yes		New information or evidence available and budget impact. Otherwise reviewed within three years of Ministerial ratification.

Regional									
Country	**Agencies providing data**	**Health Technology**	**Process of reassessment of initial decision**	**Approach to reassessment**					**Circumstances in which reassessment is completed**
				STA	**MTA**	**Full HTA**	**Effectiveness and economics**	**REA only**	
Italy	ASSR	MedTech	Yes[119]		Yes				Introduction of new devices
Italy	Veneto	Both	Yes	Yes					No specific circumstances defined
Spain	AETSA	Both	Yes[120]	Yes					New data and evidence

[116] Reassessment is done when considered necessary by the GCPT
[117] However, some reports are updated
[118] HTA programme aimed at disinvestment
[119] Medical devices only, not for high cost technologies
[120] Emergent technology reports

Regional									
Country	**Agencies providing data**	**Health Technology**	**Process of reassessment of initial decision**	**Approach to reassessment**					**Circumstances in which reassessment is completed**
				STA	**MTA**	**Full HTA**	**Effectiveness and economics**	**REA only**	
Spain	avalia t	Both	Yes[121]	Yes	Yes	Yes		Yes	Potentially obsolete technologies require reassessment and also technologies which are conditioned to real practice data collection
Spain	Madrid	MedTech	Yes	Yes	Yes		Yes	Yes	Reports updated every 5 years
Spain	OSTEBA	Both	Yes[80]	Yes	Yes			Yes	Potentially obsolete technologies require reassessment. Clinical practice guidelines need to be updated at least every 5 years.
Spain	AQUAS	Both	Yes (pharma)	Yes	Yes			Yes	New data and evidence
Spain	SCS	Both	No[122]	Yes			Yes		New information or evidence available and budget impact

[121] Clinical practice guidelines and lifecycle technology assessments
[122] But can be carried out

Annex table 7: Stakeholder involvement

National									
Country	**Agencies providing data**	**Health Tech**	**Stakeholder involvement process**	**Stakeholders and stages of involvement**					**Can final decision be challenged and by who**
				Horizon scanning and topic selection	**Scoping**	**Production of assessment**	**Review of the assessment**	**Advice or decision making**	
Austria	HVB	Pharma	Yes				Industry; Clinical experts; Payers	Payers	Yes; industry
Austria	GOEG	Both	Yes		Others	Clinical experts	Clinical experts; others		No
Austria	LBI-HTA	MedTech	Yes	Payers	Industry				No
Belgium	RIZIV	Pharma	Yes			Academics, pharmacists, physicians, payers, clinical experts	Industry, academics, pharmacists, physicians, payers, clinical experts	Industry, academic, pharmacists, physicians, payers, clinical experts	Yes; industry
Belgium	RIZIV	MedTech	Yes			clinical experts, payers, academics, others	Industry, clinical experts, payers, academics, others	Industry, clinical experts, payers, others	Yes; industry
Belgium	KCE	Both	Yes		Industry, payers, patient experts, clinical experts, providers, others	Industry, clinical experts, payers, providers, others	Clinical experts, payers, providers, others		No
Bulgaria	NCPHA	Pharma	Yes			Industry, clinical experts	Clinical experts, working Committees	Clinical experts, payers, providers	Yes; industry, patient groups, professional groups, payers, providers
Croatia	AAZ	Both	Yes		Industry, clinical experts, payers, providers				No
Croatia	CHIF	Both	Yes		Industry, clinical experts, payers, providers			Payers	Yes; industry
Czech republic	SUKL	Pharma	Yes		Industry	Industry	Industry, clinical experts, payers	Industry, clinical experts, payers	Yes; industry, payers
Denmark	DMA	Pharma	Yes		Industry	Industry	Patient experts, clinical experts,	Patient experts, clinical experts,	Yes; industry
Denmark	DMC	Pharma	Yes	Industry, patient experts, clinical experts, payers, providers	Industry, Patient experts, clinical experts,	Industry	Industry, Patient experts, clinical experts,	Patient experts, clinical experts, providers,	No
Denmark	DEFACTUM	MedTech	Yes	Payers, providers	Industry, patient experts, clinical	Clinical experts	Industry, patient experts, clinical	Clinical experts, payers, providers	No

National									
Country	**Agencies providing data**	**Health Tech**	**Stakeholder involvement process**	**Stakeholders and stages of involvement**					**Can final decision be challenged and by who**
				Horizon scanning and topic selection	**Scoping**	**Production of assessment**	**Review of the assessment**	**Advice or decision making**	
					experts, payers, providers		experts, payers, providers		
England	NICE	Pharma	Yes	Industry, clinical experts, payers	Industry, patient experts, clinical experts, payers, providers	Industry, patient experts, clinical experts, payers, providers	Industry, patient experts, clinical experts, payers, providers	Industry, patient experts, clinical experts, payers, providers	Yes; industry, patient groups, professional groups, providers
England	NICE	MedTech	Yes	Industry, clinical experts	Industry, patient experts, clinical experts, providers	Industry, patient experts, clinical experts, providers	Industry, patient experts, clinical experts, providers	Industry, patient experts, clinical experts, providers	Yes; industry, patient groups, professional groups, providers
Estonia	EHIF	Pharma	Yes			Industry	Payers	Industry, patient experts, clinical experts, payers, providers, others	Yes; industry
Estonia	UT	Both	Yes	Payers	Payers	Industry, clinical experts	Clinical experts	Industry, clinical experts, providers	No
Finland	FIMEA	Pharma (inpatient)	Yes	Industry, clinical experts	Industry, clinical experts		Industry, clinical experts	Clinical experts, payers, providers	No
Finland	HILA	Pharma (outpatient)	Yes			Industry	Industry, clinical experts, payer	Payer	Yes; industry
France	HAS	Pharma	Yes			Patient experts, clinical experts, Other public health organisations	Industry, clinical experts, providers	Patient experts, clinical experts, others	Yes; Industry
France	HAS	MedTech	Yes		clinical expert (for medical procedures)	Industry (not for medical procedures)	Industry, clinical expert ,providers	Patient expert, clinical expert, payers, providers , others	Yes; Industry, professional groups, providers
Germany	GBA	Pharma	Yes	Industry				Industry, patient expert, clinical experts, payers, providers, others (all during public hearings regarding the assessment report)	No
Germany	GBA	MedTech	Yes	Missing	Missing	Missing	Missing	Missing	No
Hungary	NIPN	Pharma	Yes					Industry, clinical experts, payers	No
Ireland	NCPE	Pharma	Yes	Industry, payers	Industry	Industry	Patient experts, clinical experts	Industry, clinical experts, payers	Yes; Industry

National									
Country	**Agencies providing data**	**Health Tech**	**Stakeholder involvement process**	**Stakeholders and stages of involvement**					**Can final decision be challenged and by who**
				Horizon scanning and topic selection	**Scoping**	**Production of assessment**	**Review of the assessment**	**Advice or decision making**	
Ireland	HIQA	Both	Yes	Industry	Industry, patient experts, clinical experts, payers	Industry, patient experts, clinical experts, payers, providers, others	Clinical experts, payers, providers, others	Industry, patient experts, clinical experts, payers, providers, others	Yes; industry, patient groups, professional groups, providers, payers
Italy	AIFA	Pharma	Yes	Industry, clinical experts	Industry	Industry	Industry, payers	Patient experts, clinical experts	Yes; Industry
Italy	AGENAS	MedTech	Yes	Industry, patient experts, clinical experts		Patient experts, clinical experts	Patient experts, clinical experts		No
Latvia	NVD	Both	Yes		Industry	Industry, payers	Clinical experts, payers	Payers	Yes; industry
Lithuania	VVKT	Pharma	Yes			Payers	Industry	Industry, patient experts, clinical experts, payers	No
Lithuania	VASPVT	MedTech	No		Clinical experts	Clinical experts			No
Malta	DPA/MFH	Pharma	Yes	Industry, clinical experts		Clinical experts		Patient experts, clinical experts, payers, providers	Yes; industry
Netherlands	ZIN	Both	Yes	Patient expert, clinical experts, payers	Patient expert, clinical experts, payers	Industry, patient experts, clinical experts, payers,	Industry, patient expert, clinical experts, payers	Patient expert, clinical experts, payers	Yes; industry, patient groups, professional groups, payers
Norway	NIPHNO	Both	Yes	patient experts, clinical experts, payers	Industry, clinical experts, patient experts, payers, providers	clinical experts, patient experts	Clinical experts, patient experts	CEO at the four Regional Health Authorities in consensus	No
Norway	NOMA	Pharma	Yes	Industry, clinical experts	Industry, clinical experts, payers	Industry, clinical experts, payers	Clinical experts, payers, providers	clinical experts, payers	Yes: industry, clinicians, patient groups. Not for inpatient drugs.
Poland	AOTMIT	Both	Yes	Clinical experts	Clinical experts, providers	Industry, patient experts, clinical experts, payers,	Industry, patient experts, clinical experts, payers,	Patient experts, clinical experts, payers	No
Portugal	INFARMED	Both	Yes	Clinical experts	Clinical experts	Industry, clinical experts	Industry, clinical experts	Industry, clinical experts, payers, providers, others	No
Romania	NAMMD	Pharma	No					Clinical Experts	Yes; MAH

National									
Country	**Agencies providing data**	**Health Tech**	**Stakeholder involvement process**	**Stakeholders and stages of involvement**					**Can final decision be challenged and by who**
				Horizon scanning and topic selection	**Scoping**	**Production of assessment**	**Review of the assessment**	**Advice or decision making**	
Scotland	SMC	Pharma	Yes	Industry, clinical experts		Industry, patient experts, clinical experts	Industry, patient experts	Industry, patient experts, payers, providers	Yes; industry
Scotland	SHTG	MedTech	Yes	industry, clinical experts, payers, providers, others	Industry, patient experts, clinical experts, payers, providers, others	Industry, patient experts, clinical experts, payers, providers, others	Industry, patient experts, clinical experts, payers, providers	Industry, patient experts, clinical experts, payers, providers	Yes; industry, patient groups, professional groups, payers, providers, others
Slovakia	UNIBAFOF	Both	No			Industry, clinical experts, payers	clinical experts, payers	clinical experts, payers	Yes; industry (MAH), payers, Ministry of Health
Slovenia	JAZMP	Pharma	Yes	Industry as applicants (MAHs)	Industry as applicants for specific technologies; lawmaker on general level by setting eligibility criteria	Industry as applicants for specific technologies, others (e.g. academic institutions) for providing assessment as service to the decision-maker	Industry, as applicants for specific technologies when JAZMP deems it necessary; others (e.g. academic institutions or patient organizations) for providing assessment as service or information to the decision-maker	Industry as applicant in the administrative procedure; clinical experts, payers	Yes; industry as the applicant within the administrative procedure, appeal provisions stipulated in the legislation
Slovenia	MoH/HC	Both	Yes				clinical experts	clinical experts, payers, others	No[123]
Slovenia	HIIS	Pharma	Yes	Providers			Providers[124]	Industry as applicant in the administrative procedure; clinical experts	Yes; industry as applicant in the administrative procedure
Spain	AEMPS	Pharma	Yes		Payers, providers	clinical experts, providers	Industry, patient experts, clinical experts, payers		No[125]
Spain	ISCIII	MedTech	Yes	Industry, patient experts, clinical experts,	Industry, clinical experts, payers, providers		clinical experts		No

[123] MoH/HC is a consultative body to the minister and as such does not produce decisions that could be as such challenged legally.
[124] HIIS uses a permanent committee consisting of clinical experts for the assessment of reimbursement applications
[125] As part of the assessment procedure, there is a consultation in which patient experts, clinical experts and the marketing authorisation holder can challenge the report recommendations. Their views are taken into account to write the final version of the assessment report.

National									
Country	**Agencies providing data**	**Health Tech**	**Stakeholder involvement process**	**Stakeholders and stages of involvement**					**Can final decision be challenged and by who**
				Horizon scanning and topic selection	**Scoping**	**Production of assessment**	**Review of the assessment**	**Advice or decision making**	
				payers, providers					
Spain	Spanish Network	MedTech	Yes	Industry, patient experts, clinical experts, payers, providers	Industry, patient experts, clinical experts, payers, providers	clinical experts	clinical experts		Yes; patient groups, professional groups, payers, providers
Sweden	SBU	Both	Yes	Patient experts, clinical experts, providers	Patient experts, clinical experts, providers	Patient experts	Industry, patient experts, clinical experts		Yes; patient groups, professional groups, providers
Sweden	TLV	Both	Yes	Payers	clinical experts	Industry	Industry, patient experts, clinical experts	Patient experts	Yes; industry
Switzerland	BAG/FOPH	Both[126]	Yes	Industry, patient experts, payers, providers, others	Industry, patient experts, clinical experts, payers, providers, others	clinical experts	Industry, patient experts, clinical experts, payers, providers, others	Industry, patient experts, clinical experts, payers, providers, others	Yes; industry (pharma)
Switzerland	BAG/FOPH	Pharma	Yes		Industry, clinical experts	Industry, clinical experts	Industry, clinical experts	Industry, patient experts, clinical experts, payers, providers, others	Yes; industry
Switzerland	BAG/FOPH	MedTech	Yes	Clinical experts, payers, providers, others	Industry, clinical experts	Industry, clinical experts, providers	Clinical experts	Industry, patient experts, clinical experts, payers, providers, others	No
Wales	AWTTC	Pharma	Yes	Industry, clinical experts	Industry, clinical experts	Industry, patient experts, clinical experts	Industry, patient experts, clinical experts	Industry, patient experts, clinical experts, providers	Yes; industry, others

[126] HTA programme

Regional									
Country	**Agencies providing data**	**Health Technology**	**Stakeholder involvement process**	**Stakeholders and stages of involvement**					**Can final decision be challenged and by who**
				Horizon scanning and topic selection	**Scoping**	**Production of assessment**	**Review of the assessment**	**Advice or decision making**	
Italy	ASSR	MedTech	Yes		Industry, patient experts, clinical experts, providers	Industry, patient experts, clinical experts, providers	Clinical experts, providers	Patient experts, clinical experts, providers	No
Italy	Veneto	Both	No	NA	NA	Clinical experts	Clinical experts	Clinical experts	No
Spain	AETSA	MedTech	In progress	Clinical experts, payers, providers	Clinical experts, payers, providers		Clinical experts	Clinical experts	Yes; Clinical experts, medical or professional groups, payers, providers
Spain	AETSA	Pharma	Yes	Clinical experts, payers, providers	Clinical experts		Clinical experts		Yes; Clinical experts, medical or professional groups, payers, providers
Spain	avalia t	MedTech	No	Patient experts, clinical experts, payers, providers	Patient experts, clinical experts, payers, providers	Clinical experts	Clinical experts	Clinical experts, payers	Yes; Clinical experts, medical or professional groups, payers, providers
Spain	avalia t	Pharma	No	Clinical experts, payers, providers	Clinical experts, payers, providers	Clinical experts	Clinical experts	Payers	Yes; Clinical experts, medical or professional groups, payers, providers, patient groups
Spain	Madrid	MedTech	Yes	Clinical experts, payers, providers	Clinical experts, payers, providers	Clinical experts	Clinical experts, patient experts	Clinical experts	Yes; Clinical experts, medical or professional groups, payers, providers
Spain	OSTEBA	MedTech	No	Patient experts, clinical experts, payers, providers	Patient experts, clinical experts, payers, providers	Clinical experts	Clinical experts	Clinical experts	Yes; Clinical experts, medical or professional groups, payers, providers
Spain	OSTEBA	Pharma	Yes	Industry, clinical experts, payers, providers	Industry, clinical experts, payers, providers	Clinical experts	Clinical experts	Clinical experts	Yes; Clinical experts, medical or professional groups, payers, providers, patient groups, industry
Spain	AQUAS	MedTech	No	Clinical experts, payers, providers	Clinical experts, payers, providers	Patient experts,	Patient experts, clinical experts,	Patient experts, clinical experts, pharmaco-economists	Yes; Clinical experts, medical or professional groups, payers, providers
Spain	AQUAS	Pharma	Yes	Clinical experts	Clinical experts		Clinical experts	clinical experts, pharmaco-economists	Yes; Professional groups, patients, industry
Spain	SCS	Both	Yes	Patient experts, clinical experts, payers, providers	Industry, patient experts, clinical experts, payers, providers	Clinical experts	Industry, patient experts, clinical experts,	Clinical experts	Yes; Clinical experts, medical or professional groups, payers, providers