Mapping of HTA national organisations, programmes and processes in EU and Norway

Annexes

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May - 2017

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EUROPEAN COMMISSION

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Directorate-General for Health and Food Safety

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Luxembourg: Publications Office of the European Union, 2017

ISBN: 978-92-79-77937-4
doi: 10.2875/131490

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Appendix 1 - Roles and Tasks of HTA bodies

European (EU and EEA) HTA bodies - Roles and tasks

European Union		Organisation Main Role				Other tasks						
Country	HTA Bodies	Develop and issue HTA recom-mendations	Regulation of HT	Pricing of HT	Reim-bursement of HT	Quality standards	Clinical guidelines develop-ment	Healthcare promotion	Horizon scanning	Registries	Education	Early Dialogues and Scientific Advice
Austria (AT)	HVB	yes	no	yes	yes	yes	yes	yes	no	no	no	no
	GoG	yes	no	no	no	yes	no	yes	no	yes	yes	no
	LBI-HTA	yes	no	no	no	no	no	no	yes	no	no	no
Belgium (BE)	HIHDI (INAMI-RIZIV)	yes	no	yes	yes	no	no	yes	yes	yes	yes	no
	KCE	yes	no	no	no	no	yes	no	yes	no	no	yes
Bulgaria (BG)	NCPHA	yes	no	no	no	no	no	yes	no	yes	yes	no
Croatia (HR)	AAZ	yes	no	no	no	yes	no	no	no	no	yes	no
	CHIF	yes	no	yes	yes	no	no	no	no	no	no	no
Cyprus (CY)	*MoH (1)*	yes	yes	yes	yes	yes	yes	no	no	no	no	no
Czech Republic (CZ)	SUKL	yes	yes	yes	yes	no	no	no	no	no	no	no
Denmark (DK)	DEFACTUM	yes	no	no	no	yes	no	yes	no	yes	yes	no
Estonia (EE)	EHIF	yes	no	yes	yes	no	yes	yes	yes	yes	no	no
	MoSa	no	yes	no	no	no	yes	yes	no	yes	no	yes
	University of Tartu	yes	no	no	no	no	no	no	yes	no	yes	no
Finland (FI)	FIMEA	yes	yes	no	no	no	no	no	no	no	no	yes
	THL (2)	no	no	no	no	yes	no	yes	no	yes	yes	no
France (FR)	HAS	yes	no	no	no	yes	yes	yes	no	no	no	yes
Germany (DE)	G-BA	yes	no	no	yes	yes	yes	no	no	no	no	yes
	IQWIG	yes	no	no	no	yes	no	no	no	no	yes	no
Greece (EL)	*not indicated*	_	_	_	_	_	_	_	_	_	_	_
Hungary (HU)	NIPN	yes	yes	no	no	no	yes	no	no	no	yes	no
Ireland (IE)	HIQA	yes	no	no	no	yes	yes	no	no	no	yes	no
	NCPE	yes	no	no	yes	no	no	no	no	yes	yes	yes
Italy (IT)	AGENAS	yes	no	no	no	yes	yes	yes	yes	no	yes	no
	AIFA	no	yes	yes	yes	no	no	no	no	no	no	no
Latvia (LV)	NHS	yes	no	yes	yes	no	yes	no	no	no	no	no
Lithuania (LT)	SMCA	no	yes	no	yes	no	no	no	no	no	no	no
	VASPVT	yes	no	no	no	no	no	no	no	no	no	no

Luxembourg (LU)	CEM	yes	no	no	yes	no	yes	no	no	no	no	no
Malta (MT)	DPA/MFH	yes	no	yes	yes	no	no	no	no	no	yes	no
Netherlands (NL)	ZIN	yes	no	no	yes	yes	yes	no	yes	no	no	yes
Poland (PL)	AOTMiT	yes	no	no	no	no	no	yes	no	no	yes	no
Portugal (PT)	INFARMED	yes	yes	yes	yes	no	no	yes	yes	yes	no	yes
Romania (RO)	*no specific information available*	_	_	_	_	_	_	_	_	_	_	_
Slovakia (SK)	MoH, Working Group for Pharmacoeco-nomics, Clinical Outcomes and HTA	yes	no	no	no	yes	no	no	yes	no	no	no
Slovenia (SI)	HIIS	no	no	yes	yes	no information	no	yes	no	no	no information	no information
	JAZMP	yes	yes	yes	no	no	no	no	no	yes	no	yes
Spain (ES)	AEMPS	yes	yes	no	no	yes	yes	yes	yes	yes	yes	yes
	AETS-ISCIII	yes	no	no	no	no	no	no	yes	yes	yes	no
	AETSA	yes	no	no	no	yes	yes	yes	yes	yes	yes	yes
	Avalia-t	yes	no	no	yes	yes	yes	yes	yes	yes	yes	yes
	AQUAS	yes	no	no	no	yes	yes	no	no	yes	no	yes
	IACS	yes	no	no	no	yes	yes	yes	yes	yes	yes	yes
	SESCS	yes	no	no	no	no info	no info	no info	no info	no info	no info	no info
	OSTEBA	yes	yes	no	no	yes	yes	yes	yes	yes	yes	yes
	UETS	yes	no	no	no	No	yes	No	yes	yes	yes	No
Sweden (SE)	SBU	yes	no	no	no	No	No	no	no	no	yes	no
	TLV	yes	no	yes	yes	no	no	no	yes	yes	no	yes
United Kingdom (UK)	NICE	yes	no	no	no	yes	yes	yes	yes	yes	yes	yes
	SMC	yes	no	no	no	yes	no	no	yes	no	no	no
	SHTG	yes	no	no	no	yes	yes	no	yes	no	no	yes
	AWTTC	yes	no	no	no	no	yes	no	yes	no	yes	no
Total number of HTA bodies (answering "yes")		50	45	11	13	18	22	23	19	21	20	24	18

Luxembourg (LU)	CEM	yes	no	no	yes	no	yes	no	no	no	no	no
Malta (MT)	DPA/MFH	yes	no	yes	yes	no	no	no	no	no	yes	no
Netherlands (NL)	ZIN	yes	no	no	yes	yes	yes	no	yes	no	no	yes
Poland (PL)	AOTMiT	yes	no	no	no	no	no	yes	no	no	yes	no
Portugal (PT)	INFARMED	yes	yes	yes	yes	no	no	yes	yes	yes	no	yes
Romania (RO)	*no specific information available*	_	_	_	_	_	_	_	_	_	_	_
Slovakia (SK)	Working Group for Pharmacoeco-nomics, Clinical Outcomes and HTA	yes	no	no	no	yes	no	no	yes	no	no	no
Slovenia (SI)	HIIS	no	no	yes	yes	no information	no	yes	no	no	no information	no information
	JAZMP	yes	yes	yes	no	no	no	no	no	yes	no	yes
Spain (ES)	AEMPS	yes	yes	no	no	yes	yes	yes	yes	yes	yes	yes
	AETS-ISCIII	yes	no	no	no	no	no	no	yes	yes	yes	no
	AETSA	yes	no	no	no	yes	yes	yes	yes	yes	yes	yes
	Avalia-t	yes	no	no	yes	yes	yes	yes	yes	yes	yes	yes
	AQUAS	yes	no	no	no	yes	yes	no	no	yes	no	yes
	IACS	yes	no	no	no	yes	yes	yes	yes	yes	yes	yes
	SESCS	yes	no	no	no	no info	no info	no info	no info	no info	no info	no info
	OSTEBA	yes	yes	no	no	yes	yes	yes	yes	yes	yes	yes
	UETS	yes	no	no	no	No	yes	No	yes	yes	yes	No
Sweden (SE)	SBU	yes	no	no	no	No	No	no	no	no	yes	no
	TLV	yes	no	yes	yes	no	no	no	yes	yes	no	yes
United Kingdom (UK)	NICE	yes	no	no	no	yes	yes	yes	yes	yes	yes	yes
	SMC	yes	no	no	no	yes	no	no	yes	no	no	no
	SHTG	yes	no	no	no	yes	yes	no	yes	no	no	yes
	AWTTC	yes	no	no	no	no	yes	no	yes	no	yes	no
Total number of HTA bodies (answering "yes")		50	45	11	13	18	22	23	19	21	20	24	18

European (EU and EEA) HTA bodies - Roles and tasks

European Economic Area (EEA)		Organisation Main Role				Other tasks						
Country	HTA Bodies	Develop and issue HTA recom-mendations	Regulation of HT	Pricing of HT	Reim-bursement of HT	Quality standards	Clinical guidelines develop-ment	Healthcare promotion	Horizon scanning	Registries	Education	Early Dialogues and Scientific Advice
Norway (NO)	Hdir	yes	no	no	no	no	yes	no	no	no	no	no
	NMA	yes	yes	yes	yes	yes	no	no	yes	no	no	yes
	NIPH	yes	no	no	no	yes	yes	yes	yes	yes	yes	no
Iceland (IS)	*no information*	_	_	_	_	_	_	_	_	_	_	_
Liechtenstein (LI)	*not indicated*	_	_	_	_	_	_	_	_	_	_	_
Total number of HTA bodies (answering "yes")		3	3	1	1	1	2	2	1	2	1	1	1

(1) There is a formalised central reimbursement process that uses elements of HTA to support its decision making.

There are plans to introduce HTA formally into the process to include cost effectiveness analysis.

(2) The role of THL in the HTA process in Finland is being clarified.

Appendix 2 – Scope of HTA by country and HTA body

European (EU and EEA) HTA Bodies - Scope of HTA

European Union Country	HTA Bodies	Scope of HTA Pharma	Medical devices	Other HT	REA	REA and Economic Assessment	Full HTA	Re-assessment
Austria (AT)	HVB	yes	yes	yes	no	yes	yes	yes
	GoG	yes	yes	yes	yes	yes	yes	seldom
	LBI-HTA	yes	yes	yes	yes (drugs and devices)	no	yes	yes (mostly devices, but also some drugs)
Belgium (BE)	HIHDI (INAMI-RIZIV)	yes	yes	yes	yes	yes	yes	yes
	KCE	yes	yes	yes	no	yes	yes	yes (but happens seldom)
Bulgaria (BG)	NCPHA	yes	no	no	yes	yes	no	yes
Croatia (HR)	AAZ	yes	yes	yes	yes	no	yes	no
	CHIF	yes -	yes	Decision-making only	yes	yes	no	no
Cyprus (CY)	*MoH (1)*	–	–	–	–	–	–	–
Czech Republic (CZ)	SUKL	yes	no	no	no	yes	no	yes
Denmark (DK)	DEFACTUM	no	yes	yes	yes	yes	yes	yes - on request
Estonia (EE)	EHIF	yes - decision-maker after the assessment process	yes - decision-maker after the assessment process	no	no	yes - decision-maker after the assessment process	no	yes - decision-maker after the assessment process
	MoSa	yes (2)	yes (2)	yes (2)	no	yes	no	yes
	University of Tartu	yes	yes	yes	no	no	yes	yes
Finland (FI)	FIMEA	yes	no	no	no - see cell comments	partly yes	no - see cell comment	not routinely
	THL (3)	*yes, in exceptional cases*	*yes*	*yes*	*no*	*no*	*yes*	*no*
France (FR)	HAS	yes	yes	yes	yes	yes, as requested	yes, as requested	yes
Germany (DE)	G-BA	yes	yes	yes	yes	no	no	yes, for time-limited resolutions, but not at pre-fixed intervals
	IQWIG	yes	yes	yes	yes	yes	no	yes
Greece (EL)	*not indicated*	–	–	–	–	–	–	–
Hungary (HU)	NIPN	yes	yes	no	no	yes	no	no

Ireland (IE)	HIQA	yes - see cell comments	yes	yes	yes	yes	yes	yes
	NCPE	yes	no	no	no	yes	no	no
Italy (IT)	AGENAS	no	yes	yes	no	no	yes	no
	AIFA	yes	no	no	no	yes	no	yes
Latvia (LV)	NHS	yes	yes	no	no	yes	no	yes
Lithuania (LT)	SMCA	yes	no	no	yes	no	no	no
	VASPVT	no	yes	no	yes	no	no	no
Luxembourg (LU)	CEM	no	yes	yes	yes	yes	no	not yet
Malta (MT)	DPA/MFH	yes	no	no	no	yes	no	no
Netherlands (NL)	ZIN	yes	yes	yes	yes	yes	yes	yes
Poland (PL)	AOTMiT	yes	yes	yes	yes	yes	no	yes
Portugal (PT)	INFARMED	yes	yes	yes	yes	yes	yes	yes
Romania (RO)	*National Drug Agency MoH National Health Insurance Fund (4)*	*yes*	–	–	–	–	–	–
Slovakia (SK)	MoH, Working Group for Pharmacoeco-nomics, Clinical Outcomes and HTA	yes	yes	yes	no	yes	no	yes
Slovenia (SI)	HIIS	yes	no	no	no	yes	no	yes
	JAZMP	yes	no	no	no	yes	no	yes
Spain (ES)	AEMPS	yes	no	no info	no	yes	possible	yes - but it is not an established process
	AETS-ISCIII	no	yes	yes	yes	yes	no	yes - but there is no formal process
	AETSA	yes	yes	yes	yes	yes	yes	yes
	Avalia-t	yes	yes	yes	yes	yes (cost analysis/im	yes	yes
	AQUAS	yes	yes	yes	yes	no	yes	yes
	IACS	limited to the regional context	yes	yes	yes	yes	yes	yes
	SESCS	no info	no info	no info	no info	no info	no info	no info
	OSTEBA	yes - see cell comments	yes	yes	yes	yes	yes	yes
	UETS	limited	Yes	Yes	Yes	Yes	No	Yes
Sweden (SE)	SBU	yes	yes	yes	no	no	yes	yes

European (EU and EEA) HTA Bodies - Scope of HTA

	TLV	yes	yes	no	yes	yes	no	yes
United Kingdom (UK)	NICE	yes	yes	yes	no	yes	no	yes
	SMC	yes	no	no	no	yes	no	no
	SHTG	no	yes	yes	no	yes	yes	yes
	AWTTC	yes	no	no	no	yes	no	yes
Countries with at least one organisation answering "yes"		23	20	17	15	24	13	20

European Economic Area (EEA)		Scope of HTA						
Country	HTA Bodies	Pharma	Medical devices	Other HT	REA	REA and Economic Assessment	Full HTA	Re-assessment
Norway (NO)	Hdir	yes	yes	yes	no	yes	yes	no
	NMA	yes	yes	no	no	yes	yes	yes
	NIPH	yes	yes	no	yes	yes	yes	yes
Iceland (IS)	*no information*	–	–	–	–	–	–	–
Liechtenstein (LI)	*not indicated*	–	–	–	–	–	–	–

(1) HTA is not currently incorporated into the reimbursement process for Cyprus. However, there is a formalised central reimbursement process that uses elements of HTA to support its decision making. There are plans to introduce HTA formally into the process to include cost effectiveness analysis. However these are currently on hold while the legal framework for the NHS is to be passed by the parliament so that the process of incorporating formal HTA into the reimbursement process can be restarted and the dedicated unit established.

(2) MoSa receives an application from a company

(3) The role of THL in the HTA process in Finland is being clarified. Information on THL in the whole document reflects the role of FinOHTA within THL up until May 2016

(4) Non-validated data

Appendix 3 – Organisational framework

European (EU and EEA) HTA Bodies - Organisational Framework

Country	HTA Bodies	Organisational framework											
		Type of organisation		Budget			Methods to finance HTA activities			HTA staff (1)	Commis-sioning of external experts	Proce-dures to handle conflict of interest	MoH nomi-nated to participa-te in JA3
European Union		Public	Private	Overall	Budget allocated to HTA	Budget for contracting external experts	Budget	Service fees	other	Number			
Austria (AT)	HVB	yes	no	N/A	N/A	N/A	yes	no	Long term contracting and providing services inhouse	7FTEs	yes	Yes	yes
	GoG	yes	no	n/a	450000Euro	included in the budget allocated to HTA in the organisation	Budget only (project based) from Ministry of Health	no	yes	5FTEs	yes	yes	yes
	LBI-HTA	yes	no	1.3MEuro	1.1MEuro	80,000 €	mostly budget	no submission fees no industry sponsored projects (by principle)	EU-projects, some/few extra national 3rd party projects from payers	15 FTEs	yes	no	yes
Belgium (BE)	HIHDI (INAMI-RIZIV)	yes	no	120M Euro	1,1 M Euro	very limited 9636 Euro (2015)	budget only	no	no	12 FTEs	limited	yes	no
	KCE	yes	no	In 2015: €9mln	no info	in 2015 total ca. 2.5 M Euro	budget only	no	no	52.7 FTEs	yes	yes	yes
Bulgaria (BG)	NCPHA	yes	no		35000 Euros (0,5% of the total budget)	25000 Euro	budget only	it is expected to be established	no	5FTEs	yes	yes	yes

Croatia (HR)	AAZ	yes	no	836 674,34 EUR (9.15% for HTA Departme nt=76 548,80 EUR)	67 620,00 EUR	no	budget only (plus EU project finances, eg, EUnetHTA Jas	not yet but planned in the near future, according the Ordinance on HTA	no	FTE: 2 permanent and 2 temporary Part Time: 4 part time HTA staff (maximum of 8 hours weekly - max 180 hours per year)	no	yes	yes
	CHIF	yes	no	*no info*	*no info*	*no info*	*no info*	*no info*	*no info*	*no info*	*no info*	*no info*	no
Cyprus (CY)	*MoH*	yes	no		n/a	n/a	n/a	n/a	no	no - see cell comments!	n/a	yes	yes
Czech Republic (CZ)	SUKL	yes	no	yes	based on the submission fees	no	yes	yes	no	70	no	yes	yes
Denmark (DK)	DEFACTUM	yes	no	no info	ca. 4 million DKR (aprox 537.000 euro)	no	yes	no	yes	10	no	yes	yes
Estonia (EE)	EHIF	yes	no	120000 Eur	no info	40 000€	budget only	no	no	4 FTEs	yes	yes	no
	MoSa	yes	no	250000 Euro	n/a - see cell comments	n/a	n/a	n/a	no	n/a	no	yes	no
	University of Tartu	yes	no	200000 eur	200000 eur	20 000 eur	budget only	no	no	10 persons equivalent to 7 FTEs	yes	yes	yes
Finland (FI)	FIMEA	yes	no	no info	1.264M Euro	5 k€ (for HTA-related activities	governmen t budget	no	EUnetHTA JA3	4 (230 FTEs total workforce)	yes	yes	yes
	THL (2)	*yes*	*no*	*no info*	*no info*	*no info*	*mostly*	*no info*	*EU project funds*	*15*	*no info*	*yes*	*yes*

France (FR)	HAS	yes	no	9 316 789 € (16% of the total expenses of HAS in 2015)	8 627 396€	689 393 €	Each year, the Law for Financing the Social Security (LFSS) allocates a global budget for HAS that includes its HTA activities	no information provided	no information provided	- 107 FTEs (~25% of the total FTEs at HAS	yes	yes according to the French Public Health Code (articles L 1451-1, L1452-3, R1451-1, R 161-84, R 161 86)	yes
Germany (DE)	G-BA	yes	no	n/a	n/a	n/a	no specific amount provided - see cell comments	In addition, a fee-for-service is being collected for early dialogues (about 2000-10000 Euros) Those fees are included into the overall budget.		no information provided	no	yes	yes
	IQWIG	yes	no	2015: 18,8 Mio €		External experts are involved by each assessment above. Budget is allocated to HTA assessments as said above. No other product of institute	IQWiG is financed by system surcharges (from the in and outpatient sector) . The amount of the surcharges is determined by the G-BA on an annual			no information provided	yes	yes	yes
Greece (EL)	*not indicated*	–	–	–	–	–	–	–	–	–	–	–	–

Hungary (HU)	NIPN	yes	no	n/a	less than 5%	n/a	yes	n/a	European Commission projects	14	yes	yes	yes
Ireland (IE)	HIQA	yes		€694,285 (	budget is not disaggrgated to tasks or activities	€ 40,000	budget only	no	no	6.8 FTEs across 8 posts	yes	yes	yes
	NCPE	yes		550000 Euro	n/a	n/a	yes	n/a	no	10 FTEs	n/a	yes	yes
Italy (IT)	AGENAS	yes	no	1.615.193 Euros (6 % of total budget)	1.407.693 Eu	no	yes	no	yes	17	no	yes	yes
	AIFA	yes	no	€ 84.722.965	€ 6.681.962 (7,9% of overall budget)	no	yes	no	no	50 FTE	no	yes	yes
Latvia (LV)	NHS	yes	no	no info	no specific information see cell comments	Contracting of external experts are very rare cases.	yes	yes	no	9 - All staff is full-time employed. Clinical and economical evaluation is only one of their job responsibilities .	yes but rare	yes	yes
Lithuania (LT)	SMCA	yes	no	no	n/a	n/a	n/a	n/a	no	There are 2 half-time clinical experts: one – clinical pharmacologist, MD, PhD; the second –	n/a	yes	yes

	VASPVT	yes	no	no info	30.758 Eur, approx. 3 % of the total VASPVT budget (2016).	no	budget only	no	EUnetHTA project JA3 (2016-2020), co-financed by European Commission	no specific info	no	yes (generally adopted by VASPVT)	yes
Luxembourg (LU)	CEM	yes	no	Governmental budget	The CEM has no specified budget particularly for such labelled "HTA activities".	The CEM has an annual budget about €80.000 to contract external experts for all its activities.	budget from the government	no	no	5,5 FTEs	yes	yes This procedure was launched in 2015/2016.	no
Malta (MT)	DPA/MFH	yes	no	no budget specific to HTA	no budget specific to HTA	no	yes	no	no	5	no	yes	yes
Netherlands (NL)	ZIN	yes	no	no info	5.37m euro (8% of the total ZIN budget)	no	budget only	no	no	54,14 FTE	yes	yes	yes
Poland (PL)	AOTMiT	yes	no		2.50 M EURO	2% of total HTA spending	yes	yes	no	65 FTEs	yes	yes	yes
Portugal (PT)	INFARMED	yes	no	1.5M Euro	750,000 €	750,000 €	budget from the government	no	no	25 FTEs	yes	yes	yes
Romania (RO)	*no specific information available*	–	–	–	–	–	–	–	–	–	–	–	–
Slovakia (SK)	MoH, Working Group for Pharmacoeconomics, Clinical Outcomes and HTA	yes	no	n/a -	n/a	n/a	n/a	n/a	no	5 members from Universities.	n/a	yes	yes
Slovenia (SI)	HIIS	Public	no	no info	0	0	no info	no info	no info	0	Yes	no info	no

	JAZMP	yes	no	355.600 EUR	94000 Euro	16000 Euro	yes (but not foreseen for 2017-2018)	the tarfiff system to be implemented in 2017		1,5-2 FTEs	yes	yes -	yes
Spain (ES)	AEMPS	yes	no	no info	no info	no info	yes	not yet	no	5 - see cell comments!	yes	yes	Yes
	AETS-ISCIII	yes	no	AETS does not have a dedicated budget inside ISCIII	There is an HTA budget within overall ISCIII budget, 574.510€ (in 2016)	n/a	yes	no	no	14 FTEs	yes	yes.	yes
	AETSA	yes	no	1.0M Euro	90%	10%	budget only -	no		21 FTEs	yes	yes	yes
	Avalia-t	yes	no	n/a	n/a	n/a	n/a	yes	yes	12 staff dedicated full time to HTA	yes	yes	yes
	AQUAS	yes	no	6.5M€	0.9M Euro	150,000 Euro	yes	yes	yes	15 FTEs	yes	yes	yes
	IACS	yes	no	12.4 million €	0.95M Euro	110,000 Euro	250,000 Euro	no	yes	14 FTEs + extended network of more than 300 associated researchers and collaborators	yes	yes	no
	SESCS	no info	no info	no info	no info	no info	no info	no info	no info	no info	no info	no info	no info
	OSTEBA	Yes	no	n/a	n/a	n/a	Budget	no	yes	12 FTE	Yes	yes.	yes
	UETS	Yes	no	n/a	n/a	n/a	Budget	No	no	9 FTE	Yes	Yes	No
Sweden (SE)	SBU	yes	no	8 725 000	75% (6 485	10,5% (916125Euro)	budget only, funded by governmen t	no	no	72 FTEs	yes	yes	yes

	TLV	yes	no	5,2 M € for pharma and 0,6 M € for MD (together 45 % of budget for the organisation)	not possible to specify	60000Euro	yes - see cell comments	no	no	140FTEs	yes	yes	yes
United Kingdom (UK)	NICE	yes	no	£63.1 million (2015-2016)	please see cell comments	please see cell comments	Grant in aid funding from the Department of Health	Scientific advice is self-funding through fees	yes	The total FTE of permanently employed staff across the whole institute is 604 as at 31 July 16.	yes	yes	yes
	SMC	yes	no	£2,07M	no specific budget allocated	no specific budget allocated	only budget	no	no	34.9 FTEs	no	yes	no
	SHTG	yes	no	£362,000	no specific b	no specific budget allocated	yes (only bu	occasional modest consultancy income for advice	no	10 FTEs	no	yes	no
	AWTTC	yes	no	£2.9million (3.4 million euros)	£2.4 million (2.8 million euros) = 83% of total budget*	no specific budget allocated	budget only	no	no	21.5FTEs	yes	yes	no
		Organisational framework											

European (EU and EEA) HTA Bodies - Organisational Framework

European Economic Area (EEA)		Type of organisation		Budget			Methods to finance HTA activities			HTA staff (1)	Commissioning of external experts	Procedures to handle conflict of interest	MoH nominated to participate in JA3
Country	HTA Bodies	Public	Private	Overall	Budget allocated to HTA	Budget for contracting external experts	Budget	Service fees	other	Number			
Norway (NO)	Hdir	yes	no	n/a	n/a	n/a	n/a	n/a		4	n/a	yes	yes
	NMA	yes	no	24 mill NOK	18 mill NOK	50000NOK	budget only	no	no	26 FTEs	yes	yes	yes
	NIPH	yes	no	no info	no info	no info	budget only	no	no	about 25 FTE for HTA	yes	yes	yes
Iceland (IS)	*no information*	–	–	–	–	–	–	–	–	–	–	–	–
Liechtenstein (LI)	*not indicated*	–	–	–	–	–	–	–	–	–	–	–	–

(1) Competences of the HTA staff in each of the organisation is avaliable in the individual Country HTA Profiles

(2) The role of THL in the HTA process in Finland is being clarified. Information on THL in the whole document reflects the role of FinOHTA within THL up until May 2016

Appendix 4 – Financing HTA bodies

Country	HTA Bodies	Financing						
		Budget (1)			Methods to finance HTA activities			HTA staff (2)
European Union		Overall	Budget allocated to HTA	Budget for contracting external experts	Budget	Service fees	other	Number
Austria (AT)	HVB	N/A	N/A	N/A	yes	no	Long term contracting and providing services inhouse	7FTEs
	GoG	n/a	450000Euro	included in the budget allocated to HTA in the organisation	Budget only (project based) from Ministry of Health	no	yes	5FTEs
	LBI-HTA	1.3MEuro	1.1MEuro	80,000 €	mostly budget	no submission fees no industry sponsored projects (by principle)	EU-projects, some/few extra national 3rd party projects from payers	15 FTEs
Belgium (BE)	HIHDI (INAMI-RIZIV)	120M Euro	1,1 M Euro	very limited 9636 Euro (2015)	budget only	no	no	12 FTEs
	KCE	In 2015: €9mln	no info	in 2015 total ca. 2.5 M Euro	budget only	no	no	52.7 FTEs
Bulgaria (BG)	NCPHA		35000 Euros (0,5% of the total budget)	25000 Euro	budget only	it is expected to be established	no	5FTEs
Croatia (HR)	AAZ	836 674,34 EUR (9.15% for HTA Department=76 548,80 EUR)	67 620,00 EUR	no	budget only (plus EU project finances, eg, EUnetHTA Jas	not yet but planned in the near future, according the Ordinance on HTA	no	FTE: 2 permanent and 2 temporary Part Time: 4 part time HTA staff (maximum of 8 hours weekly - max 180 hours per year)
	CHIF	*no info*	*no info*	*no info*	*no info*	*no info*	*no info*	*no info*
Cyprus (CY)	*MoH*		n/a	n/a	n/a	n/a	no	no - see cell comments!
Czech Republic (CZ)	SUKL	yes	based on the submission fees	no	yes	yes	no	70

European (EU and EEA) HTA Bodies - Financing

Denmark (DK)	DEFACTUM	no info	ca. 4 million DKR (aprox 537.000 euro)	no	yes	no	yes	10
Estonia (EE)	EHIF	120000 Euro	no info	40 000€	budget only	no	no	4 FTEs
	MoSa	250000 Euro	n/a - see cell comments	n/a	n/a	n/a	no	n/a
	University of Tartu	200000 eur	200000 eur	20 000 eur	budget only	no	no	10 persons equivalent to 7 FTEs
Finland (FI)	FIMEA	no info	1.264M Euro	5 k€ (for HTA-related activities	government budget	no	EUnetHTA JA3	4 (230 FTEs total workforce)
	THL (3)	*no info*	*no info*	*no info*	*mostly*	*no info*	*EU project funds*	*15*
France (FR)	HAS	9 316 789 € (around 16% of the total expenses of HAS in 2015)	no information provided	no information provided	Each year, the Law for Financing the Social Security (LFSS) allocates a global budget for HAS that includes its HTA activities	no information provided	no information provided	- 107 FTEs (~25% of the total FTEs at HAS
Germany (DE)	G-BA	n/a	n/a	n/a	no specific amount provided - see cell comments	In addition, a fee-for-service is being collected for early dialogues (about 2000-10000 Euros) Those fees are included into the overall budget.		no information provided
	IQWIG	2015: 18,8 Mio €		External experts are involved by each assessment above. Budget is allocated to HTA assessments as said above. No other product of institute	IQWiG is financed by system surcharges (from the in and outpatient sector) . The amount of the surcharges is determined by the G-BA on an annual basis.			**no information provided**
Greece (EL)	*not indicated*	–	–	–	–	–	–	–
Hungary (HU)	NIPN	n/a	less than 5%	n/a	yes	n/a	European Commission projects	14

Ireland (IE)	HIQA	€694,285 (3.6%)	budget is not disaggrgated to tasks or activities	€ 40,000	budget only	no	no	6.8 FTEs across 8 posts
	NCPE	550000 Euro	n/a	n/a	yes	n/a	no	10 FTEs
Italy (IT)	AGENAS	1.615.193 Euros (6 % of total budget)	1.407.693 Euros	no	yes	no	yes	17
	AIFA	€ 84.722.965	€ 6.681.962 (7,9% of overall budget)	no	yes	no	no	50 FTE
Latvia (LV)	NHS	no info	no specific information - see cell comments	Contracting of external experts are very rare cases.	yes	yes	no	9 - All staff is full-time employed. Clinical and economical evaluation is only one of their job responsibilities.
Lithuania (LT)	SMCA	no	n/a	n/a	n/a	n/a	no	There are 2 half-time clinical experts: one – clinical pharmacologist, MD, PhD; the second – junior MD.
	VASPVT	no info	30.758 Eur, approx. 3 % of the total VASPVT budget (2016).	no	budget only	no	EUnetHTA project JA3 (2016-2020), co-financed by European Commission	no specific info
Luxembourg (LU)	CEM	Governmental budget	The CEM has no specified budget particularly for such labelled "HTA activities".	The CEM has an annual budget about €80.000 to contract external experts for all its activities.	budget from the government	no	no	5,5 FTEs
Malta (MT)	DPA/MFH	no budget specific to HTA	no budget specific to HTA	no	yes	no	no	5

Netherlands (NL)	ZIN	no info	5.37m euro (8% of the total ZIN budget)	no	budget only	no	no	54,14 FTE
Poland (PL)	AOTMiT		2.50 M EURO	2% of total HTA spending	yes	yes	no	65 FTEs
Portugal (PT)	INFARMED	1.5M Euro	750,000 €	750,000 €	budget from the government	no	no	25 FTEs
Romania (RO)	*no specific information available*	—	—	—	—	—	—	—
Slovakia (SK)	MoH, Working Group for Pharmacoeconomics, Clinical Outcomes and HTA	n/a -	n/a	n/a	n/a	n/a	no	5 members from Universities.
Slovenia (SI)	HIIS	no info	0	0	no info	no info	no info	0
	JAZMP	355.600 EUR	94000 Euro	16000 Euro	yes (but not foreseen for 2017-2018)	the tariff system to be implemented in 2017		1,5-2 FTEs
Spain (ES)	AEMPS	no info	no info	no info	yes	not yet	no	5 - see cell comments!
	AETS-ISCIII	AETS does not have a dedicated budget inside ISCIII	There is an HTA budget within overall ISCIII budget, 574.510€ (in 2016)	n/a	yes	no	no	14 FTEs
	AETSA	1.0M Euro	90%	10%	budget only -	no		21 FTEs
	Avalia-t	n/a	n/a	n/a	n/a	yes	yes	12 staff dedicated full time to HTA
	AQUAS	6.5M€	0.9M Euro	150,000 Euro	yes	yes	yes	15 FTEs
	IACS	12.4 million €	0.95M Euro	110,000 Euro	250,000 Euro	no	yes	14 FTEs + extended network of more than 300 associated researchers and collaborators
	SESCS	no info	no info	no info	no info	no info	no info	no info

	OSTEBA	n/a	n/a	n/a	Budget	no	yes	12 FTE
	UETS	n/a	n/a	n/a	Budget	No	no	9 FTE
Sweden (SE)	SBU	8 725 000 €	75% (6 485 000 €	10,5% (916125Euro)	budget only, funded by government	no	no	72 FTEs
	TLV	5,2 M € for pharma and 0,6 M € for MD (together 45 % of budget for the organisation)	not possible to specify	60000Euro	yes - see cell comments	no	no	140FTEs
United Kingdom (UK)	NICE	£63.1 million (2015-2016)	please see cell comments	please see cell comments	Grant in aid funding from the Department of Health	Scientific advice is self-funding through fees	yes	The total FTE of permanently employed staff across the whole institute is 604 as at 31 July 16.
	SMC	£2,07M	no specific budget allocated	no specific budget allocated	only budget	no	no	34.9 FTEs
	SHTG	£362000	no specific budge	no specific budget allocated	yes (only budget)	occasional modest consultancy income for advice	no	10 FTEs
	AWTTC	£2.9million (3.4 million euros)	£2.4 million (2.8 million euros) = 83% of total budget*	no specific budget allocated	budget only	no	no	21.5FTEs
European Economic Area (EEA)		**Budget**			**Methods to finance HTA activities**			**HTA staff (1)**
Country	**HTA Bodies**	**Overall**	**Budget allocated to HTA**	**Budget for contracting external experts**	**Budget**	**Service fees**	**other**	**Number**
Norway (NO)	Hdir	n/a	n/a	n/a	n/a	n/a		4

	NMA	24 mill NOK	18 mill NOK	50000NOK	budget only	no	no	26 FTEs
	NIPH	no info	no info	no info	budget only	no	no	about 25 FTE for HTA
Iceland (IS)	*no information*	–	–	–	–	–	–	–
Liechtenstein (LI)	*not indicated*	–	–	–	–	–	–	–

(1) The contents of this sub-section is based on the responses received from the surveyed HTA bodies to the question "Budget for HTA activities in your organisation (*In absolute terms (in Euro) and in % to the total budget of organisation)* - subquestions: a) Overall budget b) Budget allocated to HTA assessments (including REA, full HTA, re-assessments, appraisals based on dossiers submitted by industry), c) Budget for contracting external experts

(2) Competences of the HTA staff in each of the organisation is avaliable in the individual Country HTA Profiles

(3) The role of THL in the HTA process in Finland is being clarified. Information on THL in the whole document reflects the role of FinOHTA within THL up until May 2016

Appendix 5 – Workforce

European Union Country	HTA Bodies	Workforce HTA staff (1) Number	Commissioning of external experts
Austria (AT)	HVB	7FTEs	yes
	GoG	5FTEs	yes
	LBI-HTA	15 FTEs	yes
Belgium (BE)	HIHDI (INAMI-RIZIV)	12 FTEs	limited
	KCE	52.7 FTEs	yes
Bulgaria (BG)	NCPHA	5FTEs	yes
Croatia (HR)	AAZ	FTE: 2 permanent and 2 temporary Part Time: 4 part time HTA staff (maximum of 8 hours weekly - max 180 hours per year)	no
	CHIF	*no info*	*no info*
Cyprus (CY)	*MoH*	no - see cell comments!	n/a
Czech Republic (CZ)	SUKL	70	no
Denmark (DK)	DEFACTUM	10	no
Estonia (EE)	EHIF	4 FTEs	yes
	MoSa	n/a	no
	University of Tartu	10 persons equivalent to 7 FTEs	yes
Finland (FI)	FIMEA	4 (230 FTEs total workforce)	yes
	THL (2)	*15*	*no info*
France (FR)	HAS	107 FTEs (~25% of the total FTEs at HAS	yes
Germany (DE)	G-BA	no information provided	no
	IQWIG	no information provided	yes
Greece (EL)	*not indicated*	–	–
Hungary (HU)	NIPN	14	yes
Ireland (IE)	HIQA	6.8 FTEs across 8 posts	yes
	NCPE	10 FTEs	n/a
Italy (IT)	AGENAS	17	no
	AIFA	50 FTE	no
Latvia (LV)	NHS	9 - All staff is full-time employed. Clinical and economical evaluation is only one of their job responsibilities.	yes but rare
Lithuania (LT)	SMCA	There are 2 half-time clinical experts: one – clinical pharmacologist, MD, PhD; the second – junior MD.	n/a
	VASPVT	no specific info	no
Luxembourg (LU)	CEM	5,5 FTEs	yes
Malta (MT)	DPA/MFH	5	no
Netherlands (NL)	ZIN	54,14 FTE	yes
Poland (PL)	AOTMiT	65 FTEs	yes
Portugal (PT)	INFARMED	25 FTEs	yes

Romania (RO)	*no specific information available*	–	–
Slovakia (SK)	MoH, Working Group for Pharmacoeconomics, Clinical Outcomes and HTA	5 members from Universities.	n/a
Slovenia (SI)	HIIS	0	Yes
	JAZMP	1,5-2 FTEs	yes
Spain (ES)	AEMPS	5 - see cell comments!	yes
	AETS-ISCIII	14 FTEs	yes
	AETSA	21 FTEs	yes
	Avalia-t	12 staff dedicated full time to HTA	yes
	AQUAS	15 FTEs	yes
	IACS	14 FTEs + extended network of more than 300 associated researchers and collaborators	yes
	SESCS	no info	no info
	OSTEBA	12 FTE	Yes
	UETS	9 FTE	Yes
Sweden (SE)	SBU	72 FTEs	yes
	TLV	140FTEs	yes
United Kingdom (UK)	NICE	The total FTE of permanently employed staff across the whole institute is 604 as at 31 July 16.	yes
	SMC	34.9 FTEs	no
	SHTG	10 FTEs	no
	AWTTC	21.5FTEs	yes
Number of ogs answering yes to comissioning of external experts			32

European Economic Area (EEA)		**Workforce**	
		HTA staff (1)	**Commissioning of external experts**
Country	**HTA Bodies**	**Number**	
Norway (NO)	Hdir	4	n/a
	NMA	26 FTEs	yes
	NIPH	about 25 FTE for HTA	yes
Iceland (IS)	*no information*	–	–
Liechtenstein (LI)	*not indicated*	–	–

(1) Competences of the HTA staff in each of the organisation is avaliable in the individual Country HTA Profiles

Appendix 6– Use of HTA from other jurisdictions

European (EU and EEA) HTA bodies - Use of HTA from other jurisdictions

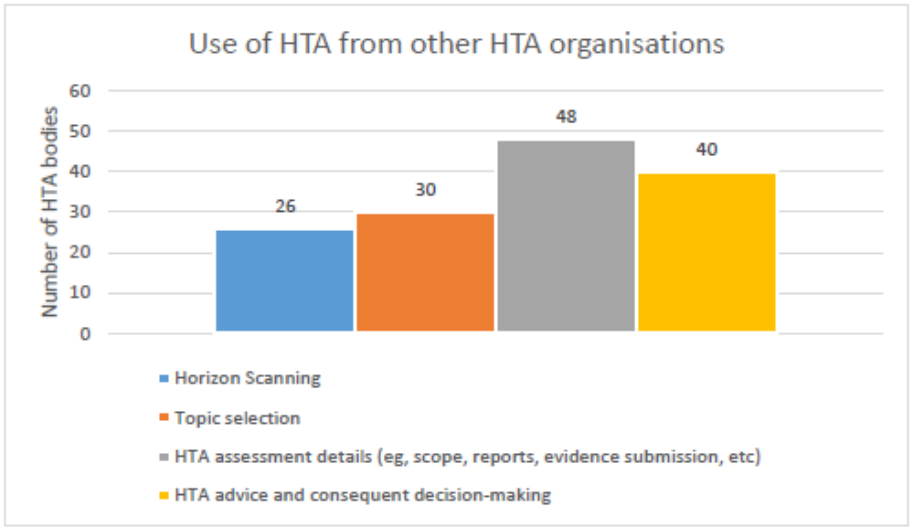
European Union Country	HTA Bodies	Use of HTA from other jurisdictions Yes or No	If Yes Horizon Scanning of HTA	Topic selection	HTA assessment info (scope, reports evidence submissions, etc)	Info about HTA advice and consequent decision-making	Other
Austria (AT)	HVB	yes	yes	yes	yes	yes	see cell comment
	GoG	yes	yes	yes	yes	yes	
	LBI-HTA	yes	yes	yes	yes	no	
Belgium (BE)	HIHDI (INAMI-RIZIV)	Yes	yes	yes	yes	yes	all types are applicable as documentation
	KCE	Yes	yes	yes	yes	no	
Bulgaria (BG)	NCPHA	yes	no	yes	yes	yes	
Croatia (HR)	AAZ	Yes	no	yes	yes	yes	
	CHIF	no info					
Cyprus (CY)	*MoH*	yes	no	yes	yes	yes	
Czech Republic (CZ)	SUKL	yes	no	yes	yes - see cell comments	Yes, but only to gain additional information for our assessment	
Denmark (DK)	DEFACTUM	yes	no	no	yes	yes	
Estonia (EE)	EHIF	yes	no	no	yes	yes	
	MoSa	yes	yes	yes	yes	yes	
	University of Tartu	Yes	Yes	Yes	Yes	Yes	
Finland (FI)	FIMEA	yes	yes	yes	yes	yes	
	THL (1)	*yes*	*yes*	*yes*	*yes*	*yes*	
France (FR)	HAS	yes	no	yes	yes	yes	
Germany (DE)	G-BA	yes	no	no	yes	yes	
	IQWIG	yes	no	no	yes	no	
Greece (EL)	*not indicated*	–	–	–	–	–	–
Hungary (HU)	NIPN	yes	no	no	yes	yes	
Ireland (IE)	HIQA	yes	yes	yes	yes	yes	

	NCPE	yes - please see cell comment	not specified	not specified	not specified	not specified	
Italy (IT)	AGENAS	yes	yes	yes	yes	no	
	AIFA	Yes	no	no	yes	yes	
Latvia (LV)	NHS	yes	no	no	yes	yes	
Lithuania (LT)	SMCA	yes	no	no	yes	yes	
	VASPVT	yes	no	yes	yes	yes	
Luxembourg (LU)	CEM	yes	no	no	yes	yes	
Malta (MT)	DPA/MFH	yes	no	no	yes	yes	
Netherlands (NL)	ZIN	yes	yes	yes	yes	no	
Poland (PL)	AOTMiT	yes	no	no	yes	yes	
Portugal (PT)	INFARMED	yes	yes	yes	yes	yes	no
Romania (RO)	*no specific information available*	–	–	–	–	–	–
Slovakia (SK)	MoH, Working Group for Pharmacoeco-nomics, Clinical Outcomes and HTA	yes	yes	yes	yes	yes	
Slovenia (SI)	HIIS	yes	no	no	yes	yes	
	JAZMP	yes - see the cell comments	no	yes	yes	yes	
Spain (ES)	AEMPS	no -					
	AETS-ISCIII	yes	yes	no	yes	yes	
	AETSA	yes	yes	yes	yes	yes	
	Avalia-t	yes	yes	no	yes	no	yes
	AQUAS	yes	no	no	yes	yes	
	IACS	yes	yes	no	yes	yes	
	SESCS	no info	no info	no info	no info	no info	no info
	OSTEBA	yes	yes	yes	yes	yes	

	UETS	Yes	Yes	Yes	Yes	Yes	
Sweden (SE)	SBU	yes	no	yes	yes	no	
	TLV	yes	yes - see cell comment	no	yes - Yes, especially NICE and SMC	yes	
United Kingdom (UK)	NICE	no					
	SMC	Yes	no	no	yes	no	
	SHTG	yes	yes	yes	yes	yes	
	AWTTC	yes	yes	yes	yes	yes	
Number of orgs responding "yes"	50	46	23	27	45	37	
European Economic Area (EEA)		**Use of HTA from other jurisdictions**					
			If Yes				
Country	**HTA Bodies**	**Yes or No**	**Horizon Scanning of HTA**	**Topic selection**	**HTA assessment info (scope, reports evidence submissions, etc)**	**Info about HTA advice and consequent decision-making**	**Other**
Norway (NO)	Hdir	yes - see cell comments	yes	yes	yes	yes	
	NMA	yes	yes	yes	yes	yes	
	NIPH	yes	yes	yes	yes	yes	
Iceland (IS)	*no information*	-	-	-	-	-	-
Liechtenstein (LI)	*not indicated*	-	-	-	-	-	-
		3	3	3	3	3	

(1) The role of THL in the HTA process in Finland is being clarified.

Horizon Scanning	26
Topic selection	30
HTA assessment det	48
HTA advice and cons	40



Appendix 7 – EUnetHTA output use

European (EU and EEA) HTA bodies - EUnetHTA output use

Country		Use of EUnetHTA tools								Use of EUnetHTA Joint Assessments	
			If Yes								
European Union	HTA Bodies	Yes or No	HTA Core Model ©	POP Database	EVIDENT Database	Evidence Submission Templates	Guidelines	Intranet	Other	Yes or No	Reasons for decision to use/not to use
Austria (AT)	HVB	yes	yes - testing own software	yes	no	yes - testing	yes, as reference	no		yes	
	GoG	yes	no	mainly	no	no	no	no		yes	We adapted the report „Fecal Immunochemical Test (FIT) versus Guaiac-based fecal occult blood test (FOBT) for colorectal cancer screening"; furthermore when starting a new project, we look first if there is a EUnetHTA report available or not.
	LBI-HTA	yes	yes	yes	no	yes	yes	yes		yes	Almost all EUnetHTA joint assessments, but if those not being commissioned by Austrian politicians are actually used, is questionable. Barriers: • language and no time to produce exec sum in German • no topic for Austria • non-relevancy of aspects
Belgium (BE)	HIHDI (INAMI-RIZIV)	yes	yes	yes	no	no	yes	no		yes	as documentation; all pharmaceutical reports were utilised
	KCE	Yes	yes - see cell comments	yes	no	no	yes	yes		yes	· EUnetHTA. Sorafenib for the treatment of progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hürthle cell) thyroid carcinoma, refractory to radioactive iodine. ID: SA-[3]. EUnetHTA; 2015. · EUnetHTA. Ramucirumab in combination with paclitaxel as second-line treatment for adult patients with advanced gastric or gastro-oesophageal junction adenocarcinoma. 2015. Pilot ID: WP5 - SA4
Bulgaria (BG)	NCPHA	yes	yes	yes	no	no	yes	yes		no	We start now to organise our work

Croatia (HR)	AAZ	Yes	yes	yes	yes	yes	yes	yes	yes	yes	
	CHIF	No								No	
Cyprus (CY)	*MoH*	yes	no	yes	yes	no	yes	no		no	Not yet, as the topics already assessed were not relevant to reimbursement decisions taken
Czech Republic (CZ)	SUKL	no - not yet								no	If the joint assessments were available at the time of appraisal, SUKL would have used it as another/supplementary source of information. As the assessment is carried out in the form of an administrative procedure initiated upon application (of the marketing authorization holder) the timing has not been favourable so far.
Denmark (DK)	DEFACTUM	yes	yes	yes	no	no	yes	yes		yes	Endovascular therapy using mechanical thrombectomy devices for acute ischaemic stroke (Version 1.4, February 2016) Rapid relative effectiveness assessment of new pharmaceuticals for the treatment of chronic hepatitis C.
Estonia (EE)	EHIF	no								no	Low awareness of the EUnetHTA activites and low relevance of EUnetHTA's current assessments (topics not relevant for us)
	MoSa	no								no	Low awareness of the EUnetHTA activites and low relevance of EUnetHTA's current assessments (topics not relevant for us)
	University of Tartu	Yes	Yes	Yes	Yes	No	Yes	Yes		Yes	In case the topics are relevant for Estonia

Finland (FI)	FIMEA	yes	yes	no	no	no	yes	no		yes	Ramucirumab for the treatment of gastric cancer, New pharmaceuticals for the treatment of chronic hepatitis C However, the barriers to utilise joint assessments include: - Lack of economic evaluation - Long delay after marketing authorization before joint assessment is published - Small number of joint assessments available
	THL (2)	*yes*	*yes*	*yes*	*no*	*no*	*yes*	*yes*		*yes*	
France (FR)	HAS	yes	yes	yes	yes	no	yes	yes		yes	**Pharmaceutical assessment department** utilised ZONTIVITY, VORAPAXAR joint assessments **Med Dev assessment department** comments: Only a few MDs were assessed by EUnetHTA. The major barriers to utilisation are due to the scope of interest of the HTA bodies. When a EUnetHTA joint assessment is available, it targets the procedure and rarely points out the brand name of the MD. The CNEDiMTS (committee in charge of medical device assessment) has to assess implantable MDs but also external prosthesis for amputees. This kind of MDs is rarely assessed by other agencies. **Medical and Interventional Procedures Assessment department :** But only once at this moment since the process of EUnetHTA joint assessments is just beginning with few hindsight at the moment. We are at the moment assessing thrombectomy procedure based on the pilot rapid assessment of "Endovascular therapy using mechanical thrombectomy devices for acute ischaemic stroke".
Germany (DE)	G-BA	yes	no	no	no	no	yes	no		no	non - compatability with G-BA process, both time-, procedure-, and quality-wise
	IQWIG	yes	no	yes	no	no	yes	no		no	We would if the joint assessments would refer to a clear level of quality.
Greece (EL)	*not indicated*	–	–	–	–	–	–	–	–	–	–

Hungary (HU)	NIPN	yes	yes	no	no	no	yes	yes		yes	CANAGLIFLOZIN FOR THE TREATMENT OF TYPE 2 DIABETES MELLITUS RAMUCIRUMAB IN COMBINATION WITH PACLITAXEL AS SECOND-LINE TREATMENT FOR ADULT PATIENTS WITH ADVANCED GASTRIC OR GASTRO-OESOPHAGEAL JUNCTION ADENOCARCINOMA
Ireland (IE)	HIQA	yes	yes	yes	no	yes	yes	yes		yes	We are currently preparing a national report of the EUnetHTA HTA of mechanical thrombectomy which we led on Barriers to using other reports to date: does not fit with high priority topics for our HTA programme or out of synch from a timing perspective e.g. colorectal cancer screening EUnetHTA HTA came after our national HTA was complete
	NCPE	yes	no	yes	no	no	no	no		yes - canagliflozin	As Ireland is an 'early launch' country, NCPE are usually one of the first agency's in Europe to receive new product submissions, so by the time these (new product submissions) go through the EUnetHTA joint assessment process, the NCPE assessment is usually complete
Italy (IT)	AGENAS	yes	yes	yes	yes	yes	yes	yes		Yes	Transcatheter mitral valve repair in adults with chronic mitral valve regurgitation
	AIFA	no								no	
Latvia (LV)	NHS	yes	no	no	no	no	yes	no		yes	Rapid Relative effectiveness Assessment of new Pharmaceuticals for the treatment of Chronic Hepatitis C (2015) Canagliflozin for the treatment of type 2 Diabetes Mellitus (2014) Renal denervation systems for treatment resistant hypertension (2013)
Lithuania (LT)	SMCA	yes	yes	no	no	no	yes	no		no	EUnetHTA joint assessment were not used because they were not relevant, e.g. an application for reimbursement was not received in Lithuania, product has not been launched in Lithuania, or the joint assessment appeared too late.
	VASPVT	yes	yes	yes	yes	no	yes	yes		yes	1. Endovascular therapy using mechanical thrombectomy devices for acute ischaemic stroke. 2. Renal denervation systems for treatment-resistant hypertension. 3. Transcatheter implantable Devices for mitral valve repair in adults with Chronic Mitral Valve Regurgitation. 4. Duodenal-jejunal bypass sleeve for the treatment of Obesity with or without type ii Diabetes Mellitus.

Luxembourg (LU)	CEM	yes	yes	yes (access during JA2)	yes (access during JA2)	No	yes	yes (access during JA2)	yes see cell com-ment	no	CEM is only concerned with medical devices hence the REAs that have been published by EUnetHTA to date are not relevant to the CEM since these only concern pharmaceuticals; The subjects of the full HTAs that have been produced to date have not been relevant or linked to any request that the CEM has received so far besides the FIT vs FOBT for colorectal cancer screening was partly used for one request on implementing a new colorectal cancer screening program in Luxembourg; The full HTAs are relatively complex and comprehensive which is unfortunately not feasible for the CEM; CEM only extracts information that is relevant.
Malta (MT)	DPA/MFH	no								yes - Canagliflozin for the treatment of type 2 Diabetes Mellitus	
Netherlands (NL)	ZIN	Yes	no	yes	no	no	yes	no		yes	ramucirumab; bypass sleeve; canagliflozin; zostavax.

Poland (PL)	AOTMiT	yes	yes -	yes -	no	no	yes -	no		no	The one potentially useful (duodenal-jejunal bypass sleeve for the treatment of obesity with or without type II diabetes mellitus) happened to be out of the scope in terms of population - There are no formal obstacles to use joint assessments on the same base as other evidence found in systematic review; there is no specific regulation enabling it's uptake as final submission document (this would promote MAH as AOTMiT does only very specific HTA reports itself while it critically asses the submissions) - current AOTMIT assessments were not covered by the topics assessed in joint reports - the submission assessment process is strictly defined by law, which determine the requirements of the assessment such as: o limited time of 60 days from MoH order (an orders come w/o forewarning) o structure of submission reports, including eg. the issue of cost-effectiveness against stiff c-e threshold or CER/CUR assessment; o language (HTA is a part of administrative process while Polish is obligatory as default in administrative process documents)
Portugal (PT)	INFARMED	yes	yes	yes	yes	no	yes	yes		yes	Reuse of assessments alredy done in order to save time and resources
Romania (RO)	*no specific information available*	–	–	–	–	–	–	–	–	–	–

Slovakia (SK)	MoH, Working Group for Pharmacoeco-nomics, Clinical Outcomes and HTA	yes	yes	yes	yes	yes	yes	yes		yes	Pilot rapid assessment on Balloon Eustachian Tuboplasty for the treatment of Eustachian tube dysfunction Pilot rapid assessment on Biodegradable Stents for the treatment of refractory or recurrent benign oesophageal stenosis. Pilot rapid assessment on 'Canagliflozin for the treatment of type 2 diabetes mellitus' Pilot rapid assessment on 'Duodenal-jejunal bypass sleeve for the treatment of obesity with or without Type II Diabetes Mellitus' Pilot rapid assessment on Ramucirumab in combination with Paclitaxel as second-line treatment for adult patients with advanced gastric or gastro-oesophageal junction adenocarcinoma Pilot rapid assessment on Renal denervation systems for treatment-resistant hypertension Sorafenib for the treatment of advanced or metastatic progressive differentiated thyroid cancer
Slovenia (SI)	HIIS	not yet								not yet	We have't searched for EUnetHTA Joint Assessments results yet
	JAZMP	no not to date, but interest to use them from now on.								no -	The EUnetHTA tools and joint assessments have not been used to date, but are ready to use them combined with national implementation during the JHTA3 process and later.
Spain (ES)	AEMPS	no -								no - but see the next cell comments!	AEMPS recently joined EUnetHTA JA3. We were not involved in previous JA1 and JA2 and therefore, we have not previous experience with these Joints reports. However, we intend to actively participate in JA3 and contribute to the preparation of joint reports that can be used and exploited to our national activity
	AETS-ISCIII	yes	yes	yes	yes	yes	yes	yes		yes	Duodenal-jejunal bypass sleeve for the treatment of obesity with or without Type 2 Diabetes was used for natioanl HTA AETS-ISCIII has also collaborated in the production of Joint Assessments (Biodegradable stents for the treatment of refractory or recurrent benign oesophageal stenosis)
	AETSA	yes	yes	yes	no	yes	yes	yes		yes	"Balloon Eustachian tuboplasty for the treatment of Eustachian tube dysfunction". "Canaglifozin"
	Avalia-t	yes	yes	yes	yes	yes	yes	yes	yes	yes	EUnetHTA assessment are always used if considered appropriate to answer our question.
	AQUAS	yes	yes	no	no	no	yes	yes		yes	JA2 Vorapaxar REA

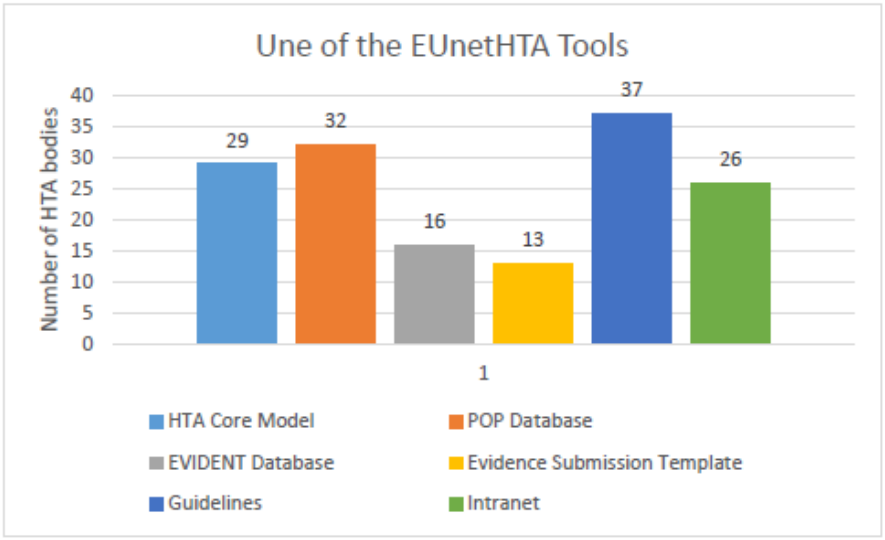
	IACS	yes	yes	yes	yes	no	yes	yes		yes	
	SESCS	no info	no info	no info	no info	no info	no info	no info	no info	no info	no info
	OSTEBA	yes	yes	yes	yes	yes	yes	yes		No yet	We are involved in Joint assessments in JA3
	UETS	Yes	Yes	No	No	No	Yes	No		Yes	
Sweden (SE)	SBU	yes	no	yes	no	no	yes	yes		yes	Whether the topics have relevance and fit current prioritization for Swedish healthcare.
	TLV	yes	yes	no	no		yes	yes		yes	
United Kingdom (UK)	NICE	yes		yes	yes	yes		yes		no	There has been little overlap between the topics chosen for EUnetHTA assessments and topics completed for national assessment. Where there has been overlap the EUnetHTA assessment has been available too late for it to inform a national assessment. • Our national assessment does not include a separate decision based on REA, instead it includes a single decision based on cost effectiveness. To use a EUnetHTA REA assessment the data in the REA would need to be consistent with evidence submitted by the companies to inform the NICE cost effectiveness assessment (that is the values for clinical effectiveness in the EUnetHTA REA would have to be the same as the values used in the company health economic model). • There is insufficient transparency of the EUnetHTA assessments as the company submission of evidence is not published • Once EUnetHTA assessments were perceived to be fit for purpose, a revision to the procedure guide would be required. The process of revising the procedure guide would normally include: o pilot and evaluation of the proposed change o stakeholder consultation o sign off from senior management and the NICE board.
	SMC	no								no	Very limited use of EUnetHTA joint assessments (eg, small amount of data from the sorafenib assessment was used in SMC assessment of sorafenib) Timing of EUnetHTA joint assessments is not in line with SMC's requirements
	SHTG	yes	yes	yes	yes	yes	yes	yes		yes	JA2 WP5 REAs on: renal denervation, mitral valve technologied and thrombectomy devices. We have adapted these to provide advice for NHSScotland.
	AWTTC	no								no	The topic of using joint assessment reports has not been discussed within the organisation and so unable to list any barriers to utilisation. However, in principal we would be open to exploring this
Number of orgs responding yes		38	29	30	15	12	35	24		30	

European Economic Area (EEA) Country	HTA Bodies	Use of EUnetHTA tools: Yes or No	If Yes: HTA Core Model ©	POP Database	EVIDENT Database	Evidence Submission Templates	Guidelines	Intranet	Other	Use of EUnetHTA Joint Assessments: Yes or No	Reasons for decision to use/not to use
Norway (NO)	Hdir	yes								yes	
	NMA	yes	no	yes	yes	yes - partly	yes	yes		yes - Ramucirumab in combination with pactitaxel as 2-nd line treatment for adult patients with advanced gastric or gastro-oesophagal junction adenocarcinoma	1. Choice of scope/ topic for REA not in line with national HTA request 2. Timing and Timeline of REA not in line with national HTA request 3. Limitation of the REA to efficacy and safety assessment- NOMA always requires pharmacoeconomic analysis as mandatory part of HTA 4. Readability of EUnetHTA reports- not «fit for purpose»?
	NIPH	yes	only when working on EUnetHTA reports	yes	no	no	yes	yes			reuse HTA reports or systematic reviews from other organizations if they are relevant for the topics we are working on (national work program)
Iceland (IS)	*no information*	-	-	-	-	-	-	-	-	-	-
Liechtenstein (LI)	*not indicated*	-	-	-	-	-	-	-	-	-	-
			3	0	2	1	1	2	2	2	

(2) The role of THL in the HTA process in Finland is being clarified.

European (EU and EEA) HTA bodies - EUnetHTA output use

HTA Core Moc	29
POP Database	32
EVIDENT Data	16
Evidence Subr	13
Guidelines	37
Intranet	26



Appendix 8– HTA system organisation

European (EU and EEA) HTA bodies - HTA system organisation

European Union Country	Models of organisation of national HTA systems based on main role						
	One national HTA body, having only one main role - HTA recommen-dations	One national HTA body, with regulatory functions	One national HTA body, with P(&/or)R functions	One national HTA body, regulatory +P(&/or)R functions	Two or more national HTA bodies, at least one with regulatory functions	Two or more national HTA bodies, at least one with P(&/or)R functions	Two or more national HTA bodies, combining regulatory and P(&/or)R functions
Austria (AT)						HVB (P&R), GOG, LBI (HTA only)	
Belgium (BE)						INAMI-RIZIV (P&R) KCE (HTA only)	
Bulgaria (BG)	NCPHA						
Croatia (HR)						CHIF (P&R) AAZ (HTA only)	
Cyprus (CY)				MoH			
Czech Republic (CZ)				SUKL			
Denmark (DK)	*DEFACTUM*						
Estonia (EE)							MoSA (reg) *SMA (reg)* EHF (P&R) Uni of Tartu (HTA only)
Finland (FI)		FIMEA					
France (FR)	HAS						
Germany (DE)						GBA (Reimbursement) IQWIG (HTA only)	
Greece (EL)	no specific information						
Hungary (HU)		NIPN					
Ireland (IE)						NCPE (Reimbursement) HIQA (HTA only)	
Italy (IT)							AIFA (reg, P&R) AGENAS (HTA only) Plus regional HTA agencies with varying HTA mandates and remits
Latvia (LV)			NHS				
Lithuania (LT)							SMCA (reg and Reimbursement), *NHIF (P&R)* VASPVT (HTA only)
Luxembourg (LU)			CEM				

Malta (MT)			DPA/MHF				
Netherlands (NL)			ZIN				
Poland (PL)	AOTMiT						
Portugal (PT)				INFARMED			
Romania (RO)							National Drug Agency MoH National Health Insurance Fund
Slovakia (SK)	MoH; Working Group for Pharmacoeco-nomics, Clinical Outcomes and HTA						
Slovenia (SI)							HIIS (P&R) *Health Council at MoH* JAZMP (Reg and Pricing)
Spain (ES)					AEMPS (Reg) Spanish HTA Network (HTA only) Plus regional HTA agencies with varying HTA mandates and remits		
Sweden (SE)						TLV (P&R) SBU (HTA only)	
United Kingdom (UK)	NICE HTA bodies in devloved administrations of Scotland and Wales (SMC, SHTG, AWTTC)						
Total count of countries	6	2	4	3	1	6	5

European Economic Area (EEA)	Models of organisation of national HTA systems based on main role						
Country	One national HTA body, having only one main role - HTA recommen-dations	One national HTA body, with regulatory functions	One national HTA body, with P(&/or)R functions	One national HTA body, regulatory +P(&/or)R functions	Two or more national HTA bodies, at least one with regulatory functions	Two or more national HTA bodies, at least one with P(&/or)R functions	Two or more national HTA bodies, combining regulatory and P(&/or)R functions
Norway (NO)							NMA (reg, P&R) NIPH (HTA only) Hdir (HTA coordination)
Iceland (IS)	no information						
Liechtenstein (LI)	no information						

Appendix 9– HTA bodies - other tasks

European (EU and EEA) HTA bodies - other tasks

European Union	Other tasks perfomed by national HTA bodies						
Country	Quality standards	Clinical guidelines development	Healthcare promotion	Horizon scanning	Registries	Education	Early Dialogues and Scientific Advice
Austria (AT)	HVB, GOG	HVB	HVB, GOG	LBI	GOG	GOG	_
Belgium (BE)	_	KCE	INAMI-RIZIV	INAMI-RIZIV KCE	INAMI-RIZIV	INAMI-RIZIV	KCE
Bulgaria (BG)	_	_	NCPHA	_	NCPHA	NCPHA	_
Croatia (HR)	AAZ	_	_	_	_	AAZ	_
Cyprus (CY)	MoH	MoH					
Czech Republic (CZ)	_	_	_	_	_	_	_
Denmark (DK)	DEFACTUM	_	DEFACTUM	_	DEFACTUM	DEFACTUM	_
Estonia (EE)	_	EHIF, MoSa	EHIF, MoSa	EHIF, Uni of Tartu	EHIF, MoSa	Uni of Tartu	MoSa
Finland (FI)	_	_	_	_	_	_	FIMEA
France (FR)	HAS	HAS	HAS				HAS
Germany (DE)	GBA, IQWIG	GBA				IQWIG	GBA
Greece (EL)	*no info*						
Hungary (HU)	_	NIPN	_	_	_	NIPN	_
Ireland (IE)	HIQA	HIQA	_	_	NCPE	HIQA, NCPE	NCPE
Italy (IT)	AGENAS	AGENAS	AGENAS	AGENAS	_	AGENAS	_
Latvia (LV)		NHS	_	_	_	_	_
Lithuania (LT)	_	_	_	_	_	_	_
Luxembourg (LU)	_	CEM	_	_	_	_	_
Malta (MT)	_	_	_	_	_	DPA/MHF	_
Netherlands (NL)	ZIN	ZIN	_	ZIN	_	_	ZIN
Poland (PL)	_	_	AOTMiT	_	_	AOTMiT	_
Portugal (PT)	_	_	INFARMED	INFARMED	INFARMED	_	INFARMED
Romania (RO)	*no info*						
Slovakia (SK)	MOH Working Group	_	_	MOH Working Group	_	_	_
Slovenia (SI)	_	_	HIIS	_	JAZMP	_	JAZMP
Spain (ES)	see details on "Roles and Tasks" for each of the Spanish HTA Network member agencies						
Sweden (SE)	_	_	_	TLV	TLV	_	TLV
United Kingdom (UK)	NICE, SMC, SHTG	NICE, SHTG, AWTCC	NICE	NICE, SMC, SHTG, AWTCC	NICE	NICE, AWTCC	NICE, SHTG
Total count of countries	12	14	12	10	11	14	12

European Economic Area (EEA)	Other tasks perfomed by national HTA bodies						
Country	Quality standards	Clinical guidelines develop-ment	Healthcare promotion	Horizon scanning	Registries	Education	Early Dialogues and Scientific Advice
Norway (NO)	NMA, NIPH	Hdir, NIPH	NIPH	NMA, NIPH	NIPH	NIPH	NMA
Iceland (IS)	no information						
Liechtenstein (LI)	no information						

Appendix 10– National HTA processes organisation

Type of HTA	AUSTRIA		BELGIUM		BULGARIA	
	Number	Time to complete	Number	Time to complete	Number	Time to complete
STA	353 (*HVB process*) 5 (*LBI process*) varies from year to year (under 10 approximately) (*GOG process*)	3 to 4 weeks 4 months from 1-2 weeks to 12 months - depends on political need.	50 (RIZIV-INAMI), 91 HTA reports between 2006-2016 (KCE) I (*non-invasive medical devices*): this is very variable - from 150 in 2015 to only 2 so far in 2016 II (*invasive medical devices*): 280 (80 needing detailed assessment + 200 'generic dossiers' / year (also includes re-assessments)	13 weeks (without clock stop of max 90 days that could be requested by Company only) - INAMI-RIZIV process About 9-12 months, Up to 14 months - KCE process I: no specific timing - INAMI-RIZIV process: Up to 14 months - KCE process II: 100 days - INAMI-RIZIV process; Up to 14 months - KCE process	40	90 days
MTA	no 2 varies from year to year (under 10 approximately)		n/a I and II: n/a		n/a	
Initial Assessment	see STA cell 7 varies from year to year (under 10 approximately)	see STA cell between 4 and 7 months from 1-2 weeks to 12 months - depends on political need.	50 (RIZIV-INAMI), 91 HTA reports between 2006-2016 (KCE) I: this is very variable - from 150 in 2015 to only 2 so far in 2016 II: no distinction made in statistics in "initial assessment" and "re-assessment"; therefore: data not available	see above I and II: see above	40	90 days
Re-assessment	see cell comment 2 no	1-2 weeks 4 months n/a	SINGLE TECHNOLOGIES: 70 = 10 (revisions of initial assessment) + 60 (modification of reimbursement) MTA: 5 (RIZIV-INAMI), no reassessments at KCE I: none II: no distinction made in statistics in "initial assessment" and "re-assessment"; therefore: data not available - For KCE: exceptional reassessment (e.g. TAVI report after publication of trial results)	STA: 13 weeks (without clock stop of max 90 days that could be requested by Company only) MTA: - 13 weeks in case assessment is based on information submitted by company(ies) - no timelines in case assessment is based on information not submitted by company(ies)	2	90 days

Type of HTA	AUSTRIA		BELGIUM		BULGARIA	
	Number	Time to complete	Number	Time to complete	Number	Time to complete
REA	no 7 (initial and re-asssessment STAs) variable (only MTAs)	n/a 4 months up to 12 months - depends on political need.	n/a - all are full HTAs (RIZIV-INAMI), KCE: full HTAs n/a - all are full HTAs		0	
REA and economic assessment	see STA cell no variable (only STAs)	see STA cell n/a up to 12 months - depends on political need	n/a - all are full HTAs (RIZIV-INAMI), KCE: full HTAs n/a - all are full HTAs		41	90 days
Full HTA	no 2 (MTAs) no	n/a 4-7 months n/a	125 (RIZIV-INAMI), 91 HTA reports between 2006-2016 (KCE) --> HTA reports are usually incl. economic part, except when findings in medical part make the economic part redundant (e.g. in case there is no reliable evidence) I: this is very variable - from 150 in 2015 to only 2 so far in 2016 II: all are full HTAs	Depends on type of assessment done (STA, MTA, reassessment) - see information above (RIZIV-INAMI process, about 9-12 months, up to 14 months for KCE)	0	0

Type of HTA	CROATIA		CYPRUS		CZECH REPUBLIC		DENMARK	
	Number	Time to complete	Number	Time to complete	Number	Time to complete	Number	Time to complete
STA	AAZ: 4-5 CHIF: 50-60	AAZ: 4-5 months CHIF: up to 15-60 days for appraisals	*no specific data*	*no specific data*	390	Proceeding actual average lengths: full initial assessments: 224 days, variations to the conditions: 190 days, rapid assessments: 30 days)	2	3-6 months
MTA	AAZ: up to 4 per year at national level; CHIF: up to 5 for appraisal process	AAZ: 4-9 months CHIF: up to 15-60 days for appraisal	*no specific data*	*no specific data*	68 (performed with reassessments only)	from 46 days (rapid) to 370 (complex reassessments)	8	6-12 months
Initial Assessment	AAZ: up to 9 CHIF: up to 65	See data in the above 2 cells for both AAZ and CHIF	*no specific data*	*no specific data*	see STA cell	224 days (STAs) - see details in STA cell	10	see STA and MTA cells
Re-assessment	if decision-makers request it, no iformation on number	n/a	*no specific data*	*no specific data*	336	Depends if it is an STA or MTA - see cell's comment	no	n/a

Type of HTA	CROATIA		CYPRUS		CZECH REPUBLIC		DENMARK	
	Number	Time to complete	Number	Time to complete	Number	Time to complete	Number	Time to complete
REA	AAZ: 4-5 per year	AZZ: 4-5 months	*no specific data*	*no specific data*	approx. 290	n/a	n/a	n/a
REA and economic assessment	CHIF: 50-60 (all submission files need to include budget impact analysis)	CHIF: 15-60 days	*no specific data*	*no specific data*	no specific number provided - see cell comment	Depends if it is an Initial asessment or reassessment - see cell comment	n/a	n/a
Full HTA	AAZ: up to 3 per year (without primary full economic analyses because they are still not mandatory in Croatia)	AZZ: between 4 and 9 months	*no specific data*	*no specific data*	n/a	n/a	10	see STA and MTA cells

Type of HTA	ESTONIA		FINLAND		FRANCE		GERMANY	
	Number	Time to complete	Number	Time to complete	Number	Time to complete	Number	Time to complete
STA	no information 4 to 6	no information 30-50 weeks	Inpatient - 5-7 (max capacity 10-15); outpatient - 40-45	Inpatient - 10/12 weeks; outpatient - 90/100 days	232inclusion assessments 95 initial assessments no information available	less than 90 days - initial assessment less than 90 days (initial assessment) <180 days (on National Health Insurence request) or 1 year (on MoH, Professional org., patient rep. request, according to annual program)	no information	no information
MTA	no information no	no information n/a	no	no	45 (MTAs) full reasssessments 6 initiall assessments and 6 re-assessments no information available	90-180 days 1 year 1 year	no information	no information
Initial Assessment	no information 4 to 6	no information 30-50 weeks	see STA	see STA	see STA cell see cells above no information available	see STA cell see cells above see cells above	2016: 63, 10 (pharm. Charact.) 2	6 months total (assessment, hearings, appraisal) after dossier has been handed in (the latest with market entry), 90 days
Re-assessment	no information n/a	no information n/a	outpatient - n/a; inpatient - <5	outpatinet - n/a; inpatient - 90/100 days	330 reassessments (STAs) to maintian drugs on community pharmacy lists; and 45 (MTAs) full reassessments 104 STAs and 6 MTAs - please see cell's comments no information available	90-180 days no information available no information available	2016 - 10 assessments	

Type of HTA	ESTONIA		FINLAND		FRANCE		GERMANY	
	Number	Time to complete	Number	Time to complete	Number	Time to complete	Number	Time to complete
REA	n/a n/a	n/a n/a	n/a	n/a	No specific figures for REA were provided, however, majority of assessments are REAs 95 initial STAs and 104 re-assessments (MTAs) no information available	90 days 90 days (STAs) and 1 year (MTAs) <180 days (on National Health Insurence request) or 1 year (on MoH, Professional org., patient rep. request, according to annual program)	see Initial Assessment and Re-assessment cells	see Initial Assessment and Re-assessment cells
REA and economic assessment	no information n/a	no information n/a	see STA (inpatient economic assessment includes costs and budget impact analysis)	see STA (inpatient economic assessment includes costs and budget impact analysis)	Between Nov 203 and Oct 2015 -35 EE submitted by manufacturers assessed by HAS n/a n/a	90 days n/a n/a	n/a	n/a
Full HTA	n/a see STA cell	n/a see STA cell	n/a	n/a	Usually MTAs that are full reassessments 12 MTAs no information available	variable 1 year 1 year	n/a	n/a

Type of HTA	GREECE		HUNGARY		IRELAND		ITALY	
	Number	Time to complete	Number	Time to complete	Number	Time to complete	Number	Time to complete
STA	n/a	n/a	approx. 90-100 apprpox 90-110 (for medical aids) apporx 4-5 (for healthcare technologies)	6,1 weeks: 43 days (0. day: when the submission arrives from the NHIF to the NIPN) 2,1 weeks:15 days (0. day: when the submission arrives from the NHIF to the NIPN) - medical aids 4,3 weeks: 30 days (0. day: when the submission arrives from the NHIF to the NIPN) - healthcare technologies	20 variable (2015 - 5)	90 days stop clock 8-12 weeks	no information made available only horizon scanning reports - 3	no information made available 16 weeks
MTA	n/a	n/a	no no	no no	no no information	n/a 6-12 months	not performed 5	n/a 52 weeks
Initial Assessment	n/a	n/a	see STA see STA	see STA see STA	20 variable	90 days stop clock from 8-12 weeks to 6-12 months	no information made available 8 (including horizon scanning reports)	no information made available from 16 to 52 weeks
Re-assessment	n/a	n/a	no no	no no	no no information	n/a no information	no information made available not performed	no information made available n/a

Type of HTA	GREECE		HUNGARY		IRELAND		ITALY	
	Number	Time to complete	Number	Time to complete	Number	Time to complete	Number	Time to complete
REA	n/a	n/a	n/a	n/a	no no information	n/a no information	not performed not performed	n/a n/a
REA and economic assessment	n/a	n/a	see STA see STA	see STA see STA	20 variable	90 days stop clock from 8-12 weeks to 6-12 months	no information made available not performed	no information made available n/a
Full HTA	n/a	n/a	n/a	n/a	no variable	n/a up to 12 months	not performed 8 (including horizon scanning reports)	n/a from 16 to 52 weeks

Type of HTA	LATVIA		LITHUANIA		LUXEMBOURG		MALTA	
	Number	Time to complete	Number	Time to complete	Number	Time to complete	Number	Time to complete
STA	34	180 days (time from application to decision making, legally defined)	62 In total around 16 assessments were carried out in the past 5 years, more than half of it is adaptation from other countries. 2-3 original assessments carried out a year.	60 days Average - 3 months. Time varies depending on the topic	has been done by CEM, please see comment (1)		12	3 months
MTA	no	n/a	no no	n/a n/a	has been done by CEM, please see comment (1)		8	12 months
Initial Assessment	34	180 days (time from application to decision making, legally defined)	62 see STA cell	60 days see STA cell	has been done by CEM, please see comment (1)		20	from 3 to 12 months
Re-assessment	Reassessments are done on case-by-case basis when new clinical or economic information is available.	180 days (time from application to decision making, legally defined) 90 days is a time limit for price changes.	no no	n/a n/a	No		5	1 to 3 months

Type of HTA	LATVIA		LITHUANIA		LUXEMBOURG		MALTA	
	Number	Time to complete	Number	Time to complete	Number	Time to complete	Number	Time to complete
REA	no	n/a	see STA cell see STA cell - budget impact assessment is performed on request	see STA cell see STA cell	No		n/a	n/a
REA and economic assessment	see STA cell	see STA cell	no no	n/a n/a	Economic assessment and budget impact analyses have been done by CEM; no REA since no pharmaceuticals		25 (including re-assessments)	from 1 to 12 months
Full HTA	no	n/a	no no	n/a n/a	No Full HTA but MINI-HTA, rapid reviews and tech/quick notes		n/a	n/a

Type of HTA	Netherlands		POLAND		PORTUGAL		ROMANIA		SLOVAKIA	
	Number	Time to complete	Number	Time to complete	Number	Time to complete	Number	Time to complete	Number	Time to complete
STA	40-50 10-15	between 60 and 365 days between 150 and 365 days	approx 200 yearly (2015 - 219)	For pharmaceuticals, medical devices or special food supplements assessed on the base of the MAH submission: 60 days (+up to 14 days); for pharmaceuticals in off-label indication - up to 14 days (an apprisal (expert opinion) of Transprency Council essential; an assessment not required by law, but issued in practice); for procedures and non-standard orders: not restricted or spcified by MoH	317 1	Inpatient: 30,5 weeks (152,5 working days) Outpatient: 8,2 weeks (41 working days) Median time: 38,7 weeks as for pharma	info not provided	info not provided	approx 30	approx 12 weeks
MTA	no no	n/a n/a	n/a		Yes		info not provided	info not provided	no	n/a
Initial Assessment	35-60 5-10	between 60 and 365 days between 150 and 365 days	see STA cell	see STA cell	the numbers above are for initial assessments	the numbers above are for initial assessments	info not provided	info not provided	see STA cell	see STA cell
Re-assessment	0-5 0-5	between 60 and 365 days between 150 and 365 days	n/a	n/a	0	n/a	info not provided	info not provided	approx 10	approx 12 weeks

Type of HTA	Netherlands		POLAND		PORTUGAL		ROMANIA		SLOVAKIA	
	Number	Time to complete	Number	Time to complete	Number	Time to complete	Number	Time to complete	Number	Time to complete
REA	REA only = ~50% of all assessment REA only = ~90 to 95% of all assessments	between 60 and 180 days between 150 and 365 days	approx. 160 per year (2015 - 133; 2014 - 191),	for pharmaceuticals in off-label indication - up to 14 days (an apprisal (expert opinion) of Transprency Council essential	n/a	n/a	info not provided	info not provided	no	n/a
REA and economic assessment	REA and economic assessment or Full HTA = ~ 50% REA and economic assessment or Full HTA = ~ 5 to 10%	between 90 and 365 days between 150-365 days	approx. 95 per year (2015 - 86; 2014 - 102)	see STA cell	777+1	Inpatient: 30,5 weeks (152,5 working days) Outpatient: 8,2 weeks (41 working days) Median time: 38,7 weeks as above	info not provided	info not provided	40	approx 12 weeks
Full HTA	no information on exact division of REA and economic assessment and Full HTA no information on exact division of REA and economic assessment and Full HTA	between 90 and 365 days between 150-365 days	n/a	n/a	n/a	n/a	info not provided	info not provided	no	n/a

Type of HTA	SLOVENIA		SPAIN		SWEDEN	
	Number	Time to complete	Number	Time to complete	Number	Time to complete
STA	Up to 340 (that includes approx 300 by JAZMP, 4 by Health Council and the rest - by the HIIS)	90+60 days (JAZMP process) approx 4 month (Health Council Process)	44 38-44	4-7,5 months varies (between 2 (REAS) and 6+ months (other HTAs))	**SBU process:** 11 a) 5 (4 initial and 1 reassessment) - original HTAs, b) 6 (3 initial and 3 reassessments) - SBU commentaries on HTA reports from the other HTA agencies **TLV process: 109** a) 54 initial assessments b) 55 initial assessments	**SBU process:** a) 52 weeks - original HTAs, b) 12-24 weeks - SBU commentaries on HTA reports from the other HTA agencies **TLV process: 109** a) 17 weeks b) 13 weeks (26 weeks for reassessments)
MTA	no	n/a	no no	n/a n/a	**SBU process:** 13 a)7 (3+4) - original HTAs, b) 6 re-assessments - SBU commentaries on HTA reports from other HTA agencies, **TLV process: 2** a) 2 reassessments	**SBU process:** a)78 weeks - original HTAs, b) 12-24 weeks- SBU commentaries on HTA reports from other HTA agencies **TLV process:** a) 4-40 weeks
Initial Assessment	see STA information		~~44~~ 38-44	4-7,5 months varies (between 2 (REAS) and 6+ months (other HTAs))	**SBU process:10** (4+3+3) - see cell B3 and B4 **TLV process: 109**	**SBU process:** 52 weeks - STAs original HTAs, 12-24 weeks - STAs and commentaries and 78 weeks - MTAs original HTAs **TLV process:** 17 weeks; 13 weeks - both STAs
Re-assessment	no information	n/a	yes, but none is completed yet 1 (HTA)	n/a 2-6 months	**SBU process: 14** **TLV process: 2**	**SBU process: STAs** - a) 52 weeks - original HTAs, b) 12-24 weeks - SBU commentaries on HTA reports from the other HTA agencies **MTAs** - a) 52 weeks - original HTAs, b) 12-24 weeks - SBU commentaries on HTA reports from the other HTA agencies **TLV process: MTAs** a) 4-40 weeks

Type of HTA	SLOVENIA		SPAIN		SWEDEN	
	Number	Time to complete	Number	Time to complete	Number	Time to complete
REA	no	n/a	no 28 (includes both REAs and REAs+economic assessment)	n/a varies (between 2 (REAS) and 6+ months (other HTAs))	**none for either SBU or TLV process**	n/a
REA and economic assessment	see STA information	see STA information	44 see cell above	4-7,5 months see cell above	**TLV process:** among the indicated 109	**TLV process:** from 4-40 weeks for MTA re-assssments to 70 weeks for STAs intitial assessments; 13 weeks - initial STAs
Full HTA	no	n/a	no no	n/a n/a	**SBU process: 12 (We are not including SBU Comments)** **TLV process: among the indicated 109**	SBU process: see cells C3-6 TLV process: from 4-40 weeks for MTA re-assssments to 17 weeks for STAs intitial assessments; 13 weeks - initial STAs

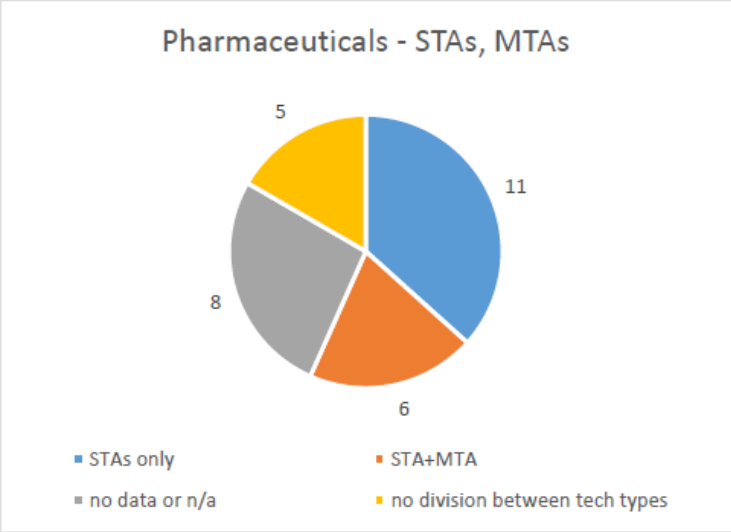
Type of HTA	UNITED KINGDOM		NORWAY	
	Number	Time to complete	Number	Time to complete
STA	England: 45 TAs, 3 HSTs, 20 ESNMs 36 MIBs, 7 MTEPs, 1 DAPs, 35 IPs Scotland: 75 full and 26 abbreviated assessments 15 - ENAS, 10 - IMTOs Wales: 29 (full submissions), 15 (limited submissions)	England: 35 weeks (TAs and HSTs), 13 weeks (ESNMs) 5 weeks MIBs, 38 weeks MTEPs, 63 weeksDAPs, 32 weeksIPs Scotland: 18-30 weeks (Full STA), 18-22 weeks (abbreviated) 13-26 weeks Wales: approx. 21 weeks	30 (approximately 20 on new active substance, approximately 10 on new indication) 15-20 on pharmaceuticals and 4 -6 on medical devices	180 days after MAH submits an application Approximately 170 days after reception of documentation from the manufacturer.
MTA	England: 5 technology appraisal multiple technology assessments 5 DAPs Scotland: no 1 ENAS Wales: no	England:52 weeks 63 weeks DAPs Scotland: n/a 52-78 weeks Wales: n/a	no 1-2 on pharmaceuticals and 2-3 on medical devices	n/a Approximately 1 year
Initial Assessment	England: see STA cell 36 MIBs, 7 MTEPs, 6 DAPs, 35 IPs Scotland: see STA cell 36 Wales: see STA cell	England: see STA cell 5 weeks MIBs, 38 weeks MTEPs, 63 weeksDAPs, 32 weeksIPs Scotland: see STA cell from 13-26 weeks to 52-78 weeks Wales: see STA cell	see STA cell see STA cell	see STA cell see STA cell
Re-assessment	England: 5 technology appraisal multiple technology assessments 2 MTEPs, 2 DAPs, 14 IPs Scotland: no 25 ENAS, 10 - IMTOs Wales: 1	England: 52 weeks 16 weeks MTEPs; 63 weeks full update 30 weeks accelerated updated DAPs; 32 weeks IPs Scotland: n/a 13-26 weeks Wales: 21 weeks	no no assignments for re-asssments yet	n/a n/a

(1) Luxembourg comment:

Since the introduction of the CEM date, the CEM responded to 49 requests with different subjects. Requests were of different nature ranging from (a) simple to highly complex evaluation of HTs, surgical procedures, medical aids and health services; (b) introduction and revision of (new) medical acts in the nomenclature; (c) literature reviews. Mean duration of CEM response to request:
- 13 months for complex requests (≈ STAs; MTAs; but also: complete fee schedule introductions or introduction of numerous new medical acts in fee schedule)
- 6 months for simple requests (≈ inital assessments; STAs and MINI-HTAs but also: introduction of few new medical acts in fee schedule or adaptation/modification of yet existing fees)

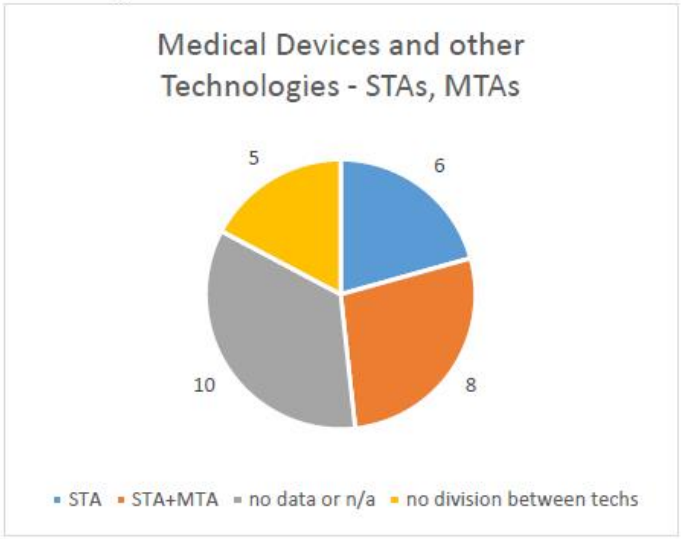
Type of HTA	UNITED KINGDOM		NORWAY	
	Number	Time to complete	Number	Time to complete
REA	England: no 49 IPs Scotland: no no Wales:	England: n/a 32 weeks IPs Scotland: n/a n/a Wales:	no	n/a
REA and economic assessment	England: 73 9 MTEPs, 8 DAPs Scotland: see STA cell 36 Wales: 44	England: from 13 weeks (ESNMS) to 35 weeks (TAs) to 52 weeks (re-assessment MTAs) from 16 to 38 weeks MTEPs,63 weeks (30 weeks accelerated update) DAPs Scotland: see STA cell from 13-26 weeks to 52-78 weeks Wales:approx 21 weeks	see STA cell see STA cell	see STA cell see STA cell
Full HTA	England: no no Scotland: no no Wales: no	England: n/a n/a Scotland: n/a n/a Wales: n/a	no see MTA cell	no see MTA cell

Pharmaceuticals - STAs, MTAs



STAs only	11
STA+MTA	6
no data or	8
no division	5

MedDevices and other technologies



STA	6
STA+MTA	8
no data or	10
no division	5

Appendix 11– Info provision to HTA

European Union		Who collects and provides the info to undergo HTA?								
		Company*			HTA Organisation**			Third Party		
Country	HTA Bodies	Pharmaceuticals	Medical Devices	Other Techs	Pharmaceuticals	Medical Devices	Other Techs	Pharmaceutica	Medical Devices	Other Techs
Austria (AT)	HVB	yes - outpatient settings, formally established process (legislature)	no information on HTA of MedDevs in outpatient settings	no info	no	no information on HTA of MedDevs in outpatient settings	no info	no	no	no info
	GoG	no	no	no	yes	yes	yes	no	no	no
	LBI-HTA	no	no	no	yes	yes	yes	no	no	no
Belgium (BE)	HIHDI (INAMI-RIZIV)	yes - formally established process (legislature)	yes - invasive medical devices	no info	no	yes - can use evidence from other HTA agencies too, eg. KCE	no info	no	no	no info
	KCE	no	no	no	yes	yes	yes	no	no	no
Bulgaria (BG)	NCPHA	yes	n/a - no formal inclusion of HTA	n/a	no	n/a - no formal inclusion of HTA		no	n/a - no formal inclusion of HTA	n/a
Croatia (HR)	AAZ	no	no	no	yes	yes	yes	no	no	no
	CHIF	yes	yes	no info	no	no	no info	no	no	no
Cyprus (CY)	*MoH (1)*	*yes*	*n/a - no formal inclusion of HTA*	*n/a - no formal inclusion of HTA*	*no*	*n/a - no formal inclusion of HTA*	*n/a - no formal inclusion of HTA*	*no*	*no*	*no*
Czech Republic (CZ)	SUKL	yes	n/a - no formal inclusion of HTA	n/a	no	n/a - no formal inclusion of HTA	n/a	no	no	no
Denmark (DK)	DEFACTUM (2)	n/a (2)	no	no	n/a (2)	yes	yes	n/a (2)	no	no
Estonia (EE)	EHIF	yes	no info provided	no info provided	yes	no info provided	no info provided	no	no	no info provided
	MoSa (3)	*yes*	*no info provided*	*no info provided*	*yes*	*no info provided*	*no info provided*	*no*	*no info provided*	*no info provided*
	University of Tartu	no	no	no	yes	yes	yes	no	no	no
Finland (FI)	FIMEA	yes - outpatient and inpatient settings	n/a	n/a	inpatient settings - sometimes	n/a	n/a	no	n/a	n/a
	THL (4)	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a

France (FR)	HAS	yes - specific process depends on type of HTA (STA/MTA; planned assessments/application from the companies)	yes - specific process depends on type of HTA	yes	yes - specific process depends on type of HTA (STA/MTA; planned assessments/application from the companies)	yes - specific process depends on type of HTA	yes	no	no	no
Germany (DE)	G-BA	yes	yes for MD with 'pharmaceutical character' ; for high risk class MD as part of a method	no	no	yes - depends on type of medical device	yes -	no	no	no
	IQWIG	yes	yes	no	no	yes - depends on type of medical device	yes	no	no	no
Greece (EL) (5)	*not indicated (5)*	–	–	–	–	–	–	–	–	–
Hungary (HU)	NIPN	yes	yes	n/a	no	no	n/a	no	no	no
Ireland (IE)	HIQA	no	no	no	yes	yes	yes	no	no	no
	NCPE	yes	n/a	n/a	no	n/a	n/a	no	n/a	n/a
Italy (IT)	AGENAS	n/a	no	no	n/a	yes	yes	n/a	no	no
	AIFA	yes	n/a	n/a	no	n/a	n/a	no	n/a	n/a
Latvia (LV)	NHS	yes	yes	n/a	no	no	n/a	no	no	n/a
Lithuania (LT)	SMCA	yes	n/a	n/a	no	n/a	n/a	no	n/a	n/a
	VASPVT	n/a	no	no	n/a	yes	yes	n/a	no	no
Luxembourg (LU)	CEM	n/a	no	no	n/a	yes	yes	n/a	no	no
Malta (MT)	DPA/MFH	yes	n/a	n/a	no	n/a	n/a	no	n/a	n/a
Netherlands (NL)	ZIN	yes	yes - but not mandatory	yes - company can provide information	no	no	yes, however, company can provide information	no	yes	no information provided
Poland (PL)	AOTMiT (6)	yes	yes	yes	yes	yes	yes	no	no	no
Portugal (PT)	INFARMED	yes	yes	no	no	yes	yes	no	no	no
Romania (RO)	*not indicated*	–	–	–	–	–	–	–	–	–

Slovakia (SK)	MoH, Working Group for Pharmacoeco-nomics, Clinical Outcomes and HTA	yes	yes	no information	no	no	no information	no	no	no information
Slovenia (SI) (7)	HIIS	yes	n/a	n/a	no	no	n/a	no	no	n/a
	JAZMP	yes	n/a	n/a	no	no	n/a	no	no	n/a
Spain (ES) (8)	AEMPS	no	n/a	n/a	yes	n/a	n/a	no	n/a	n/a
	AETS-ISCIII (8)	see footnote (8)								
	AETSA									
	Avalia-t									
	AQUAS									
	IACS									
	SESCS									
	OSTEBA									
	UETS									
Sweden (SE)	SBU	no	no	no	yes	yes	yes	no	no	no
	TLV	yes	yes - consumables	n/a	no	yes - specific type of devices	n/a	no	no	n/a
United Kingdom (UK)	NICE	yes	yes	no info	yes	yes	no info	yes	yes	
	SMC	yes	n/a	n/a	no	n/a	n/a	no	n/a	n/a
	SHTG	n/a	yes	n/a	n/a	yes	n/a	n/a	no	n/a
	AWTTC	yes	n/a	n/a	no	n/a	n/a	no	n/a	n/a
Total number of coutries with at least 1 answer "yes" per category		23	12	4	11	16***	15	3	4	2
European Economic Area (EEA)										
Country										
Norway (NO) (9)	Hdir	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
	NMA	yes	yes	yes	no	no	no	no	no	no
	NIPH	yes	yes	no info	no	yes	yes	no	no	no
Iceland (IS)	*no information*									
Liechtenstein (LI)	*not indicated*									

(*) - - The company submits the evidence dossier but they are not involved in the actual assessment.

(**) - HTA organisation carries out its own HTA and itself identifies the evidence to use (not using evidence submitted from company)

(***) - the number includes also data on Spain that indicated HTA body as being responsible for collecting the evidnece for HTA of medical devices (see footnote 8 and SPAIN HTA Profile for details)

(1) CYPRUS: HTA is not currently incorporated into the reimbursement process for Cyprus. However, there is a formalised central reimbursement process that uses elements of HTA to support its decision making. There are plans to introduce HTA formally into the process to include cost effectiveness analysis

(2) DENMARK: Assessment of pharmaceuticals has been a responsibility of the Danish regions and organised in 2 different tracks (KRIS and RADS) since 2009 until January 2017. From January 1, 2017 a new Pharmaceutical Council (Medicinrådet) is to be implmented as a merger of this two processes (a separate organisation within the Danish Regions). The processess of the new organisation is not yet known.

(3) ESTONIA: Ministry of Social Affairs (MoSa) does not perform HTA, but an application (submission for P&R decision) from a company is submitted to MoSa. MoSa supports the development of an HTA processin Estonia.

(4) FINLAND: The role of THL in the HTA process in Finland is being clarified.

(5) GREECE: Currently in Greece there is no formalised HTA process supported by a formal national legal framework and organisations that have a specific mandate to perform national HTA

(6) POLAND: AOTMiT utilises two HTA processes based on the type of technology and regulated by two different legislative acts: an HTA process based on evidence submission by a company (as set by the Reimbursement Act), and an HTA process without evidence submission by a company (as set by the Act on Health Care Benefits)

(7) SLOVENIA: At the moment, there is no established HTA procedure and no dedicated (institutionalized) HTA agency in Slovenia. There are several governmental organizations in Slovenia using some elements of HTA information but no unified approach is established: a) Health Council of the MoH for the evaluation of new/large health programmes (ie, new medical treatments (prevention, early disease discovery, diagnostics, therapy, procedures for acute and non-acute treatment, palliative care, nursing, and rehabilitation),
b) National Health Insurance Institute of Slovenia for reimbursement of medicinal products,
c) Agency for Medicinal Products and Medical Devices of the Republic of Slovenia for evaluation of high cost drugs

(8) SPAIN: The Spanish HTA reports for pharmaceuticals are known as Therapeutic Positioning Reports (in Spanish, IPT).
HTA programme in Spain is different from reimbursement process but they are closely related.
Agency of Medicines and Medical Devices (AEMPS), the 17 regional authorities and the Ministry of Health-DG Pharmacy (HM-DG Pharmacy) are involved in the HTA of pharmaceuticals.
Non-pharma assessments can be performed both by individual regional HTA agencies, and in cooperation within the framework of the Spanish HTA network.
In non-pharma asessments for national decisoin-making purposes, HTA agency carries out its own HTA and identifies the evidence to use itself.
Identificatoin of the Agency to carry out a specific assessment in this case goes through the Spanish HTA Network. Please see SPAIN HTA Profile for details on the process

(9) NORWAY: HTA process is organised through a national system for Managed Introduction of New Health Technologies within the specialist health service (assessment of pharmaceuticals, medical devices and other technologies in inpatient settings) and through the system of preapproved reimbursement of pharmaceuticals (Blåresept; outpatient setting - see definition of inpatient below). Inpatient setting is defined as where the Regional Health Authorities have the responsibility for ensuring that specialized health care is provided.

Appendix 12– Decision making on the basis of HTA

European Union	Decisoin-making on the basis of HTA												
	What decisions does HTA inform?									Weight of HTA			
	Reimbursement			Pricing			Other						
Country	Pharma	Medical devices	Other Techs	Pharma	Medical devices	Other Techs	Clinical guidelines	Quality standards	Capital investment (hospitals)	Other	Informative	Advisory	Obligatory
Austria (AT)	yes - outpatient setting (HVB)	yes (HVB)	no	yes - outpatient setting (HVB)	no	no	no	yes - only pharma	yes - only med devs	see cell comments		yes - med devs, other techs	yes - outpatient setting pharma (HVB)
Belgium (BE)	yes (INAMI-RIZIV)	yes (INAMI-RIZIV)	yes	yes (INAMI-RIZIV)	yes (INAMI-RIZIV)	yes	yes - only pharma	yes - non-invasive med devs only	no			yes (KCE)	yes - pharma (INAMI-RIZIV)
Bulgaria (BG)	yes	n/a	n/a	yes	n/a	n/a	no	no	no			yes	
Croatia (HR)	yes (CHIF)	yes (CHIF)	yes (AAZ on request from MoH)	yes (CHIF)	yes (CHIF)	yes (CHIF)	yes (AAZ)	no	yes (AAZ)		yes (AAZ)	no	yes (CHIF)
Cyprus (CY)	*yes (1)*	*no info*	*no info*	*no info*	*no info*	*no info*	*no info*	*no info*	*no info*	*no info*	*no info*	*no info*	*no info*
Czech Republic (CZ)	yes outpatient	n/a	n/a	yes outpatient	n/a	n/a	yes (pharma)	no	no				yes
Denmark (DK)	n/a (2)	yes	yes	no info (2)	no	no	yes - med devs and other techs	yes - med devs and other techs	yes - med devs and other techs	budget decisions		yes	
Estonia (EE)	yes	yes	yes	yes	yes	yes	yes - med devs and other techs	yes - med devs and other techs	no			yes	
Finland (FI)	yes - outpatient settings	n/a	n/a	yes - outpatient settings	n/a	n/a	no	no	no	Uptake in hospital formulary (inpatient Pharma)		yes - inpatient pharma	yes - outpatient pharma
France (FR)	yes	yes	yes	yes	yes	yes	yes - if appropriate	no	yes, but not directly			yes	yes
Germany (DE)	no	yes	yes	yes	no	no	no	yes - pharma-ceuticals and other techs	no	no	1) yes (for HTAs produced by GBA) 2) yes - for HTAs produced by IQWIG outside of the formal process of contributing to GBA HTA	yes (IQWIG HTAs produced for GBA)	Yes (GBA for pharma pricing decisions, medical devices and other technologies reimbursement decisions)
Greece (EL)	no HTA process (3)												
Hungary (HU)	yes	yes	no info	no info	no info	no info	yes	no info	no info			yes	
Ireland (IE)	yes (NCPE)	no - see cell comments	no	yes (NCPE)	no	no	yes	no	yes - med devs and other techs	Policy decisions, design of new programmes, Commissioning - for other techs		yes (HIQA process for both techs; med devices)	yes (pharma NCPE process)
Italy (IT)	yes (AIFA)	yes	no info	yes (AIFA)	no	no info	yes - med devs	yes - med devs	yes - med devs	tenders (procurement) - med devs		yes (AGENAS)	yes - pharma (AIFA)

Latvia (LV)	yes outpatient	yes outpatient	n/a	yes	yes	n/a	no	no	no				yes
Lithuania (LT)	yes outpatient	yes (VASPVT)	n/a	no	no	n/a	no	no	no		yes - med devs		yes (pharma)
Luxembourg (LU)	n/a	yes	yes	n/a	no	no	yes - med devs and other techs	yes - med devs and other techs	yes - med devs and other techs		yes - med devs and other techs		
Malta (MT)	yes	n/a	n/a	yes	n/a	n/a	no	yes (pharma)	no			yes - see the cell comments	
Netherlands (NL)	yes	yes	yes	yes	no	no info	no	no	no			yes	
Poland (PL)	yes	yes	yes	yes	yes	yes	no	no	no				yes
Portugal (PT)	yes	yes	yes	yes	yes - maximum price	yes - maximum price	no	no	yes, in the future - med devs and other techs			yes	yes - med devs and other techs and depends on the technology and assessment type
Romania (RO)	yes	no	no	no specific information									
Slovakia (SK)	yes outpatient	yes	no info	yes	yes	no info	no	no	no			yes	
Slovenia (SI)	yes	n/a	yes	yes	n/a	yes	no info	no info	no info		yes (HIIS)	yes - (JAZMP)	yes - other techs
Spain (ES)	yes	yes	yes	yes	no	no	yes	yes	no			yes	
Sweden (SE)	yes (TLV)	yes (TLV)	no	yes (TLV)	yes (TLV)	no	yes (SBU) - pharma	no info	yes - med devs/methods			yes (SBU; TLV - assessment of methods of using medical devices)	yes (TLV; with regards to informing pricing of medicines and medical device consumables)
United Kingdom (UK)	yes	yes	no information	no	no	no info	yes - pharma (England), med devs (England, Scotland)	yes - pharma (England)	yes - pharma (England), med devs (England, Scotland)	Comissioning - pharma and med devs (England); disinvestment - med devs (Scotland)	yes - specific types of HTAs of pharma in England and of med devs in Scotland	yes - pharma (Scotland) and med devs (England); specific types of HTA of med devs (Scotland)	yes - specific types of HTAs of medicines in England; HTA of medicines in Wales
Total count of countries saying yes:	23	19	12	20	9	7	13	9	10		6	19	17

European Economic Area (EEA)	Decisoin-making on the basis of HTA												
	What decisions does HTA inform?										Weight of HTA assessment		
	Reimbursement			Pricing			Other						
Country	Pharma	Medical devices	Other Techs	Pharma	Medical devices	Other Techs	Clincial guidelines	Quality standards	Capital investment (hospitals)	Other	Informative	Advisory	Obligatory
Norway (NO)	yes outpatient setting	yes - system of managed introduction of new technologies (in-patient)	yes - system of managed introduction of new technologies	no	no	no	yes - system of managed introduction of new technologies	no	yes - system of managed introduction of new technologies			yes - system of managed introduction of new technologies	yes - pharma (Blåresept, outpatient setting)
Iceland (IS)	no info												
Liechtenstein (LI)	no info												

(1) CYPRUS: HTA is not currently incorporated into the reimbursement process for Cyprus. However, there is a formalised central reimbursement proc that uses elements of HTA to support its decision making. There are plans to introduce HTA formally into the process to include cost effectiveness ana However these are currently on hold while the legal framework for the NHS is to be passed by the parliament so that the process of incorporating forr the reimbursement process can be restarted and the dedicated unit established. Currently there is no formal inclusion of HTA in the process for medi

(2) DENMARK: Assessment of pharmaceuticals has been a responsibility of the Danish regions and organised in 2 different tracks (KRIS and RADS) sinc until January 2017. From January 1, 2017 a new Pharmaceutical Council (Medicinrådet) is to be implmented as a merger of this two processes (a sepa

within the Danish Regions). The processess of the new organisation is not yet known.

(3) GREECE: There is no formalised HTA proces for any type of technology.
Placement of pharmaceuticals on a positive list for reimbursement is not informed by an HTA process (there is no distinction between inpatient and c
The Ministry of Health is a decision-maker on reimbursement of medical devices for outpatient settings, and
hospitals are in charge for decision-making for inpatient settings.

(4) ROMANIA: Reimbursement of drugs process is indicated as being informed by a score-card system based on the assessments produced in other EU

Appendix 13– Stakeholder engagement in HTA

European Union	Stakeholder engagement (SE)					
	Is there a set process for stakeholder engagement?			Which groups of stakeholders are engaged?		
Country	Pharmaceuticals	Medical devices	Other Technologies	Pharma	Medical devices	Other Technologies
Austria (AT)	yes (HVB process)	yes (LBI process)	yes (GOG)	Industry Clinical experts Payers	Industry Clinical experts Payers Providers Patients - LBI HTA is piloting patient involement in scoping, focus groups, NOT professional patients but "real" patients	Clinical experts
Belgium (BE)	yes	yes	no information	Industry Clinical experts Payers Academics, Pharmacists, Physicians KCE: all possible relevant stakeholders can be invited. There is no exclusion of industry, patients, or other stakeholders that might provide relevant information.	Industry Clinical experts Payers Pharmacists, Physicians, Care givers	no information
Bulgaria (BG)	yes	n/a	n/a	Industry Clinical Experts Payers Providers Qualified pharmacists, economists, statisticians, legal experts and their specialists	n/a	n/a
Croatia (HR)	AAZ: not fully established in practice, proposed in the national HTA guidelines CHIF: no information available	AAZ: not fully established in practice, proposed in the national HTA guidelines CHIF: no information available	AAZ: not fully established in practice, proposed in the national HTA guidelines CHIF: no information available	AAZ: industry, clinical experts, payers, providers CHIF: no information available	AAZ: industry, clinical experts, payers, providers CHIF: no information available	AAZ: industry, clinical experts, payers, providers CHIF: no information available
Cyprus (CY)	*no specific information provided/available*					
Czech Republic (CZ)	yes SE process differs slightly for initial assessments and re-assessments	n/a	n/a	Industry Clinical experts Payers	n/a	n/a
Denmark (DK)	n/a	yes	yes	n/a	Industry Clinical experts Patient experts Payers Providers	Industry Clinical experts Patient experts Payers Providers
Estonia (EE)	yes	there is no formal process set up, however, stakeholders might be involved as described on case by case basis	there is no formal process set up, however, stakeholders might be involved as described on case by case basis	Industry Patient experts Clinical experts Payers Providers University	Industry Clinical experts Payers Providers	Industry Clinical experts Payers Providers
Finland (FI)	Inpatient: yes Outpatient: yes	n/a	n/a	Inpatient: Industry , Clinical experts Payers, Providers Outpatient: Industry, Clinical experts, Payers	n/a	n/a

France (FR)	yes	yes	yes	Industry Patient experts Clinical experts Payers Providers Specifications: Members of Transparency Committee and CEESP: expert practitioners (doctors, pharmacists), specialists in methodology and epidemiology and members of patient and consumer associations, members in an advisory role: representatives of the Social Security Directorate, the Directorate-General for Health, the Directorate-General of Care Provision, the National Health Insurance Fund, the French National Agency for Medicines and Health Products Safety.	Industry Patient experts Clinical experts Payers Providers	Industry Patient experts Clinical experts Payers Providers
Germany (DE)	yes - written and oral hearings	no for MD with 'pharmaceutical character' Yes for methods using high risk MD	yes - written and ora	Pharmaceutical companies, experts of medical and pharmaceutical sciences, umbrella organisations of industry and pharmacists	n.a./as a principle, all stakeholders who would be affected by a G-BA resolution need to be involved	as a principle, all stakeholders who would be affected by a G-BA resolution need to be involved
Greece (EL)	*no specific information provided/available*					
Hungary (HU)	no	no	n/a	Industry Clinical experts Payers	Industry Clinical experts Payers	n/a
Ireland (IE)	yes (NCPE)	yes (HIQA)	yes (HIQA)	Industry Patient experts Clinical experts Payers	Industry Patient experts Clinical experts Payers Providers Methodological experts, international subject matter experts	Industry Patient experts Clinical experts Payers Providers Methodological experts, international subject matter experts
Italy (IT)	yes	yes	n/a	Industry Patient experts Clinical experts Payers	Industry Patient experts Clinical experts	n/a
Latvia (LV)	yes	yes	n/a	Industry Clinical experts Payers	Industry Clinical experts Payers	n/a
Lithuania (LT)	yes	no - some non-structured involvement exists, see cell comments	n/a	Industry Patient experts Clinical experts Payers	no info	n/a
Luxembourg (LU)	n/a	no	no	n/a	n/a	n/a
Malta (MT)	yes	n/a	n/a	Industry Patient experts Clinical experts Payers Providers	n/a	n/a
Netherlands (NL)	yes	yes	no information	manufacturer(s), physician groups, patient groups	manufacturer(s), physician groups, patient groups	no information
Poland (PL)	yes	yes	yes	Industry Patients Clinical Experts Payers	Industry Patients Clinical Experts Payers	Industry Patients Clinical Experts Payers
Portugal (PT)	yes	Only informal, for other then aplicant	Only informal, for other then aplicant	Industry Clinical experts Payers Other entities from the MoH	Industry Clinical experts Payers Providers Other entities from the MoH	Industry Clinical experts Payers Providers Other entities from the MoH

Romania (RO)	*no specific information provided/available*					
Slovakia (SK)	no	no	n/a	clinical experts and payers	clinical experts and payers	n/a
Slovenia (SI)	yes	n/a	yes	Industry Clinical Experts Payers Providers (only HIIS) Pharmacists, Wholesalers (only IZAMP)	n/a	Clinical Experts Payers Representatives of civil society
Spain (ES)	yes	yes	yes	Industry Patient experts Clinical experts Payers Providers	Industry Patient experts Clinical experts Payers Providers	Industry Patient experts Clinical experts Payers Providers
Sweden (SE)	SBU: yes TLV: yes	SBU: yes TLV: yes	SBU: yes TLV: yes	SBU: industry, patient experts, clinical experts, providers TLV: industry, patient experts, clinical experts, payers	SBU: industry, patient experts, clinical experts, providers TLV: industry, patient experts, clinical experts, payers	SBU: industry, patient experts, clinical experts, providers TLV: industry, patient experts, clinical experts, payers
United Kingdom (UK)	yes (NICE, SMC, SHTG, AWTTC)	yes - very elaborate involvement process in each of the programmes (NICE, SHTG)	n/a	**NICE:** TAs and HSTs Industry Patient experts Clinical experts Payers Providers ESNMs Industry Clinical experts providers **SMC**: Industry Patient experts Clinical experts Payers Providers **AWTTC:** Industry Patient experts Clinical experts	NICE: Industry Patient Experts Clinical Experts Providers **SHTG:** Industry Patient experts Clinical experts Payers Providers	n/a
Total count of countries :	20	15	11			

European Economic Area (EEA)	Stakeholder engagement (SE)					
	Is there a set process for stakeholder engagement?			Which groups of stakeholders are engaged?		
Country	Pharmaceuticals	Medical devices	Other Technologies	Pharma	Medical devices	Other Technologies
Norway (NO)	no informtion	yes (System of Managed introduction of new technologies)	n/a	no information	Industry Patient experts Clinical experts Payers Providers	n/a
Iceland (IS)	no information					
Liechtenstein (LI)	no information					

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Appendix 15– HTA Bodies

European Union	
Country	**HTA Bodies**
Austria (AT)	Hauptverband der Österreichischen Sozialversicherungsträger (Association of Austrian Social Insurance Institutions) - HVB
	Gesundheit Österreich GmbH/Geschäftsbereich - GoG
	Ludwig Boltzmann Institute for Health Technology Assessmen - LBI-HTA
Belgium (BE)	National Institute for Health and Disability Insurance - HIHDI (INAMI-RIZIV)
	Belgian Health Care Knowledge Centre - KCE
Bulgaria (BG)	National Center of Public Health and Analyses - NCPHA
Croatia (HR)	Agency for Quality and Accreditation in Health Care and Social Welfare - AAZ
	Croatian Health Insurance Fund - CHIF
Cyprus (CY)	*Ministry of Health*
Czech Republic (CZ)	State Institute for Drug Control - SUKL
Denmark (DK)	DEFACTUM (Social & Health Services and Labour Market, Danish Regions)
Estonia (EE)	Estonian Health Insurance Fund - EHIF
	Ministry of Social Affairs - MoSa
	University of Tartu
Finland (FI)	Finnish Medicines Agency - FIMEA
	National Institute for Health and Welfare - THL
France (FR)	French National Authority for Health (Haute Autorité de Santé) - HAS
Germany (DE)	Federal Joint Committee - G-BA
	Institute for Quality and Efficiency in Health Care - IQWIG
Greece (EL)	*not indicated*
Hungary (HU)	National Institute of Pharmacy and Nutrition - NIPN
Ireland (IE)	Health Information and Quality Authority - HIQA
	National Centre for Pharmacoeconomics - NCPE
Italy (IT)	National Agency for Regional Health Services - AGENAS
	Italian Medicines Agency - AIFA
Latvia (LV)	National Health Service - NHS

Lithuania (LT)	State Medicines Control Agency of Lithuania - SMCA
	State Health Care Accreditation Agency - VASPVT
Luxembourg (LU)	Cellule d'expertise médicale - CEM
Malta (MT)	Ministry of health, Directorate for Pharmaceutical Affairs - DPA/MFH
Netherlands (NL)	National Health Care Institute - ZIN
Poland (PL)	Agency for Health Technology Assessment and Tariff System - AOTMiT
Portugal (PT)	National Authority of Medicines and Health Products - INFARMED
Romania (RO)	*National Drug Agency* *Ministry of Health* *National Health Insurance Fund*
Slovakia (SK)	MoH, Working Group for Pharmacoeco-nomics, Clinical Outcomes and HTA
Slovenia (SI)	Health Insurance Institute of Slovenia - HIIS
	Agency of the Republic of Slovenia for Medicinal Products and Medical Devices - JAZMP
Spain (ES)	Spanish Medicines Agency - AEMPS
	The Institute of Health Carlos III - AETS-ISCIII
	Andalusian Agency for Health Technology Assessment - AETSA
	The Galician Agency for Health Technology Assessment - Avalia-t
	The Agency for Health Quality and Assessment of Catalonia - AQUAS
	Health Sciences Institute in Aragon - IACS
	Evaluation and Planning Unit - Directorate of the Canary Islands Health Service - SESCS
	Basque Office for Health Technology Assessment - OSTEBA
	Health Technology Assessment Unit, Madrid - UETS
Sweden (SE)	Swedish Agency for Health Technology Assessment and Assessment of Social Services - SBU
	Dental and Pharmaceutical Benefits Agency - TLV
United Kingdom (UK)	National Institute for Health and Care Excellence - NICE
	Healthcare Improvement Scotland – Scottish Medicines Consortium - SMC
	Healthcare Improvement Scotland – Scottish Health Technologies Group - SHTG
	All Wales Therapeutics and Toxicology Centre - AWTTC

European Economic Area (EEA)	
Country	**HTA Bodies**
Norway (NO)	Norwegian Directorate of Health - Hdir
	Norwegian Medicines Agency - NMA
	The Norwegian Institute of Public Health - NIPH
Iceland (IS)	*no information*
Liechtenstein (LI)	*Office of Public Health*

Appendix 16– Country profile template

Country		
EU/EEA Member		
Population		http://ec.europa.eu/eurostat/tgm/table.do?tab=table&init=1&plugin=1&pcode=tps00002&language=en

National legal framework for HTA

Organisations involved in the national HTA processes

Technology	Early Dialogue	HTA						Decision-making on the basis of HTA			
		Assessment	Appraisal	REA (Relative Effectiveness Assessment)	REA and Economic Evaluation	Full HTA	Commer	Reimburse	Pricing	Other	Comments
Medicines											
Medical devices											
Other technologies											

	Use of HTA from other jurisdictions						Use of EUnetHTA tools							Use of EUnetHTA Joint Assessments	
Re-assessment	Yes or No	If Yes					Yes or No	If Yes						Yes or No	Reasons for decision to use/not to use
		Horizon Scanning of HTA	Topic selection	HTA assessment info (scope, reports evidence submissions, etc)	Info about HTA advice and consequent decision-making	Other		HTA Core Model ®	POP Database	EVIDENT Database	Evidence Submission Templates	Guidelines	Intranet	Other	

Use of HTA from other jurisdictions																
Technology	Yes or No	If Yes					Use of EUnetHTA tools						Use of EUnetHTA Joint Assessments			
		Horizon Scanning of HTA	Topic selection	HTA assessment info (scope, reports evidence submissions, etc)	Info about HTA advice and consequent decision-making	Other	Yes or No	If Yes					Yes/No	Reason for decision to use/not use		
								HTA Core Model ®	POP Database	EVIDENT Database	Evidence Submission Templates	Other				
Pharmaceuticals																
Medical devices																
Other Technologies																

Appendix 17– Questionnaire

Mapping of HTA national organisations, programmes and processes in EU

Contract SANTE/2016/B4/020

QUESTIONNAIRE[1]

To be completed by **22 August 2016** and sent back to

jc@stellalliance.se and SANTE-HTA-NETWORK@ec.europa.eu – THANK YOU!

Country	
Organisation	
Contact information[2]	Name:
	E-mail:
	Tel (with country code please):
Legal mandate of the organisation *Short description; free text answer*	
Organisation's main role *Please indicate all that are applicable*	1. Develop and issue HTA recommendations 2. Regulation of health technologies 3. Pricing of health technologies 4. Reimbursement of health technologies 5. Other – please specify:
Other tasks carried out by the organisation *Tick all that apply*	☐ Quality Standards ☐ Development of clinical guidelines ☐ Healthcare promotion ☐ Detection of new technologies (e.g. horizon scanning) ☐ Registries ☐ Education ☐ Early Dialogues and Scientific Advice Other *please specify*
HTA staff competence/expertise and education	Please indicate: - Total number of FTEs (internal staff only) - Technical positions (number of FTEs) and qualifications required to fill in the positions *(e.g., Economist (MSc or PhD), Librarian (MSc), Epidemiologist, etc.)* Comments:
Budget for HTA activities in your organisation	Please indicate for the body/department performing HTA - Overall budget - Budget allocated to HTA assessments (including REA, full HTA, re-

[1] This questionnaire is to inform research being contracted by the European Commission on behalf of the HTA Network.
[2] Contact details of the person completing the questionnaire

In absolute terms (in Euro) and in % to the total budget of organisation[3]	assessments, appraisals based on dossiers submitted by industry) - Budget for contracting external experts Comments:
Methods to finance HTA activities *(eg, Budget only, submission fee, other – please indicate)*	Comments:
Does your organisation have a formal official conflict of interest policy and procedure?	Yes/No Comments:
Does your organisation use HTA information from other jurisdictions?	Yes/No If yes, please specify if it is - Information used about horizon scanning and topic selection - Information used about HTA assessment (e.g. other agency scopes, reports, evidence submissions) - Information used about HTA advice and decision making (eg, other agency recommendations and decisions)
Does your organisation use joint assessments prepared by EUnetHTA?	Yes/No If yes, which EUnetHTA joint assessments were utilised: If No, could you please list major barriers to utilisation as perceived by your organisation:
Does your organisation use any of the EUnetHTA tools to produce your HTA information?	Yes/No If yes, please select from the list below: 1. HTA Core Model® 2. POP Database 3. EVIDENT database 4. EUnetHTA Evidence Submission templates 5. EUnetHTA Guidelines 6. EUnetHTA Intranet 7. Other, please specify Comments:

[3] Data for 2015 or the last year available

EW-07-17-156-EN-N