HTA in Greece and in Europe How do we compare & what do we expect?

Olympios Papadimitriou
President SFEE
General Manager
Novo Nordisk Hellas

Staffing varies a lot in HTA organizations – Full Time Employees is the common denominator

European Union		Workforce	
Country	HTA Bodies	HTA staff (1)	Commissioning of external experts
		Number	
Austria (AT)	HVB	7FTEs	yes
	GÖG	5FTEs	yes
	LBI-HTA	15 FTEs	yes
Belgium (BE)	KHKD/ SNAVB (KCE)	12 FTEs	limited
	KCE	62.7 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 (3 ID FTEs total workforce)	yes
	THL (2)	10	no info
France (FR)	HAS	207 FTEs (**) % of the total FTEs at HAS	yes
Germany (DE)	G-BA	information provided	no
	IQWiG	no information provided	yes

European Union		Workforce	
Country	HTA Bodies	HTA staff (1)	Commissioning of external experts
		Number	
Greece (EL)	not indicated	--	--
Hungary (HU)	NIPH	18	yes
Ireland (IE)	HIQA	6.8 FTEs across 8 posts	yes
	NCPE	10 FTEs	n/a
Italy (IT)	AIFA(AS)	17	no
	AIFA	50 FTE	no
Latvia (LV)	NVD	3 - no. 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	34,14 FTE	yes
Poland (PL)	AOTMiT	65 FTEs	yes
Portugal (PT)	INFARMED	25 FTEs	yes

European Union		Workforce	
Country	HTA Bodies	HTA staff (1)	Commissioning of external experts
		Number	
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)	HIS	2	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	10 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	[illegible] FTE of permanently employed staff across the whole organisation is 834 as at 1 July 16.	yes
	SMC	14.5 FTEs	no
	SHTG	10 FTEs	no
	AWTTC	21.5FTEs	yes

Greece: 2 committees with part-time employees

Mapping of HTA national organizations, programmes and processes in EU and Norway, EU Commission, May 2017

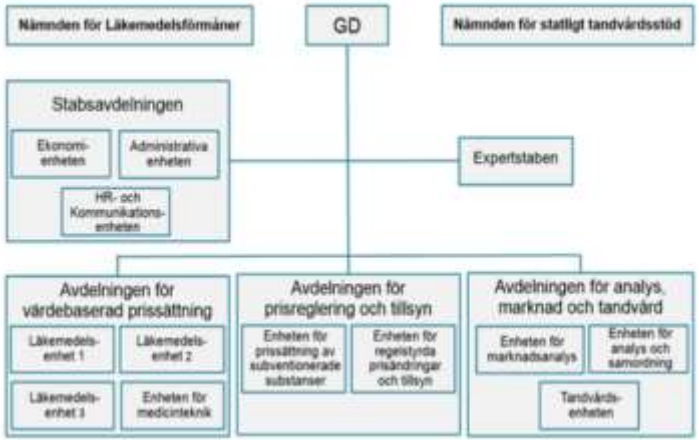
The example of NICE: staff roles & responsibilities

Centre director	The centre director is responsible for delivering all outputs of the Centre for Health Technology Evaluation. The centre director must also ensure that appraisals are carried out in line with the published appraisal process and methods.
Programme director	The programme director is responsible for all aspects of managing and delivering the appraisal work programme. The programme director interacts with the NICE sponsor branch at the Department of Health and Social Care and other national bodies, and with healthcare industry bodies. The programme director is responsible for signing off guidance at specific stages of an individual appraisal. The programme director is also responsible for ensuring that appraisals are carried out in line with the published appraisal process and methods.
Associate director	The associate director is responsible for developing individual appraisals within the appraisal programme and has delegated responsibility, from the programme director, for approving documentation for consultation at specific stages of an individual appraisal.
Project manager	The project manager is responsible for planning individual appraisal timelines, ensuring the timelines and process are followed, and liaising with consultees, commentators and other individuals and organisations contributing to the appraisal.
Administrator	The administrator is responsible for supporting the project manager in the planning and management of individual appraisals, including ensuring the timelines and process are followed, and liaising with consultees, commentators and other individuals and organisations.
Technical lead	The technical lead is the analyst responsible for the technical aspects of the appraisal, including liaising with the ERG, scoping the appraisal, preparing drafts of guidance and advising the appraisal committee. There may be more than 1 technical lead for an appraisal.
Technical adviser	The technical adviser is responsible for the technical quality of the appraisal. This involves providing advice on technical issues, and if appropriate, reviewing and quality assuring the work of the technical lead. The technical adviser also ensures a consistent approach is taken across the appraisal programme.
Communications lead	The communications lead is responsible for circulating and communicating the guidance to appropriate groups within the NHS in England, and to patients and the public.
Guidance Information services lead	The guidance information services lead is responsible for supporting the technical lead in scoping the appraisal. The information services lead gathers information to support the production of a draft scope and continues to track key information throughout the life cycle of the appraisal to support the work of the technical lead.

Editorial lead	The editorial lead is responsible for ensuring that all guidance documents are accurate, clear and consistent. The editorial lead prepares the final versions of the guidance and information for the public.
Public Involvement Programme (PIP) public involvement adviser	The PIP is the team at NICE that supports and develops public involvement across NICE's work programme. A PIP public involvement adviser is assigned to each appraisal and supports patient and carer consultee organisations, their representatives, and individual patients or carers throughout the appraisal. This may include making it easier to attend workshops or meetings, giving advice on completing submissions and statements, consultation responses or other documentation, and nominating experts. The PIP public involvement adviser also supports the lay members of the appraisal committees and supplies the patient and carer organisations for the 'information for the public' tab of the guidance page of the NICE website.
Commercial and Managed Access Programme (CMAP)	The CMAP will be responsible for managed access activities, including the Cancer Drugs Fund and Patient Access Schemes Liaison Unit. This team will support commercial engagement between companies and NHS England when a commercial access agreement or patient access scheme is needed to address specific uncertainties within a topic.
Resource impact lead	The resource impact lead works with the technical lead and clinical experts to produce guidance-related costing tools. The tools consist of a resource impact report and template to help organisations assess the financial impact of implementing NICE guidance. They are published at the same time as the guidance and are subject to a limited consultation. The resource impact lead also provides input at the topic selection stage, assessing the potential financial impact of each topic scoped.
Implementation adviser	The implementation adviser provides support from the scoping stage through to post-publication activities, liaising with the internal NICE teams, development teams and external organisations to support the implementation of NICE guidance, including the development of implementation support tools.
Pathways lead	The pathways lead is responsible for ensuring there is a process in place for making guidance accessible through NICE Pathways. This includes ensuring that new guidance is included in new or existing NICE Pathways with agreement from the Centre for Health Technology Evaluation management team.
Adoption lead	The medicines and technologies programme adoption team lead will work with the NHS to provide a systematic approach to the adoption of new technologies such as pharmaceuticals, diagnostic and monitoring devices, surgical implants and other technologies that improve the care given to patients.

The example of the Swedish TLV (The Dental and Pharmaceutical Benefits Agency)

- TLV is a central government agency since 2002
- 140 employees who determine whether a pharmaceutical product, medical device or dental care procedure shall be subsidized by the state.
- TLV´s budget for 2018 is 13,5 M Euro
- The mission is to decide which medicines, medical devices and dental care treatments shall be reimbursed.
- TLV has two Boards with decision-making powers: the Board for Pharmaceutical Benefits, and the Board for Dental Benefits.
  - The Board for Pharmaceutical Benefits rules on pricing and reimbursement for new medicines and other products which are part of the reimbursement system.



Published guidance: Comparison of data accepted/ requested by regulatory versus HTA agencies

Clinical trial data is the core requirement for all agencies. Safety data, quality of life data and economic analyses are also commonly requested but not required by all agencies, with the latter being a requirement for national HTA agencies only.

Agency accept/offer guidance on evidence type	EMA	EUnetHTA	HAS	G-BA	AIFA	ZINL	Spain	TLV	NICE	SMC
Trial data	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Indirect comparisons	NS	✓	✓	✓	NS	NS	NS	✓	✓	✓
Systematic Reviews/ Meta-analysis	NS	✓	✓	✓	✓	NS	NS	✓	✓	✓
Real-world-evidence	NS	NS	✓	NS	NS	NS	NS	NS	✓	NS
Safety data	✓	✓	✓	✓	✓	✓	✓	NS	✓	✓
QoL data	✓	✓	✓	✓	NS	✓	✓	NS	✓	✓
Economic evidence	NS	NS	✓	NS	✓	✓	✓	✓	✓	✓
Other sources (e.g. dose ranging studies)	✓	NS	✓	NS	✓	✓	✓	NS	✓	NS

*✓ = guidance available on evidence type

*NS = not specified. Though an agency's methods guide may not specifically outline its acceptance of a particular type of evidence it does not necessarily mean that submission of such evidence would be found unacceptable.

Published guidance: National HTA agencies request the broadest range of evidence types

		EMA	Eunet-HTA	HTA
Trial data	RCT trial design.	✓	✓	✓
	Patient-relevant (i.e. morbidity) over surrogate measures (e.g. HbA1C).		✓	✓
	Placebo-comparison and active comparison acceptable.	✓		
	H2H data against the standard of care, which may vary from country to country.		✓	✓
IC	Adjusted methods over naïve-comparisons.		✓	✓
	Use of Mixed Treatment Comparisons, Network Meta Analyses, and the Bucher Method.		✓	✓
SRs/NMAs	Sys Review and Meta Analysis to be used when >2 trials and if appropriate.		✓	✓
	Detailed description of the data included and the methods used necessary.		✓	✓
RWE	No specific guidance on the submission of observational or other forms of RWE given.		✓	✓
Safety	Comparative safety data vs other available therapies.		✓	✓
	Data from RCTs or the SPC, and request long-term data, if available		✓	✓
QoL	QoL important.		✓	✓
HE	CEA (specifically CUA)			✓
	Generic QoL, such as EQ-5D, are preferred sources of utility data			✓
	Country specific cost inputs.			✓
	Clinical inputs sourced from SRs, RCTs, or clinical data included in the dossier			✓

Comparing Use of HTA in Pharmaceutical Policy among Earlier and More Recent Adopters in the European Union

- In all countries, the assessment criteria used include **effectiveness, safety, relative effectiveness, and economic data.**
-
- In group A countries (England, Germany, France, and Sweden) the main objectives are **improving quality of care, ensuring equal access, and efficient use of resources.**
- Group B countries (Poland, Bulgaria, Hungary, and Romania) have established HTA organizations with official guidelines but **often seek the decisions of other developed countries.**
- They place considerable emphasis on the **budget impact** of new therapies, and HTA is also used as a cost estimation tool for state budgets.
- HTA organizations have been developed dynamically not only in high-income countries but also in countries with limited resources.
- **"The experience and evolution of both can be used by countries that are in the dawn of creating an HTA organization."**

Comparing Use of Health Technology Assessment in Pharmaceutical Policy among Earlier and More Recent Adopters in the European Union
Alexandra Beletsi et al., Value in Health Regional Issues, Volume 16 , 81 – 91 (2018)

EFPIA policy principles published 16.01.2019

- EFPIA published on the 16th January 2019 the external policy principles on Cross-Country Collaborations on Medicines' Pricing and Access.
- EFPIA and SFEE, as an EFPIA member, support policies that deliver access to innovative treatments for patients, while ensuring the financial sustainability of our healthcare systems.
- In some cases this may be through cross-country collaborations, in others, patient access to medicines and healthcare system sustainability may be better served through national procedures.
- **Joint Clinical Assessment (JCA) and joint Health Technology Assessment (HTA)**: The multiplication of clinical assessments and HTA processes at European, national and regional levels creates **risks of duplication of processes** and of **conflicting outcomes**, ultimately resulting in potential **access delays**.
- **Information sharing, purchasing and Joint pricing negotiations**: EFPIA and SFEE believe that joint pricing negotiations should have a long-term objective of **broadening access for patients** and stimulating the medical innovation that patients need.
- That means **not using them solely for short-term, financial cost containment goals achieved through the negotiation of the lowest price**.
- They should be based on solid legal grounds and offer legal predictability (such as on confidentiality of net prices and commercially sensitive information) to participating companies.
- The **value of innovative medicines**, measured through actual outcomes and benefits for patients rather than financial interest, **should be the basis of pricing negotiations**, including joint pricing negotiations.

The external policy principles on Cross-Country Collaborations on Medicines' Pricing and Access that EFPIA published on the 16th January 2019 are available on the EFPIA website https://www.efpia.eu/media/412513/policy-principles-on-cross-country-collaborations-on-medicines-pricing-and-access.pdf

HTA in Greece

- Sufficient resources have to be ensured
- A regular operational flow has to be ensured
- HTA should not be used as an official “access delay mechanism”
- Can HTA co-exist with the clawback concept?

Thank you