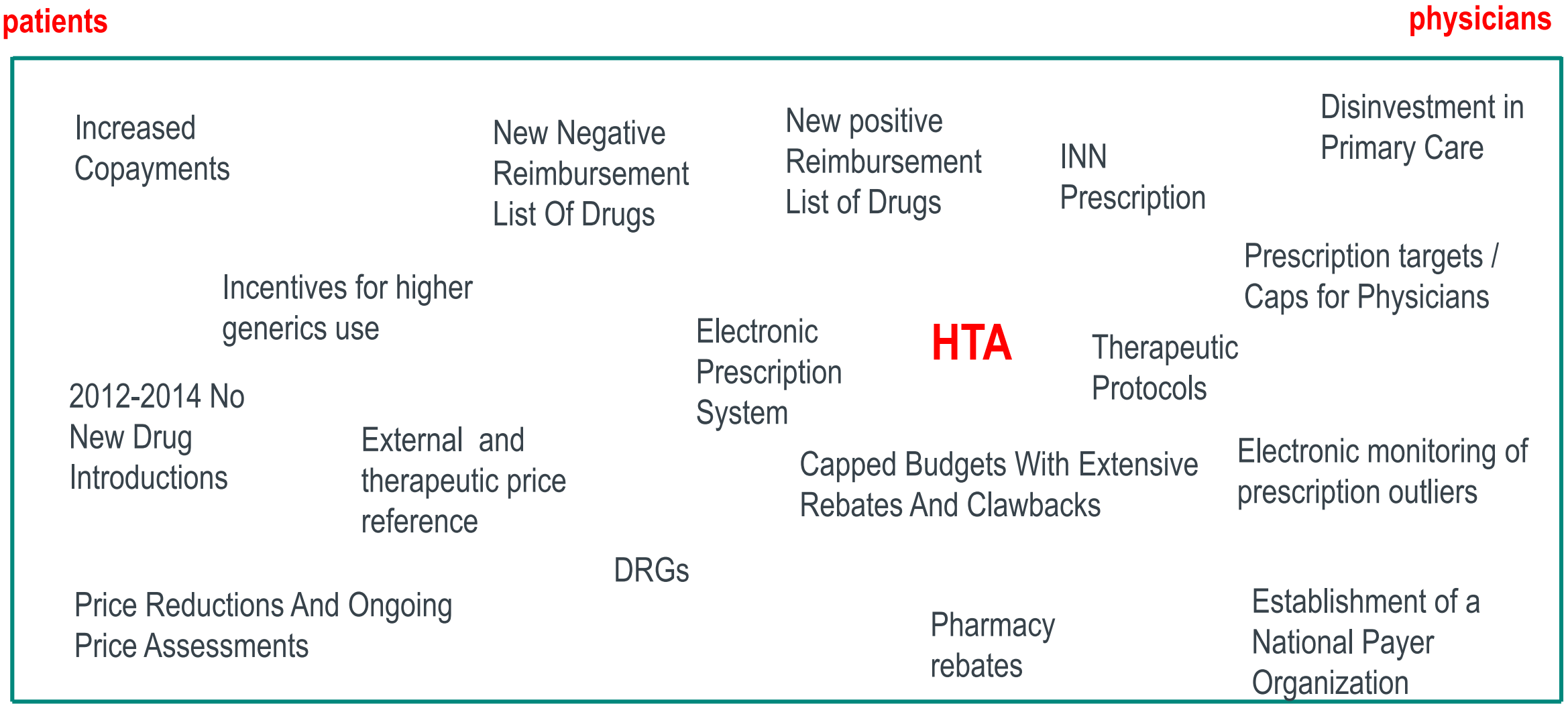
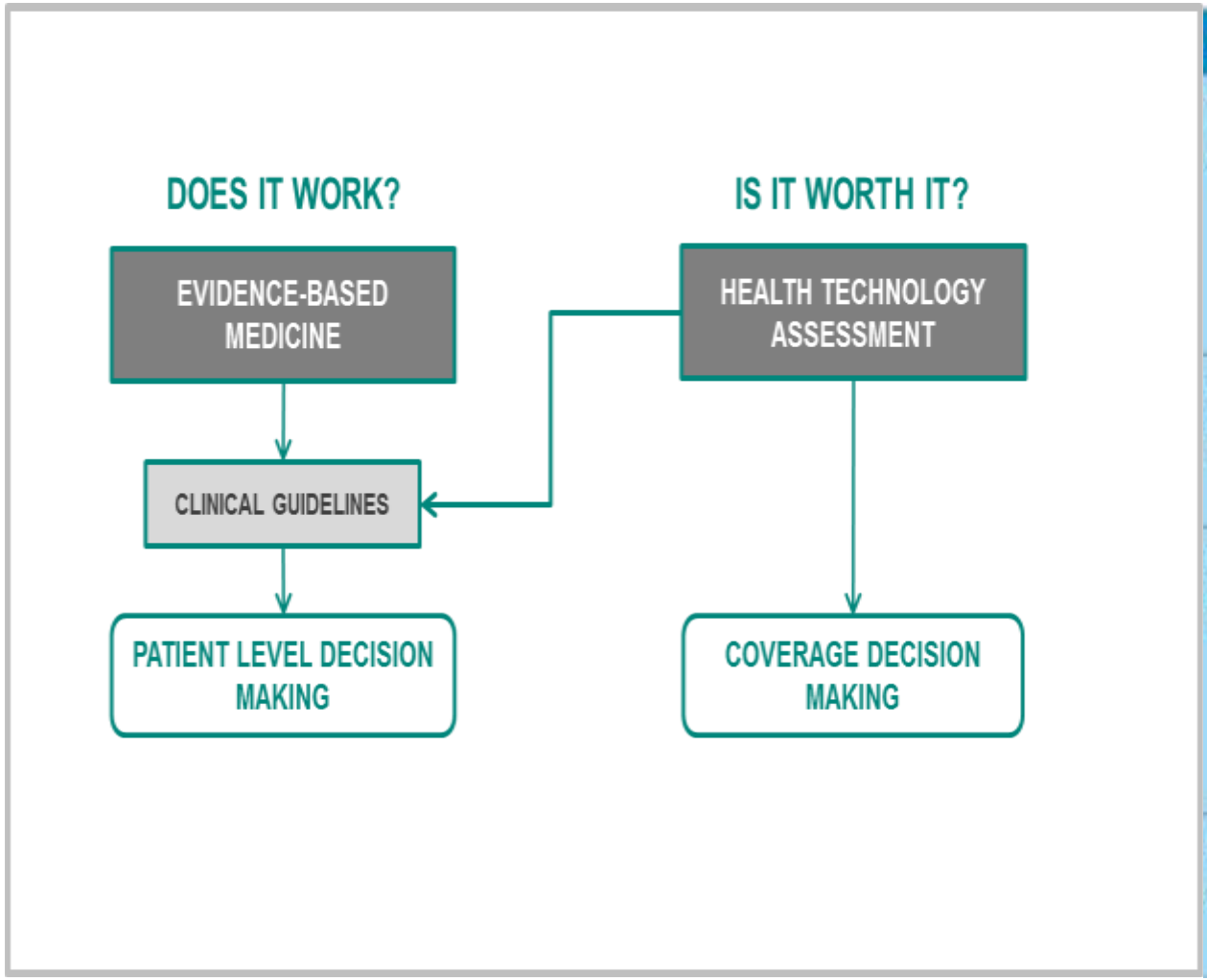
ISSUES IN THE IMPLEMENTATION OF HEALTH TECHNOLOGY ASSESSMENT IN GREECE

22/01/2019

HTA was conceived as an additive measure in the cost containment armamentarium during the memorandum years…



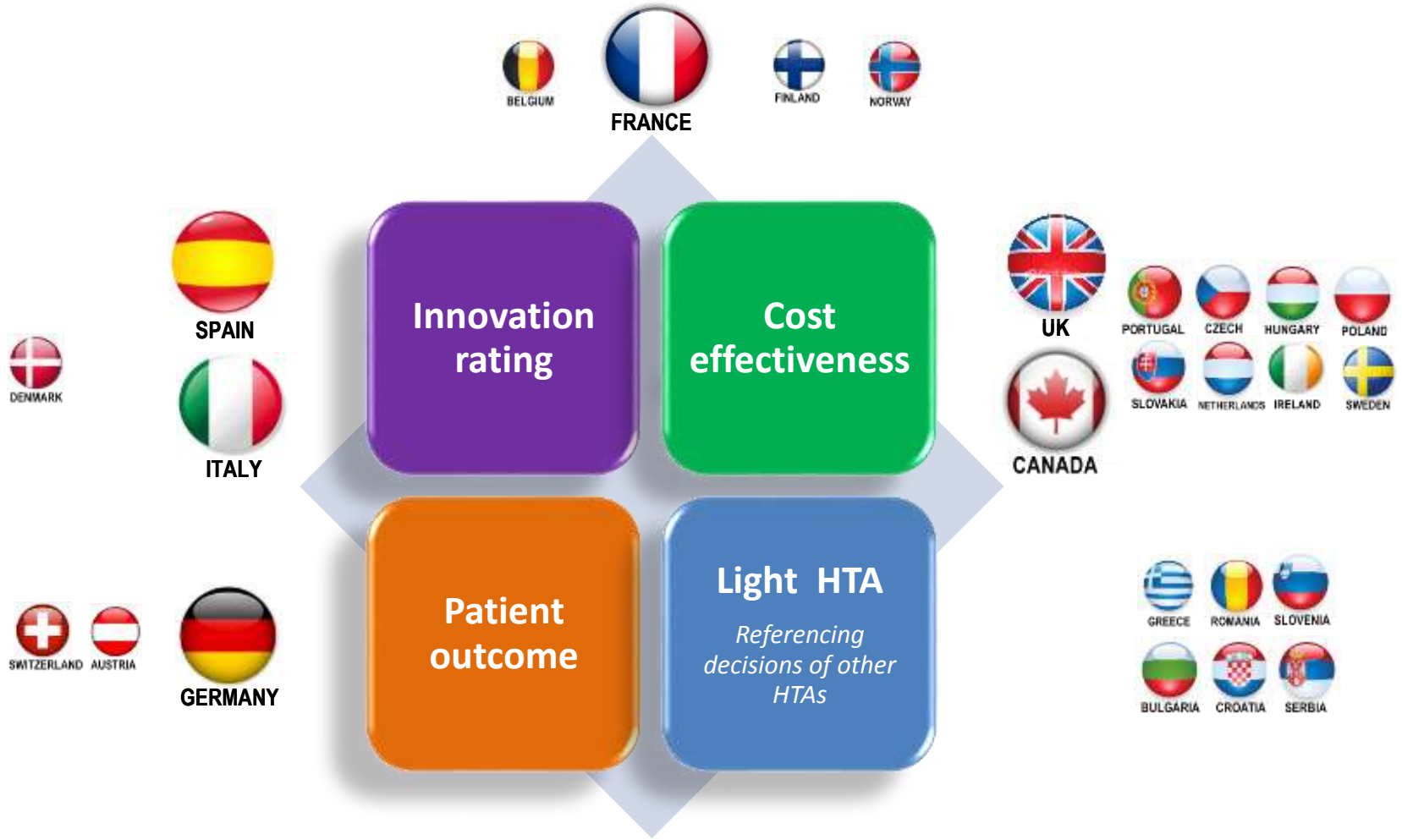
Evidence based medicine and HTA address distinct pharmaceutical policy questions. HTA improves system efficiency and performance and is not directed to cost containment per se…



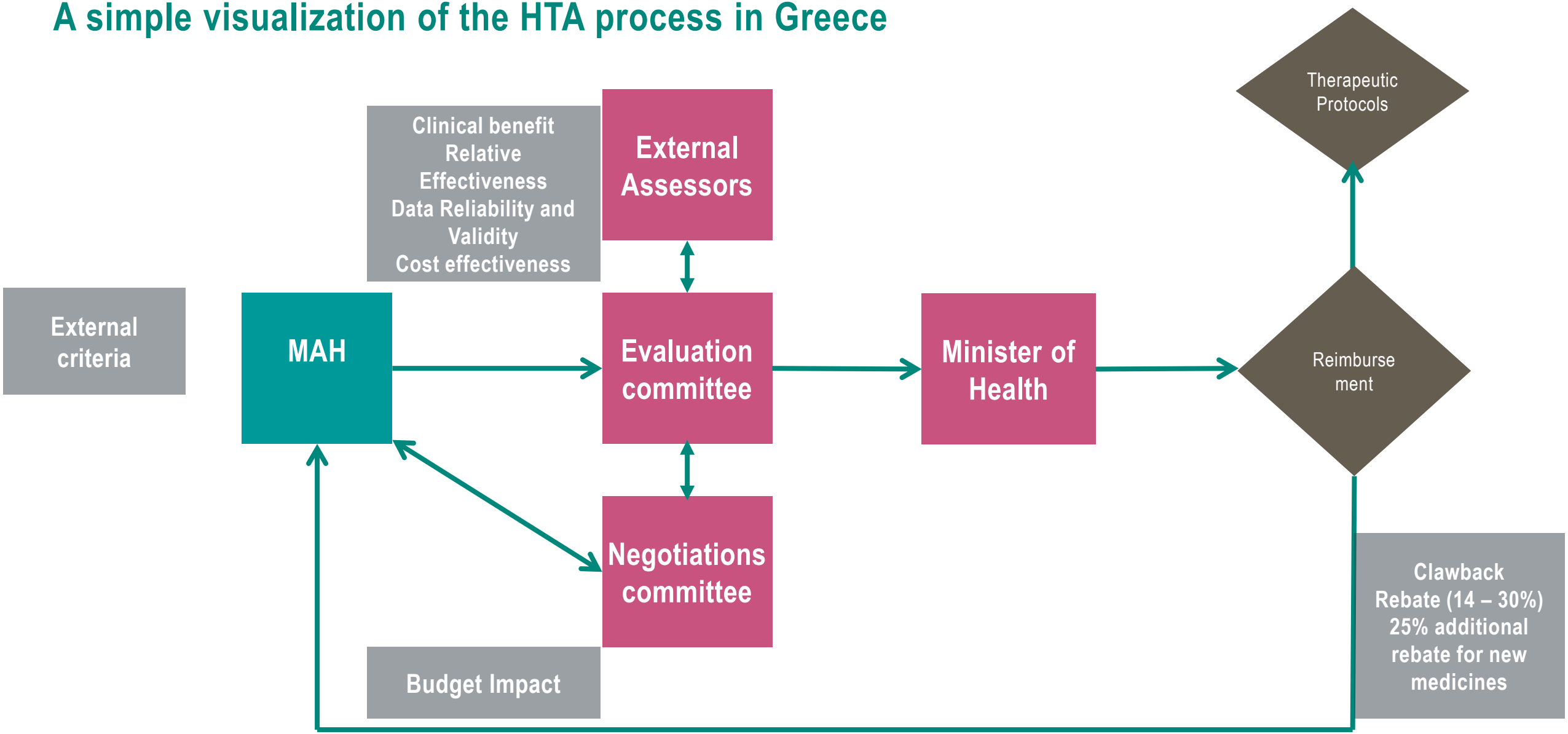
Objective	Factors to consider
1. Improving the health of the population	• reducing burden of illness – the severity of the disease for the individual patient – the burden of the disease on the society • health gain in terms of gain over a relevant comparator • impact on carers and families
2. Improving economic prosperity	• impact on carers and families • impact on the economy – the size of the economy (GDP) and rate of growth
3. Meeting social and political priorities	• equity issues • ethical issues • relevance to national priorities and values • attributes of the patients who would benefit (e.g. they are children or another priority group?)
4. Getting value for money	• allocative efficiency – maximizing benefit subject to budget constraints – cost-effectiveness – budget impact, given likely numbers of patients treated

https://htai.org/wp-content/uploads/2018/02/17023_HTAi_AsiaForumBackground2015.pdf

Health Technology Appraisal paradigm in Europe



A simple visualization of the HTA process in Greece



Criteria and Austerity measures

Decision Makers

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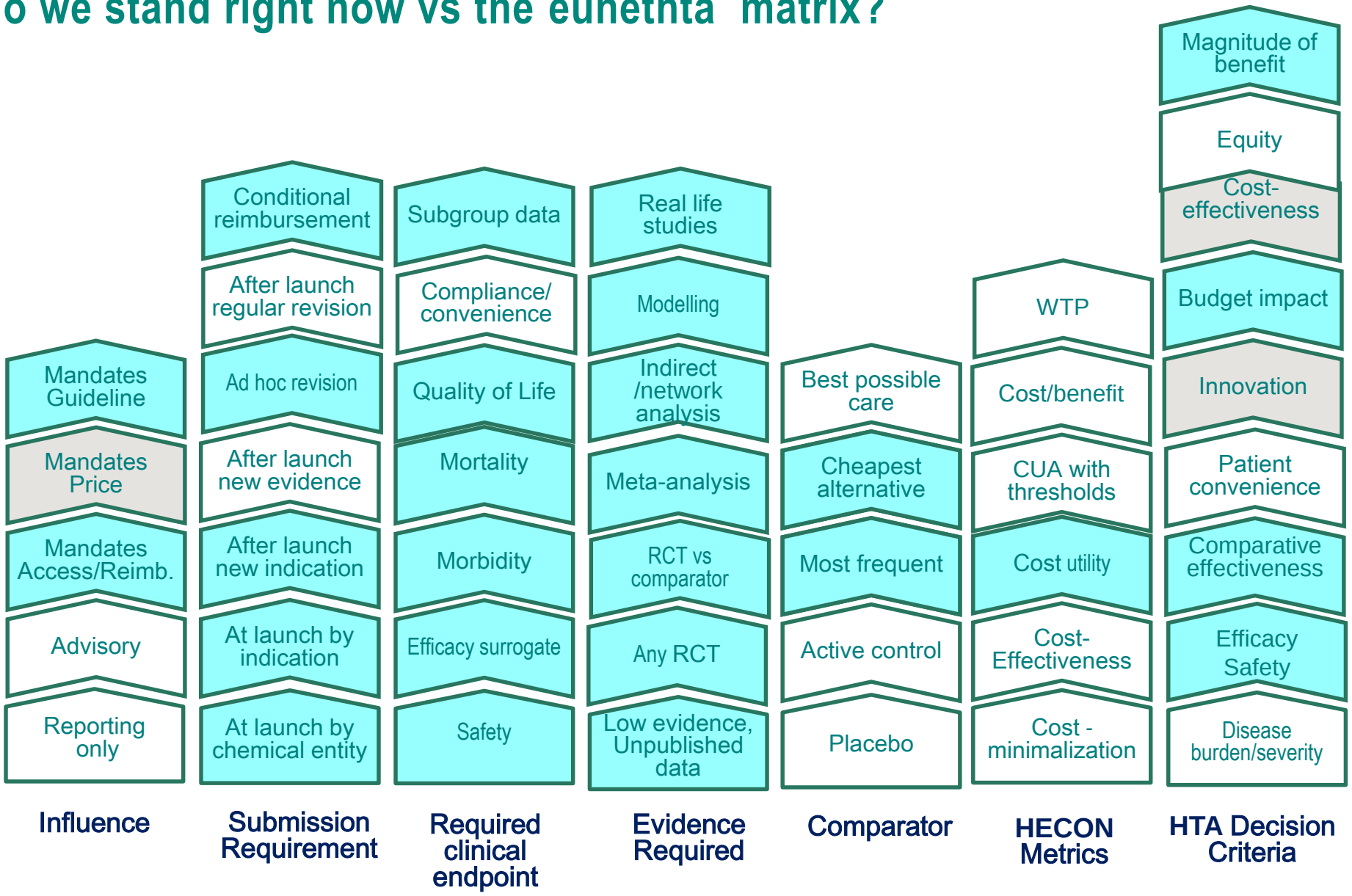
Infant status problems

- **No piloting process**
- Assessors: Who, how, what do they assess? How are they trained?
- Heterogeneity of Criteria: Portuguese approach on GRADE application, IQWIG approach on assessing magnitude of clinical benefit, No guidelines for cost effectiveness, no link between clinical / relative assessment and negotiation, too much emphasis on regulatory documents,
- Submission Guidelines?
- Confidentiality Issues especially related to pricing / discount / budget impact data
- Inadequate consultation process

- **Need to establish a MoH – Industry collaboration team to address arising issues in the implementation of HTA process**

Where do we stand right now vs the eunethta matrix?



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The two Committees have distinct roles. We are still searching for the HTA model we will follow… Is it one or two processes?

HTA Committee

- Recommends on product inclusion or exclusion
- Product restrictions if included
- Revision of the positive list

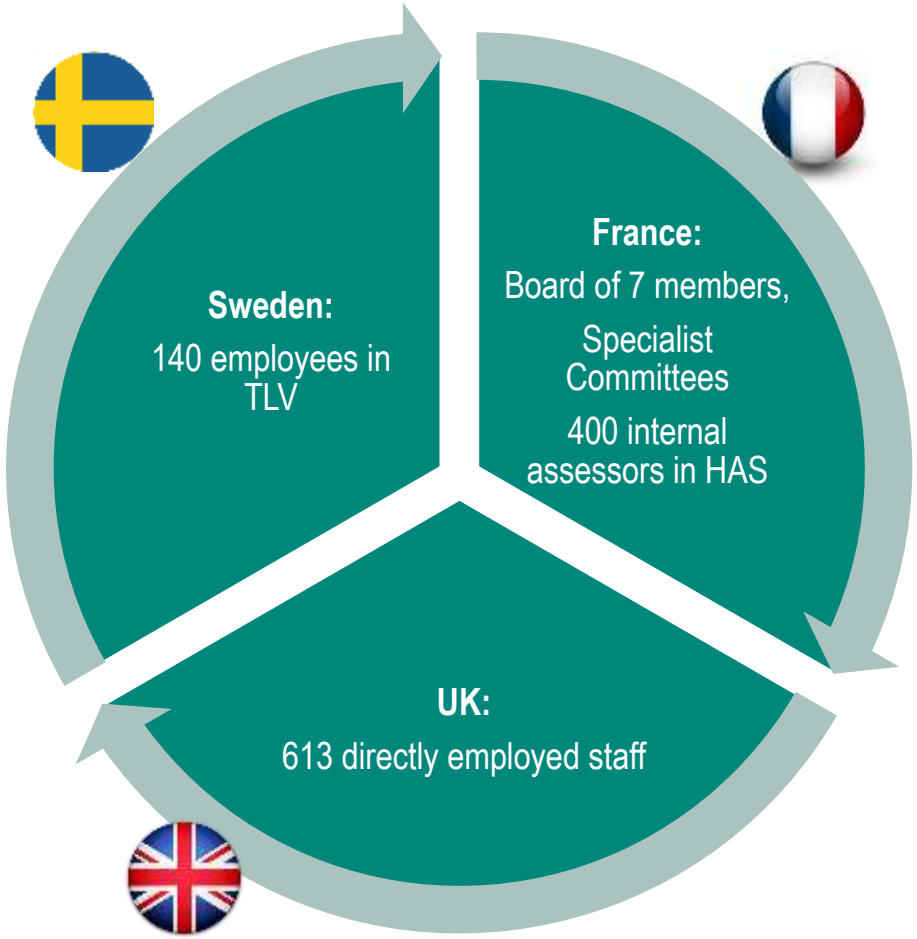
Negotiation Committee

- Recommends reimbursement prices or discounts
- Recommends to HTA committee on budget impact of negotiated products
- Prepares agreement with MAHs

Issues and weaknesses identified in the HTA process in Greece

The size and the status of part time committees in Greece seems unsustainable

Appropriate Staffing?



- 10 part time board members in HTA Committee
- 9 part time members of Negotiation Committee
- 11 full time administrative staff
- Assessors?

There are cases in which either an abbreviated HTA process or even exclusion of medicines from HTA process should be applied

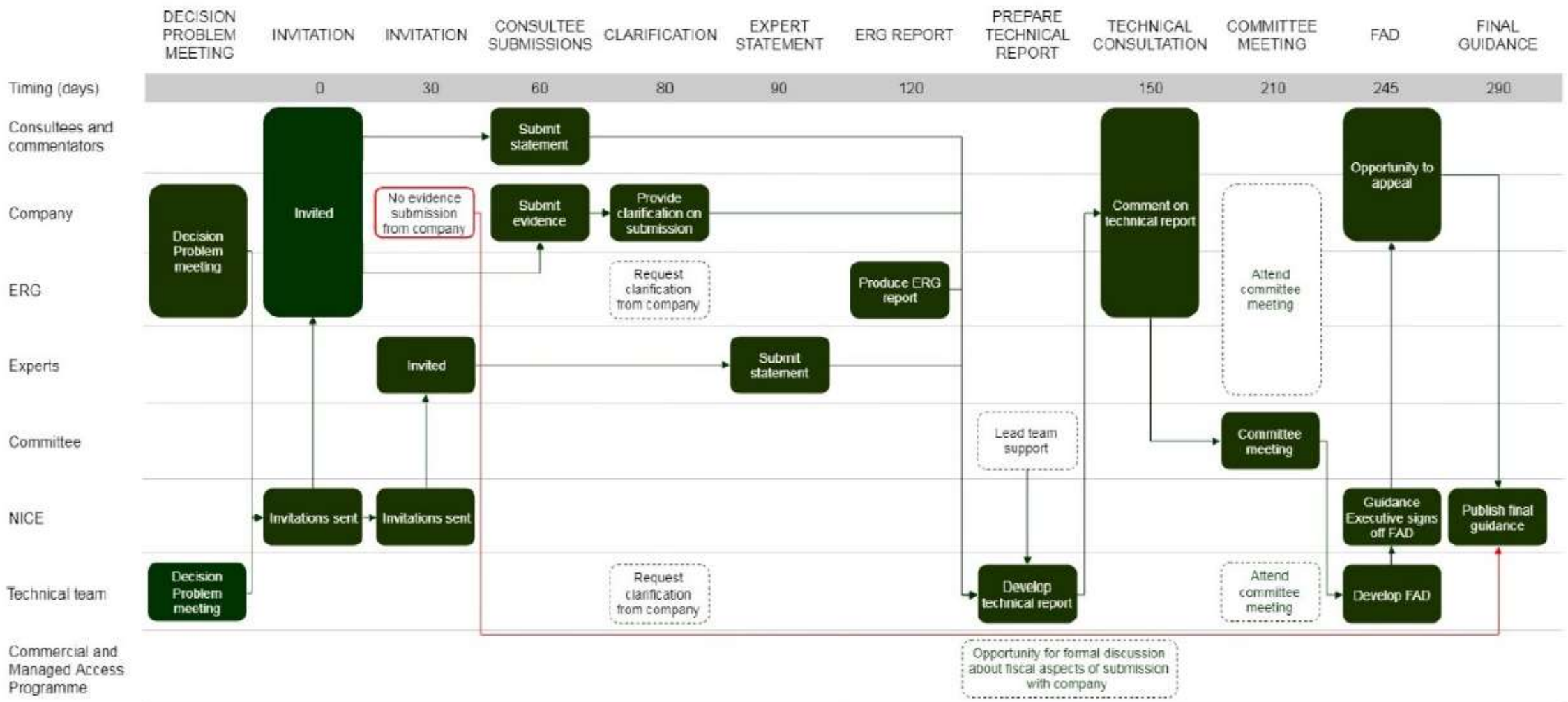
Abbreviated process

Therapeutic category	Exclusion from clinical evaluation	Exclusion from negotiation process
Vaccines	Inclusion in the National Immunization Program is decided by the National Immunization Committee	Negotiation may need to be run prior to inclusion in the NIP
Biosimilars	There is no clinical data to be evaluated. Biosimilars are approved with one study only, while the remaining indications are approved by extrapolation. They are not subjected to data protection	A process with financial offers with individual payers can lead to better savings
Generics	No clinical data to be evaluated	Unless the price of generics exceeds the price of reference products, there is no negotiation rationale. These products do not need to undergo an HTA evaluation
Blood products/	Special categories of products covering specific local needs. They should have automatic reimbursement upon pricing	No inclusion in negotiation process

Transparency and Stakeholder Involvement Issues

- ❑ Activity Log of Submissions and their progress
- ❑ Publication of HTA assessment and appraisal documents as well as negotiation outcomes
- ❑ Public hearings
- ❑ Industry participation in all process stages
- ❑ EOPYY / IDIKA data accessibility
- ❑ Patient Involvement in conveying patient clinical experience with the disease or current therapies or system inadequacies
- ❑ Appeal Process

NICE transparency and stakeholder involvement



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A checklist for assessment reports was developed as a means of improving transparency and consistency in HTA as an initiative of the International Network of Agencies for Health Technology Assessment (INAHTA)

Preliminary Information
1. Are there appropriate contact details for provision of further information?
Checklist for HTA reports
2. Are those who prepared the HTA report identified as authors or in other ways?
3. Is there a statement regarding conflict of interest?
4. Is there a statement on whether the report has been externally reviewed?
5. Is there a short summary that can be understood by the non-technical reader?
Why the Assessment Has Been Undertaken
6. Is reference made to the question that is addressed and the context of the assessment?
7. Is the scope of the assessment specified?
8. Is there a description of the health technology that has been assessed?
How the Assessment Has Been Undertaken
9. What sources of information have been used?
11. Is there information on the basis for interpretation of selected data?
12. Are the results of the assessment clearly presented?
The Results of the Assessment
13. Is there interpretation of the assessment results?
Implications of the Assessment Results and Conclusions
14. Are the findings of the assessment discussed?
15. If relevant to the assessment, are medico-legal implications considered?
16. Are the conclusions from the assessment clearly stated?
17. Are there suggestions for further action?

Hailey D. International Journal of Technology Assessment in Health Care, 19:1 (2003), 1–7

How could Greek patients participate in the HTA process?

Patient group participation

Law 4512 indicates only:

7. Η Επιτροπή Αξιολόγησης μπορεί να καλεί εκπροσώπους συλλόγων ασθενών και επιστημονικών σωματείων ή εταιρειών ιατρικών ειδικοτήτων για να εκφράσουν τις απόψεις τους.

Steps	Potential engagement points
Invitation of HTA Committee to MAH	***Patient group recommendation regarding priority setting of HTA files***
HTA Committee meetings	***Patient group participation in the HTA process***
Dissemination of introductory report to HTA Committee members	***Patient group recommendation to HTA Committee***
Report of HTA Committee sent to Negotiation Committee	***Patient group recommendation to Negotiation Committee***
Final decision	***Patient group consultation / vote***
Appeal process	***Patient group consultation / vote***

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The concept of fiscal impact in negotiations

- The concept of fiscal impact is not compatible with current legislation on the clawback of pharmaceutical spending:
  - Hospital Level: Clawback is characterized as revenue
  - In out-hospital care see the following extract from the new positive list in August 2018:

22. Το Β2β/Γ.Π.οικ. 61676/9-8-2018 έγγραφο της Γενικής Δ/νσης Οικονομικών Υπηρεσιών του Υπουργείου Υγείας, σύμφωνα με το οποίο από την εφαρμογή της παρούσας απόφασης δεν προκύπτουν δημοσιονομικές επιπτώσεις στον προϋπολογισμό του ΕΟΠΥΥ καθότι δεν μεταβάλλεται το ανώτατο όριο της φαρμακευτικής δαπάνης του, όπως αυτό καθορίστηκε με το ΜΠΔΣ, πέραν του οποίου ενεργοποιείται ο μηχανισμός αυτόματης επιστροφής (CLAW BACK). Επίσης δεν προκαλείται δαπάνη σε βάρος του Κρατικού Προϋπολογισμού.

Monthly EOPYY Reimbursement STATIN R - August 2018 vs June 2018

	Monthly EOPYY Reimbursement (€)			
	August	**June**	**Δ**	**Δ %**
Product A 20/14	5,21 €	5,78 €	-€0,57	-9,9%
Generic A 20/30	14,30 €	6,19 €	€8,11	131,0%
Generic B 20/28	13,34 €	5,78 €	€7,56	130,9%
Generic B 20/14	15,15 €	5,78 €	€9,38	162,3%
Generic C 20/30	14,30 €	6,19 €	€8,11	131,0%
Product A 40/14	6,51 €	7,04 €	-€0,53	-7,5%
Generic B 40/28	16,29 €	7,03 €	€9,26	131,8%
Generic B 40/14	18,53 €	7,04 €	€11,49	163,3%
Generic C 40/30	17,46 €	7,53 €	€9,93	131,9%
Product A 10/14	5,52 €	5,91 €	-€0,39	-6,6%
Generic AL 10/30	10,16 €	6,32 €	€3,83	60,6%
Generic B 10/28	9,47 €	5,90 €	€3,56	60,4%
Generic C 10/30	10,16 €	6,32 €	€3,83	60,6%
Product A 5/14	4,91 €	7,04 €	-€2,13	-30,3%
Generic A 5/30	6,62 €	7,53 €	-€0,91	-12,2%
Generic B 5/28	4,06 €	7,03 €	-€2,97	-42,3%
Generic B 5/14	4,61 €	7,04 €	-€2,43	-34,5%
Generic C 5/30	6,64 €	7,53 €	-€0,89	-11,9%

August Positive List: ΦΕΚ 3431/B/17-08-2018
June Positive List: ΦΕΚ 2268/B/15-06-2018

In conlusion…

HTA is here to stay

HTA needs inclusive stakeholder involvement in order to overcome the problems arising in its infancy

Need to abolish additional rebate of 25%, external HTA reference criteria etc

Need to establish processes for Horizon Scanning and HTA Scope in order to reduce the number of submissions

Need to work extensively on transparency as a means to establish credibility and sustainability

HTA is not about restricting innovation in order to subsidize the off patent market.

HTA is about better resource allocation and better clinical practice. It should be at the core of the system!

THANK YOU!