

# The purchasers Perspective at 9<sup>th</sup> International Pharma Compliance Congress and Best Practice Forum Brussels

## Compliance with the context of Value based pricing in France

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Former Transparency committee member 1998-2011

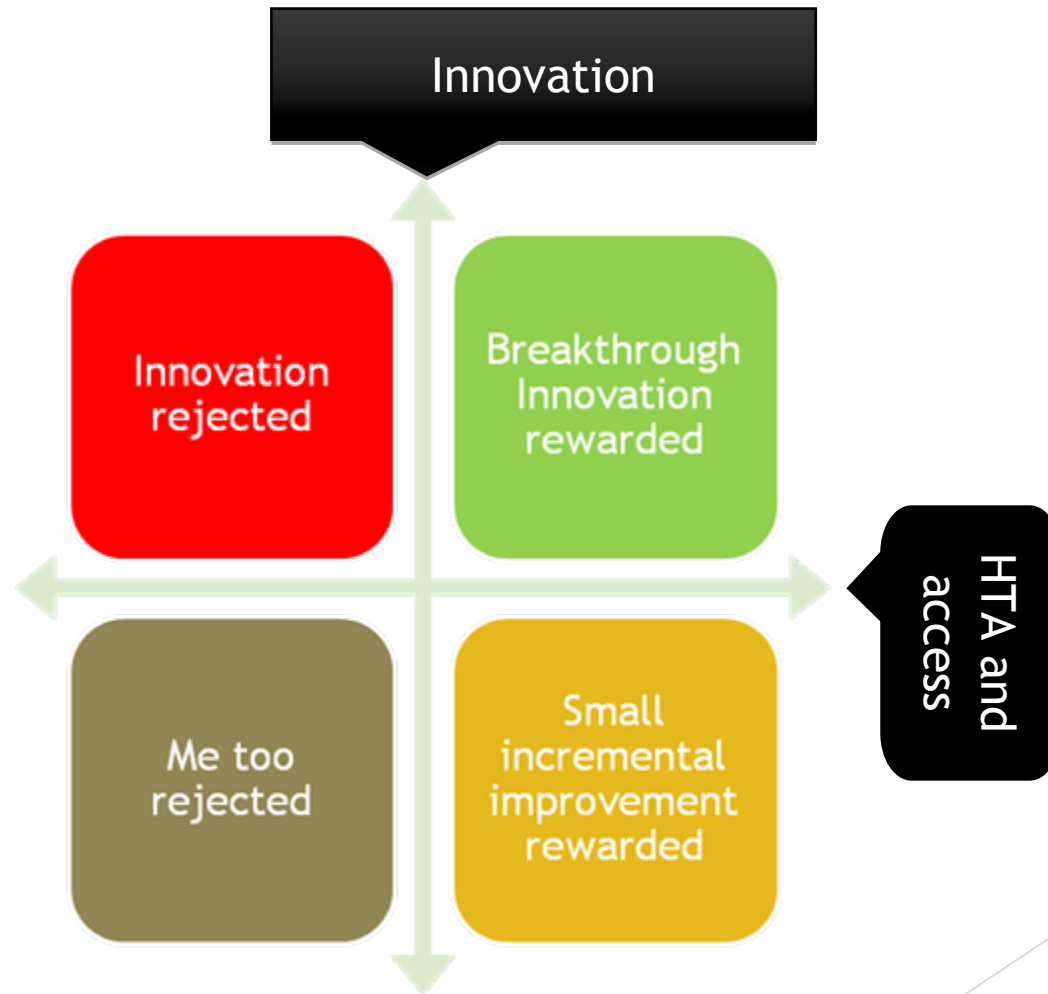
Guideline committee member (HAS, ANSM FRANCE) 1996-  
2014

External adviser (device and drug committee, sick fund,  
Ministry of Health)

Early engagement MédiQualité Ω, CMO<sub>1</sub>



# Switch challenge in opportunities





# How to estimate your ROI?

► Price =  $f(\Delta, \text{ICER}, \text{GNP}/H, \text{€}/\text{£}_{bn}, \phi, n_i, N_p, \$_{i/\text{ROI}})$





"Everything is worth what its purchaser will pay for it."  
"Res quaeque tanti est, quanti emptorem invenerit."

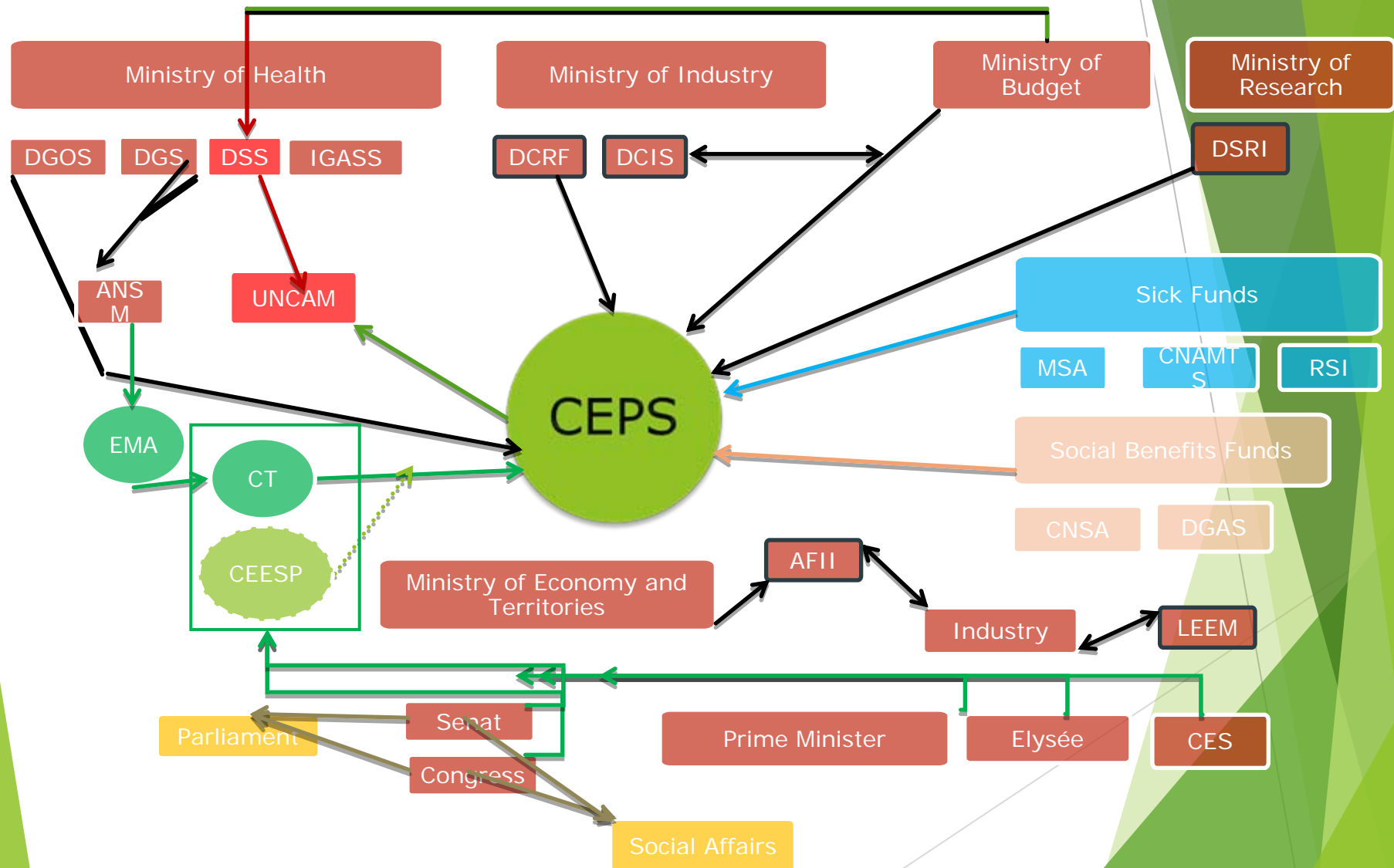
Quote from Publilius Syrus ; Sentences - 1<sup>st</sup> . B.C.







# Access to market in France





# Steps of access

- ▶ Early access [Name patient and cohort ATU]
- ▶ MA
- ▶ Time for assessment by CT 117 days for a first approval
- ▶ Time between CT appraisal and first hearing by CEPS 23 days
- ▶ CEESP if ASMR 3 and > 20 millions € on sales/year
- ▶ Time for negotiation and first price proposal by CEPS 65 days
- ▶ Time for financial agreement signed with CEPS 16 days
- ▶ Time to publication at the French Official Journal 36 days
- ▶ Public Hospital tendering if applicable
- ▶ Lower involvement at each step: optimize access and secure your contract!





I'm looking for the  
Department of  
Budget, can you  
help me ?

I can see you're an  
academic. Maybe  
you should quit  
hoarding knowledge  
and help manage  
the country.

Quit disturbing me,  
I'm working on HTA  
for gene therapy.  
A key decision-  
maker should  
always know where  
they're headed to.





# Compliance and rule of law at all steps

- ▶ For each stakeholder there is a set of legal requirements (HTA, CEPS, insurance payers, commissioners, hospitals, tender)
- ▶ Evolving national and legal framework
- ▶ Benchmark from others (best practices, national, regional, local, early access scheme)
- ▶ Legal review through the whole process of the product from cradle to grave (LOE)
- ▶ Think outside the box, anticipate, update and be flexible within the legal framework (supervision of junior officers)



# Thank you very much for your attention !

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