

The purchasers Perspective at 9th International Pharma Compliance Congress and Best Practice Forum Brussels

Compliance with the context of Value based pricing in France

Olivier WONG, MD, MSc

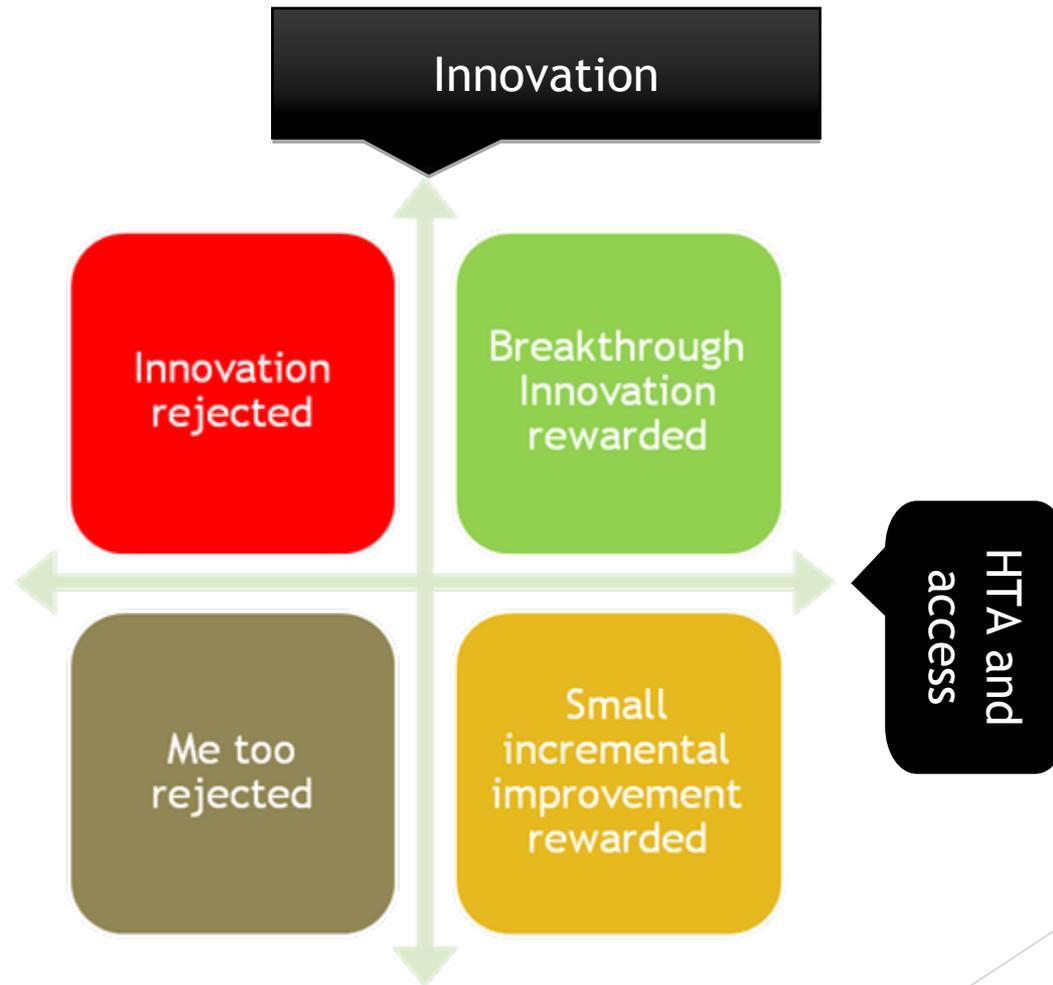
Former Transparency committee member 1998-2011

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

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

Early engagement MédiQualité Ω, CMO₁

Switch challenge in opportunities



How to estimate your ROI?

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



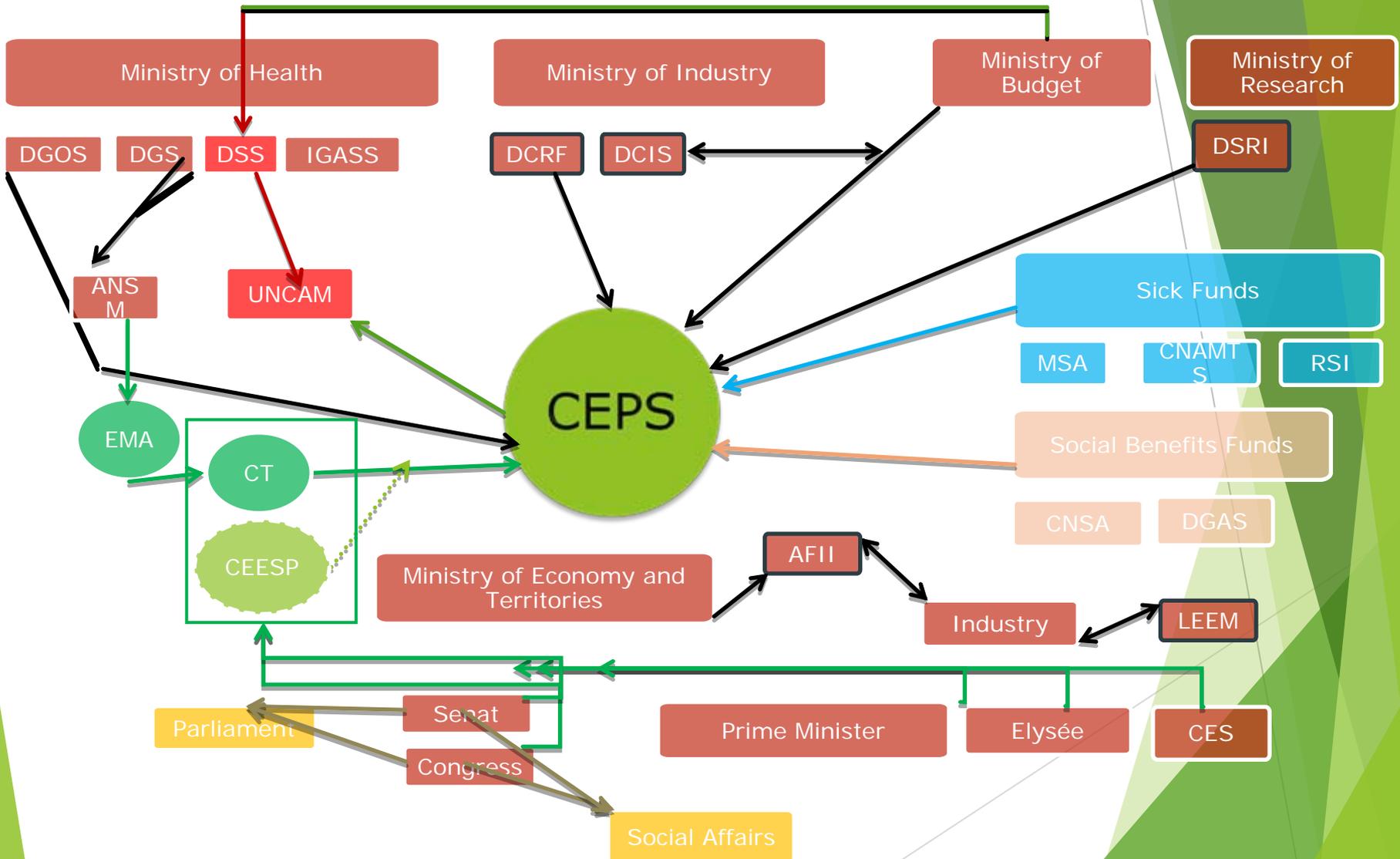
“Everything is worth what its purchaser will pay for it.”
“Res quaeque tanti est, quanti emptorem invenerit.”

Quote from Publilius Syrus ; Sentences - 1st . B.C.





Access to market in France



Steps of access

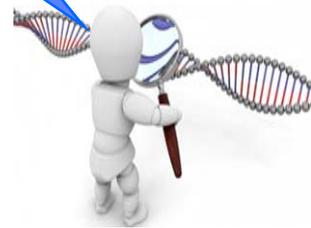
- ▶ Early access [Name patient and cohort ATU]
- ▶ MA
- ▶ Time for assessment by CT 117 days for a first approval
- ▶ Time between CT appraisal and first hearing by CEPS 23 days
- ▶ CEESP if ASMR 3 and > 20 millions € on sales/year
- ▶ Time for negotiation and first price proposal by CEPS 65 days
- ▶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

▶ Olivier WONG, MD, MSc



owong@cpmf.org

