Académie nationale de Pharmacie

ORDEM DOS FARMACÊUTICOS 1835

THE NEEDS OF THE HEALTH SYSTEMS: FROM EFFICACY TO EFFECTIVITY

ANA PAULA MARTINS
President of the Portuguese Pharmaceutical Society

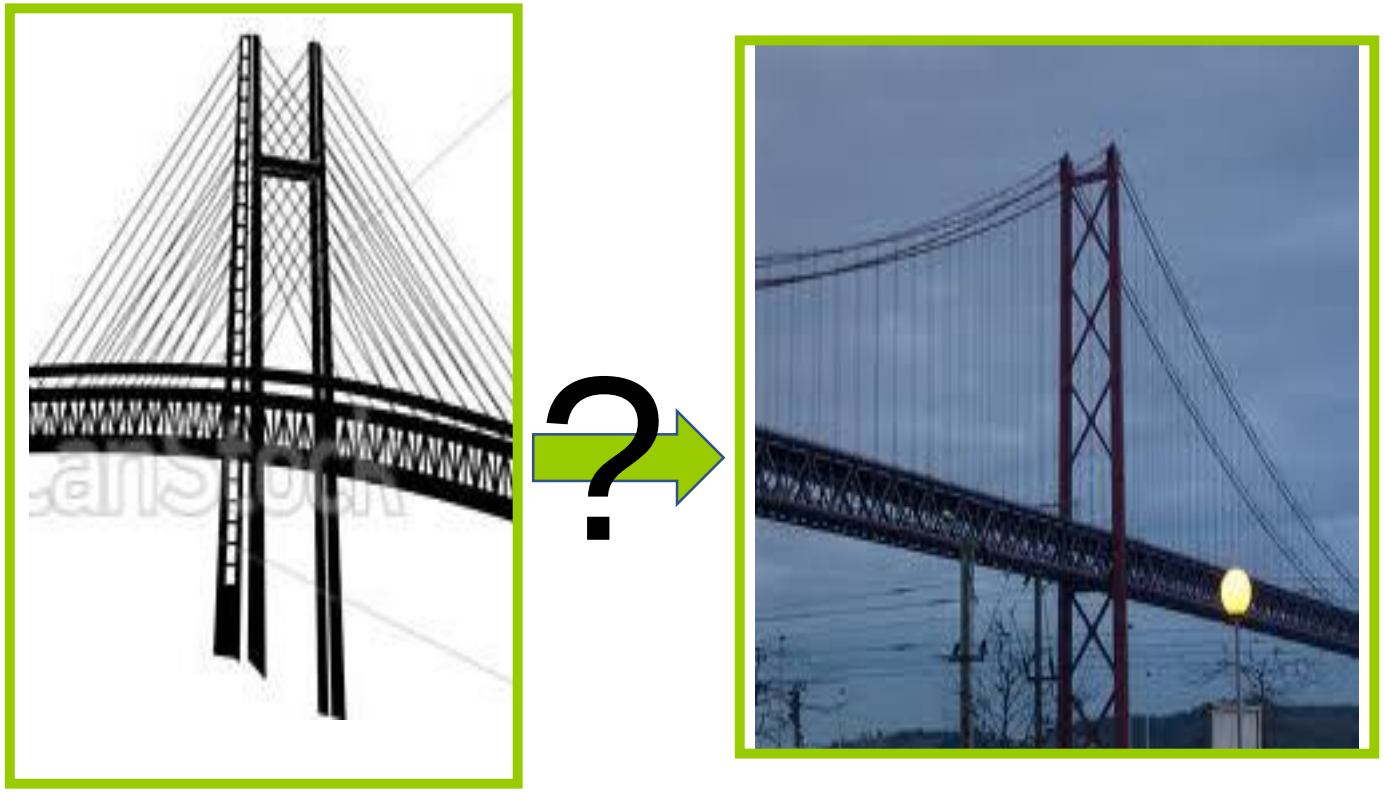
SUMMARY

- Efficacy and effectiveness : bridgind the gap.....
- HTA – a social benefit, a united Europe for all citizens
- HTA – Advances in Portugal and cooperation in Europe

The need of Bridging the Gap

Bridging the efficacy–effectiveness gap: a regulator's perspective on addressing variability of drug response

Hans-Georg Eichler, Eric Abadie, Alasdair Breckenridge, Bruno Flamion, Lars L. Gustafsson, Hubert Leufkens, Malcolm Rowland, Christian K. Schneider and Brigitte Bloechl-Daum



FROM EFFICACY TO EFFECTIVITY

FROM EFFICACY TO EFECTIVENESS

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ISPOR TASK FORCE REPORT

Prospective Observational Studies to Assess Comparative Effectiveness: The ISPOR Good Research Practices Task Force Report

Marc L. Berger, MD[1,], Nancy Dreyer, PhD, MPH[2], Fred Anderson, PhD[3], Adrian Towse, MA[4], Art Sedrakyan, MD, PhD[5], Sharon-Lise Normand, PhD[6]*

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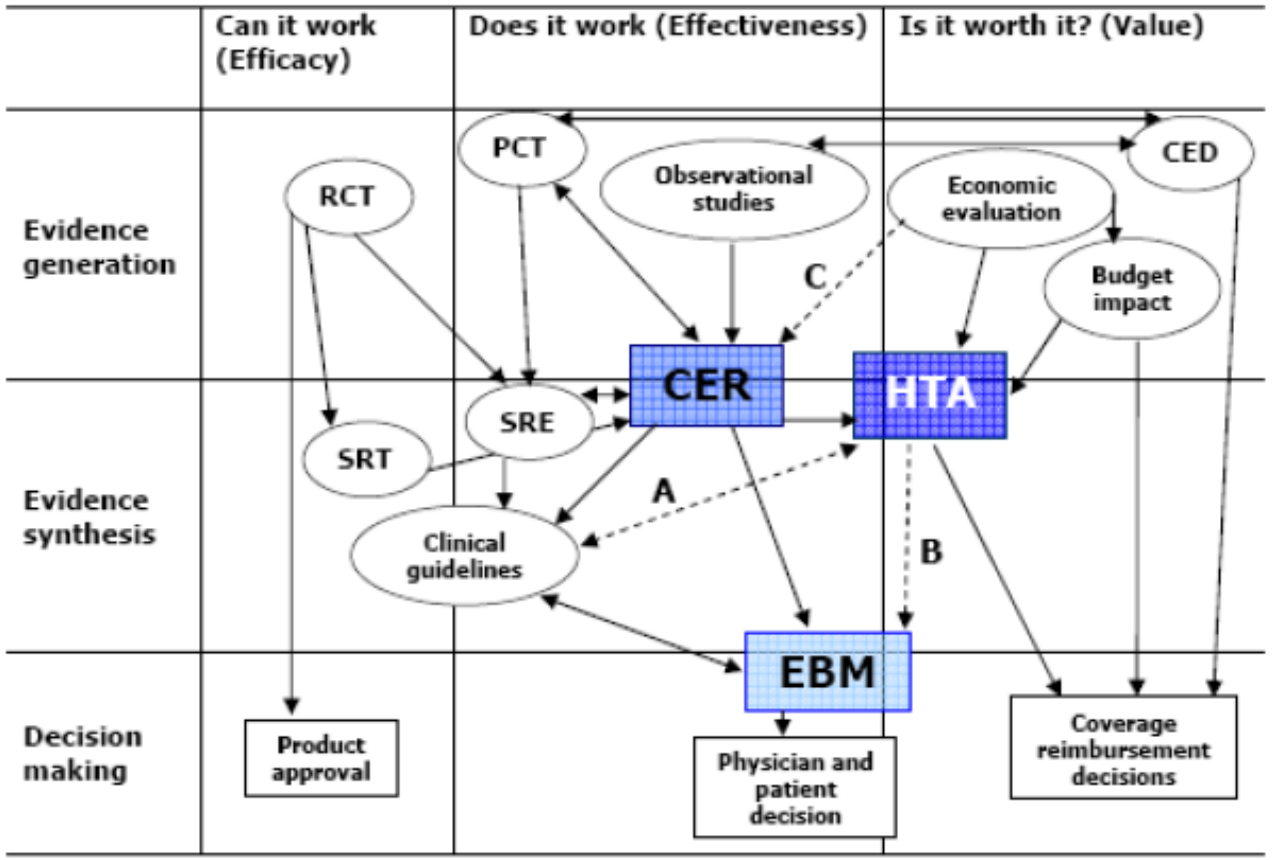
ABSTRACT

Table 1 – Categories of intervention effects.

Term	Efficacy	Relative efficacy	Effectiveness	Relative effectiveness
Definition: *Extent to which*	An intervention does more good than harm under *ideal* circumstances	An intervention does more good than harm, under *ideal* circumstances, compared with one or more alternative interventions	An intervention does more good than harm when provided under the *usual* circumstances of health-care practice	An intervention does more good than harm compared with one or more intervention alternatives for achieving the desired results when provided under the *usual* circumstances of health-care practice
Key features	Randomization versus placebo; select patients; high-volume centers	Randomization versus active control; or use of indirect comparisons of trials versus placebos or active comparators	Observational study; heterogeneous patient population; typical treatment environment; comparison typically made to other treatments	Observational study of several competing interventions; or randomized naturalistic pragmatic clinical trial

HOW DO WE MEASURE COMPARATIVE EFFECTIVENESS?



Abbreviations: CED= coverage with evidence development; CER=comparative effectiveness research; EBM=evidence based medicine; HTA=health technology assessment; PCT=pragmatic clinical trial; RCT=randomised controlled trial; SRE= systematic review of evidence; SRT= systematic review of trials.

THE NEEDS OF THE HEALTH SYSTEMS: FROM EFFICACY TO EFFECTIVITY

The Innovative Medicines Initiative: an engine for regulatory science

Michel Goldman[1], Nathalie Seigneuret[1] and Hans-Georg Eichler[2]

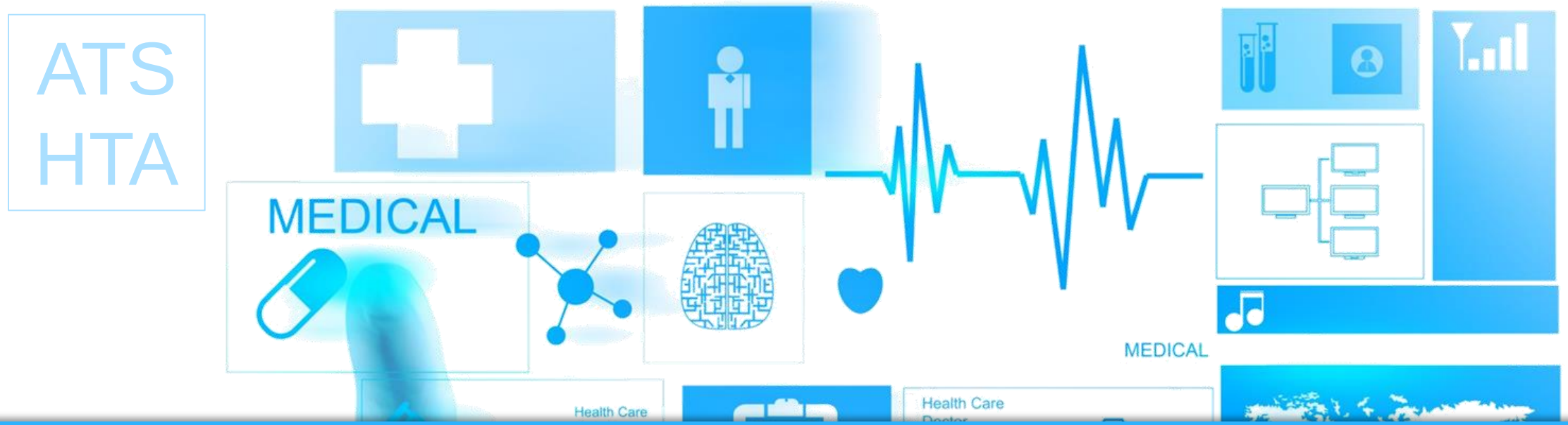
Since its launch in 2008, the Innovative Medicines Initiative has catalysed the formation of many consortia to address challenges in drug development and regulation. As it moves into its second phase, we highlight key outcomes so far and the lessons learned.

New methods to assess the effectiveness of new drugs under 'real-life' conditions. A paradigm change is needed to better integrate real-world data into drug development and to provide health technology assessment (HTA) agencies with the tools they need to reach the right decisions regarding the effectiveness of new medicines. This is the **focus of the GetReal consortium**, which gathers academic institutions, HTA agencies, regulators, patient organizations, small- and medium-sized enterprises and pharmaceutical companies.

Nature Reviews, Drug Discovery, Vol 14, January 2015.

GetReal: http://www.imi-getreal.eu/

HTA – A SOCIAL BENEFIT, A UNITED EUROPE



HTA is an important tool that helps National Authorities to analyze and establish the added value of new technologies when compared to existing ones.

Source: European Commission - Directorate General For Health And Food Safety, *Strengthening of the EU cooperation on Health Technology Assessment (HTA) Online public consultation report*

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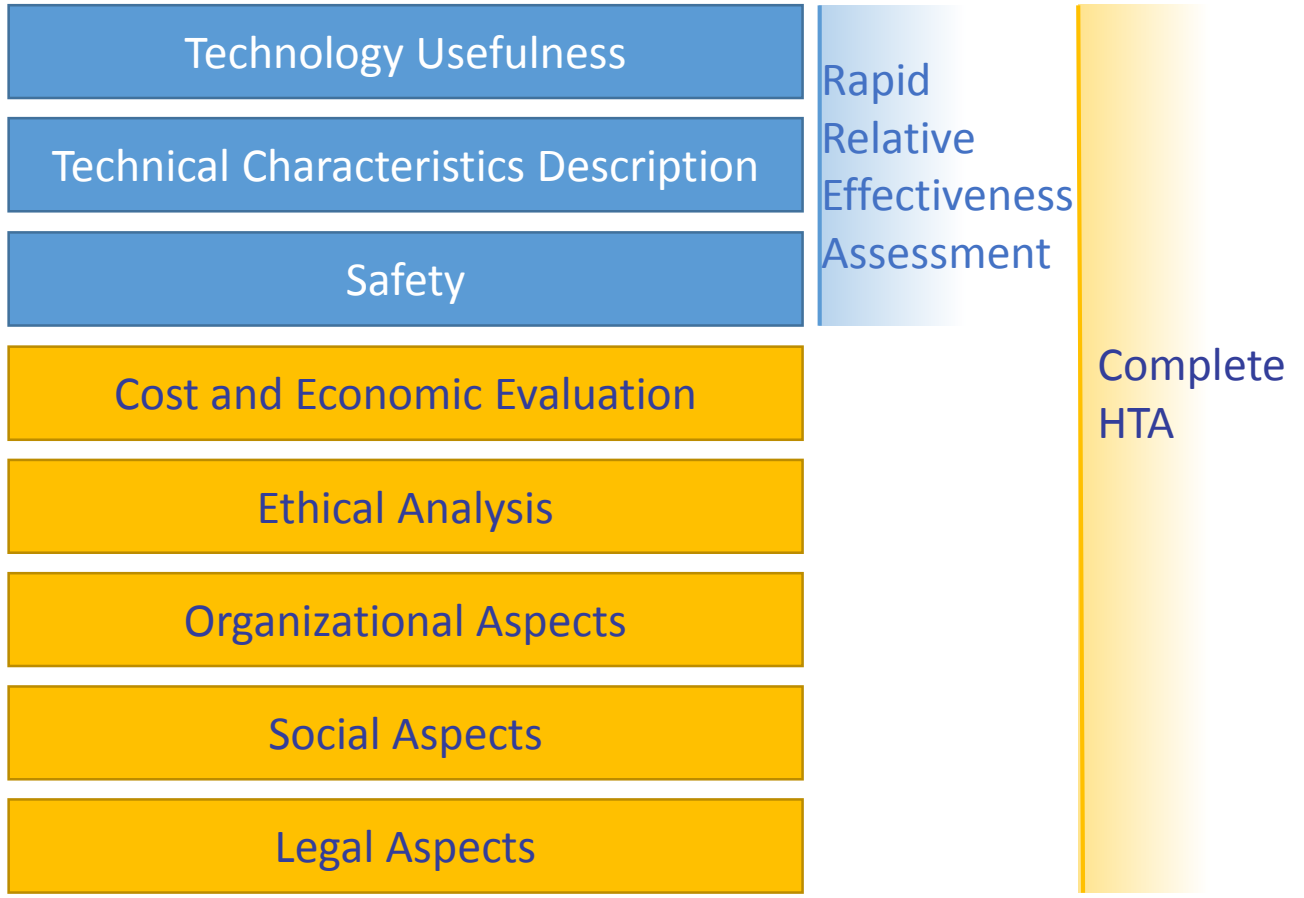
HTA – A SOCIAL BENEFIT, A UNITED EUROPE

SEPT 2016

European Commission

INCEPTION IMPACT ASSESSMENT

- Health expenditure in EU: 1.300 billions € /year
- Market entry of new technologies with low added value but with high budgetary pressure
- Member States recognize the importance of HTA
- HTA has costs and consumes specialized resources
- Cooperation between Member States arises for joint or shared evaluation
  - EUnetHTA 1 | 2010-2012
  - EUnetHTA 2 | 2012-2015
  - EUnetHTA 3 | 2016-2020 (>70 members)
- HTA model (2 ways)



HTA – A SOCIAL BENEFIT, A UNITED EUROPE

Patient Participation considered…

- VERY IMPORTANT (67%)
- IMPORTANT (27%)

User/patient point of view allows to meet…

- Needs
- Quality of Life
- Treatment preferences
- Side effects acceptance
- Therapy adherence

Patient involvement improves process and decision regarding…

- CREDIBILITY
- JUSTICE
- EQUITY

HTA – ADVANCES IN PORTUGAL

SiNATS

HEALTH TECHNOLOGIES ASSESSMENT NATIONAL SYSTEM IN PORTUGAL

SiNATS

CREATE THE FUTURE

Título: ***Sistema Nacional de Avaliação de Tecnologias de Saúde para Portugal (SiNATS) – Criar o futuro***

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Edição: ***Duarte, D (INFARMED, I.P.)***

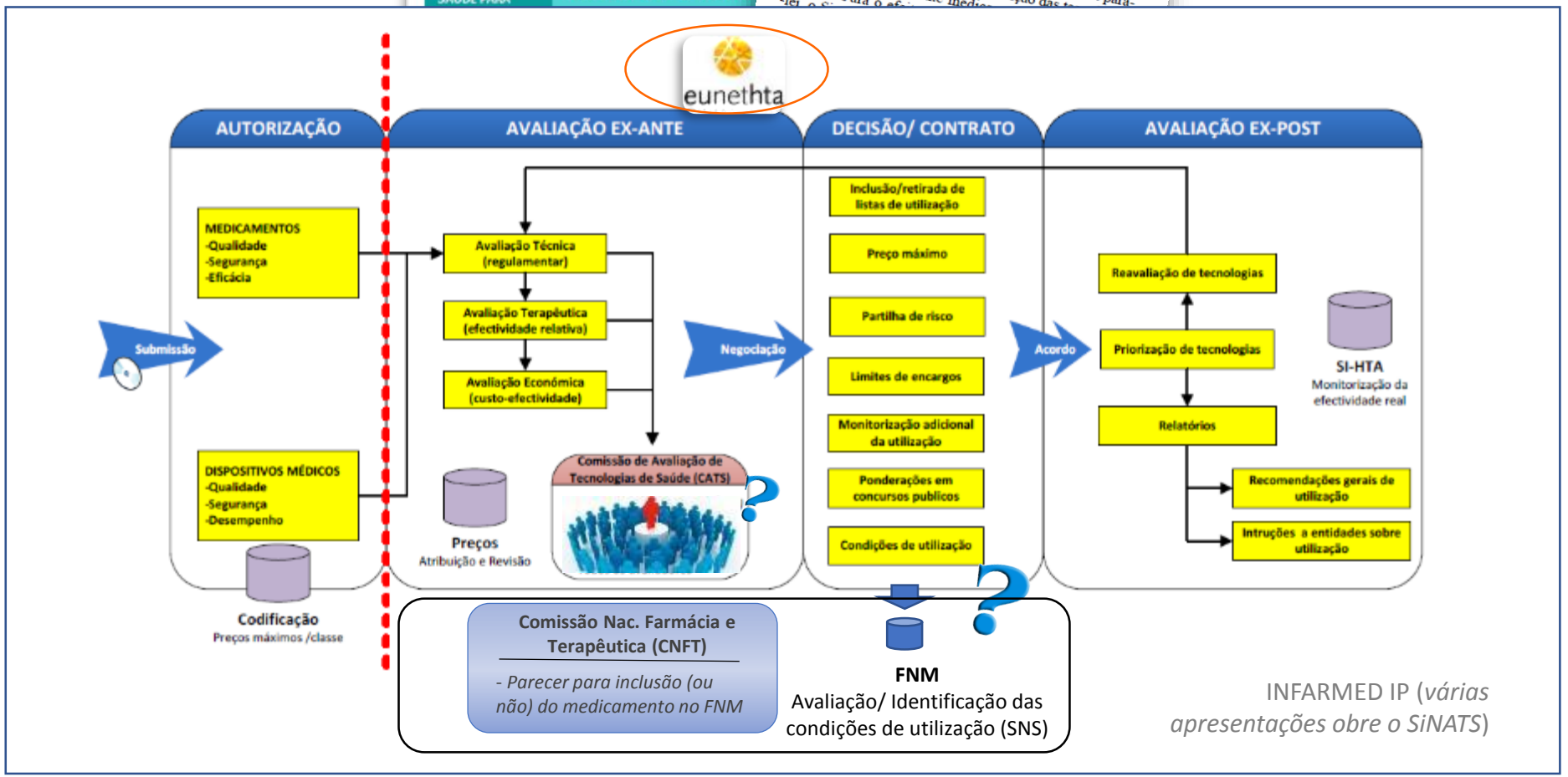
Julho de 2014

Health Technologies Assessment Commission (CATS)

Methodology for Pharmacotherapeutic Assessment

Evolução do Sistema Nacional de ATS (VI)

Novo Modelo SiNATS



INFARMED IP (*várias apresentações obre o SiNATS*)

REINFORCE COOPERATION IN EUROPE BOOSTS INNOVATION

European Commission - Press release

Assessing health technology in the EU: Commission proposes to reinforce cooperation amongst Member States

Brussels, 31 January 2018

Assessing health technology in the EU: Commission proposes to reinforce cooperation amongst Member States

Vice-President Katainen said: *"Reinforcing Health Technology Assessment co-operation at EU level boosts innovation and improves competitiveness of the medical industry. The healthcare sector is a crucial part of our economy, it accounts for approximately 10% of the EU's GDP. We are proposing a regulatory framework that will bring benefits to patients all over Europe, whilst encouraging innovation, helping the take-up of high-quality medtech innovations and improving the sustainability of health systems across the EU."*

Commissioner for Health and Food Safety, Vytenis Andriukaitis, added: *"Today, the Commission has put the wheels in motion for better quality, innovative healthcare for the benefit of patients, especially those with unmet medical needs. I also expect this initiative to result in a more efficient use of resources by Member States through the pooling of resources and exchanges of expertise, thereby avoiding duplications in the assessment of the identical products".*

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THANK YOU! MERCI! OBRIGADA

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