

THE REIMBURSEMENT PROCESS: OPPORTUNITIES WITH THE HTA-R REGULATION

CLÁUDIA FURTADO | 09/04/2025 | PPRI NETWORK MEETING



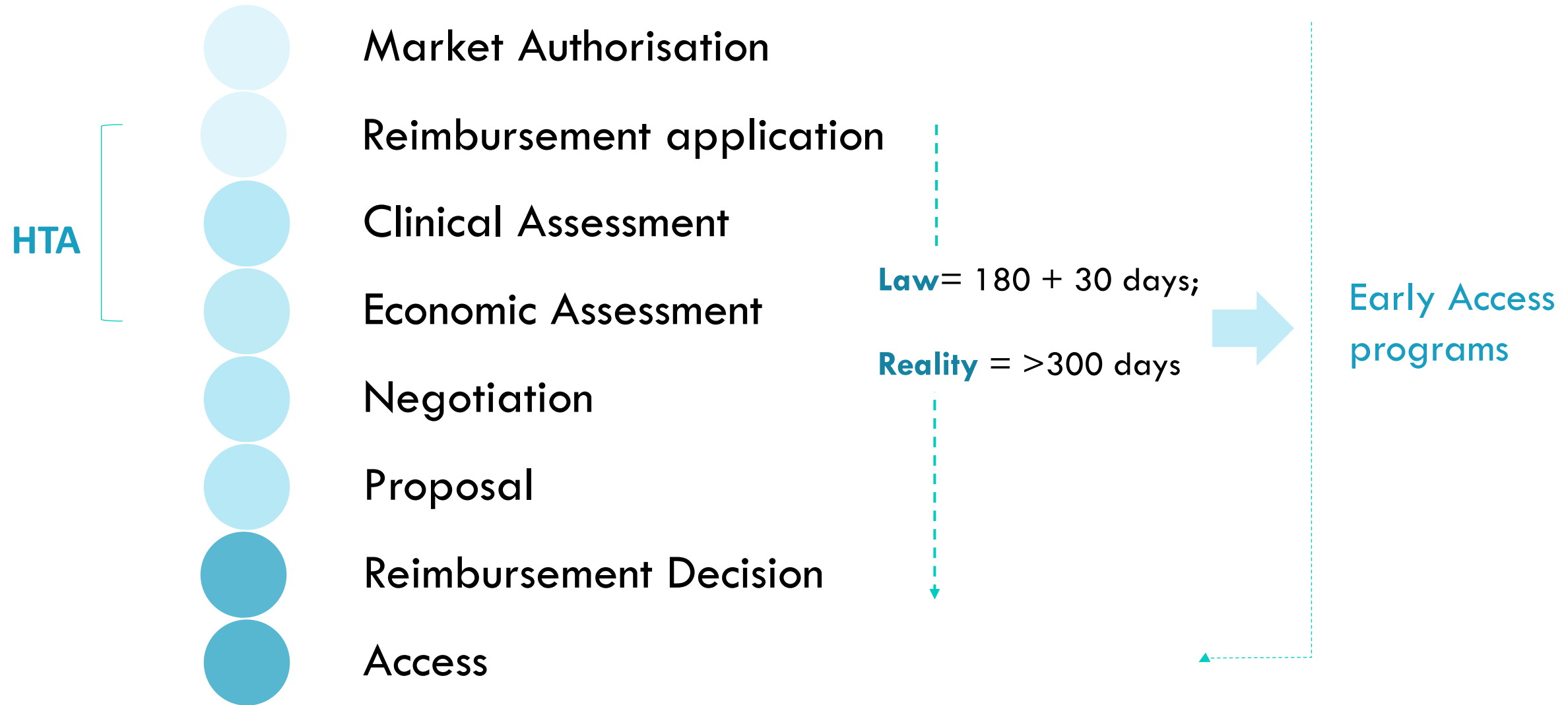
REIMBURSEMENT PROCESS IN PORTUGAL

Current process

Our main challenges

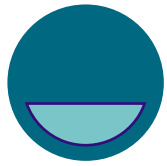
Opportunities with HTAR

REIMBURSEMENT PROCESS IN PORTUGAL



CLINICAL ASSESSMENT

After
CHMP
opinion or
MA



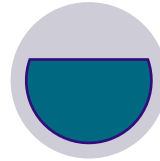
Initial proposal
PICO

HTA group of evidence
(Clinical Experts) and
HTA Executive
Committee

:

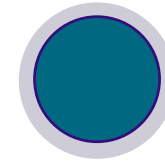
Patients (written input)

Shared with MAH



Assessment of
clinical evidence
& added benefit

HTA group of
evidence



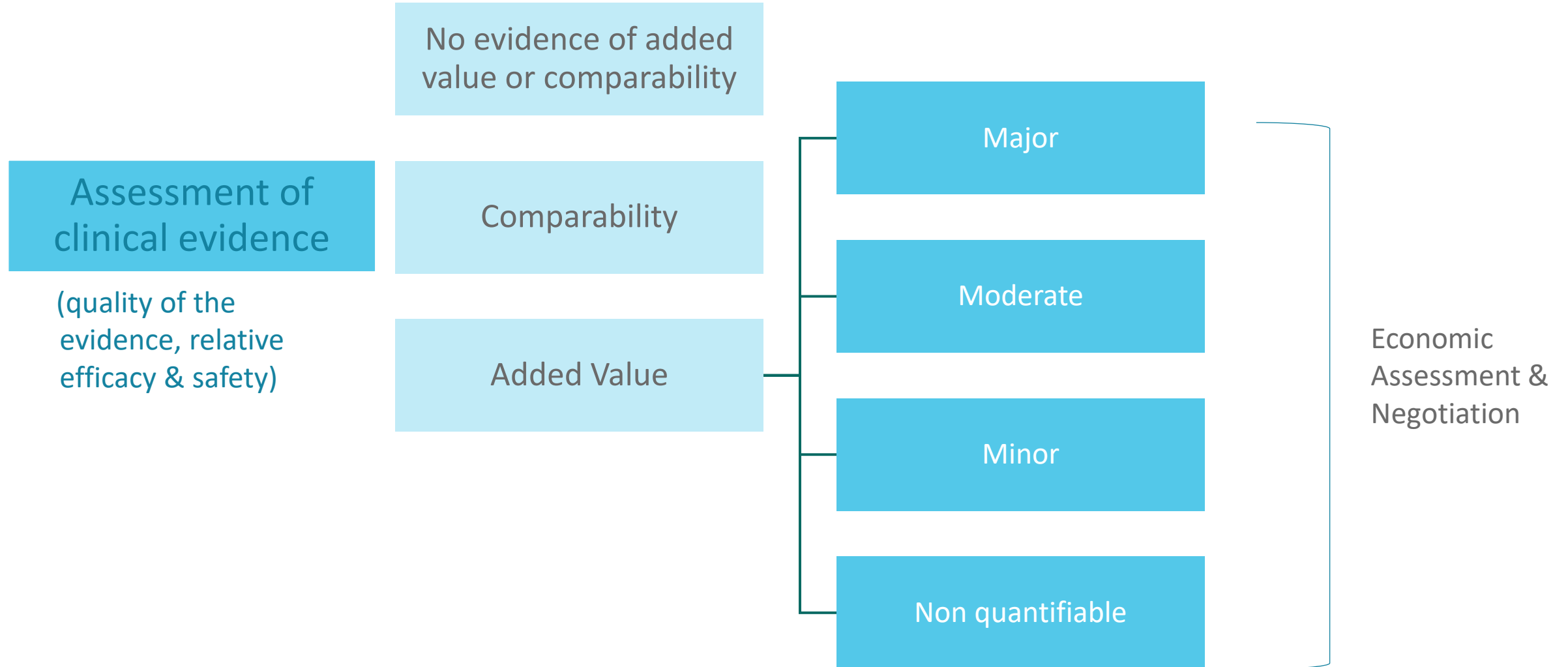
Final Report

HTA Exec Com.

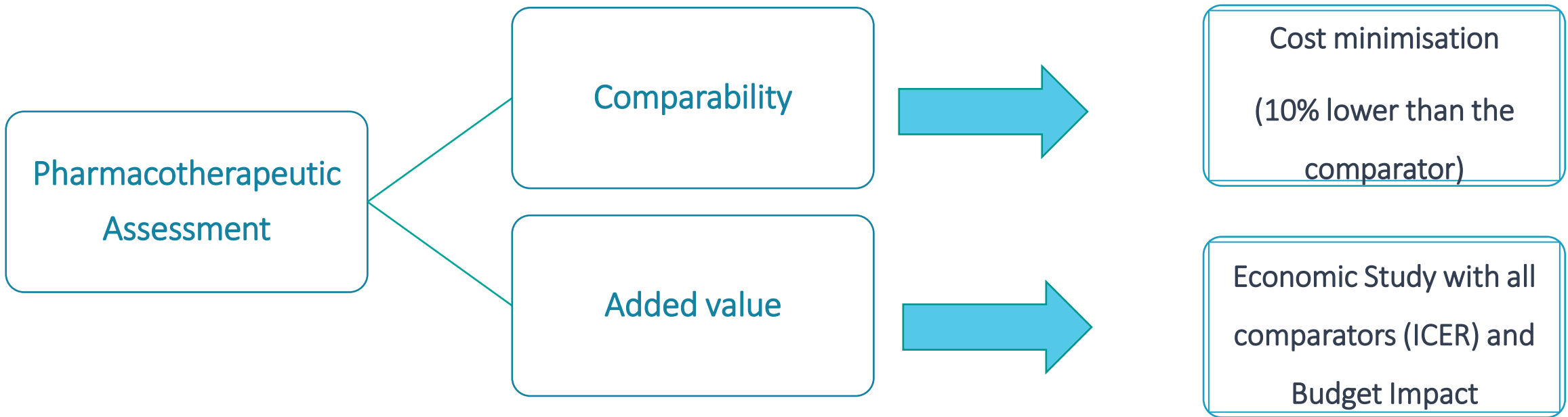


For all new medicines, new indications & extensions of indications

CLINICAL ASSESSMENT (APPRAISAL OF EVIDENCE)



ECONOMIC ASSESSMENT



NEGOTIATION

- Pharmacotherapeutic assessment (extension of benefit & uncertainty)
- ICER & Budget Impact
- Affordability
- Therapeutic alternatives currently in market or under assessment
- Horizon scanning (National system and IHSI)
- Information on other countries (HTA reports & reimbursement conditions)
- Regulatory/pharmacovigilance issues
- Other...

NEGOTIATION

Managed entry agreements (for 2 years)

- Mostly based on Price reductions & Cap expenditures
- Price/volume
- Applied to almost all new drugs in inpatient sector and some specific groups in outpatient sector (eg. antidiabetics, anticoagulants)

NEGOTIATION

Conditional financing based on health outcomes

To address upfront high payments & uncertainty on long term effectiveness

- Phased Payment and dependent on results
 - Reduces the uncertainty of up front payments on single administration drugs
 - Requires registers

Examples in Portugal

CAR T CELLS – payment conditional to overall survival (National Cancer Registry)

SMA medicines – payment conditional to pre defined outcomes for a determined period of time – SMA register

DECISION & IMPLEMENTATION

☐ **Decision by Ministry of Health**

☐ **National Pharmacotherapeutic Commission**

National Formulary update;

Therapeutic positioning of new drugs

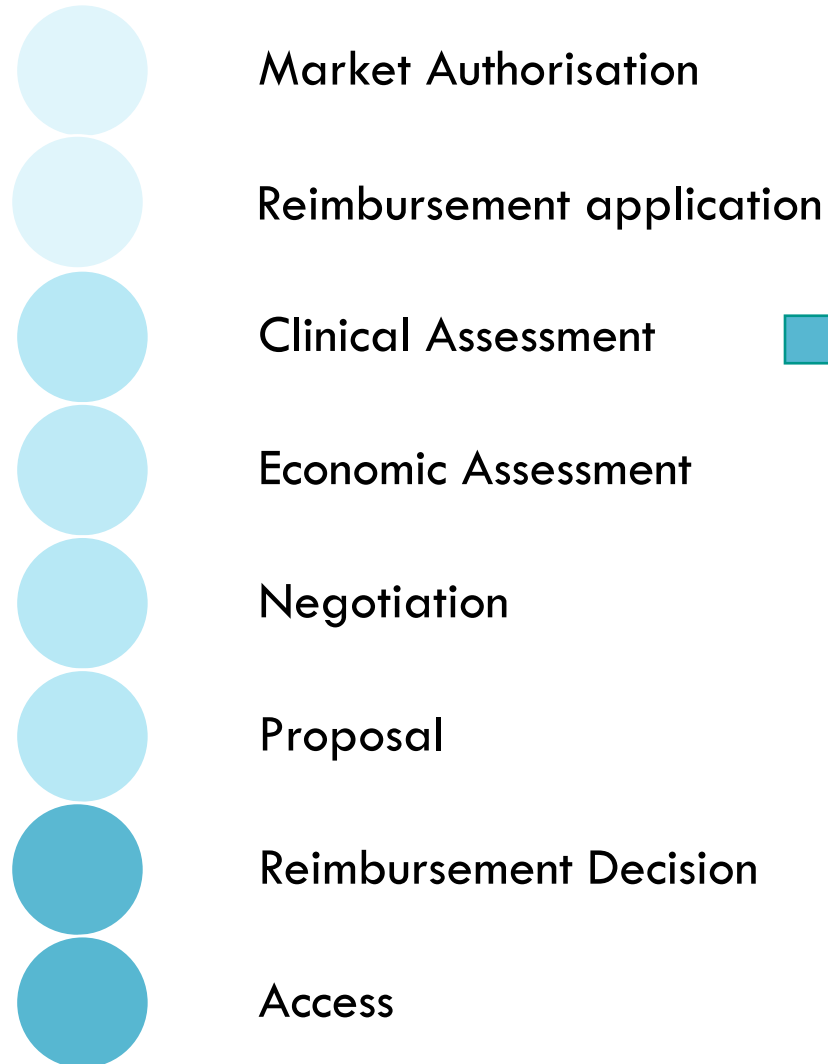
☐ **Decision by each hospital to acquire/prescribe**

Strenghts & Weaknesses of our current system

- Systematic assessment for all new medicines...but limited resources
- Robust HTA assessmentbut with delays
- Delays lead to pressure for earlier access >> Early Access programs >> impact negotiation
- Negotiations for sustainable conditions take time

Opportunities with HTA R?

REIMBURSEMENT PROCESS IN PORTUGAL



- ✓ JCA report replaces Group of evidence report
- ✓ Assessment time will decrease
- ✓ More efficient use of clinical experts

With the Implementation....

We are taking opportunity to adapt the legislation:

- Introduce prioritisation criteria for drugs and MD
- Implement a differentiated approach (simplify in low-risk drugs)
- Improve patient engagement in HTA assessment (HTA Committee?)
- Promote an articulation between different entities from MoH and NHS to ensure a smoother adoption
- More transparency on decisions & timings

THANK YOU
OBRIGADA

claudia.furtado@infarmed.pt