Drug regulation and access to CV medicines

Does the EU regulatory system facilitate or hinder fast and equal access to novel cardiovascular drugs across Europe?

Alar Irs

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ESC
European Society of Cardiology

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Does the regulatory system facilitate or hinder access to cardiovascular drugs across Europe?

- **Having witnessed the move from the fragmented national/decentralised decisions to common EU processes over the last 25+ years – it does indeed facilitate access.**
- **Thank you very much!**

- The complex world we operate in
- Opportunities of the (EU) regulatory system to support access
- Do we or do we not

What do we need for fast and equal access?

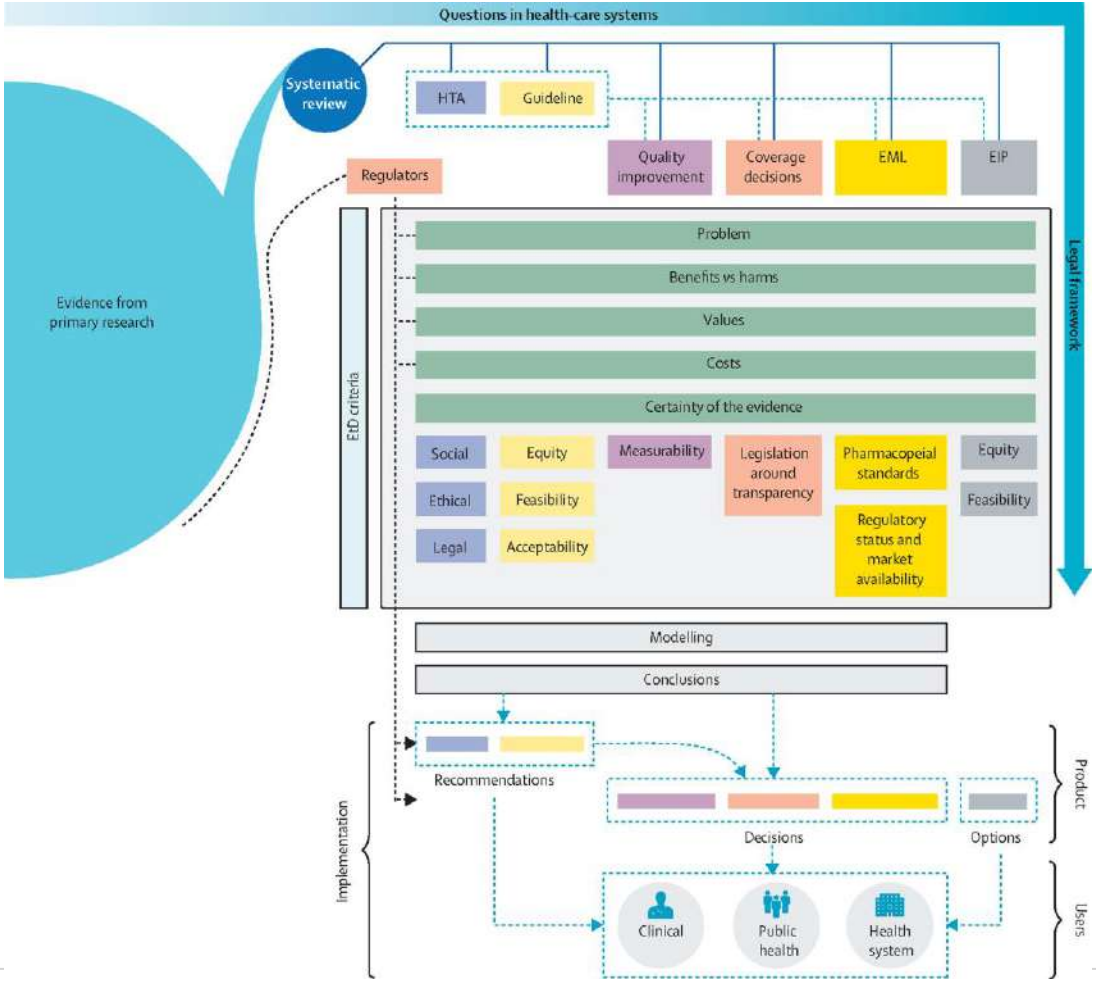
- Medicinal products of acceptable quality to be available
- Evidence standards for describing patient benefit (or risk)
- Good quality clinical evidence
- Streamlined processes at *every step,* etc.

Lancet Public Health 2022;
7: e378–90

The ecosystem of health decision making: from fragmentation to synergy

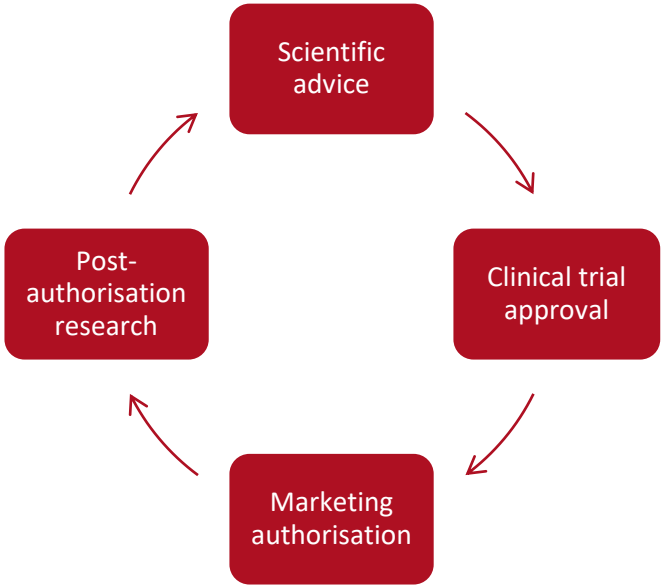
Holger J Schünemann, Marge Reinap, Thomas Piggott, Erki Laidmäe, Kristina Köhler, Mariliis Põld, Brendalynn Ens, Alar Irs, Elie A Akl, Carlos A Cuello, Maicon Falavigna, Michelle Gibbens, Luciana Neamtiu, Elena Parmelli, Mouna Jameleddine, Lisa Pyke, Ilse Verstijnen, Pablo Alonso-Coello, Peter Tugwell, Yuan Zhang, Zuleika Saz-Parkinson, Tanja Kuchenmüller, Lorenzo Moja

- **A decision made in isolation from other decisions on the same topic could cause misleading, unnecessary, or conflicted inputs to the health system and, therefore, confusion and resource waste.**
- **The better we align the more and the earlier patient benefit we see**


Questions in health-care systems
Systematic review
Evidence from primary research
HTA
Guideline
Regulators
Quality improvement
Coverage decisions
EML
EIP
Legal framework
EtD criteria
Problem
Benefits vs harms
Values
Costs
Certainty of the evidence
Social
Equity
Measurability
Legislation around transparency
Pharmacopeial standards
Equity
Ethical
Feasibility
Feasibility
Legal
Acceptability
Regulatory status and market availability
Modelling
Conclusions
Recommendations
Decisions
Options
Product
Implementation
Clinical
Public health
Health system
Users

- Historically, the regulatory bodies (as the rare clearly legislated and institutionalised decision step) have had a strong say in shaping the body of evidence for a new medicine
- The regulators have been blamed for having a limited contact to and understanding of the reality
- Progress is imminent, other players join in

Regulators' opportunity/obligation – to accept a role in the global evidence generation strategy



Facilitate or hinder?

- **15+ years of voluntary HTA dialogue - now EU law**
- **Voluntary harmonisation in CT approvals – now EU law**
- **1 opinion/decision for all MS and beyond**
- **Public assessment reports widely used downstream**
- **Publication of clinical data**
- **Old-fashioned in MA standards?**
- **Realistic in RWE?**

- **Regulators have a regulated role**
- **Regulators' main opportunities to support access are in**
  - operating predictable effective procedures
  - supporting the evidence generation according to standards that also facilitate next decisions
  - clearly communicating detailed grounds for opinions for downstream use
  - providing support in horizon scanning to prepare health systems
- **Regulatory process can always be even faster but with cost in quality and resource implications**
- **Regulators do not operate in vacuum – advances in scientific and clinical thinking translate into changes in regulatory standards**

Thank you