

Medicines

In collaboration with
WHO Europe

Infarmed 25⁺
Associação Nacional de Medicamentos
& Produtos de Saúde, I.P.

Facing the Challenges:
Equity, Sustainability and Access

29-30 November 2018

INFARMED | Lisbon - PORTUGAL



PROSPECTIVES

Bridging the gap: Regulatory & HTA

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ABSTRACT

Patient access to innovative medicines requires decision-making by different players in the healthcare system. These decisions are based on the evidence generated for individual medicines and in the context of their use.

The EMA is working with down-stream decision makers in a number of areas to improve the efficiency of processes by ensuring that evidence generated by sponsors is relevant for the needs of both regulatory authorities and HTA/P&R bodies.

Activities include parallel advice on evidence generation plans; exchange on the regulatory assessment to facilitate Relative Effectiveness Assessment; methodologies for post-licensing evidence generation; as well as opportunities for exchange of information regarding horizon scanning and prioritisation. The aim is to facilitate a chain of decision making that ultimately leads to access for patient to innovative medicines.