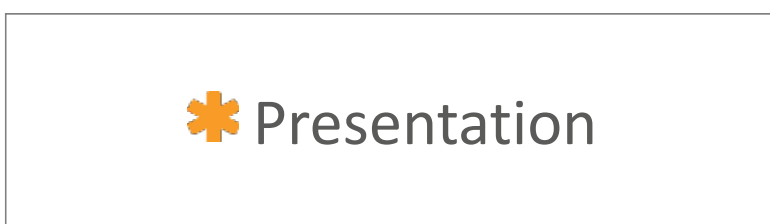




European Federation of Pharmaceutical
Industries and Associations

EFPIA Oncology Platform – Time to patient access

Date: June 2018



Why

Over the last decade, significant advances have been achieved in cancer outcomes and a new wave of scientific innovation is generating an unprecedented level of choice and promise in cancer treatments.

However, this innovation is arriving at a time when many governments in Europe are maintaining flat or declining healthcare budgets with a mismatch between the disease burden and the allocation of resources

As a consequence we assist to:

- Disconnect between regulatory and HTA/ pricing & reimbursement procedures resulting in delayed/ denied access
- Increasingly challenging HTA environment resulting in restricting patient access to new oncology treatments
- Slow adaptability of healthcare systems to the speed of evolution in cancer treatment (combination therapy, personalized medicines, immuno-therapy)
- Restrictive value assessment frameworks reluctance to use RWD/ surrogate endpoints, inadequate assessment of socio-economic impact

What

To address these challenges we propose to develop a model process on how regulatory, HTA and P&R body processes should adapt to reflect scientific evolution to accelerate the time for patients to benefit from a new cancer medicine by

- Mapping existing situations from regulatory approval to reimbursement decisions
- Benchmarking current country systems versus the 180 days rule to understand what works and what does not across countries
- Identifying best practices that can be replicate across countries
- Setting out why and how the systems should change
- Developing a set of principles for change (hierarchy of outcomes for regulatory, HTA and payers)
- Proposing key performance indicators (speed of access, equity, quality of coverage?) that can be used to evaluate country systems and assess the gap between regulatory approval, HTA and commissioning of care
- Outlining how patient involvement can be increased

How

- Consultancy company to perform the mapping
- Case studies from companies (maybe)
- Roundtable with stakeholders to brainstorm potential solutions

Deliverables

- Mapping of country situation
- Catalogue of best practice
- Menu catalogue with recommendations for change and KPIs to which national systems could refer in developing their own processes
- Infographic and mini booklet/leave behind to leverage in discussing with national policymakers and stakeholders solutions effective in other countries that could be adjust to meet the particular situation in their country.