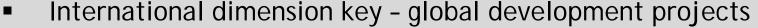


## Catalysing the integration of science and technology in development

- Catalysis strengthened support to industry welcome
  - But it will only be used/effective (& reduce need for animal studies) if commercial sensitivity is respected
- Avoid blocking
  - don't set out detailed rules/standards in law
  - ensure adaptable dynamic frameworks
  - don't apply rules developed for human medicines without considering applicability
  - ensure science prevails over politics
  - help public to have confidence in authorised novel technologies
  - cater for novel approaches to manufacture



- develop capability on novel therapies with Regulators outside EU;
- learn together and define requirements together aim for international guidance (even VICH ultimately)
- divergence = additional (animal) studies
- 3Rs first question the need for animal studies
  - mutual recognition of clinical (and safety) trial data
  - best use of available data including modelling
  - address countries still insisting on a batch release test in animals

