

International Cooperation on Harmonisation of Technical Requirements
for Registration of Veterinary Medicinal Products



Stimulating Innovation, the voice of the Industry

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What is innovation?



>Oxford Dictionnary?

1. The action or process of innovating.
2. A new method, idea, product, etc.

>Cambridge Dictionnary?

1. a new idea, method, design or product, etc.
2. the use of new ideas and methods
3. the development of new ... (products, designs, or ideas):

What is innovation?



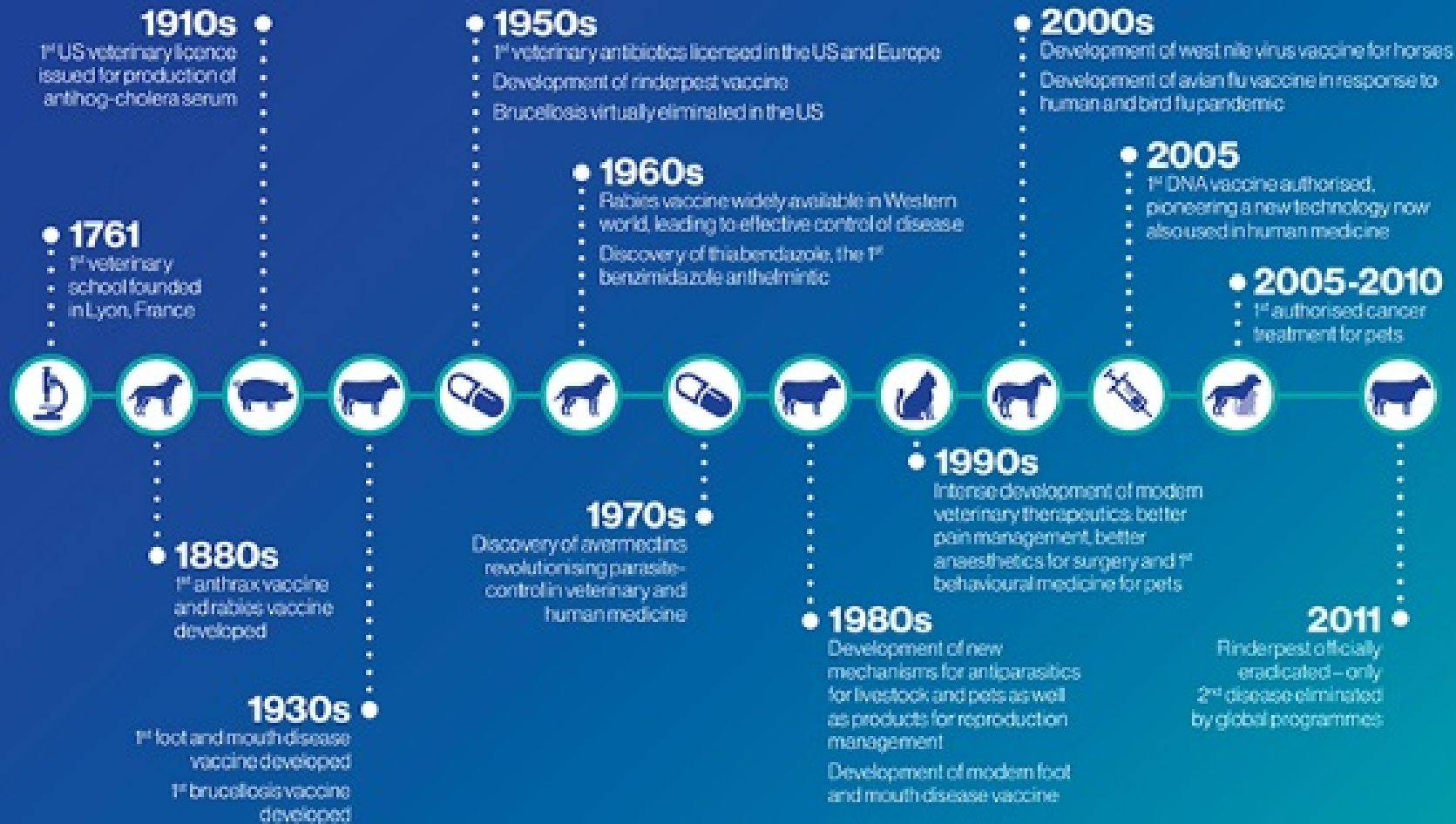
> Wikipedia?

- Innovation can be simply defined as a "new idea, creative thoughts, new imaginations in form of device or method".[1] However, innovation is often also viewed as the application of better solutions that meet new requirements, unarticulated needs, or existing market needs.[2] Such innovation takes place through the provision of more-effective products, processes, services, technologies, or business models that are made available to markets, governments and society. The term "innovation" can be defined[by whom?] as something original and more effective and, as a consequence, new, that "breaks into" the market or society.[3] Innovation is related to, but not the same as, invention,[4] as innovation is more apt to involve the practical implementation of an invention (i.e. new/improved ability) to make a meaningful impact in the market or society,[5] and not all innovations require an invention. Innovation often[quantify] manifests itself via the engineering process, when the problem being solved is of a technical or scientific nature. The opposite of innovation is exnovation.

Innovation in our world?



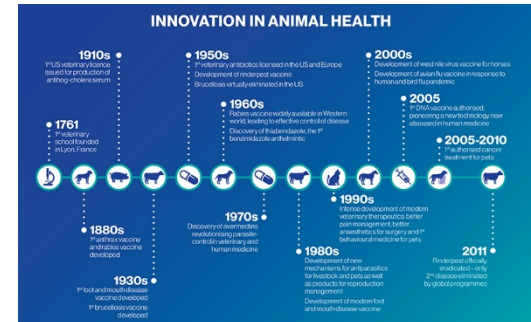
INNOVATION IN ANIMAL HEALTH



Innovation in our world?



- There is not one innovation
 - “New new” or “development”?
 - Usually not a big bang...
 - First in class compound or best in class
 - Market size (MUMS, minor markets)
 - New species and / or formulation
 - New indication...
- Global Benchmarking Survey 2015 defines it as follows:
 - Innovation is generally recognised as the development of new molecules, new technologies, new formulations and routes of administration.
 - However innovation may also be seen as a new product for a company using an existing active ingredient.



The “right” regulatory environment for innovation?



- > In line with mission of agencies,
- > while safeguarding the health of animals, human and the environment, via appropriate requirements on quality, safety and efficacy,
- > stimulating the approval of new, better, more appropriate solutions for the health and welfare needs of animals everywhere...



The “right” regulatory environment for innovation?



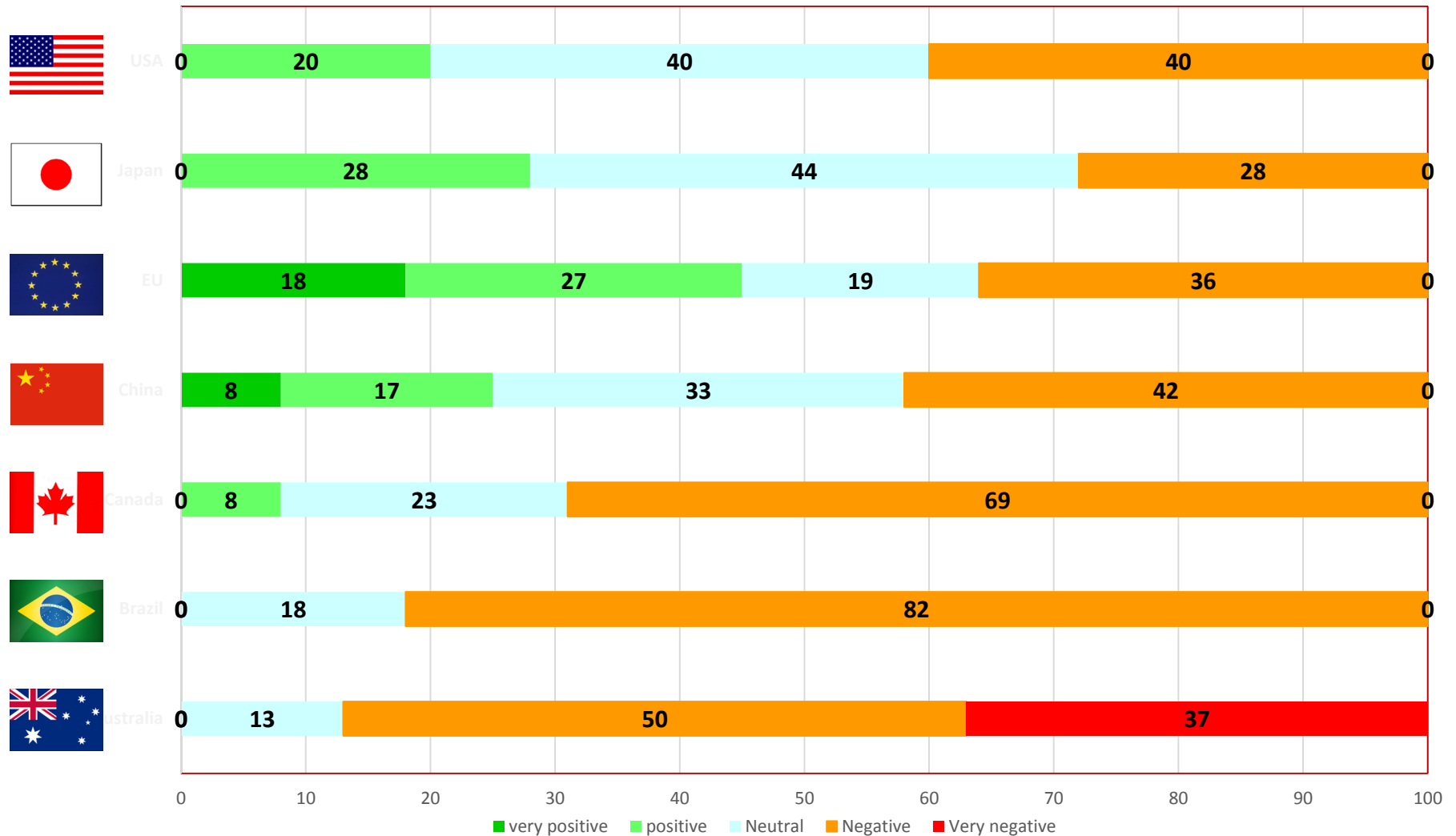
> Clear but flexible requirements

- Clarity on current product requirements
- Flexible enough...
 - To cope with new technology
 - To perform an scientific benefit – risk assessment
 - To recognize work done by (other) competent authorities

> If we ask industry...



Perception of impact of the regulatory environment on innovation (GBS 2015)



The “right” regulatory environment for innovation?

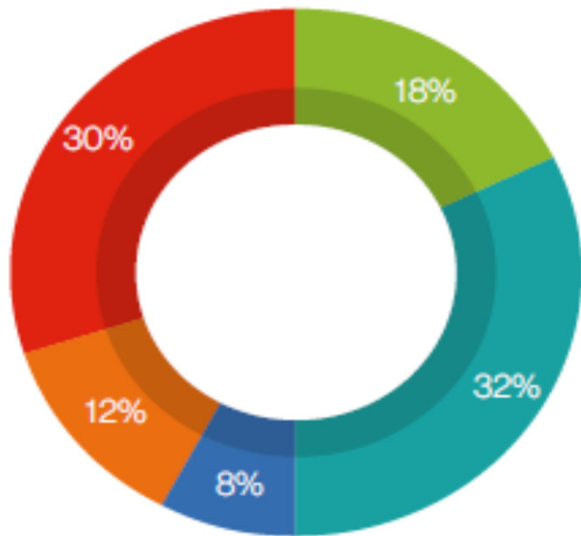


- > The biggest concerns for industry are...
 - ✓ increasing cost & time for development of a new product
 - Impact protection IP and technical data
 - ✓ creation of significant uncertainty or unpredictability
 - Science based decision making
 - Duration development requires stability

Stimulating innovation: what companies wish for.... (GBS 2015)



Regulatory changes companies want (GBS survey 2015)



- 30% agency efficiency, ↑ staffing (in some places)
- 32% risk-based policies, innovation fast-track
- 18% specific processes streamlined
- 12% internationalization of data requirements
- 8% improved consultation agency industry

Some more wishes...

- expanding, harmonized e-submissions
- more inter-agency working + mutual recognition
- acceptance of high-quality foreign data from well-regulated countries
- regional collaboration on simultaneous assessments
- mutual recognition of GMP
- fast-track, conditional licenses

Stimulation of innovation : a closer look at some topics



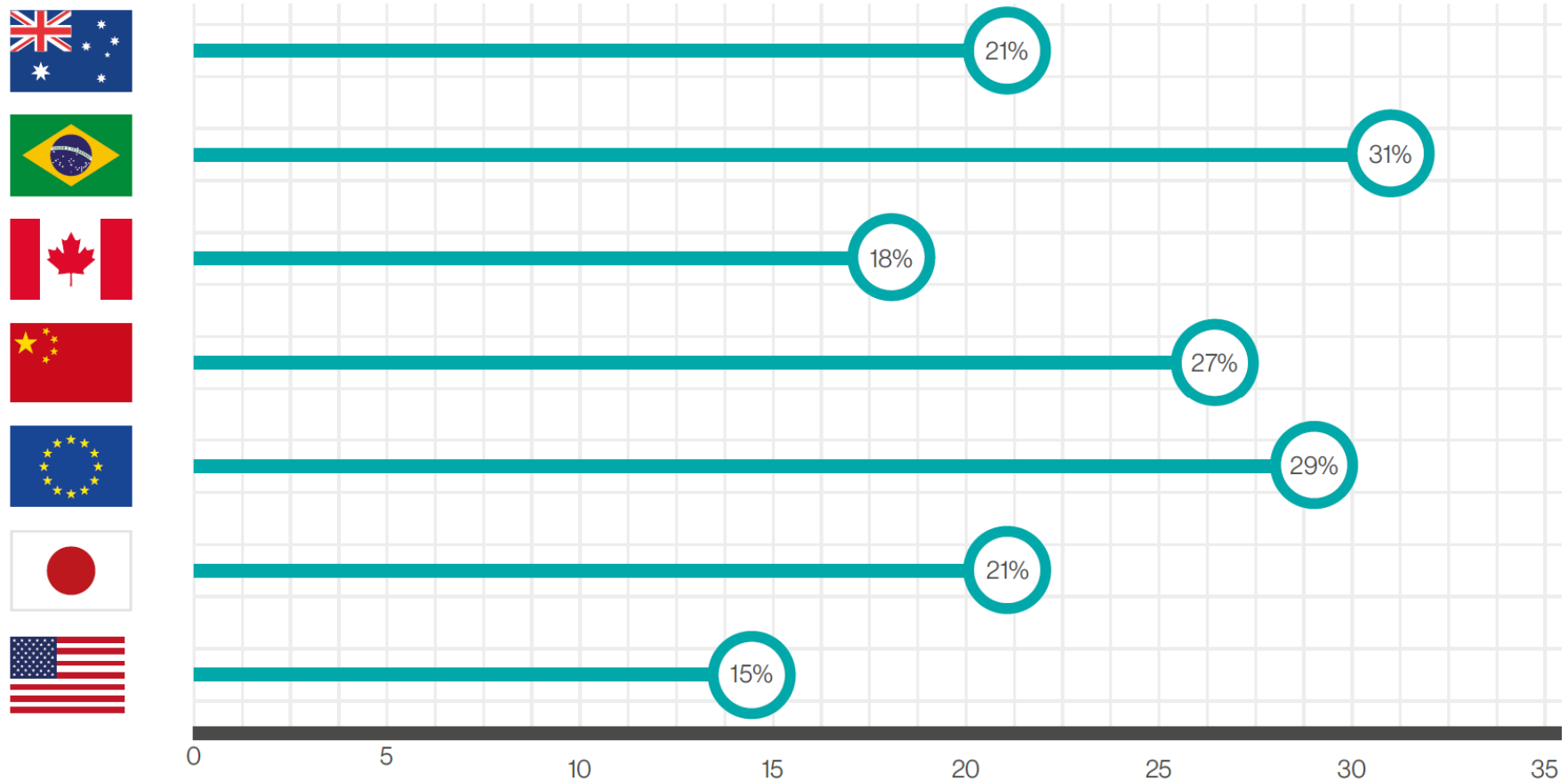
- > Appropriate spending on maintenance:
 - defensive R&D and administrative burden
- > Sufficient consultation possibilities
- > Sufficient protection of technical documentation
- > Convergence of regulatory guidelines



Stimulating innovation by appropriate spending: defensive R&D



> Mandatory Defensive R&D (MDR&D) as a % of total R&D



Stimulating innovation by offering sufficient consultation options...



- > Aim: better quality dossiers
- > Industry sometimes doesn't know...
 - New technology
 - New company
 - New geography
- > More on how than on what...
 - No guarantee...
- > Consultation throughout the development of a product
 - Or even earlier
 - Example: EMA approach to consultation



EMA slide on facilitating development of new veterinary products



Supporting SMEs

Financial and administrative assistance to small pharmaceutical companies

Innovation Task Force (ITF) Briefing

Advice on how to advance innovative medicines

Minor Use Minor Species (MUMS) limited market designation and incentives

Assisting companies who develop medicines for limited markets

Scientific advice

Providing scientific advice to companies on the appropriate tests and studies in the development of a veterinary medicine

Presubmission meetings

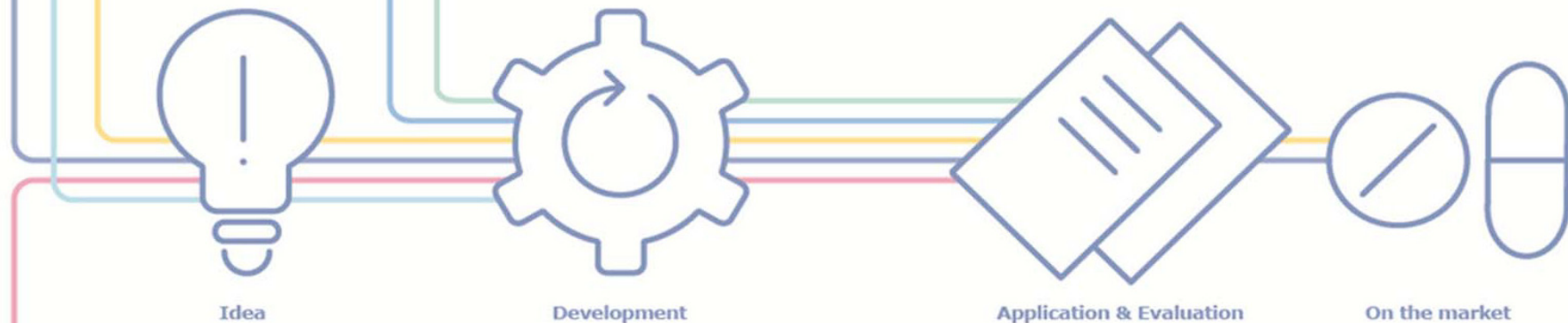
Companies advised on regulatory questions

Facilitating development of new veterinary medicines in Europe

The European Medicines Agency (EMA) protects and promotes public and animal health in Europe. Through EMA's Committee for Medicinal Products for Veterinary Use (CVMP), scientific experts from across the European Union assess veterinary medicines across their lifecycle and provide expertise on animal health and wellbeing.

New treatment options for animals in Europe are needed and the Agency has set up a number of tools to provide scientific and regulatory support to companies to encourage the development of innovative veterinary medicines.

In support of these efforts, in 2015 EMA established the Ad Hoc Expert Group on Veterinary Novel Therapies (ADVENT) to develop guidance on the requirements for authorisation of products that are new to veterinary medicine.



Ad Hoc Expert Group on Veterinary Novel Therapies (ADVENT)

European expertise to support novel veterinary medicines across the lifecycle

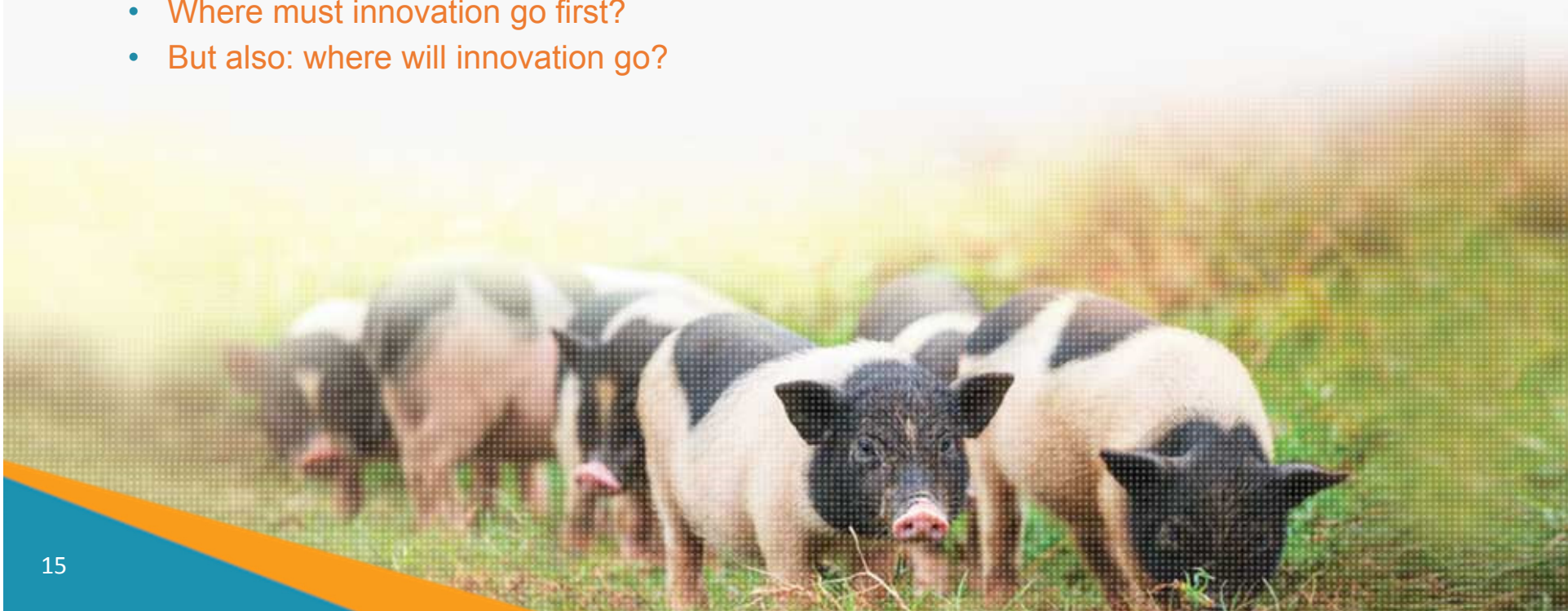
General guidance in support of innovation

EMA guidelines and stakeholder interaction

Stimulating innovation by sufficient protection of technical documentation



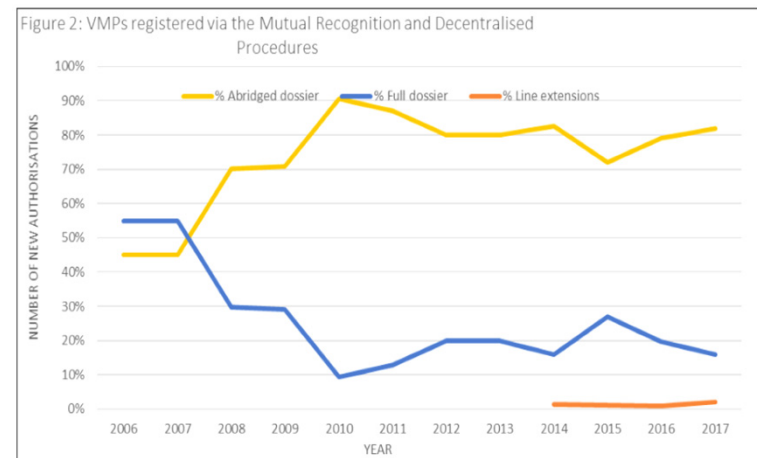
- > Needed for fair return on investment for innovation.
- > Maintaining confidentiality of data as well as awarding appropriate protection of data where significant new data are generated.
- > Big differences between geographies:
 - from zero to 10-18 years
 - Where must innovation go first?
 - But also: where will innovation go?



Stimulating innovation by sufficient protection of technical documentation



- > Need balance between appropriate protection and access for “generic” products
- > What is appropriate time?
 - “ROI”, so smaller market equals more time
 - Different for bigger (new product) vs. smaller investment (new species/claim,...)
 - Also new claims to stimulate on label use
 - Even in big EU market: prolongation to save/stimulate innovation



Stimulating innovation by improved regulatory convergence



- > Alignment with international standards critical
- > Allows for recognition of assessments
 - Done by other competent authorities
 - Sharing the same guidelines
 - Saves resources and facilitates submissions
 - Example: Canada-Australia-New Zealand
 - Example: Mutual Recognition Procedures:
 - EU
 - Africa





>A regulatory environment that is:

- Protective for animal health, human health and environment (one health)
- Stimulating innovation, big and small, by appropriate IP and data protection and appropriate requirements reducing administrative burden and defensive R&D
- Stimulating innovation by appropriate early consultation options
- Stimulating innovation by sharing the work and recognizing each other's work (assessment)



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