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Impact of the new regulatory framework on innovation

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Impact of the new Regulation on innovation

- Reg.2019/6 (VMR) became applicable 1 year ago
- Too soon for a retrospective analysis
- Reflections about topics that could facilitate or impede innovation
  - Based on recent experiences in R&D

Five references to 'innovation' in Reg 2019/6 (zero in Directive 2001/82/EC)

Provisions intended to stimulate innovation: Article 23 (limited markets), Article 39-40 (protection technical documentation), distinct category and requirements for 'biologicals non-immunologicals', special requirements for 'novel therapies' etc.

a future-proof regulation?

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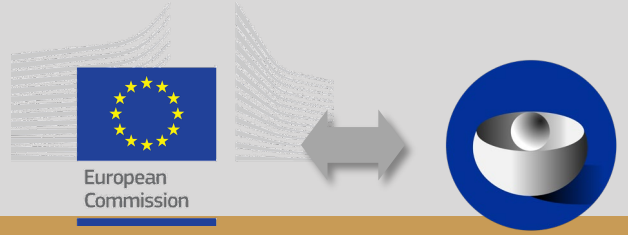
ALIGNMENT EU COMMISSION - EMA

- Reg 2019/6 text based on current knowledge
- Applicability of current provisions/definitions to future (unknown) innovations? TBD
- EU Commission input about correct interpretation



Questions:

When is it appropriate to contact the EU Commission before the EMA? And how?

What if the literal interpretation of the VMR introduces unintended obstacles to registration of safe and efficacious VMPs?

WHERE THE OBSTACLES TO INNOVATION COULD BE?

- Now specific requirements for novel therapies in Annex II. However novel therapies entered the market also under the old Directive/old Annex II
  - Scientific advice and pragmatism filled the gap
- Deviations from Annex II were - and still are - often acceptable if properly justified
- But the Industry cannot deviate from definitions/provisions in the Reg 2019/6

WHERE THE OBSTACLES TO INNOVATION COULD BE?

- **The hard definitions/requirements in the Reg 2019/6 could hinder innovation (no flexibility) while the lack of guidance can be resolved**

  Example of definitions

  - *'antimicrobial'*: if broad interpretation, AM restrictions will be applied to non-antimicrobial VMPs
  - *'new' active substance*: if too restrictive interpretation, CP becomes mandatory for VMPs. This may impact VMPs (such as some vaccines) intended for very limited geographic areas.

Recent positive experiences of quick amendments:

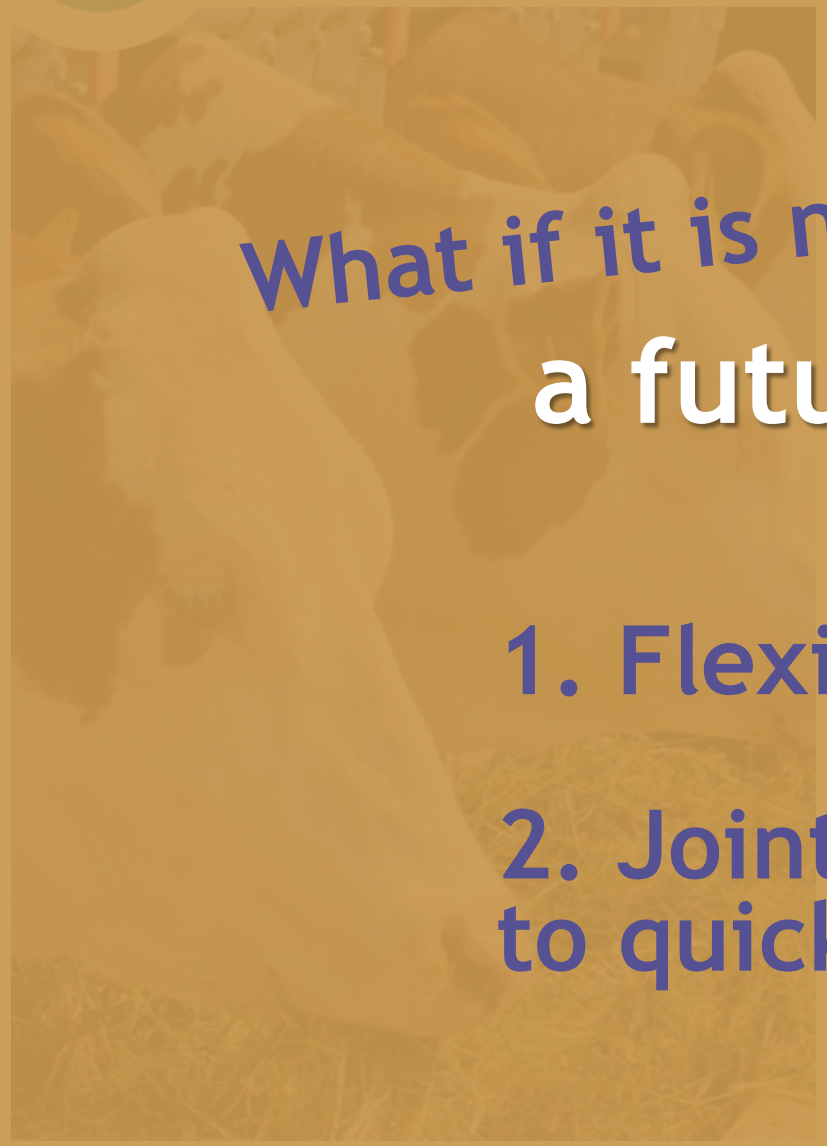
- Art 152(2) about deadline for compliance to new labelling requirements
- Removal of GLP requirement for non-safety pre-clinical studies

Is a similar timely action possible for unintended obstacles to innovation?

WHERE THE OBSTACLES TO INNOVATION COULD BE?

And if guidance is provided

Value of having high-level technical guidance early enough, but cautious to not develop too detailed guidance too quickly (example: gene therapy) – Balance to be found



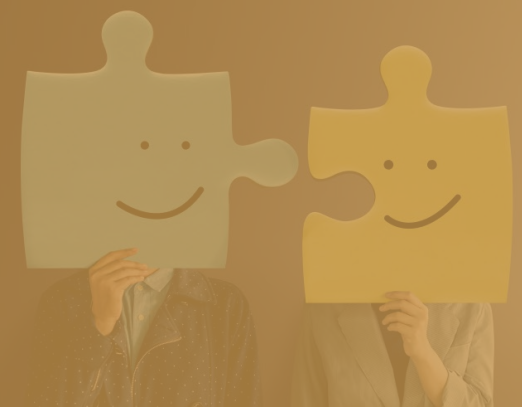
What if it is not a future-proof regulation?

1. Flexibility

2. Joint efforts (EMA, EC, Industry) to quickly address the challenges

INTERACTIONS WITH THE AGENCY DURING R&D

- **Thank you for the EMA scientific support to innovation (ITF, scientific advice)**
- **Expanding the scopes of existing tools would provide additional benefit**
  - For example, the scientific advice: more flexibility on allowed questions, within the boundaries of Reg. 726/2004 (Art 56.3-57)
  - Informal interactions beyond/in parallel to SA and ITF



VMR FOCUS on INNOVATION: ARTICLES 23 & 40

- **Article 23 – limited market**
  - CVMP developing guidance for limited market products (and claims?) not eligible for Art.23

    Such guidance increases predictability → positive effect on innovation
  - Less positive: no data reduction for part II

- **Article 40 – periods of protection of technical documentation**
  - CVMP draft guidance about eligibility for Art 40.5: increases predictability → positive effect on innovation

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Eligibility to Art.40.5 via scientific advice?

- It may include pre-assessment of data
- It may qualify as pre-assessment of classification

} Flexibility in SA questions

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If additional 4 years of protection are granted (Art. 40.5), what impact on generics?

- Generics stay on the market (w/o the variation 'protected' by Art 40.5)?
- Reference product with better benefit-risk or lower resistance risk co-exist with generics?

VMR FOCUS on INNOVATION: VACCINES

vPTMF - vaccine platform technology master file
VAMF - vaccine antigen master file

- Increase predictability of assessment and potential for cost savings → positive effect on innovation
- The admin burden should not reduce the value of the incentive. Example: multiple variations required for every change to the VAMF

Vaccines and innovation - beyond VMR and Annex II

- Association of vaccines: GL requires to replicate full clinical program
- Re-launch of the vet vaccine initiative would stimulate innovation
- Challenges from specific EP Monographs on new/improved vaccines

→ More interactions with EDQM would be welcome

NEW ‘BENEFITS’ for the BENEFIT/RISK ASSESSMENT

- **Change in terminology: from ‘positive therapeutic benefits’ to ‘positive effects’**
  - Opportunity for new types of ‘benefits’
- **Confirmation of validity of new benefits/effects → positive effect on innovation**

- **Examples:**
  - Quality of Life claims
  - ‘Benefit for the group/herd’ vs traditional individual benefit
  - Indications for use in healthy animals
  - Value of the ‘additional benefits’ in the overall assessment
  - Claims of reduction of antibiotic use

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Challenges to innovation beyond the New Vet Regulation

OTHER CHALLENGES

- TiO2 potential ban of use
- Substances restricted or banned under REACH
  - Eg Triton-X and PFAS with impact on both products and locations of manufacturing sites
- EU PBT assessment criteria detrimental to some types of products
- New packaging and waste legislation → additional labelling requirements
- One substance, one assessment initiative
- Over-regulation of clinical trials at Member States level

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New vet regulation & innovation: positive elements but also new questions and challenges

Favorable environment for innovation with:

- Predictability
- Flexibility
- Alignment and dialogue among stakeholders

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Thank you!