

# Session 4: Veterinary vaccines: proposal to facilitate licensing in exceptional circumstances (emergency)

## Revision of Annex 1, Title II and IV to comply with new Regulation (Art. 21,22,22a+b)

- ❖ Create a subchapter for emergency vaccination
- ❖ **Benefit Risk Assessment instead of no risk policy**
- ❖ Early input/dialog with Authorities
- ❖ Distinguish:
  - approved Master Files (cells, platforms, antigens) yes / no
  - GMO derived vaccines yes / no
- ❖ Reduction of requirements on Safety and Efficacy (no field trials)
- ❖ **Final batch testing by non animal tests only**
- ❖ Shorten administrative procedure pre- and post scientific assessment to accelerate placing on the market
- ❖ Upgrade procedure to a regular license

### Ready for further discussion and active contributions:

General: [iabs.org](http://iabs.org)

Platforms: [zapi-imi.eu](http://zapi-imi.eu)

3Rs and consistency: [vac2vac.eu](http://vac2vac.eu)

Final Meeting, Leuven or Hannover, January 2020

3R Meeting (IABS and VAC2VAC), Bangkok, December 2019,

Training of assessors when required

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