Session 2: Veterinary vaccines: proposal to facilitate licensing in general

Revision of Annex 1, Title II and IV

- Distinguish: - regular licensing reflecting major vs minor markets (MUMS)
  - emergency vaccination (exceptional circumstances)

  Benefit Risk Assessment instead of no risk policy
- Early input/dialog with Authorities
- Coordinated cooperation with NRAs, OMCLs and GMP-inspectors
- Obligatory centrally approved **Master Files** (cells, platforms, antigens) will accelerate scientific assessment
- Definition GMO to update to the variety of novel technologies
- Shorten administrative procedure pre- and post scientific assessment to accelerate placing on the market
- 3Rs: facilitate introduction of non-animal tests for final batch control

  better characterisation of final products

  introduction of **consistency approach**

Ready for further discussion and active contributions:

General:	iabs.org	
Platforms:	zapi-imi.eu	Final Meeting, Leuven or Hannover, January 2020
3Rs and consistency:	vac2vac.eu	3R Meeting (IABS and VAC2VAC), Bangkok, December 2019,
		Training of assessors when required

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