Update from VICH about transition to non-animal based veterinary batch release testing: focus on potency

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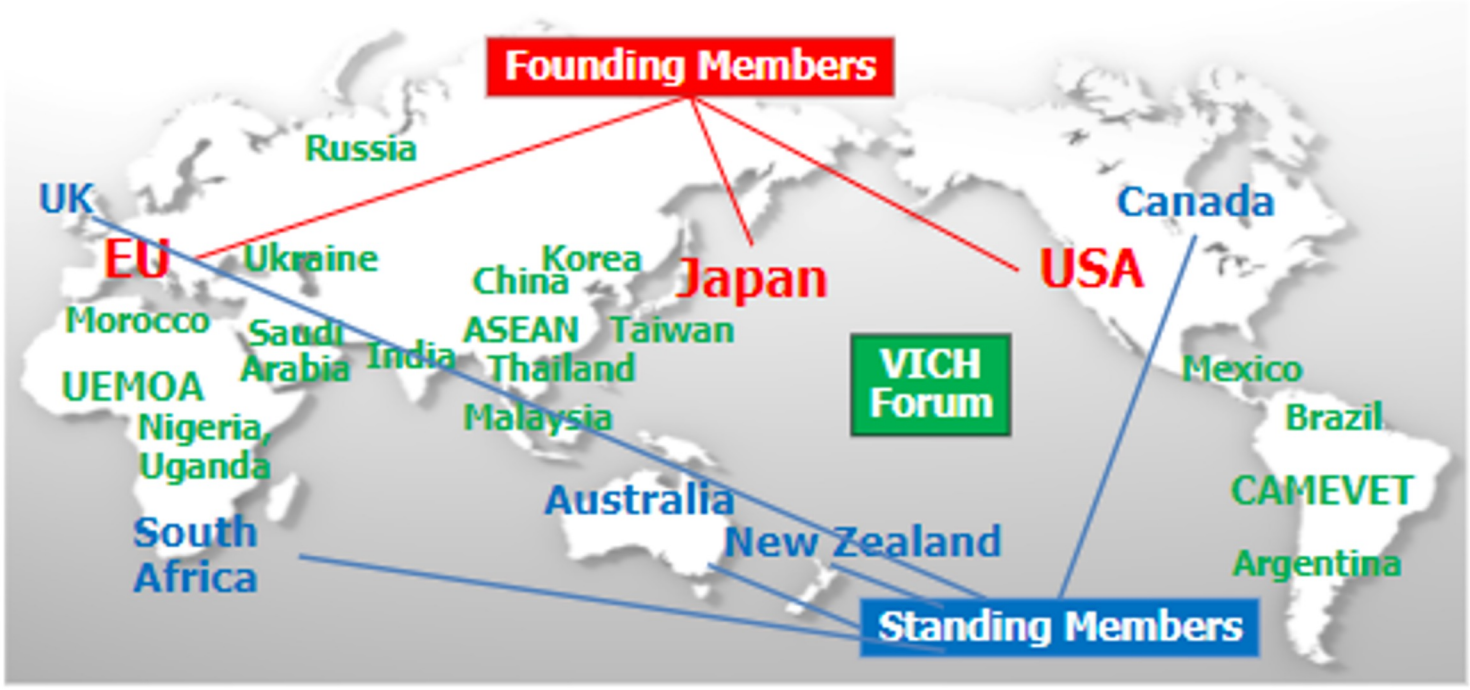
WHAT IS VICH?

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



WOAH : Associate Member, HealthforAnimals : Secretariat

WHAT IS THE ROLE OF VICH?

- To harmonise **technical** requirements for data necessary for registration

- To develop and implement VICH Guidelines

  Study and testing methodology

  - Quality, safety and efficacy (including bioequivalence)

  Post-marketing safety monitoring

  - Pharmacovigilance

IT IS NOT THE ROLE OF VICH TO

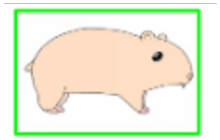
- Provide guidance to establish regulatory systems and regulations for marketing authorisations
- Make final decision which studies are necessary to obtain a marketing authorisation
- Assess data or provide guidance on the assessment approach
- Grant marketing authorisations
- Establish safety standards

These are typically the roles of national competent authorities and governments!

BATCH POTENCY TEST

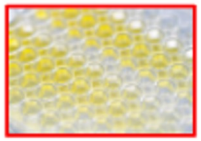
Batch potency test is a requirement for batch release of veterinary vaccines to ensure the batch provides the adequate level of protection

Hamster for Leptospira



Mice serology for Rabies

ELISA for Leptospira



IN VITRO METHODS

PROs

- **Ethical reasons**
- **Removal of animal variability**
- **Shorter testing period**

CHALLENGES

- **During development:**
  - **time,**
  - **technologies (identification of specific reagents, reference/standard)**
  - **correlation to existing methods,**
  - **set up of specifications**
- **For implementation:**
  - **test should be transferable in GMP environment**
- **Regulatory constraints in:**
  - **recognition,**
  - **acceptance,**
  - **implementation in the global regulatory setting**

REGULATORY ACCEPTANCE INCREASES

Non exhaustive examples!

- **European Pharmacopeia 5.2.14. "Substitution of i*n-vivo* method(s) by *in-vitro* method(s) for the quality control of vaccines"**
- **9CFR § 113.8 *"In vitro* tests for serial release"**
- **USDA VS Memorandum No.800.112 "Guideline for *in-vitro* assay validation"**
- **Indian Pharmacopeia 2.7.20 "Substitution of *in vivo* methods by *in vitro* methods for the quality controls of vaccines"**
- **Seibutsugaku-teki Seizai-Kijun "National Standards for veterinary biologicals"**

Need to go further!

MANDATE

- **VICH Concept paper on principles for technical guidance for the transition to *in vitro* methods for batch potency tests in veterinary immunologicals adopted January 2024**
  - **Review the information in European Pharmacopeia chapter 5.2.14 (Substitution of *in vivo* method(s) by *in vitro* method(s) for the quality control of vaccines)**
  - **Review other global guidance as well as the ICH work in this area**
  - **Build a similar guideline to be assessed by the Biologicals Expert Working Group**
- **Batch potency test subgroup established (1st visio meeting May 2024)**

PARTICIPANTS

- **Representatives of regulatory bodies**
  - **Europe**
  - **USA**
  - **Japan**
  - **Australia**
  - **Canada**
  - **Switzerland**
- **Representatives of Animal Health industries**
  - **AnimalhealthEurope**
  - **Animal Health Institute**
  - **JVPA (Research Institute for Animal Science in Biochemistry and Toxicology)**
  - **Animal and Plant Health New Zealand**

GUIDELINE: OBJECTIVE AND SCOPE

- **Provide set of harmonized technical recommendations for the transition to *in vitro* methods for batch potency tests**
- **In particular when a direct correlation between *in vivo* and *in vitro* assays is not possible (measurements units not comparable,….).**
- **Scope: Vaccines**
- **Out of scope:**
  - **live vaccines where the batch potency test is performed by titration (*in vitro* method) as recognized in a majority of countries worldwide**
  - **any product that currently uses an *in vitro* potency test already**

GUIDELINE: MAJOR ITEMS

- **No contra-indication with local requirements**
- **No details on validations of the methods (already provided in other guidelines)**
- **Importance of antigen content and link to biological functionality**
- **Multiple assays in spite of an unique one could be necessary**
- **Tests to assess the adjuvants might be considered**
- **Sub potent batches should be discriminated**

GUIDELINE: DEADLINES

- **No specific timelines for this process**
- **Rounds of comments involving all the organisations and the members**
- **Visio meetings every 4-6 months**

THANK YOU FOR YOUR ATTENTION


VICH
www.vichsec.org