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VICH concept paper on principles for technical guidance for the transition to in-vitro methods for batch potency tests in veterinary immunologicals

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The Veterinary International Convention on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) is a program initiated by the EU, Japan, and the United States to harmonize technical requirements for the registration of veterinary medicinal products. While typically developing technical guidance necessary for registration, it has also established several exceptional guidelines aimed at achieving the goal of the 3Rs principles in animal testing. These guidelines are administrative guidance to advance the 3Rs rather than technical requirements for the registration.

Guidelines concerning the replacement of batch potency testing (BPT) were proposed by the EU based on this concept. However, under the agreement that they would serve as technical guidance, the concept paper was finalized by the VICH Steering Committee in 2023.

In the EU, this concept is already implemented as European Pharmacopoeia monograph 5.2.14 "Substitution of in-vivo method(s) by in-vitro method(s) for the quality control of vaccines." In the United States, requirements for using in vitro tests are specified in 9CFR § 113.8 "In Vitro Tests for Continuous Release Testing," and validation of these tests is conducted according to Veterinary Services Memorandum 800.112.

In Japan, alternative test methods to in vivo potency testing for vaccines are approved as long as they are reasonable.

Thus, while the replacement of in vivo BPT with in vitro testing is fundamentally possible, international harmonization requires further discussion within VICH member countries. The task of drafting the guidelines was assigned to the Biologicals expert working group/BPT subgroup, which has held several meetings to date. Several conceptual and scientific issues have been identified and discussed extensively. The draft guidelines are currently under review by members, aiming for finalization by the EWG.

