International Workshop on Alternative Methods to Reduce, Refine, and Replace the Use of Animals in Human Vaccine Potency and Safety Testing

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Few medical interventions have had a greater impact on human health than vaccines. Immunization efforts have resulted in the global eradication of smallpox, and the elimination of polio, measles, and rubella in the Americas. Prior to the release of post-licensing production lots of vaccine, regulatory authorities require testing to ensure potency and safety, which can involve large numbers of animals that experience unrelieved pain and distress. NICEATM-ICCVAM organized an international workshop with ECVAM, JaCVAM and Health Canada to review the state of the science and identify priority activities to advance scientifically sound alternative methods that can reduce, refine and replace animal use in vaccine potency and safety testing. Nearly 200 scientists from 13 countries identified relevant knowledge and data gaps, and identified necessary priority research, development, and validation activities. Diphtheria and tetanus toxoids, pertussis, rabies, anthrax, inactivated polio, and combination vaccines were identified as the highest priority vaccines because they use large numbers of animals and induce significant pain and distress during testing. Research into specific mechanisms of vaccine protection and identifying clinically relevant immunological markers was considered necessary to successfully implement *in vitro* alternatives. Participants agreed that broader acceptance and use of alternative methods would require broader access to information, increased global communication among regulatory authorities, research institutions, and vaccine manufacturers, and harmonization of testing requirements. Implementation of the workshop recommendations is expected to advance alternative methods for vaccine potency and safety testing that will benefit animal welfare while ensuring continued protection of human and animal health.

Theme: Safety and Efficacy Testing of Chemicals: Pharmaceuticals and Biologicals

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