Recent changes to legislation under the ACVM Act and how these impact on research

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This presentation will primarily focus on relatively new changes to legislation that are applicable to the research and development sector, and how these apply to trial work. The requirement to hold a provisional or research approval for trial work will be explained and the fact that this applies to all organisations and individuals, including CRIs, industry, researchers and university institutions.

The forthcoming introduction of generic approvals under certain circumstances will be outlined. As a result of the proposed new approvals, compliance costs will be reduced and approval requirements for NZFSA and ERMA (which already issues generic approvals) will be aligned.

The purpose and scope of the ACVM Act and legislation will be explained, encompassing the reason for provisional and research approvals by relating this back to the risks managed under the ACVM Act. When assessing risks to be managed, it must be demonstrated that the products registered are not likely to cause unacceptable risks to:

- public health
- trade in primary produce
- animal welfare or
- agricultural security.

Registration is required as under the ACVM Act. Thus, agricultural compounds can only be legally imported or manufactured for sale, sold or used in New Zealand if they are registered, exempt from registration (via Regulations), or approved under special circumstances.

To assist researchers in preparing applications, the key differences between provisional and research approvals will be explained. Common deficiencies found in applications to the ACVM Group will be touched on, as well as the need to apply for approvals well ahead of anticipated research start dates. Data protection with regards to the development of novel actives will be summarised.

NOTE: A document outlining detailed guidelines to assist applicants is available from www.nzpps.org.