National Regulatory Processes

Obstacles facing industry in Southeast Asia
ASEAN Economic Community

• Single market initiative from the Association of Southeast Asian Nations (ASEAN)

• Came into effect on 1 January 2016

• Region comprises ten countries

• 620 million people
ASEAN Economic Community (continued)

• Existing registration framework fragmented

• No intra-ASEAN registration recognition

• Talks of harmonisation but no significant progress has been made

• Talents in severe shortage
Thailand

- Registration framework bases almost exclusively on WHO publication that dates back decades
  - Newer compounds that are not recommended by this book face incredibly stiff challenge
  - Incredibly challenging to register formulations at dosage different from those recommended in this book despite supporting data
Thailand (continued)

• Infrastructure cannot cope with registration requirements

• Loose protection for registration holders
  • Me-too registrations can piggyback on existing registration’s data package

• Unrealistic requirement for LLIN registration
Malaysia

• New Guideline on Product Chemistry Data for pesticide registration in 2016
  • Comprehensive information is required
    • Both technical AI and finished product – manufacturing process, packaging specification, physical and chemical properties, and SDS of raw materials
  • GLP/ISO reports are required on certain studies
    • Storage stability test and toxicity reports (acute oral and acute dermal)
  • GHS compliant SDS
Malaysia (continued)

• Long evaluation/review process
  • Every feedback from Pesticide Board takes 3-4 months
Philippines

• Inconsistency of requirements/procedure
  • Published requirements are usually unclear
  • Data requirements can depend on the consultant
  • Consultant works on rotation basis
Philippines (continued)

• Local efficacy study is required
  • Limited researchers are available in Philippines to carry out study
Philippines (continued)

• Post Marketing Surveillance 2016

  • Submission of additional dossiers/requirements after full approval

  • Full six-pack and chronic toxicity of finished product are now required
Vietnam

- Space spray and residual spray registration difficult
  - Local field trial at multiple locations
  - Costly field trial
  - No guarantee that investment will yield a successful application
What we need from you...

Your industry partners are hoping that programmes and managers such as yourselves can work with them to bring about reforms to the existing regulatory structure. It needs to be more streamline and make business sense. The opportunity cost does not fall only on businesses but also your shoulders as end-users of the products. The sooner we can bring the products out to the market the sooner you can deploy them in your programmes.
Thank you

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