

RBM VCWG Meeting

PQT-VC Approach to Post-Market Activities

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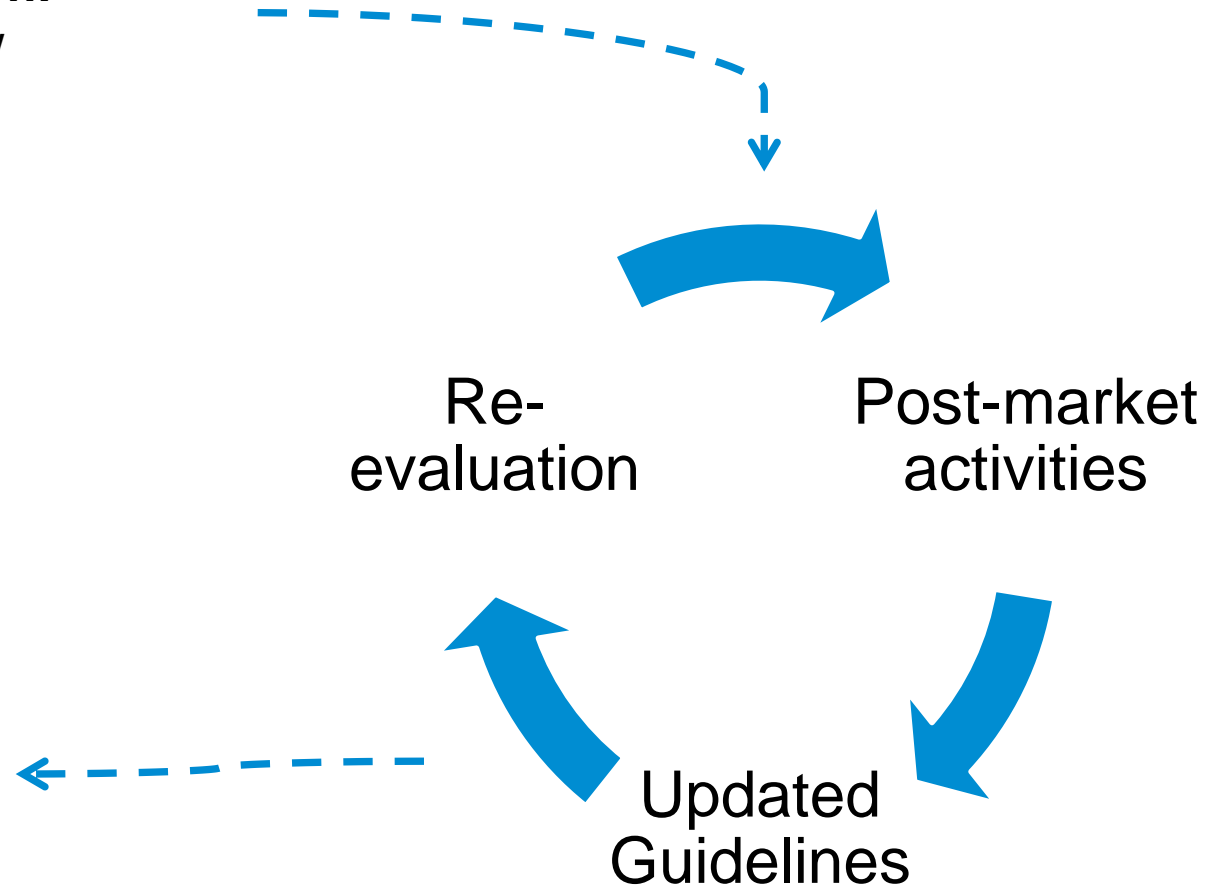
WHO Prequalification – Vector Control

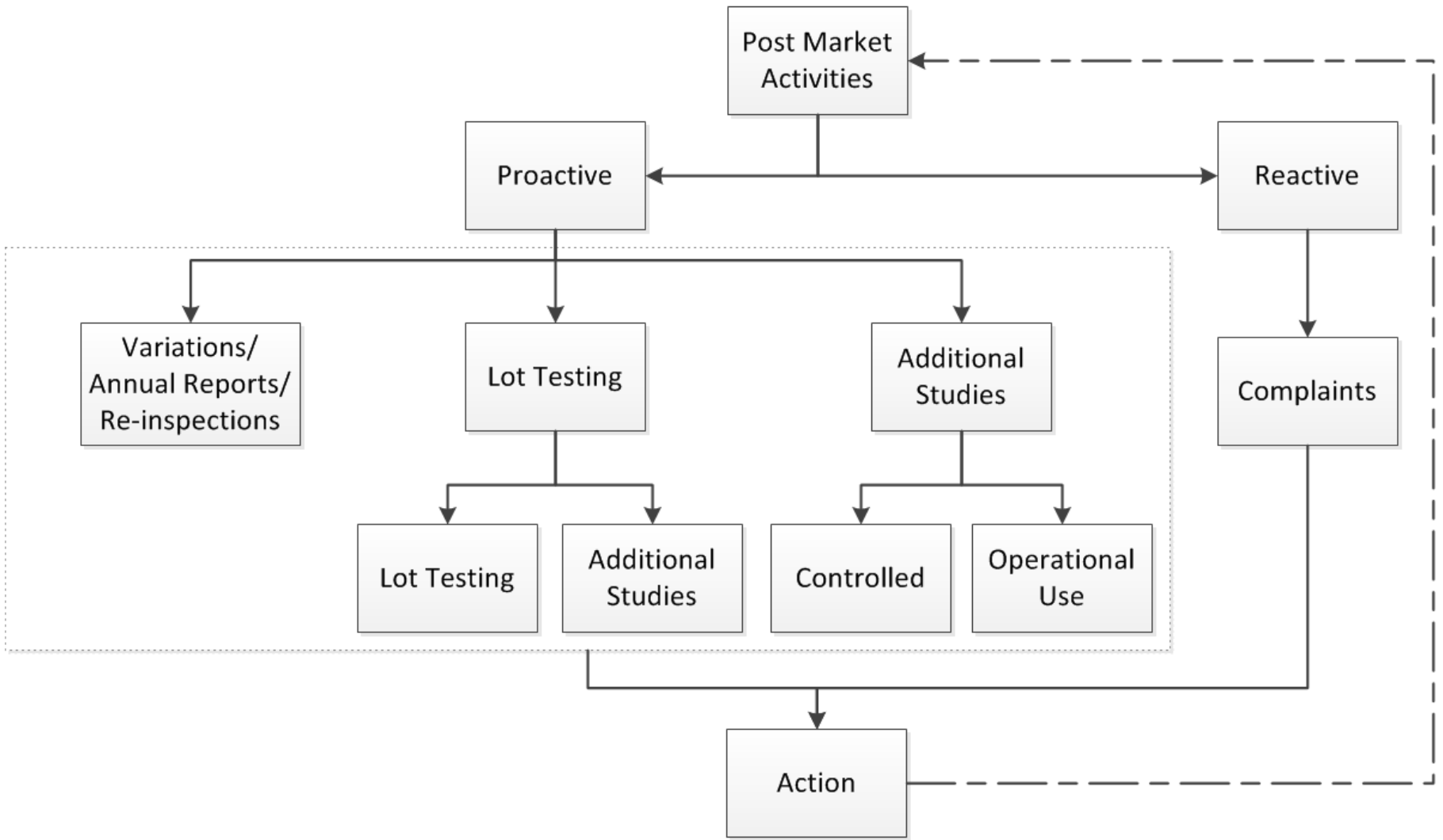


Regulatory Lifecycle

Pre-market evaluation:
Conversions and New applications

End of Product Life-cycle:
Withdrawal or Delisting



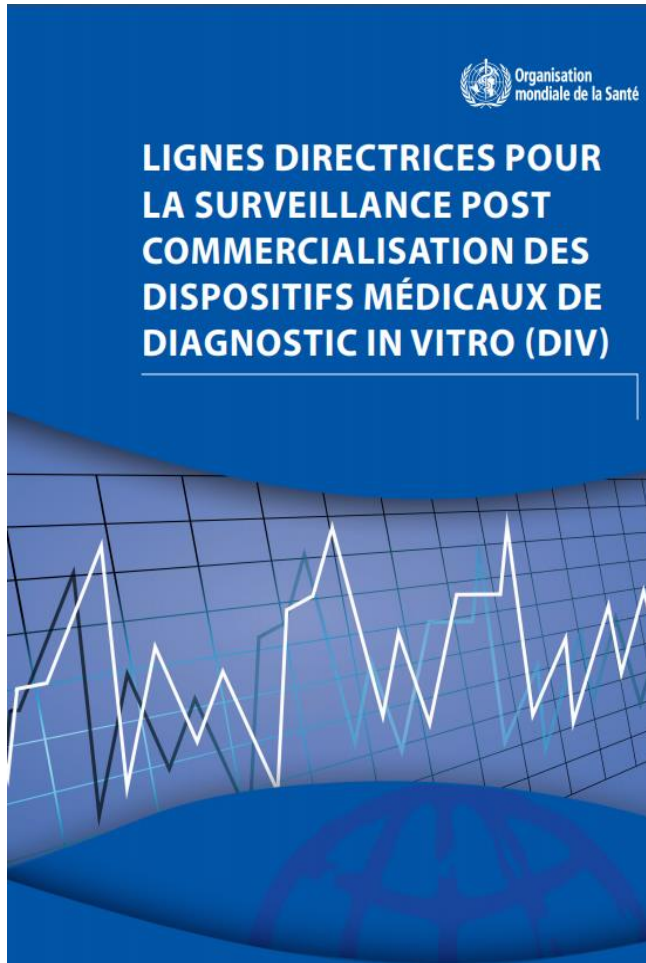


Post-Market Roles

Everyone plays a part -

- Manufacturers
- End Users
- Procurers
- National Control Programs
- National Regulatory Authorities
- WHO

WHO normative guidance on PMS for IVDs



- One chapter for each stakeholder
 - Manufacturers
 - End-users (& implementing partners)
 - National regulatory authorities
 - National reference laboratories
- Template forms and report
 - IVD complaint report
 - Manufacturer investigation report
 - Field safety corrective action report
- http://www.who.int/diagnostics_laboratory/postmarket/en/