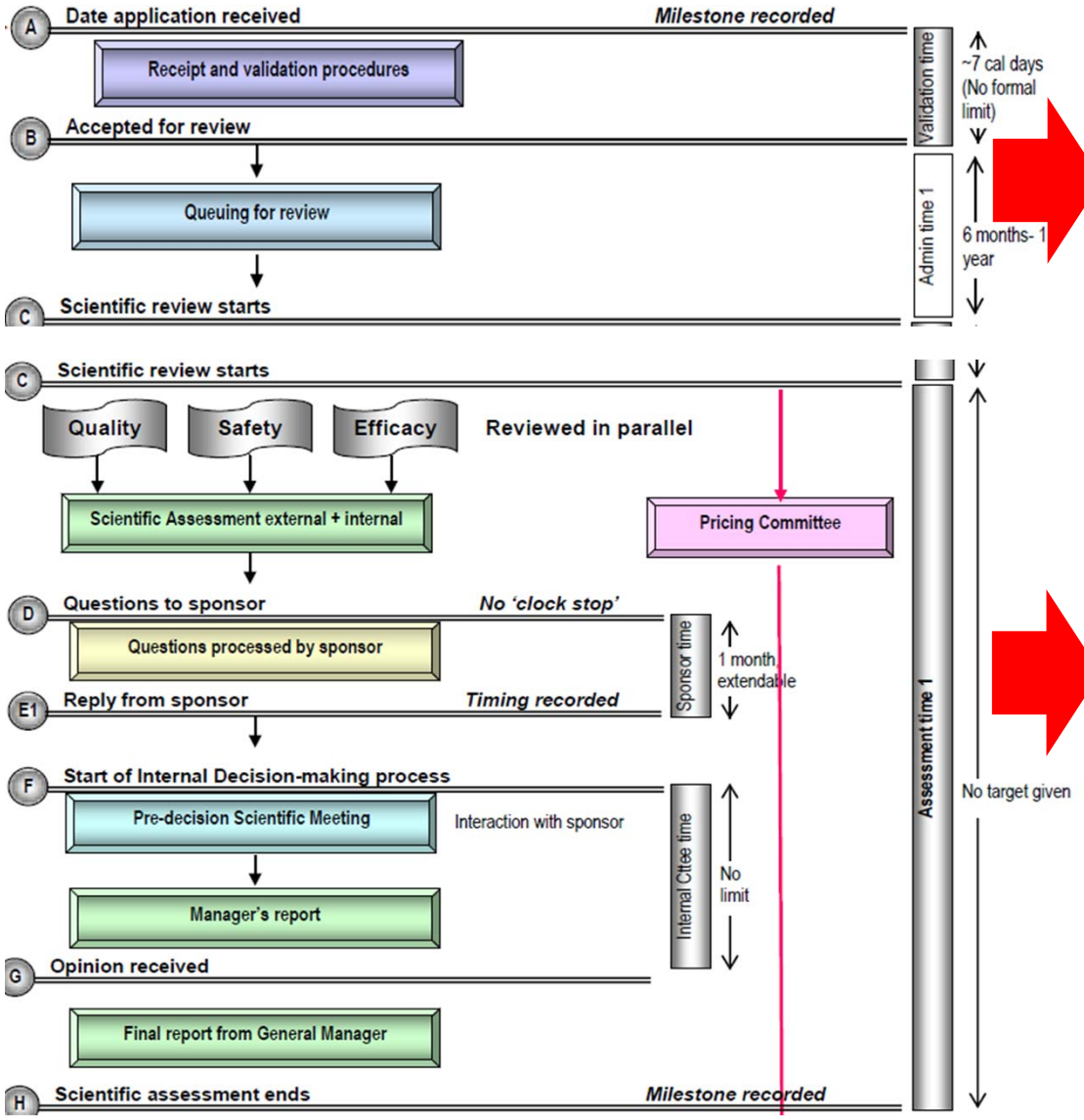
Review Initiation Strategies agencies

Chinese Taipei -TFDA, CDE
Peru
Indonesia
Singapore
Health Canada
Thailand
Saudi Arabia

Screening and Kick off meeting



Time to questions can be effected by a number of things eg:

- Screening
- Kickoff meeting
- Type of review
- Internal vs external review
- Ad hoc or batched questions
- Lack of explicit targets

Time to approval can be effected by a number of things eg:

- Time answer questions
- Committee procedures
- Other activities included
- Resource available

Screening/validation/verification

- Issue terminology Validation means different things to different agencies and across medical devices
  - Manager
  - Reviewers,
  - Project manager
- Generics vs NAS may have different success during the screening
- What
  - Depends on who is doing the screening in terms of items/depth
  - Question is if reviewers do the screening can add more work as doing both
- Screening time
  - 25 working days - Singapore
  - 20 working days – filing meeting – Chinese Taipei
  - 45 calendar days Health Canada
  - 30 days in Indonesia
  - Saudi Arabia – 10days
- When are fees charged, during screening – in devices may depend on class but models

Early identification of serious deficiencies

- Opportunities to identify serious deficiencies
  - Kick off meeting/filing meeting
  - During the review
  - 1st scientific assessment
- Rejection

Consultation needs

- Who (Drugs)
  - Internal
    - HC biostats, lawyers
  - External experts
    - HC SAC and Adhoc committees
    - AC for high risk - twice a month – external experts
    - External experts, academic
    - Medical advisory committee
    - External person on contract
    - Payment - expense
    - Can contract a proportion of the review to an expert if required - will get an internal check to ensure meet regulatory needs
  - Advisory vs binding
    - Advisory

Other Review Strategies

- Notified bodies - Medical devices
- Pre-submission meeting, discuss if dossier is ready for submission – data point.