New Zealand’s experience with an abbreviated evaluation scheme
ICDRA Berne 2008
If you build it

Will they come?

Lively, Google’s virtual world, has been a flop

Economist 21
Aug 2008
Background

• Late 2006 application backlog of 200 files
  – Average time from submission to approval >3 years
  – Significant number of hospital medicines supplied via an exemption to legislation

• Medsafe Proposed:
  – Fee increase for full evaluation
  – Improved performance (Initial evaluation <135 days)
  – Abbreviated evaluation option

• Result:
  – Submission of a further 160 application in month prior to commencement of new fee
    • Equivalent to 3 years work
    • Limited abbreviated evaluation applications

• 2008 Abbreviated evaluation option extended
Abbreviated Evaluation Process

• Optional
  – At submission of application
  – Prior to commencement of evaluation
  – For new or generic prescription medicines

• Limited
  – Applications already approved by a recognised regulatory authority
  – Medicine is on market in that country
  – Application is identical in all aspects
  – Application contains full CTD format dataset and
  – Copies of all evaluation reports, letters and responses

• Streamlined
  – Review of expert regulatory reports
  – Includes NZ specific risk elements
Essential Hospital Medicines

• Abbreviated scheme also applies to products:
  – in routine use in hospitals
  – where continuing use is endorsed by hospital drugs committee or medical college
  – containing same active ingredient as “brand name” previously approved by Medsafe >5yrs ago but no longer available
  – manufactured in GMP licensed facility
  – labeled to Medsafe or recognised regulatory authority requirements

• Target
  – New formulations or manufacturers of older products
  – Small volume anaesthetic medications
  – Cardiac anaesthetic agents
Recognised Regulatory Authorities

Limited to:

- Therapeutic Goods Administration (TGA)
- United States Food and Drug Administration
- Health Products and Food Branch Health Canada
- European Medicines Evaluation Agency (centralised procedure only)
- Medicines and Healthcare Products Regulatory Agency
Assumptions underlying scheme

Medsafe:
Trusted process and experience of recognised regulators
Understood the regulatory process of these regulators
Agreed that it was unlikely to identify significant new problems with approved products that met our abbreviated requirements
Accepted that its strength was in managing risks within context of local market
  – Focus of evaluation on safety issues that directly affect our market (largely generic medicines)
  – Labelling, product names, pack sizes etc
Medsafe’s Experience

- **2007**
  - 300 outstanding applications
    - 50 new medicines
    - 250 generic medicines
  - Abbreviated evaluations
    - 1 new medicines
    - 3 generic medicines

- **2008**
  - 250 outstanding applications
    - 35 new medicines
    - 215 generic medicines
  - Abbreviated evaluations
    - 4 new medicines
    - 8 generic medicines
Learning Points

• Legislation may be an obstacle to innovation
  – NZ Medicines Act requires submission of CTD + external reports

• Trust of another regulator's decision and understanding their system are different tasks
  – Third generic problem

• Significant culture change is required
  – Refocussing organisation to concentrate on its strengths may help
Learning Points

• Key industry driver for change
  – Perceived benefits or risks from adoption of another regulator's decision in your market
  – Medicines funding system

• Perverse incentives supporting status quo may exist

• Insufficient drivers for change include:
  – Improved timeliness
  – Decreased cost

• Information sharing agreements make adoption of an abbreviated scheme easier
Process re-engineering

• Abridged assessment schemes are best introduced into a change environment
  – Use organisational and market strengths
    • NZ 70% of medicines funded are generic

• Lead the process by introducing
  – quality systems and operating procedures
  – new rules on accepting and rejecting applications
  – support for staff training and development

• Make the decisions
  – abbreviated evaluation is a tool so use it