



Australian Government  
Department of Health  
Therapeutic Goods Administration



# The ACSS Consortium And The Generic Medicines Work-Sharing Trial

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# Introduction

- What is the ACSS Consortium
- GMWST Scope and Times
- Our First Submission
- Conclusions and the Future

# What is the ACSS Consortium

- The ACSS Consortium was formed in 2007 by four regulatory authorities



Health  
Canada

Santé  
Canada

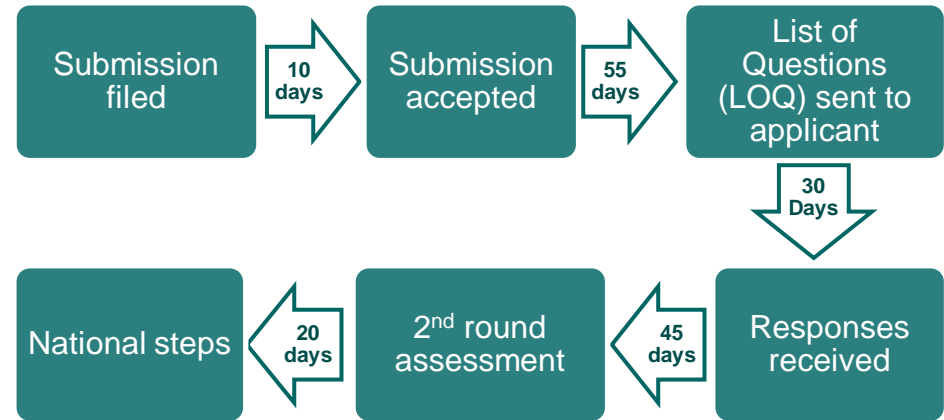


 SWISSmedic

- The governance is lead by the Heads of Agencies
- Active Working Groups
  - New Chemical Entities
  - Biosimilars
  - Information Technology
  - Generic Medicines
  - Complementary Health Products *(previously called Complementary Herbal Products)*

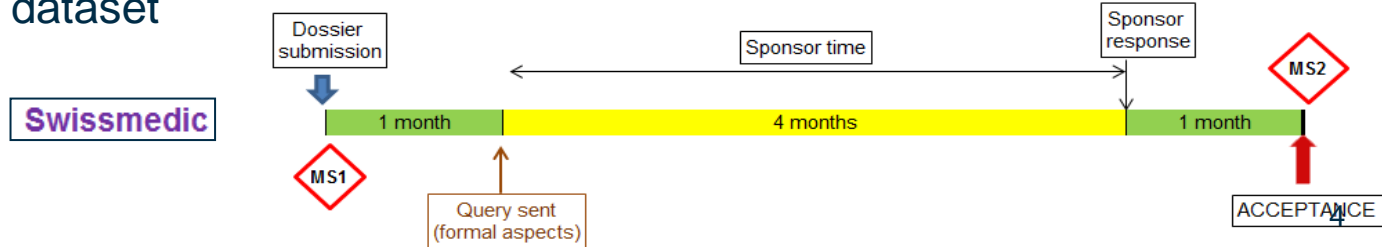
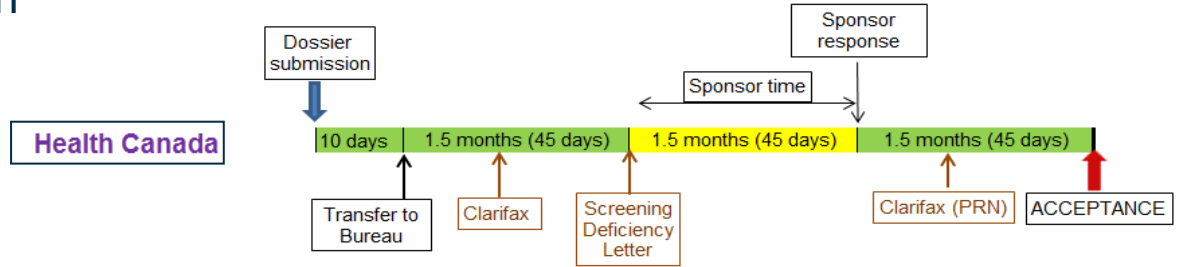
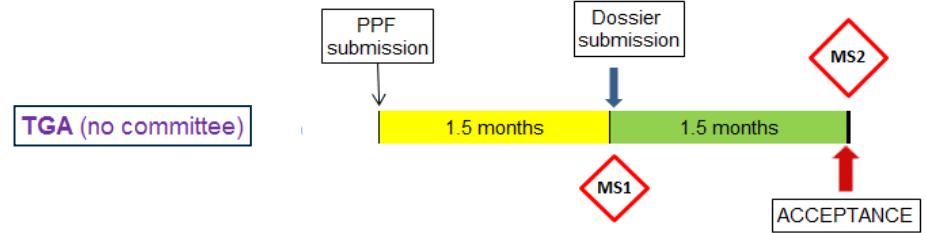
# GMWST scope and times

- Limited to simple dosage forms (solutions and immediate release solid orals)
- Application to 3 of 4 countries with a Reference Regulatory Agency (RRA) and Concerned Regulatory Agencies (CRAs) similar to EU Decentralised Procedure
- Completion targeted to 5 months after acceptance to encourage applications



# Our First Submission

- Major obstacle was the difference in pre-acceptance procedures
- Needed much presubmission communication
- Identified differences in the dataset and the requirements
- Ensured complete dataset at submission



# Our First Submission

- Application filed and accepted in Australia, Canada and Switzerland in July 2016
  - Modules 2-5 of the data sets the same
  - Module 1 was different in the three countries.
  - It included 2 single dose BE studies:
    - 3 way crossover proposed vs EU Reference vs EU Reference fasted
    - 2 way crossover proposed vs EU Reference fed
  - For Australia Module 1 included a justification for the Overseas Reference.
  - There were also 2 ASMFs
- Submission was more complicated than expected

# Our First Submission

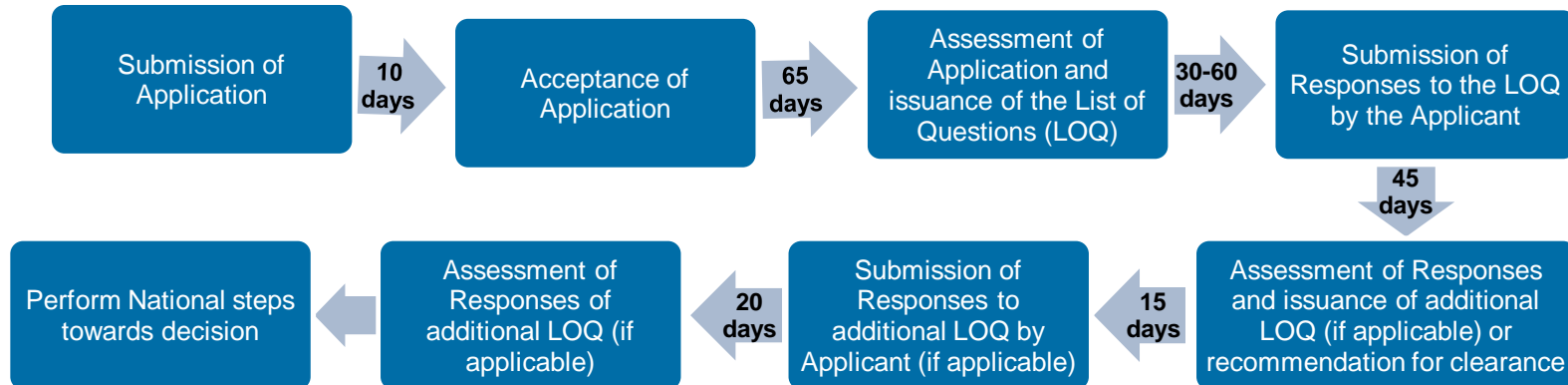
- The TGA was the RRA with HC and Swissmedic as CRAs
  - The questions from all three agencies were put to the Applicant on time
  - Time for response was extended
  - Second round of questions needed
- Application was approved in Switzerland in late March, in Australia in early April and approval has been recommended in Canada
  - Time to the first decision in all ~9 months
- The time taken compared to the target timeframes was:
  - About the same in Australia
  - 4.5 months quicker in Canada
  - 7.5 months quicker in Switzerland

# Conclusions and the Future

- Presubmission communications were important
- First Submission was more complicated than expected
  - Extra time required by Applicant to respond to the Round 1 Qs
  - Evaluation took an extra round
  - The Agencies were able to cope with this
- Overall timeframe was 9 months rather than the target 5 months.
  - Saving Applicant and Governments money
- Pros and cons for Applicant
  - Submit to the Agencies concerned at the same time
  - Answer a single list of questions at a known time

# Conclusions and the Future

- Widen future scope
  - from only immediate release oral solid and solution dosage forms
  - to any possible generic products.
- Allow submission to only 2 of the 4 agencies
- The timeframes will be amended to give an time from acceptance to decision of 6½ / 7½ months



# Interested?

- Expression of Interest Form, Questions and Answers and Operational Procedures documents and can be obtained by emailing [tga.international@tga.gov.au](mailto:tga.international@tga.gov.au)
- or
- Visit the website <https://www.tga.gov.au/acss-generic-medicine-work-sharing-trial>





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**ACSS**  
**CONSORTIUM**

AUSTRALIA  
CANADA  
SINGAPORE  
SWITZERLAND

# Excerpt from EOI

Summary of Bioequivalence Studies Differences					
	Information in application to be filed with the proposed RRA (please specify TGA, HC, SMC or HSA):	Information in application to be filed with the CRA (please specify TGA, HC, SMC or HSA):	Information in application to be filed with the CRA (please specify TGA, HC, SMC or HSA):	Information in application to be filed with the CRA (please specify TGA, HC, SMC or HSA):	Brief discussion of noted differences
Synopsis of Biostudy(ies)					
Reference Product Used					
Indications approved for the reference product					
Approved strengths of reference product					