Harmonization of Electronic Assembly, Submission, and Review Processes

NAFTA TWG Meeting

Vancouver, Canada

Dec. 3-5, 2003

Topics

- Review of harmonization efforts
- On-going projects and activities
- New initiatives
- Updates
- Future activities

Canadian-U.S. Harmonization

- Common objective: more efficient, effective registration process through use of information technology – range of tools

- Began efforts 1996

- Close collaboration on use of tools, guidance, lessons learned

On-going activities

- Encourage submission of study reports in electronic format w/Adobe PDF as standard
  - Inter-operates w/common software - word processing, spreadsheet, statistical analysis – to generate PDF
  - Scan/OCR legacy paper – to generate PDF
  - Inexpensive for data submitters to adopt

On-going activities - continued

- Train reviewers in use of Adobe Acrobat
  - Evaluate studies – text and tables
  - Prepare review documents
  - Use w/statistical analysis, spreadsheet, word processing software
- Supports detailed evaluation of individual study reports

New Initiative – E-Index

- Tool to identify studies in submission
- Consistent with OECD Dossier harmonized guidelines
- Supports single electronic submission to multiple countries/regions
- Pilot joint review submissions in 2004 – Bayer, Syngenta, DowAgrosciences + PMRA and OPP

E-index

New initiative – Checklist of Administrative Information

- Guides submitters on assembly of required documents for U.S. and Canadian submission
- Identifies common and unique elements
- References required forms

Checklist concept

OPP Element	PMRA Element	OPP Reference	PMRA Reference
Application	Application	Form 8570-1	Form 6005
CSF	PSF	Form 8570-4	Form 6003
FQPA Summary	N/A	PRN 97-1	N/A

Updates

- OPP announcement: encourages submission of OECD dossier formatted submissions in electronic format

- PMRA adopts OPP's technical specifications for creation of PDF

- PMRA adopts OPP's approach for claiming and segregating confidential business information

Updates - continued

- Study report binders – PMRA will accept simpler style used by U.S. submitters

- DER templates harmonization
    - Full collection posted on PMRA Web site
    - OPP to post full collection in near future

- Study report templates preparation by OPP
    - Mirror DER templates to facilitate their use
    - Posting to Web as each discipline completed

Future activities

- CropLife America and OPP considering a 3rd Electronic Submission and Review Workshop in 2004 (March 2000, January 2003)
- PMRA and OPP continue to exchange ideas, approaches, lessons learned
- PMRA's forms-based, on-line application submission process- Summer 2004
- OPP - Fee for Service? – New opportunities!