Health Canada Santé Canada

Canadian Regulatory Perspective

Dr. James Macdonald
AIDS and Viral Disease Division, Health Canada

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Health Products and Food Branch
Direction générale des produits de santé et des aliments

Bill C-9

- Canada's implementation of August 30, 2003 WTO decision
- Compulsory licence for export
- Regulations in final phase
- Must meet Food and Drugs Act and Regulations for Canada
- Mandatory anti-diversion (colour and marking)
- Wider scope than TB, Malaria and HIV/AIDS

Pediatric Formulation Approval

- Formal indication for use in pediatric population would require a Phase III Study.

However,

- General HIV/AIDS indication with pediatric dosing:
  - Basic indication of efficacy
  - Some indication there is no difference in safety profile
  - Pharmacokinetic data
  - Acceptable pre-clinical profile

Fixed Dose Combination (FDC) Product

1) New FDC is generic bioequivalent to existing FDC
   - Bioequivalence data only
2) New FDC developed by combining individual components from a well studied multi-drug regimen
   - BE Study comparing new FDC to individual components
   - Supporting data (literature or previously filed)

Fixed Dose Combination (FDC) Product

3) Individual components that are well studied individually but the multi-drug regimen is not well studied or used in a novel dosing regimen
   - Bridging toxicology studies (minimum)
   - Appropriate PK and pharmacodynamic studies
   - Clinical study(s) to support the combination of active ingredients or the novel dosing regimen
4) New Chemical entity
   - Full pre-clinical and clinical package