

ADVERSE EFFECTS REPORTING PROJECT

- ▶ FRAMEWORK FOR REPORTING, EVALUATION AND MANAGEMENT OF AER IN DEVELOPMENT

- ▶ INCORPORATE MANDATORY REPORTING FOR REGISTRANTS AND VOLUNTARY REPORTING FOR MEDICAL COMMUNITY, OGD AND PRIVATE CITIZENS

- ▶ INCORPORATE REPORTING ON:
 - ◆ HEALTH EFFECTS
 - ◆ ENVIRONMENTAL EFFECTS
 - ◆ PRODUCT QUALITY
 - ◆ PRODUCT EFFICACY
 - ◆ ANIMAL EFFECTS - DOMESTIC, WILD



ADVERSE EFFECTS REPORTING - PMRA STATUS

- ▶ PROJECT PLAN DEVELOPED, CONTRACT INITIATED
- ▶ FOCUS GROUP DISCUSSIONS - DEFINE REQUIRED REPORTING FOR EACH SCIENTIFIC AREA; PARTICIPATION OF ENVIRONMENT CANADA
- ▶ ONGOING ENVIRONMENTAL SCAN - OTHER AGENCIES
 - ◆ COMPREHENSIVENESS, TIMING OF REPORTS, REPORTING DETAILS ETC.
- ▶ OPTIONS DEVELOPMENT



ADVERSE EFFECTS REPORTING - PMRA STATUS *Cont'd*

- ▶ INITIATED ASSESSMENT OF DATA BASE INFRASTRUCTURE REQUIREMENTS FOR REPORTING PROGRAM

- ▶ RECOGNITION THAT SCOPE OF FRAMEWORK IS LARGE - DOABLE/AFFORDABLE/ EXTERNAL EDUCATION

- ▶ REDUCE OVERLAP/DUPLICATION BY BUILDING ON WHAT IS ALREADY AVAILABLE
 - ◆ PRODTOX CONNECTION FOR HEALTH COMPONENT

