

*Attachment 5***COMPONENTS OF A "TWO-WAY" ALERT PROGRAMME**

1. Documentation
 - Definition of a crisis/emergency and under what circumstances an alert is required
 - Standard Operating Procedures (SOPs)
 - Mechanism of health hazards evaluation and classification
 - Language of communication and transmission of information

2. Crisis Management System
 - Crisis analysis and communication mechanisms
 - Establishment of contact points
 - Reporting mechanisms

3. Enforcement Procedures
 - Follow-up mechanisms
 - Corrective action procedures

4. Quality Assurance System
 - Pharmacovigilance programme
 - Surveillance/monitoring of implementation of corrective action

Contact Points

For the purpose of this agreement, the contact points for any technical question, such as exchange of inspection reports, inspectors training sessions, technical requirements, will be:

For Canada:

The Director General, Therapeutic Products Programme, Health Canada, Holland Cross, (Locator3102D2), 1600 Scott Street, Ottawa, Ontario, K1A 1B6, Canada
Telephone 1-613-957-0369, Fax 1-613-952-7756, e-mail dann_michols@hc-sc.gc.ca

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