

ATTACHMENT IV

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
 - Access to manufacturer's submissions, adverse incident reports and Conformity Assessment Body reports
 - Establishment of contact points
 - Reporting mechanisms

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

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