

*Attachment 6***PHASES OF A CONFIDENCE BUILDING PERIOD**

The determination of the equivalency of the GMP compliance programmes by the Joint Sectoral Group will be designed around the following three phases :

1. Review and evaluation of documentation (exchange of documentation)
  - Legal Instruments (regulations/legislation/directives)/guidelines on GMPs
  - Inspection programmes (scope, policies, directives, procedures)
  - Crisis management systems (scope, criteria, policies, directives, procedures)
  - Requirements for inspection reports
  - Analytical laboratory systems
  - Alert reports
  
2. Evaluation of processes and procedures
  - Audit of systems and procedures
  - Exchange/evaluation of reports
  - Monitoring of alert systems including handling of recalls
  - Joint inspections of manufacturers to determine equivalency of inspection methods
  - Exchange of inspectors or organization of joint workshops (optional)
  
3. Decision making on the success of the exercise and conclusions
  - Evaluation of results of the confidence building exercise
  - Action to take, development of options and solutions to address issues
  - Determination of competent agencies that meet evaluation criteria
  - Establishment of the conditions and mechanisms for on-going maintenance of the certification programme (develop quality management system, audit mechanism and a consultation/on-going dialogue process).

\* \* \* \* \*