

Appendix 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/Legislations 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.