ARTICLE X

Civil Liability

1. Nothing in this Agreement is intended to change or modify the law in the territory of either Party applicable to civil liability of manufacturers, distributors, suppliers, Regulatory Authorities or governments, to consumers or among each other, in respect of the design, Manufacture, testing, inspection, distribution or sale of Medicines that have undergone Conformity Assessment pursuant to this Agreement.

2. Each Party shall promptly notify the other Party of any proceedings in the territory of such Party arising from or in connection with Conformity Assessment performed by the other Party pursuant to this Agreement.

3. Each Party shall, at the other Party's request, take reasonable steps to cooperate with the other Party in any proceedings which arise from or relate to a Conformity Assessment undertaken pursuant to this Agreement. Such cooperation shall include, subject to limits imposed by their respective laws, rendering reasonable assistance in obtaining relevant documents and in gaining access to material witnesses.

ARTICLE XI

Requests for and Transmission of GMP Inspection Reports

1. Upon written request by the Regulatory Authority of one Party, the Inspection Service of the other Party shall forward a copy of the last GMP Inspection report of a manufacturing site or contract testing laboratory in the case where analytical operations are contracted out. Such a request may be for:

(a) a "full inspection report" comprising a Site Master File (compiled by the manufacturer and verified by the Inspection Service) and a narrative report by the Inspection Service; or

(b) a "detailed report" responding to specific queries about a manufacturer by the other Party.

2. If the manufacturing operations of the Medicines in question have not been inspected within two years, or a particular need to inspect has been identified, a specific and detailed inspection may be requested.