PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

WHAT IS PIC/S ?

The Pharmaceutical Inspection Co-operation Scheme (PIC/S) was established in 1995 as an extension to the Pharmaceutical Inspection Convention (PIC) of 1970.

PIC/S is a non-binding co-operative arrangement between Regulatory Authorities in the field of Good Manufacturing Practice (GMP) of medicinal products for human or veterinary use. It is open to any Authority having a comparable GMP inspection system. PIC/S comprises more than 50 Participating Authorities coming from all over the world (Europe, Africa, America, Asia and Australasia). The exact list of PIC/S Participating Authorities is available on the PIC/S web site (www.picscheme.org).

PIC/S aims at harmonising inspection procedures worldwide by developing common standards in the field of GMP and by providing training opportunities to inspectors. It also aims at facilitating co-operation and networking between competent authorities, regional and international organisations, thus increasing mutual confidence.

This is reflected in PIC/S' mission which reads as follows: "To lead the international development, implementation and maintenance of harmonised GMP standards and quality systems of inspectorates in the field of medicinal products."

As the Scheme is an arrangement between Regulatory Authorities, it is very flexible, dynamic and proactive. A Committee of the Participating Authorities' representatives (PIC/S Committee) supervises the operation of the Scheme. All decisions are taken unanimously. The Committee is assisted in its task by 7 Sub-Committees (e.g. on the training of inspectors, on GMDP harmonisation, etc.), by an Executive Bureau, which steers the Organisation in-between meetings, and by a small Secretariat, which mainly assists the Committee, the Sub-Committees, the Bureau and Participating Authorities in their duties.

WHAT IS GMP ...?

GMP is defined as follows in the PIC/S GMP Guide: "Good Manufacturing Practice is that part of Quality Assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorisation or product specification."

Put in other words: GMP ensures that the production of medicines meets the required quality standards.