



**PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME**

South Africa attains PIC/S membership: a first for Africa

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Improving health care in developing countries remains a priority for the global health community, consequently access to health care, including medicines, is on the agenda of policymakers, national medicines regulatory authorities (NRA), industry and many non-governmental organizations.

Background

Globally, significant resources are being committed to actively support efforts to expand access to medicines in accordance with the leadership responsibilities of national governments and international regulatory agencies. This is evident through a wide range of partnership initiatives an example of which is the Pharmaceutical Inspection Co-operation Scheme (PIC/S).

PIC/S is designed to assist NRAs strengthen their GMP Inspectorate and regulatory standards. This is accomplished in a number of ways namely: through member countries harmonizing their medicine Inspectorate quality systems and GMP guidelines; promoting networking between Competent Authorities and developing mutual confidence; exchanging information and practical experience on GMP and related topics; mutual training of inspectors and lastly support of the GMP Inspectorate. As of 1 January 2009 PIC/S membership totaled 36 Participating Authorities representing amongst others, Argentina, Australia, Canada, Israel, Malaysia, Singapore, South Africa and various European countries

It is acknowledged that the role of a NRA is to guarantee the quality, safety and efficacy of medicines made available to the public and that Good Manufacturing Practices (GMP) are the mainstay of quality assurance in pharmaceutical production and control.

GMP recommendations and legislation alone do not determine the success of quality assurance in practice. Quality (as a concept) and GMP compliance by the Pharmaceutical Industry are also dependent on effective implementation, appropriate enforcement and a common interpretation and understanding of the GMP principles by the authority's GMP Inspectorate team and by the regulated Industry.

The Medicines Control Council (MCC) of South Africa was invited to join PIC/S as a new Participating Authority on 1 July 2007.

South Africa's Quest for PIC/S membership

South Africa's journey to attain PIC/S membership was not without its share of challenges. Buy-in from all stakeholders was necessary to allow for a joint strategy approach. This included gaining political backing, and support from government and the Pharmaceutical Industry.

The first requisite to improving the availability of good quality medicines in South Africa was to obtain political support and determination for the harmonisation of medicine GMP requirements with international standards. In addition Industry support for the strengthening of the national regulatory system with regard to the promotion of Good Manufacturing Practices (GMPs) had to be obtained. There was fortunately no challenge for these prerequisites as both the State and the Industry were willing and supportive.

Once an Industry-MCC partnership had been established, it was necessary to investigate what the legislative amendments to the existing Act (Medicines and Related Substances Act 101 of 1965), were required to enable the enforcement of the provisions called for by PIC/S. It was concluded that legislation development and enactment which would allow companies that manufacture (total or partial) pack/label, import, export distribute and/or test medicine, to hold a Manufacturing License from the MCC, was necessary.

At the same time the MCC Inspectorate needed to develop a Quality Management System that addressed a suitable code of practice, conflict of interest, standard operating procedures outlining Inspectorate activities and appropriate Inspectorate enforcement, in line with the provisions of the Medicines Act.

In order to ensure that pharmaceutical products available in South Africa meet national, and international, standards of safety, efficacy and quality, it was necessary to employ a harmonised approach to GMP, in line with the PIC/S prescribed requirements and global criteria of GMPs. Therefore, the MCC together with the Pharmaceutical Industry had to adapt and adopt the PIC/S GMP Guidelines to support the national regulatory framework.

Pharmaceutical Industry support for the setting of acceptable standards for the manufacturing of medicinal products of the highest quality was gained by holding a series of workshops [12 workshops, from January 2004 to January 2005] involving the MCC and Industry. Implementation of the agreed and updated GMP Guideline document was obtained within 2 years after submission of the PIC/S membership application.

The next hurdle faced by the MCC was to increase the capacity of the GMP Inspectorate through strengthening the administrative, structural and technical elements of medicine regulation and inspection. In addition a Quality Manager was appointed to ensure compliance with the newly developed quality system.

The MCC was then faced with the challenge of ensuring Industry compliance with the updated GMP requirements. The goal of the Regulator was to advance Industry's GMP standards to an acceptable level using and developing the variety of experiences and technical expertise available in the country and calling in external expertise where needed. A joint workshop on the important aspects in the new guidelines was held in February 2006 during which they were discussed, debated and clarified. In order to ensure GMP compliance, the MCC, by means of its open-door policy, attempted to advise and guide, without taking on the role of a consultant.

Finally, in September 2006, the MCC was assessed by a team comprising of senior inspectors from five PIC/S Participating Authorities. The observations made during the assessment were responded to and on 1 July 2007 the MCC of South Africa received PIC/S membership - a first for Africa!

When assessing the journey of South Africa to attain PIC/S membership, it is obvious that the MCC's endeavours as a single player would have had limited impact. All players, whether government, administration or industry needed to contribute and cooperate in order to meet the common goal.

Currently, the MCC's approach to strengthen regulatory capacities by tapping into the pool of PIC/S expertise offers South Africa a forum to exchange information and technical expertise. PIC/S membership also gives South Africa the opportunity to draw on the technical resources from developed countries through joint collaboration and to build up technical capacity and a repository of information in the country.
