Induction
The Commonwealth Pharmacists Association (CPA) was invited by the WHO to send a representative to attend the 42nd meeting of the organisation’s Expert Committee on Specifications for Pharmaceutical Preparations. On the recommendation of Ivan Kotzé, president of the CPA and PSSA executive director, it was decided that Miranda Viljoen, a representative of the industry sector (SAAPI) of the PSSA, should attend the meeting.

The purpose of the meeting was to review various elements relating to drug quality control and quality assurance. Topics discussed included good manufacturing practices (GMP), inspection, distribution and trade of pharmaceuticals, risk analysis, counterfeit medicines, stability and international collaboration. The Committee also discussed quality specifications for paediatric medicines and for antimalarial, antituberculosis and anti-HIV medicines. It also reviewed activities relating to prequalification, regulatory guidance, international reference materials, International Nonproprietary Names (INN), and quality control testing. The meeting was held at the WHO headquarters in Geneva from 15 to 19 October 2007.

The Expert Committee is one of several such committees which are the official advisory bodies to the Director General of the WHO. The object of the meeting was to set and implement WHO international standards and norms in the area of quality assurance.

Participants
The meeting was attended by:
1. WHO Expert Advisory Team members from Argentina, Belgium, China, Ethiopia, Hungary, South Africa, Thailand and USA.
2. Technical Advisers from Denmark, India, Luxembourg and Sweden. Special advisers from Hungary, Uganda and United Kingdom also attended
4. Representatives from Specialised Agencies and Related Organisations including the Global Fund to Fight AIDS, Tuberculosis and Malaria
5. Representatives from Intergovernmental Organisations such as the EC – European Commission, Council of Europe and EMEA – European Medicines Agency
7. Observers from PIC/S – Pharmaceutical Inspection Co-operation Scheme. Pharmacopoeias Council of Europe, China, Korea, Russia and United States
8. Members of the WHO Secretariat

Proceedings
Dr Howard Zucker, Assistant Director-General of the WHO, opened the meeting on behalf of the Director General, Dr Margaret Chan. He shared the WHO six point objectives with the participants of the meeting.

There are two health objectives, two strategic needs and two operational approaches i.e.:
1. Promoting development
2. Fostering health security
3. Strengthening health systems
4. Harnessing research, information and evidence
5. Enhancing partnerships
6. Improving performance

Dr Zucker explained that the mission of the HTP (Health Technology and Pharmaceuticals) cluster, for which he is responsible, is to maintain health and reduce morbidity and mortality through access to and optimal use of available new health technology and medicines.

Reports were presented by the representatives of the following organisations:

1. The Global Fund (GF):
Dr Joelle Daviaud gave an update of the Global Fund Quality Assurance Policy Implementation. She reported that while the GF is not a procurement agency, it elaborates procurement policies for quality assured medicines and health products.

The GF is a financial institution, with approximately 48% of grant funds being used for medicine and health product procurement. It was reiterated that ac-
cess to and continued availability of quality assured medicines and health products are essential to fight AIDS, malaria and TB. The GF has published a guideline on Procurement and Supply Management in which it outlines the GF policies. These are based on three principles:

- Procure quality assured products at the lowest price
- Adhere to National and International Laws
- Conduct procurement in a transparent and competitive manner

2. European Medicines Agency (EMEA)

Dr R Luigetti reported on recent activities carried out at EMEA with the two major initiatives being:

1. The formation of a Paediatric Committee (PDCO) following the introduction of the new Paediatric Regulation. One of the main tasks of this committee is to evaluate the Paediatric Investigation Plans (PIPs) and drug development plans for the paediatric population. This will be mandatory for new products from July 2008.

2. A joint European Commission/EMEA conference on the EU Clinical Trials Directive which was held in October 2007. The main purpose of the conference was to discuss the possibility of amending the Directive, in order to make it more suitable for stakeholder needs.

Regarding quality issues, Dr Luigetti reported that a revision of the EU guideline on radiopharmaceuticals had been published on the EMEA website for comment. Work on Near Infrared Spectroscopy is ongoing. In addition implementation in the EU of the ICH documents Q8 (Pharmaceutical Development), Q9 (Quality Risk Management) and Q10 (Quality Systems) was continuing.

Concerning GMP Dr Luigetti reported that the EMEA was in the process of revising the EU-GMP guide, and in particular Annex 1 (sterile manufacture) and Annex 2 (Biologics).

3. European Directorate for the Quality of Medicines (EDQM)

Dr Miller gave an account of the activities of the EDQM. He reported that Dr Suzanne Keital had been appointed as the new Director of the EDQM. The EDQM had undertaken a number of new activities during the past year including that of acting as Council of Europe Committee on Blood transfusion and Organ Transplantation. In order to reflect this, the EDQM name has been changed to European Directorate for the Quality of Medicines and Healthcare.

EDQM has also become the repository of the International Standards for Antibiotics and is responsible for their replacement and distribution.

The committee was informed that the 6th edition of the European Pharmacopoeia had been published in July 2007 and will become effective in January 2008. It was reported that three supplements will be published annually and that a new Edition would be published every three years.

Dr Miller reported that an expert group on Traditional Chinese Medicine had been established so that Ayurvedic products could be covered.

4. International Conference on Harmonisation (ICH)

Dr Jean-Louis Robert provided an overview of the developments in the ICH quality guidelines.

He outlined the ICH’s new vision in relation to pharmaceutical quality viz: “Develop a harmonised pharmaceutical quality system applicable across the lifecycle of the product emphasizing an integrated approach to quality risk management and science.”

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Regarding Q8: Pharmaceutical Development, Annexure Q8 (R) is under discussion. This annexure shows how concepts and tools (e.g. design space), as outlined in the core Q8 document, could be put into practice by an applicant for all dosage forms.

In addition, the annexure describes the principles of Quality by Design (QbD), and the use of Quality Risk Management (QRM).

These concepts, tools and principles could provide opportunities to enhance science-and risk-based regulatory approaches to ensure product quality during its lifecycle.

The concept of knowledge transfer and the implementation of Q8 (Pharmaceutical Development), Q9: (Quality Risk Management), Q10 (Pharmaceutical Quality System) were discussed.

5. International Conference of Drug Regulatory Authorities (ICDRA)

It was announced that the Swiss Agency for Therapeutic Products will be hosting the 13th International Conference of Drug Regulatory Authorities in Bern, Switzerland from 16 – 19 September 2008.

6. Pharmaceutical Discussion Group (PDG)

The Pharmaceutical Discussion Group reported that a number of “general method” pharmacopoeial texts had been revised. These harmonised texts would be published in the respective pharmacopoeias.

International Federation of Pharmaceutical Manufacturers and Associations/European Federation of Pharmaceutical Industries and Associations (IFPMA/EFPIA)

Dr Hoepfner and Dr Stoddard gave a presentation on the WHO Certificate of Pharmaceutical Product (CPP) Scheme from an industry perspective and suggested a number of improvements to the scheme.

Conclusions

The outcome of the meeting was an interim report of the WHO Expert Committee for Pharmaceutical Preparations which:

- Summarised the discussions
- Gave recommendations to WHO and Member states
- Included newly proposed guidelines

The final report will be presented to the WHO Governing Bodies for comments, and endorsement. This will constitute new WHO technical guidelines that will be implemented by member states. The full report will be published shortly, by the WHO and will be available for reference purposes from the SAAPI office at 52 Glenhove Road, Melrose.