The 2008 – 2009 year has been a good one for SAAPI. Membership has increased and the services we are able to provide to our members and the pharmaceutical industry as a whole have improved.

Committee
My thanks for this goes to my small but hardworking committee, the SAAPI office as well as the support provided by the Southern Gauteng offices in Glenhove Road and the National office in Pretoria. Special mention must go to Miranda Viljoen who runs the SAAPI office and so takes a huge workload off the committee who frequently find balancing time between their regular work and the voluntary input required for SAAPI difficult to manage, Lynette Terblanche my deputy who so willingly has stepped in to fill a gap when I have not been able to attend a meeting or function, and Fleur Hartman who has been the driving force behind our annual multi-day conferences. Fleur retires shortly and we hope that this means she will have more time for SAAPI and not that we will lose her altogether. Coleen Cairncross has been very involved with the academic institutions and the setting up of courses and programmes that in time will be recognised by SAQA and will then benefit the industry, Aadila Patel, Simone Rudolph-Shortt and Marie de Beer are our representatives for the far away places of Western Cape, KwaZulu-Natal and Eastern Cape and they do their best with the smaller membership and industry in these areas. There are the others who are involved in the technical committee, those who provide comment on Guidelines and legislation, and then put the responses together for submission and many more areas where the involvement may be small but it forms the part of a whole, much bigger picture and makes SAAPI what it is.

Annual Conference
The major event of the year was the annual conference held on 28 and 29 July 2008 entitled ‘Advances in Quality Management and electronic Common Technical Document (eCTD) submission’. This conference was extremely well attended with approximately 290 delegates from all over the country. We were fortunate to be able to secure international speakers of excellent calibre and the second day on the eCDT presented by Dr Olaf Schoepke was an eye-opener to all who are involved in the compilation of registration dossiers.

CPD events
An extremely useful workshop on ‘How to appraise and submit biostudies’ was held in Johannesburg in April 2008, and repeated in Cape Town the following month to a smaller, but delighted group of delegates. This, the first ‘out of Gauteng’ workshop, has hopefully paved the way for others to follow.

Other CPD events included a presentation on the new regulatory legislation by Johannes Gaeseb of the Namibian Medicines Control Council followed by a very fruitful Q & A session where much more information was gleaned.

A CAMS workshop was held in November to hear about and discuss the proposed legislation to regulate this growing sector of the pharmaceutical industry. The Health Products Association (HPA) and Self Medication Association of SA (SMASA) were both very involved in the presentations and
the ensuing discussion and view points gave the attendees much food for thought.

A workshop on the comparison between the Common Technical Document (CTD) and Medicines Registration Form (MRF 1) and the latest technology in the use of barcodes was held in February 2009.

Pharmacy Week
Pharmacy Week in September 2008 focused on the pharmaceutical industry as a whole and not only the community and hospital sectors as tended to be the case in previous years. Miranda Viljoen and Lynette Terblanche represented SAAPI on the Pharmacy Week committee and their input and ‘industry perspective’ on matters was greatly valued. The Pharmacy Week campaign concluded with a hard hitting video about pharmaceutical waste disposal, a campaign to collect and destroy expired medicines from the community. A generic Patient Information Leaflet (PIL) intended for all consumers of medicine explaining the information found in a PIL, its importance and the reasons for inclusion was also developed and distributed.

Website
The SAAPI website (http://www.saapi.org.za) is now established and provides a wealth of information for those in the pharmaceutical industry – from legislation, consultancy services, employment opportunities, links to international organisations and much more.

Comments on draft legislation
The following legislation/guidelines were commented on either directly or through PSSA or the Trade Organisations: Implementation of Safety Related Package Insert Notifications
- Guide to Good Manufacturing Practice for medicines in South Africa
- Post-Registration Amendments
- SA Code of Practice for the Marketing of Medicines
- SARS draft interpretation note on R&D tax incentives
- Medicines and Related Substances Amendment Bill 2008
- National Health Amendment Bill 2008
- Rules Relating to Good Pharmacy Practice
- Changes to Medicine Schedules
- Guideline on Proprietary Names for Medicinal Products

General
Meetings were held with both Prof Green Thompson and SAPC on the Patient Information Leaflet, in particular the replacement of the PI in the medicine container with the PIL, and the creation of a central repository for all PIs.

Miranda Viljoen was invited to London to give a talk on regulatory affairs in South Africa at a Management Forum Workshop, which she did as a SAAPI representative.

Treasurer’s report – provided by Cecil Abramson
The finances of the Association continue to be managed and used well.

The sources of income are mainly investment interest, (these by nature must be conservative), income from subscriptions, and any profit made from CPD and other conference activities.

The expenses are well controlled. Monies are spent wisely for the benefit of the members, and contributions to student bursaries via FPE at PSSA head office as well as to the “Pharmacy Week” project.

The distributable reserves as at the end of the financial year (30 September 2008) had increased by 29% through prudent management and hard work by the committee. This includes the employment of a manager, Miranda Viljoen, which in turn has improved service to members, immensely.

SAAPI’s sincerest thanks go to Antoinette Snyman at head office for her efficient assistance, and support, as well as to our auditors, Mervitz & Malan.

Contd from p. 40

Lower Urinary Tract symptoms in Men

Major references: