On 18 and 19 March 2014 the Pharmaceutical Inspection Co-operation Scheme (PIC/S) and Parenteral Drug Association (PDA) in cooperation with the Medicines Control Council (MCC) hosted an experienced based training course in Sandton, Johannesburg on Good Manufacturing Practice (GMP) for Active Pharmaceutical Ingredients (API’s) applying national and international accepted standards.

This follows the global trend for an increase in regulatory oversight over the manufacture of Active Pharmaceutical Ingredients (API’s) and the requirements from national medicines regulatory authorities to pronounce on the Good Manufacturing Practice compliance of API sites with acceptable standards of GMP. The course is intended for national medicine regulatory authorities GMP Inspectors and the API Industry.

Dr Joey Gouws, the Deputy Registrar of the Medicines Control Council and current Chairperson of PIC/S gave the opening address.

The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) are two international instruments between countries and pharmaceutical inspection authorities, which provide together an active and constructive co-operation in the field of GMP.

PIC/S’ mission is "to lead the international development, implementation and maintenance of harmonised Good..."
Manufacturing Practice (GMP) standards and quality systems of inspectorates in the field of medicinal products."

The method in which this is done is by developing and promoting harmonised GMP standards and guidance documents; training competent national medicine authorities, in particular inspectors; assessing (and reassessing) inspectorates; and facilitating the co-operation and networking for competent authorities and international organizations within the area of GMP.

There are currently 44 Participating Authorities in PIC/S which includes inter alia the national medicines regulatory authorities from Australia, Canada; FDA USA; Singapore, Israel, European Union, Argentina amongst others. In addition applications for PIC/S membership have been received from Japan, Brazil, Turkey, Uganda.

PDA Europe gemeinnuetzige GmbH founded in March 2007, is located in Glienicke near Berlin and is a subsidiary of the Parenteral Drug Association, Inc., an American non-profit corporation. The goal of PDA is to promote science and research in the range of pharmaceutical and biopharmaceutical technology in the broadest sense and to address the fast development in these areas. PDA accomplishes this aim by means of holding suitable events, such as lectures, and discussion meetings as well as the distribution of scientific publications.

The GMP seminar for API manufacturing took place on 18-19 March 2014, Sandton where a number of erudite speakers from FDA USA, the Dutch Health Care Inspectorate, The Netherlands, the European Commission, and members of PDA Europe gave presentations in this field.

Delegates to the course included members of national medicines Inspectorates and members from the Industry from South Africa, Korea and countries in Africa.

The Eucalyptus tree originated in Australia and now grows in a number of other countries.

The oil, which is mainly derived from the leaves by steam distillation and rectification, is almost colourless and has a strong camphoraceous odour and taste. The main content of the oil is cineole.

Eucalyptus oil has been used in many countries for centuries and is the ingredient of many preparations such as inhalants, vaporizers, ointments and lozenges. It is also used in the cosmetic and fragrance industry.

A number of studies and research articles have been published on the use of Eucalyptus oil and cover such conditions as fungal skin infections, wound antiseptics and dental and oral hygiene.

A study published in the journal “Clinical Microbiology & Infection (February 2006) found that the oil may have anti-bacterial effects on bacteria in the upper respiratory tract. The conclusion stated that the results of the study suggest that further studies to clarify the role of the oil in the treatment of respiratory tract infections are warranted.

The distillation unit in the museum was apparently hand-made and designed for use in South Africa and is the first plant used in this country to produce Eucalyptus Oil.
The conference theme is “Harnessing the power of pharmacy - expanding the cube”.

It will be interesting to find out what the organisers have in mind with this theme, but to whet our appetites a few of the presentation topics are;

**Employer, employee, locum - what are my rights and responsibilities?**
- Rights and responsibilities of the Responsible Pharmacist
- Rights and responsibilities of the employee pharmacist

**Our future in the hands of the young.**
*The challenge of communicating with the millennium generation.*

**Practising pharmacy in the era of digital communication.**
*Using social media to market yourself, your services and the profession*  
*Confidentiality in this day and age*

**The heart of pharmacy - caring for our patients.**
*Pharmacovigilance*  
*Reflections from a patient’s perspective*

In addition to this, the Annual General Meeting of the Society is scheduled to be held on Saturday afternoon the 6th May 2014 at which the usual reports will be presented and will include those by the President on behalf of the National Executive Committee and the Treasurer on the financial position of the Society.

In addition to this any Motions submitted by Branches or Sectors will be debated and discussed and if approved will become Resolutions that will require action by the NEC during the coming year.

Finally, after the unusual weather that we have experienced in Gauteng recently, let us hope for clement weather during this Conference - P.E. is a place where it can rain horizontally on occasion which can be most unpleasant and disruptive.
The theme for the 57th AGM and 28th Conference of 2014 was “Taking Stock”, reflecting on 20 years of democracy in South Africa and what has been achieved during this period in the Hospital and Institutional Pharmacists’ Sector. Also to identify what still needs to be done and to re-energize our efforts to provide a quality pharmaceutical service in hospital and institutional settings. The Conference was held from 6th to 9th March, again at the Champagne Sports Resort in the Central Drakensberg.

The platform was set for pharmacists to share knowledge and practical experience with their peers and to present their research and actual workplace findings. The conference also allowed for valuable networking opportunities with colleagues from around the country; with the trade representatives at their stands during lunch and tea breaks and at the social evening functions. This is a winning recipe that makes SAAHIP a “good” friend of the trade and to whom we are grateful in making the conference a possibility and success every year.

Southern Gauteng’s delegation

Of the 21 delegates from Southern Gauteng Branch, one was a podium presenter, and one presented three different posters; The Southern Gauteng Branch congratulates Delyne Subrayen for winning the poster presentation award that was given to her at the prestigious Aspen Pharmacare Gala function on Saturday evening, which rounds off the AGM and Conference.

Academic Programme

With 38 podium and poster presentations, all areas of hospital and institutional pharmacy were well represented and covered. Topics such as “Antibiotic stewardship”, “Role of a ward pharmacist”, “TTO counselling to promote and optimise patient medication compliance”, “Surgical antibiotic prophylaxis”, “Financial implications of poor compliance with Standard Treatment Guidelines for switching patients onto second-line antiretroviral therapy” were among the topics discussed.

Speakers

The proceedings were opened by motivational speaker, John Ingram, which ensured the perfect setting to inspire the delegates for the remainder of the conference! The President of the PSSA, Dr Johann Kruger also had the opportunity to address the SAAHIP delegates and it was an honour to have him as a guest during the conference. The workshop theme was “Taking Stock” and was chaired by Mr Bada Pharasi and Professor Andy Gray. The NDP (National Drug Policy for South Africa) was carefully scrutinised by the various branches to identify how far we have progressed on the various aspects set out in the document, and what still needs to be achieved. The Southern Gauteng Branch was tasked with evaluating and identifying shortcomings on registration/licensing of practitioners and premises. Informative feedback was given to the SAAHIP General Council by each branch chairperson, following the workshop sessions.

Another keynote address was made by the Registrar of the SA Pharmacy Council, followed by many questions and comments from the floor.

CPDs continue on a monthly basis at various branches, and the SAAHIP website is utilised to publish presentations and research. Shaun Zeelie from the Free State/Northern Cape branch has been tasked with the website as one of his focus areas.

...../continued on page 5
**Portfolio Reports/ Focus Areas for Southern Gauteng Branch**

(A) Training (“Become a Pharmaco-economic Expert,” and “CPD”)

Feedback was given with regard to the hospital pharmacy financial terminology document, which will soon be forwarded to the SAAHIP EXCO for further input, and then distributed to all SAAHIP members for final input before being published on the SAAHIP website; the second phase will involve guidelines on preparing budgets.

CPDs continue on a monthly basis at various branches, and the SAAHIP website is utilised to publish presentations and research. Shaun Zeelie from the Free State/Northern Cape branch has been tasked with the website as one of his focus areas.

B) Marketing and Recruitment.

Feedback was given by the Southern Gauteng Branch Chairperson, Pieter van der Merwe, on the development of a generic PowerPoint presentation that can in future be utilized by all branches at functions like the Community Service Pharmacist information sessions and Intern Exam Preparation sessions. The idea is to communicate the same message to all potential SAAHIP members. The content of the PowerPoint presentation includes benefits to members belonging to SAAHIP and the PSSA, the structure of SAAHIP, and Conference, to name a few. The final presentation is in place and ready to be distributed to the various branch chairpersons to utilize at the CSP information sessions planned for June/July 2014.

**AGM**

SAAHIP’s Executive Committee was re-elected for a second term:

**Elected office bearers:**

- President: Stephan Moller (NW)
- Vice President: Juane van der Merwe (KZN-I)
- Honorary Secretary: Liezl Fourie (SG)
- Honorary Treasurer: Sudira Balkrishen (KZN-I)
- Immediate past president: Thanushya Pillaye (SG)

It is an honor to see the leadership role that Southern Gauteng branch members play in the Presidential Committee.

The 58th AGM and 29th Annual Conference in 2015 will again be hosted by the two Kwa-Zulu Natal branches.

Pieter van der Merwe
SAAHIP Southern Gauteng Chairperson

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The premises that the Society’s Head Office has occupied for many years in Arcadia, Pretoria have been sold and our Head Office has been obliged to seek accommodation elsewhere.

At the beginning of March the Great Trek across town began and Head Office now occupies rented office space at 442 Roderick Road in Lynwood, Pretoria. This will be a temporary arrangement for a year or so until premises that have been purchased in the same area have been renovated to accommodate the requirements of the Society.

This type of move seldom goes without a hitch no matter how well they are planned and such was the case in this instance. Communication lines that were promised didn’t materialise on time, due to the excessive amount of rain we experienced at the time and this caused a measure of inconvenience to a number of members for which the Head Office team has apologised.

The new contact details for the PSSA Head Office are:

- Telephone: 012 470 9550
- Facsimile: 012470 9556
- e-mail: pssa@pharmail.co.za
- Website: www.pssa.org.za
During 2013 SAAPI embarked on a programme of hands-on training workshops.

Eight workshops were held and all of them were oversubscribed and judging from the feedback from the delegates, were very well received. The success of these workshops can be attributed to the excellent speakers that were willing to give their time to prepare and present the training courses.

Among the presenters were Dr Andre van Zyl who has extensive experience in the field of GMP and has served on the panel of experts of WHO and the WHO Expert Committee for Pharmaceutical Specifications and Preparations. He was also the Project Manager and Head of Inspectors, for the United Nations Prequalification of Medicine program.

Joy van Oudshoorn, presented training workshops on Biostudies. Joy is a well known pharmacist in Industry with wide-ranging experience in Regulatory Affairs and Pharmaceutical Product Development and is a member of the Pharmaceutical and Analytical Committee of the Medicines Control Council.

Leneri du Toit has 25 years experience in the Industry, 9 of which were spent working for the MCC. Leneri gave a number of courses with Esthi Beukes. They have experience in many different aspects of the Pharmaceutical Industry including regulatory affairs, pharmacovigilance and the position of Responsible Pharmacist.

The workshops ranged in scope from subjects for entry level pharmacists in Industry to topics for top level experienced pharmacists.

SAAPI continues with these hands-on workshops in 2014 commencing with a Workshop in February on “How to Prepare for MCC and SAPC Inspections”. As a result of the success of this event, it will be repeated in April 2014. Also in April Dr A van Zyl will be sharing his knowledge on GMP for HVAC and Pharmaceutical Water Systems.

The SAAPI Conference committee is working hard in preparing for their annual conference which is to be held on 22 and 23 May 2014 at the Sandton Conference Centre. The theme of the conference is “Pharmaceutical Industry Today - Managing Risk”.

A number of other workshops are being planned in order to assist SAAPI members to keep abreast with new developments in Industry and with meeting their CPD requirements.
CPD 18 February, 2014

Pharmacists who attended the CPD session on 18th February and requested copies of the slides presented on the subject of “Heart failure and the recently published guidelines” are kindly advised that the slides are not available. However, the link to the Heart failure guideline published in the SAMJ and referred to in the presentation is:-

SHORT COURSE IN INJECTION TECHNIQUE

During the 4th quarter of 2012 the Southern Gauteng Branch of the Pharmaceutical Society was approached by the Medunsa University Faculty of Pharmacy to establish the interest of pharmacists in this Branch in undertaking the above course offered by Medunsa. The names and contact details of those pharmacists who showed an interest were forwarded to Medunsa for further action. There were delays in their implementation of the course and no explanatory information until we received an apology and advice on 17th March, 2014 that “we have decided to withdraw this course for a number of reasons, including the availability of a more comprehensive offering”.

PSSA WEB ADDRESS

We regularly receive enquiries regarding positions available for Pharmacists and Pharmacists Assistants. This information is made available on the PSSA Nation website www: pssa.org.za. Click on “Classifieds” which will be found at the top right of the first window that opens.

CLINICAL CPD ATTENDANCE – 2013

During the 2013 calendar year 10 Clinical CPD sessions were held at the Southern Gauteng Branch. According to records from the Attendance Registers no fewer than six members attended all 10 sessions. They are:-

Mr WH de Vos, Miss M Moolla, Mrs HP Ringo, Mr NJ Rowe, Mr R Wong, and Miss YC Yuen.
A further nine members attended 9 of the sessions they are:-

Mr V Daya, MnR JH de Beer, Mrs MJ de Pontes, Mr P Goolam, Mr N Jugram, Mr E Kramer, Mr R Parshotam, Mev AS Schmidt, MnR JS Wienecke.

We commend our members on their regular attendance of CPD session. Certificates of Merit will be issued to these members.
The other day I attended the funeral of a man I’ve known for close to 20 years. He was a heavy drinker, despite his severe diabetes and he also loved chocolate cake. He was 58 years old. He left a note. His family is devastated.

The circumstances in which someone passes away plays a role in the way we experience a death and is likely to cause one to think about the circumstances relating to the person’s demise.

With suicide there is often a suicide note, or perhaps the victim confided in someone. An empty pill bottle could be the lead, or the presence of a substantial quantity of pill fragments in the stomach may be found, but sometimes people die of an accidental overdose - these things do happen and for the families concerned, this information is very important.

In the event of an accidental overdose the conclusion as to the cause of death may be more difficult. The person will not have left a suicide note and probably no one observed the death. There may be a pill bottle, but the number of pills and the reason they are missing may not be clear. No pill fragments or perhaps only a small quantity of pill fragments may be found. An autopsy shows no other cause, with no other explanation for death, except drug intoxication. Yes, they will search for a motive or a risk for suicide. The victim might have experienced a lot of stress or suffered from a depressive episode. That is perhaps why the person was taking an antidepressant. The pivotal finding is often the presence of a high concentration of a toxic medicine in bodily fluids and/or tissue. This high medicine level or even the death itself can be the result of a gradual accumulation of lethal concentrations of the toxic medicine as a result of a pharmacokinetically mediated medicine-to-medicine interaction.

We, as pharmacists may even be the accomplices due to an error or a possible oversight. We simply didn’t realise that we were signing a person’s death warrant by dispensing the script.

Years ago, when we didn’t understand the CYP-enzymes, we possibly had an excuse for this, but today, with the knowledge that is readily available, it would be inexcusable. In 1993, Garnier et al. reviewed 299 cases of overdoses of fluvoxamine. Acute fluvoxamine overdoses were found in 221 of these cases. They then focussed on the safety of fluvoxamine when taken in an acute overdose and pointed out that the acute toxicity attributable to fluvoxamine alone was rarely severe. They came to the conclusion that at doses below 1,000 mg, symptoms were benign. At doses above 1,500 mg, there were only a few instances of seizures which were easily manageable and did not cause significant patient morbidity. They noted that fluvoxamine was taken alone in only 20% of the cases. The patient ingested multiple other medicines in addition to the fluvoxamine in the vast majority of cases. It was found that multiple medicine ingestion in overdoses is not unique to fluvoxamine, but rather is the norm.

Medicine-to-medicine interactions could have contributed to the toxicity of one or more of 13 fatalities reviewed in those case series. In the early 90’s they did not have the abundance of knowledge we have today to link these deaths to medicine-to-medicine interactions, let alone prevent them from occurring. Let us consider a few of those examples of people with accidental deaths due to accidental overdoses which involved fluvoxamine as an example. Fluvoxamine is simply a good example to consider in accidental overdoses because it is a potent inhibitor of CYP1A2 and of CYP3A4 and also inhibits CYP 2C19 moderately. It is also a substrate of both CYP1A2 and CYP2D6.

We know that when a substantial CYP inhibitor (such as fluvoxamine) is co-administered with a medicine with a narrow therapeutic index whose clearance is dependent on the inhibited pathway for elimination, such an accidental overdose can occur because concentrations of the substrate may gradually build up until the patient suffers the fatal event, which may occur without warning (like an arrhythmia due to a TCA). If either the inhibitor or the substrate is an antidepressant they could find the motive or the risk for suicide.

There is the case of a 35-year-old female who died after taking fluvoxamine, astemizole, and prochlorperazine. This is an example where the plasma levels of a medicine with a risk of arrhythmias increased. This woman died of ventricular arrhythmia as fluvoxamine strongly inhibited the 3A4-metabolism of astemizole. The cause of death was an accidental overdose.

There is the case of the 36-year-old male who died after taking fluvoxamine, nitrazepam, and propoxyphene. They found the body of this patient 3 weeks after the presumed date of the overdose. This is a more complex medicine-to-medicine interaction. There is firstly a pharmacodynamic interaction between the benzodiazepine and narcotics that can cause respiratory depression. Secondly, there is the possibility of at least two pharmacokinetically mediated medicine-to-medicine interactions as both fluvoxamine and propoxyphene inhibit the CYP3A4-metabolism of nitrazepam, leading to the increased accumulation of nitrazepam. Nitrazepam would increase gradually in the body, due to decreased CYP-metabolism, and in the presence of propoxyphene could cause the patient to go into a coma and experience pulmonary arrest and death.
There is also the case of a 71-year-old female who died after taking fluvoxamine and thioridazine. Fluvoxamine inhibits the 2D6-metabolism of thioridazine. This lead to an increased risk of QT-prolongation. In the Complienz-software you are clearly warned of this risk and that it is contra-indicated to use any CYP2D6-inhibitor when taking thioridazine.

Then there is the case of the 80-year-old male who died after taking fluvoxamine and flunitrazepam. Here the concurrent use would lead to a slow clearance of flunitrazepam (3A4-substrate) and lead to the gradual accumulation of flunitrazepam in the system of this man which lead to coma and ultimately to his death.

Strong inhibition of a specific Cytochrome P450 enzyme probably plays the most important role when considering the reasons for accidental overdoses with these patients.

Inhibition interactions are known to be the cause of many accidental deaths.

Would you have suspected interactions when being presented with these items on a script? Would you have dispensed these combinations? We, as medical professionals, may be accomplices due to a mistake we make or an oversight, or perhaps because we are simply too busy to pay sufficient attention. We don’t even realise that we are signing a person’s death warrant by dispensing the script. Ignorance, however, is not an excuse. Not today, when so much technology is available to assist us in decision-making. Medicine reactions are ranked as between the 4th and 6th leading cause of death in the U.S. Very sad that so many unnecessary mistakes still occur despite available technology, especially since we are supposed to be the caretakers of medicine and that people trust us with their lives.

I wish to respond to the excellent lead article of the February 2014 Edition, not as criticism, but rather as an additional serious related aspect of the medicine shortages not addressed by the author.

The issue that I wish to address is the lack of information about the unobtainable items and the serious implications, particularly in the community pharmacy practice, but also in the private hospital dispensary setting.

In these pharmacies the shortages are often first discovered when re-ordering an item. The staff at the wholesaler might inform you that they too are out of stock of the item and when asked the reason they don’t know, nor are they aware, when it is expected to be back on the shelf and often say – erroneously - that this item has been “discontinued” by the manufacturer.

The clerk might offer to put you through to another department and if you find the right person there you might be told the reason for the shortage and perhaps – but not often – be informed about a possible date of availability.

So now it’s more time wasted contacting the manufacturer or distributor direct and trying to find the correct person to deal with your query. To be fair, there are some companies who take these matters seriously and send out fairly regular communications regarding their current shortages and expected date for a return to a normal supply situation. These companies are commended.

The underlying issue here is another major shortage – COMMUNICATION. The absence of such a vital component in any supply chain operation permeates all levels of pharmacy business. When a particular generic medicine is not available the only alternative is the original manufacturer’s product, usually much more costly and with its own adverse financial consequences when the medical scheme insists that it will pay only for the (cheapest) generic thus leaving the irate patient to carry a large co-payment - often unaffordable and even leading to missed or half doses being taken.

It should be a requirement for all suppliers responsible for the manufacture or import and/or distribution of any medicines to inform, at least, every community and private hospital pharmacy of shortages and dates of availability of the discontinuation of items, of change of colour, shape, taste, appearance, of pricing, of withdrawal due to batch problems, of package insert changes, and any other necessary information.

Concerned Pharmacist
The impact of bleeding in trauma patients

According to the WHO, trauma is a leading cause of death with an estimated 5.8 million people dying annually as a result of trauma. Of those patients reaching the hospital in time, approximately 400,000 die due to bleeding. In South Africa, around 4,245 annual deaths occur in hospitals due to bleeding from trauma.

Many trauma patients develop hyperfibrinolysis during the first hours of resuscitation. Hyperfibrinolysis describes a situation with markedly enhanced fibrinolytic activity, resulting in increased, sometimes catastrophic bleeding. Hyperfibrinolysis occurs particularly in patients with serious traumatic brain injuries, thoracic injuries or middle face fractures and is considered to be a direct consequence of the combination of tissue injury and shock.

Tranexamic acid inhibits fibrinolysis to prevent, stop or reduce unwanted bleeding such as menorrhagia. Its antifibrinolytic action could therefore make tranexamic acid a useful drug for the treatment of bleeding in trauma patients.

The evidence

The main evidence for the use of tranexamic acid in trauma patients came from the CRASH-2 study, a double-blind, randomised, and controlled trial in 20,211 adult trauma patients with or at risk of bleeding. Patients were treated with either placebo (0.9% sodium chloride) or 1 g tranexamic acid given IV as a loading dose followed by a further 1 g given as an infusion over 8 hours. Overall mortality as well as death from haemorrhage was lower in the tranexamic acid group than in the placebo group. A follow-up analysis of the CRASH-2 trial reported that if tranexamic acid was administered within one and three hours of injury, the risk of fatal bleeding was reduced by 32% and 21%, respectively. However, if tranexamic acid is administered more than 3 hours after injury, the risk of fatal bleeding is increased.

The possibilities

Ker et al used data from the CRASH-2 study, a systematic review and WHO mortality data to estimate the possible impact of tranexamic acid on preventing deaths due to bleeding in trauma patients. According to their results, approximately 128,000 of the 400,000 annual in-hospital trauma bleeding deaths worldwide may be prevented if tranexamic acid can be administered within one hour of injury. If tranexamic acid can be administered within 3 hours of injury, approximately 112,000 of these deaths could be avoided. In South Africa, that would relate to saving an estimated 1,359 lives of the 4,245 annual in-hospital deaths from bleeding. Even if only the most conservative estimates are considered, the administration of tranexamic acid as early as possible or within 3 hours of injury, suggests that tens of thousands of lives can be saved globally.

Conclusion

The ability of tranexamic acid to inhibit fibrinolysis makes it an ideal drug to treat significant bleeding in trauma patients. Since it is more beneficial to administer tranexamic acid as early as possible (preferably within one hour of injury), it would follow that severe bleeding in trauma patients should be treated before their arrival at the hospital. Although easy storage and administration of tranexamic acid makes it an attractive option to be considered for pre-hospital treatment, its use has not yet been studied in this setting.

5. Colwell C. Initial evaluation and management of shock in adult trauma. UpToDate
New Executive Director for CPS National

The Community Pharmacist Sector (CPS) of the Pharmaceutical Society of South Africa recently announced the appointment of Jan du Toit as Executive Director to strengthen strategy, marketing and operations.

He will be instrumental in ensuring CPS fulfils its mission and to create goals and objectives that will ensure its future success.

Jan du Toit has wide experience in various fields of the profession. He is an elected member of the SA Pharmacy Council for the period 2014 to 2018 and serves on the Education Committee, CII and Audit Committee of the SAPC.

He will join CPS in April.

Johan Bothma retired as Executive Director in order to focus more on his family at this time. CPS warmly welcomes Jan to this demanding position and wishes him much success with the task at hand.

STIRRING THE POT

The current general election hype, including all the political claptrap, transparency, non-transparency and so on, made me reflect and wonder about our own organisation with respect to keeping our membership informed about the many discussions that take place at Executive level, Branch and Sector committee level and indeed behind the scenes, - so-called quiet diplomacy.

The trouble with quiet diplomacy is that the vast majority haven’t a clue what’s going on - if anything at all. All too often one hears rumours and suggestions that all is not well with the politics and unity of our profession and worse still, that these problems remain unresolved for far too long to the inevitable disadvantage of the membership.

One also hears rumours of the formation of other specific interest groupings that are considering organising themselves that could become a threat to the PSSA in time. It is inevitable that, sooner than later, the confidential discussions that take place in committees and sub-committees will be “leaked” and then there will be questions asked of our elected and appointed representatives “What did you do about it?” and “Why didn’t you tell us?” etc.

Then one hears of representatives being told at meetings to “let go” of a subject as it is “being dealt with”, yet nothing actually appears to get done. One has to wonder - are some of the committees and meetings these days really pharmacy focused or are there perhaps second agendas being considered?

“Leave pharmacy politics to the politicians. We have enough work getting pharmacy back to where it should be.”

Our profession and our Society will always be bigger than the individuals or the committees that lead it. In addition the profession is made up of more than one or two interest groups and each Sector deserves and must receive the recognition that is due to it.
Responsible Pharmacists, with their busy work schedules, might not always keep up to date with legal requirements that should be regularly reviewed, and updated if necessary, and action taken to correct any deficiencies identified.

The South African Pharmacy Council publishes the “Good Pharmacy Practice in South Africa” (GPP) manual, in which the standards for quality pharmaceutical services are set out. The GPP is a prescribed reference.

While the manual encompasses numerous standards and requirements for the practice of pharmacy, Chapter 4: Professional Standards for Pharmacy Management, in which the management structures and responsibilities are clearly defined, and a sub-section – Ethical and Professional Standards – has a further sub-section titled “Standard Operating Procedures” (SOPs); these are a “set of instructions or steps which must be followed in order to complete a specific job or task safely, with no adverse impact on the environment, and in a way that maximizes operational and production requirements.”

The Responsible Pharmacist is responsible for involvement in the compilation of a set of SOPs, and its maintenance and implementation and availability in the pharmacy.

The SOPs must, among others, ensure: that personnel are provided with all the safety, health, environmental and operational information necessary to perform a job properly; that no failures occur that could harm anyone; that the relevant SOP can serve as a training document for pharmacy personnel; that it serves as a historical record of steps in an existing process; that it could serve as an instruction of actions to be taken so that they can be reviewed in an incident investigation.

The SOPs which are required to be in place are then detailed for the various types of pharmacy practice, i.e. community, hospital, institutional, wholesale and manufacturing. Many of these SOPs are common to all sectors, but some are more specific to their respective practices, and they should be accurately followed.

Many non-compliance matters are discovered during regular inspections of pharmaceutical facilities, and their reporting usually leads to further action by the investigative arm of the Council, sometimes of a minor nature, requiring some small adjustments to the offending practices, and a possible warning; in other instances however, more serious consequences, resulting in formal committee of investigation proceedings, can be the result, and either heavy fines or suspension from the register, or both, might be imposed, leading to closure of a facility and subsequent loss of income.

Even the most minor infringement of the requirements of legislated regulations and the SOPs, is not to be ignored or disregarded, and regular review and updating of SOPs is an essential exercise to be performed by Responsible Pharmacists, as is their implementation at all times – the avoidance of falling into the Council’s disciplinary net is a high priority – ask those who have found out the hard way!