Until a few years ago PSSA AGM and Conference were eagerly awaited annuals events. More recently, the costs of a three day conference and the attendant costs of travel, accommodation, etc. have seen this event only being held every second or third year. Added to this is the increasing difficulty of obtaining meaningful sponsorship to assist in offsetting these high costs.

However, this year the AGM and Conference is being held in Johannesburg at the Indaba Hotel and Conference Centre from the 6th to the 8th of July.

Apart from the important business that is necessary to conduct at any annual general meeting a varied and interesting programme over three days has been put together for the Conference. Members are encouraged to check the PSSA website for details of the topics as well as the presenters.

The theme this year is **Wild Water – Navigating the Next Wave**. No attempt, by any country, to introduce universal health coverage has ever been plain sailing and we can anticipate some wild waters that will require careful navigation here as well. The Conference will explore the various concepts of a national health scheme and the roles that pharmacists could play in the provision of healthcare in a system of universal access.

In addition, the South African Association of Community Pharmacists will present their 2nd National Symposium that will run in parallel on the Saturday - 8th July at the same venue.

All members of the Society are very welcome to attend these functions and once again details of registration etc. are available on the PSSA website at [www.pssa.org.za](http://www.pssa.org.za).

We encourage all members to make use of this opportunity to broaden their professional horizons and make the time to attend some or all of these sessions.

**The Pharmaceutical Society of South Africa** invites all pharmacists, pharmacist interns, pharmacist’s assistants and pharmacy students to the PSSA Conference 2017.

6-8 July 2017

Indaba Hotel, Spa and Conference Centre, Fourways, JHB

Conference theme: Wild Waters – Navigating The Next Wave

*Refer to the Preliminary Programme on the next page.*

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## Conference Programme

### Thursday 6 July 2017

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<td>Session 2: 11h30-13h00</td>
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<td>Session 3: 14h00-17h30</td>
<td>PSSA AGM</td>
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<td>Evening</td>
<td>Welcome cocktail function</td>
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### Friday 7 July 2017

<table>
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<tr>
<th>Session 4: 8h30-10h30</th>
<th><strong>PSSA Plenary: Navigating the next Wave</strong></th>
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<td><em>Minister of Health/Department of Health address</em></td>
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<td><em>Council of Medical Schemes (CMS) – the anticipated impact of the NHI on the CMS and legislation</em></td>
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<td>Session 5: 11h00-13h00</td>
<td><strong>SAAPI Plenary: Ethics and dispelling the myths around Industry</strong></td>
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<td><strong>APSSA</strong></td>
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<tr>
<td>Session 6: 14h00-17h00</td>
<td><strong>Universal Health Coverage (UHC) interactive session: The next phase – what does it mean for pharmacy?</strong></td>
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<td><strong>SAPSF</strong></td>
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<td>17h00-18h00</td>
<td><strong>APSSA AGM</strong></td>
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### Saturday 8 July 2017

<table>
<thead>
<tr>
<th>Session 7: 8h30-10h30</th>
<th><strong>SAACP Symposium: Value proposition – Marketing of community pharmacy</strong></th>
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<tbody>
<tr>
<td>Session 8: 11h00-13h00</td>
<td><strong>SAACP Symposium: Community pharmacy is more than just the sale of medicine</strong></td>
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<td>Session 9: 14h00-15h30</td>
<td><strong>SAACP Symposium: Navigating the next wave</strong></td>
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<td>Session 10: 16h00-17h00</td>
<td><strong>YPG Programme: Plenary wrap up</strong></td>
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</tbody>
</table>

### Gala dinner and award ceremony

**SAACP = South African Association of Community Pharmacists; SAPSF = South African Pharmaceutical Students Federation; APSSA = Academy of Pharmaceutical Sciences in South Africa; PSSA = Pharmaceutical Society of South Africa; SAAPI = South African Association of Pharmacists in Industry; YPG = Young Pharmacists’ Group**
The Executive Committee of the South African Association of Pharmacists in Industry (SAAPI) is pleased to announce the appointment of Ms. Tammy Maitland-Stuart as the Executive Director of SAAPI, effective 1st July 2017. We are excited that Ms. Maitland-Stuart will bring leadership, a wealth of experience and creativity to the programs of SAAPI. Tammy is a pharmacist and has been involved for nearly 10 years in regulatory affairs and in responsible pharmacist positions. Additionally, Tammy’s experience also includes areas such as medical devices, health care management and corporate pharmacy.

Tammy remarks: "I look forward to this exciting chapter of my career and to serving SAAPI, our members, the Pharmaceutical Society of South Africa and our SAAPI stakeholders to advance the Pharmaceutical Industry’s contribution to benefit health care delivery in South Africa. This sector is critical as it provides essential health care products and services to the population of South Africa."

SAAPI is an association of pharmacists and allied professionals who practice in the healthcare industry and it is a Sector of the Pharmaceutical Society of South Africa.

We welcome our new Executive Director and invite you to contact her at the SAAPI Offices from July.

Tel: +27 (0)11 442 3615 extension 316
Fax: +27 (0)11 442 3661
e-mail: saapi@pssasg.co.za

Prof Douglas Oliver
President: SAAPI

A proclamation has been released announcing the commencement of the Medicines and Related Substances Amendment Act 72 of 2008 (which in turn causes the Medicines and Related Substances Amendment Act 14 of 2015 to commence) with effect from 1 June 2017. A copy of GG40869 Proclamation 20 of 2017 is on file at the offices of the Southern Gauteng Branch of the Society.

This proclamation effectively (amongst other consequences for pharmacy) does the following, though I invite pharmacists who are involved in Regulatory issues to really get to grips with these significant changes;

- Triggers the implementation of the provisions in the two Amendment Acts which provide for SAHPRA (South African Health Products Regulatory Authority).
- Brings in new definitions
- Subjects IVDs and medical devices to the regulatory control frameworks of the MCC/SAHPRA.
- Applies the bonusing and sampling restrictions to IVDs and devices
- Applies the requirements for an enforceable code of practice to IVDs and devices (18C)
- Introduces a requirement for the licensing of manufacturers, wholesalers and distributors of IVDs and devices.
- Limits wholesale channels for transactions for devices and IVDs (as for medicines)
- Introduces a new appeal procedure
Following is a summary of the sections of the Medicines Act which are amended.

**MEDICINES AND RELATED SUBSTANCES AMENDMENT ACT 72 OF 2008**

*Date of commencement:* 1 June 2017 (Proc 20 in GG 40869 of 26 May 2017) (p4)  

**MEDICINES AND RELATED SUBSTANCES AMENDMENT ACT 14 OF 2015**

*Date of commencement:* immediately after the commencement of the Medicines and Related Substances Amendment Act 72 of 2008  
*Amends ss. 1, 2, 3, 14, 15, 16, 18, 19, 20, 22A, 22B, 22C, 22H, 28, 29, 30, 31, 35; inserts ss. 2A-I; repeals s. 4 and substitutes ss. 13, 18A & 36 and certain words in the Medicines and Related Substances Act 101 of 1965; and repeals s. 44 of the Medicines and Related Substances Amendment Act 72 of 2008

The regulations that are required in terms of these amendments have not yet been published but are expected soon.

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**SOUTH AFRICAN ASSOCIATION OF COMMUNITY PHARMACISTS**  
(SAACP)

**SUID-AFRIKAANSE VERENIGING VAN GEMEENSKAPSAPTEKERS**  
(SAVGA)

P O Box 95123 Grant Park, 2051, South Africa  
Community Pharmacy House,  
60 Fanny Avenue, Norwood, Johannesburg 2192

Posbus 95123, Grant Park, 2051, Suid Afrika  
Community Pharmacy House  
Fannylaan 60, Norwood, Johannesburg 2192

E-mail: execdir@saacp.co.za  
Tel : +27 (11) 728-6668  
Fax: 086 274 0852

**Southern Gauteng Branch**  
(Representing the Community Pharmacy Sector of the PSSA)

B110/5/17  
17 May 2017

Dear Colleagues,

**PASSING OF PEP MANOLAS**

The 16th May 2017 was a very difficult and sad day for all of us, due to the passing of one of the great leaders in the Pharmacy profession, our own Honorary Secretary, a passionate member of SAACP SG branch, and the profession as a whole – Pep Manolas.

We will surely miss the contributions he committed himself to provide to the SAACP SG Branch as well as the National body.

To me, Pep Manolas was like a father, mentor, teacher and all the good things that I can mention about this stalwart of the Association and the Pharmacy from whom we learnt so much

With these few words, I would like to say with sadness that Pep is with us no more and it is up to us who are left behind, to continue the advocacy of the pharmacy profession the way he would have wanted it to be.

May his soul rest in peace.

Tshif Rabali  
Chairman  
South African Association of Community Pharmacists (SAACP)  
Southern Gauteng Branch
Hercules Gregory Manolas, known to all as Pep, sadly passed away suddenly on May 16. “My Greek brother” and I had been friends for over 60 years in fact our late parents knew one another in our home town of Germiston since the nineteen thirties. Mr. Manolas Snr referred to my Dad as Joffe, never by his first name, and this trait was continued by Pep over the years so I was simply Joffe.

It is not my intention here to mention Pep’s many achievements within organised pharmacy’s many committees at both Branch and National level as I am sure that this will be written about by those with whom he served for so many decades. Suffice it to say that South African Pharmacy, particularly community pharmacy, has lost a colleague, a friend and a tireless worker who served in various capacities in the interests of our profession.

Approximately three months ago during a telephonic discussion I openly asked Pep when he was going to give up his many involvements within the profession. His answer summed up his love of the profession and the man when he said “Joffe the Association is my life and I will never cease in our attempts to achieve our ultimate aims and objectives”.

During my long association with Pep we laughed, we cried, we agreed with one another and yes we actually had occasions where we vehemently disagreed with one another. The latter came to a head just prior to my departure for Australia and it took some time for the wounds to heal. Pep at times could be a very temperamental person as I’m sure that many can attest to but one had to understand exactly what made him tick. What do we find behind this façade?

We find a man passionate about his family, a man who deeply loved his profession, a man who loved his country and a man who loved his clients who had remained so loyal to him over many years. During my lifetime Pep and I enjoyed much happiness together at functions such as family weddings, birthdays, anniversaries, christenings etc and unfortunately we also tasted of the cup of bitterness at many a family funeral.

Conferences and meetings may not be the same without the presence of Pep Manolas but it must be remembered that this man successfully laid many a foundation for others to follow and continue in his footsteps.

My heartfelt condolences are extended to the entire Manolas family particularly to Pep’s sons Viron and Jason whose christenings many years ago I remember clearly.

MAY HIS DEAR SOUL REST IN PEACE

---

**Professional Indemnity Insurance**

You should be aware that pharmacists in all spheres of Practice require Personal Indemnity Insurance.

Not to have it is simply not an option – it is a requirement of The SA Pharmacy Council.

You should also be aware that the PSSA offers its members access to the essential cover at very competitive rates through the Professional Provident Society

For further details please contact; Tersea at PSSA Head Office on 012 470 9558

*How easy is that? The PSSA – pharmacy in action!*
Pharmacists were trained in Secundum Artem at technical colleges during the first half of the 20th century and up to the 1960s / 1970s. In the latter part of the century the responsibility for the training of pharmacists was gradually transferred to selected universities. Pharmacists traditionally used their skills to prepare various dosage forms of medication such as pills, powders, pessaries, suppositories, creams, pastes, ointments, suspensions, nose and eye drops, as examples. These were either extemporaneous preparations or were the result of dispensing a doctor’s prescription. At the time the control and supply of medicines was different when compared with the legislation of today – the restrictions on medicines were categorised into Poisons, Potentially Harmful Drugs (PHDs) and Habit Forming Drugs (HFDs).

Up until this time various foreign pharmaceutical manufacturers had established distribution facilities in South Africa, supplying their products through pharmaceutical wholesalers to pharmacies throughout the country. From the late 1940s more and more pharmaceutical manufacturers established themselves as importers and distributors of medicines or established local manufacturing plants. Some of these entities exported their products to countries north of South Africa and to Asia, Australia and New Zealand. The advent of these “ethical” medicines that had been researched and developed by pharmaceutical manufacturers around the world resulted in a gradual reduction in the preparation of extemporaneous and prescription medicines by pharmacists in community and hospital pharmacies.

In 1965 the Medicines Control Act 101 was introduced and Mr Nicola van der Merwe, a pharmacist, was appointed as Registrar of the Medicines Control Council.

Subsequently the categorisation of medicines was changed to a set of different schedules and the change defined the limitations on the free sale of the various products that were included in these different schedules.

The Pharmacy Act 53 of 1974 was gazetted and implemented, making provision for the registration of pharmacies and regulated their practice by setting scopes of practice, training standards and implementing disciplinary procedures.

Pharmacists in Community Pharmacy practice in the 70s and 80s were able to recommend certain schedule 3 products to clients, in addition to products in lower schedules and non-scheduled products. Pharmacists at that time were not permitted to touch a patient or to make a diagnosis – they could respond to the patient’s description of symptoms. Pharmacists Assisted Therapy (PAT) was introduced and was promoted to medical schemes to enable pharmacists to claim from the schemes for the treatment of their members. This dispensation was limited to the treatment of self-limiting ailments and in most cases the benefit was capped at R50 per patient per treatment.

It was in 1990, in Canada, that Dr Linda Strand and Dr Hepler introduced the concept of Pharmaceutical Care, in which the pharmacist develops a professional relationship with the patient and takes over the management of the patient’s medicine needs and treatment outcomes by implementing a pharmaceutical plan. The focus of the pharmacist shifted from medicine to a focus on patient care; an involvement with treatment assessments and definite treatment outcomes.

In the 1990s there was a drive to train community pharmacists to complete a course in Family Planning at some universities, after successful completion of which they were granted a Family Planning 22a12 permit by the Department of Health. In addition the MCC was motivated, during that time, to grant a 22a15 permit to pharmacists who had successfully completed a course in Primary Care Drug Therapy (PCDT). This permit would enable these pharmacists to diagnose and treat patients using an essential list of medicines and treatment guidelines at a primary healthcare level. At the time 69 pharmacists were granted 22a15 permits. A further development of the concept lead to community pharmacists establishing clinic facilities in their pharmacies and employing qualified nursing sisters. The concept of a pharmacist working in association with a registered nursing sister was promoted to provide healthcare screening and monitoring services.
The SA Pharmacy Council (SAPC) set out principles and criteria for a pharmacist's participation in group practice and managed care delivery system in their 1991/2 report.

A PCDT pharmacist intending to set up practice in an area should inform the patient community and the medical and supplementary health services in that area of the intended service offering. After a PCDT pharmacist has taken and recorded a patient history, a comprehensive examination of the patient is required and has also to check for various prescribed conditions.

Referral of a patient is made to a medical practitioner or other relevant supplementary health care worker by way of a formal referral letter from the PCDT pharmacist, when considered necessary.

The pharmacist makes a final diagnosis and initiates treatment after doing a SOAP analysis (Subjective symptoms and signs, Objective symptoms and signs, Analysis of symptoms and signs and the development of a Pharmaceutical plan.)

Conclusion:
A pharmacist who has successfully completed the PCDT course and registered with the SA Pharmacy Council must apply to the Director General of Health in the prescribed manner for a 22a15 permit. A PCDT pharmacist with a permit is well positioned to play an important role in providing cost effective primary health care services and becoming involved in the National Drug Insurance programme. Currently 300 pharmacists have successfully qualified and registered with the SAPC as PCDT pharmacists and the benefit to the patient community in their immediate areas cannot be under estimated.

The role of the pharmacist in Community Practice has expanded over time and is progressively being integrated into providing essential Primary Health Care Services.

Change of name of National Association of Pharmaceutical Manufacturers (NAPM)
At a recent function Mr Vivian Fritelli, CEO of NAPM announced the change in name of the NAPM to Generic and Biosimilar Medicine SA. Emphasis behind the name change was given as the recent patent expiry of many biological medicines and the cost burden of healthcare involving especially non-communicable diseases (NCDs).

The PSSA Book Department
Do you know that the Book Department has a range of essential publications for pharmacists at preferential prices for members of the PSSA?

From overseas publications such as Martindale, the Merck Manual and the Oxford Concise Medical Dictionary to local publications such as Good Pharmacy Practice, the Scheduled Substance Register, Drug wise and many more.

Ordering is as simple as 1, 2, 3.

2. Complete the Order Form and submit it.
3. Make payment via EFT or credit card.

or contact Dinette at PSSA Head Office on 012 470 9559 - How easy is that?

The PSSA – pharmacy in action!
The Golden Mortar
PSSA S. Gauteng Branch.
Johannesburg.

Re. Pharmacy assistants and the PSSA and SAPC

I am writing this letter, not to complain or evoke any negativity, merely to state some facts and my opinion on our country’s pharmaceutical profession.

Being a Qualified Post Basic Pharmacist Assistant (QPBPA), I am required to be registered with the South African Pharmacy Council of South Africa (SAPC) that in turn regulates all things relating to the pharmaceutical profession. This is supposed to be a positive element, introduced by South African law.

Being registered with the SAPC, I started asking a few questions, like: Who exactly is looking out for my interests? Who is making sure that everyone in the profession is treated and governed fairly? I initially thought that surely the SAPC and PSSA would have an equal or peer in their ranks to assist with the governing of “assistants”. To my dismay, I found that this was not the case.

I have had discussions with previous leaders of the SAPC and the PSSA to find out why there has not been such an individual appointed to look after the interests of “assistants” before and was told that such a request has not been made from an assistant yet.

Personally, I believe that in a country such as ours, set in its values of fairness and equality, this is alarming. I also feel that its governing bodies, in conducting their affairs, should retain these values. By allowing “assistants” to actively take part in the guidance and decision making of their profession, not only will fairness and equality be achieved, but greatness and much needed evolution will be achieved.

In some of my discussions with pharmacists and other assistants that have been in the industry for more than 20 years, a few concerns have come to the fore: Not all QPBPA’s have equal knowledge of the industry they are in and this is true for me. I feel that the assistant’s course has been downgraded over the past few years and obtaining the qualification has become too easy. The information contained in the course is inadequate for the needs of the assistants, pharmacists and pharmacies. I believe that an in-depth look at the course and more discussion on the topic from both the pharmacist and the assistants’ side is needed.

In my discussion with Mr. Gary Kohn, I came across a future possibility that, if addressed and implemented could change the pharmaceutical profession in leaps and bounds. This would be the introduction of a bridging and separate course for pharmacist’s assistants to obtain a B. Pharm degree on a part-time basis.

In conclusion, I personally think that representation by QPBPA is needed on the governing bodies, not only for the benefit of assistants, but for the benefit and improvement of the whole profession.

Sincerely
Anton Pieterse

Pharmacist Saves Lives

We note from a report in the Roodepoort Herald of 26 May that Hendrick van Rooyen recently donated his hundredth litre of blood. Hendrick is a member of SAAHIP. The Golden Mortar congratulates him on his achievement. It is reported that Hendrick started donating blood from the age of 16 years and claims that he was following in his father’s footsteps who had donated 127 times, until he was no longer able to do so – outstanding achievements. Hendrick plans to continue donating blood until he is also not able to do so.

While World Blood Donor Day is 14th June, 2017 it is not necessary to wait until then to donate blood and help save lives.
To the Editor, Golden Mortar

The PSSA has always been an organisation that has allowed free debate on challenges that face the profession from time to time. They then decide on a plan of action. This right is incorporated in the constitution and has been a tradition since the formation of the PSSA, in the forties.

This freedom to debate and to decide by accepting a resolution has formed the essence of the profession. Through the years the profession has faced many threats, some examples are the threat of the supermarkets in the sixties, the dispensing doctors and in the eighties the contractual discounting of fees to medical schemes, ownership of pharmacies, dispensing fees in the nineties, the PSSA constitution and policy matters. Recognition and awards are also presented in a motion for acceptance by the AGM.

The rules of debate require that there must be a mover and a seconder, to allow debate and this has preference over any loose and aimless discussion which does not end with a conclusion.

The constitution requires that the motion presented must have the relevant support of the branch or sector. It must also be forwarded timeously to the PSSA National Office, in the prescribed manner, before being distributed to the councillors who will attend the AGM.

Motions addressing similar issues cannot be tabled until the required time period of three years has lapsed. Motions that are in conflict with the constitution will not be allowed. The presidential committee has to scrutinise the motions before distribution.

Presentation of the motions at the AGM provides the councillors the opportunity to debate, change, withdraw, combine, agree or disagree with the motion. The president, in chairing the meeting has to keep discussion to the point, allowing discussion by councillors who support or disagree with the motion and to direct the discussion to come to a final resolution.

The counsellors vote on the motion resulting in acceptance or defeat, if accepted the motion becomes a resolution. During the last few years the format of the AGM has changed and there has been a tendency not to give full opportunity to debating motions. The principle has been adopted where the issues and threats are seen as ongoing matters and should thus be handled and dealt with by the Executive Director as part of his duties and functions.

Notwithstanding the above the input by councillors forms an integral part of member participation and allows for the expression of their opinions. There is currently an unhappiness in the profession with various unresolved and frustrating issues which threaten their viability and their very existence.

The constitution makes provision for the Presidential Committee and the NEC to act as caretakers between AGMs and to implement and act on resolutions and recommendations and to report back at the next AGM.

With the relaunch of the Association of Community Pharmacists the motions serving at its forthcoming AGM in July has relevance to future direction and policy of the Association. Councillors should give their input and decide on issues and policy.

Gary Kohn, FPS

———

THE MANAGEMENT OF DRUG RESISTANT TUBERCULOSIS

Attention of Pharmacists is drawn to those who are, or may be involved in the future in the treatment of TB patients we refer you to The PSSA website (pssa.org.za) and specifically to “News and Events”. Here you will find the TB Treatment Guidelines for SA as well as a Policy Framework titled INTRODUCTION OF NEW DRUGS AND DRUG REGIMENS FOR THE MANAGEMENT OF DRUG RESISTANT TUBERCULOSIS IN SOUTH AFRICA: POLICY FRAMEWORK Version 1.1: June 2015.
To the Editor,
Golden Mortar,

I am told that a decision has been taken by our National Executive Committee to limit our South African Pharmaceutical Journal to 6 issues a year.

Having been a reader of the Journal for many years, one of the highlights of being a member!

It has always given me a welcome feeling of communication, not only with the National Executive, but also with my colleagues.

Looking back over the ideas in the Journal which motivated pharmacists, and even mobilized action, whenever necessary, I wonder how we are now going to be kept informed about the huge changes we are about to face with the advent of the next phase of NHI and all that will be required from us to be involved.

I have for a number of years been “elected” by my branch to be a Councillor for the Branch to attend the Annual AGM and conference. This has also been a highlight for communication and interchange of ideas with colleagues from all over the country. Now I have been asked to sign a proxy and let our chairman carry all our votes. Nothing for the Councillors.

So, only 6 journals, no contact with Councillors, no interaction with colleagues!!.

IN THIS DAY AND AGE WHEN GOVERNMENTS ARE TOPPLED BY MEANS OF MASS COMMUNICATION!

What do my fellow colleagues have to say about this? Please give your comments to the Editor.

A loyal PSSA member.

Concerned Pharmacist

The Reference Library has proven over the years to be a valuable reference resource for pharmacists, members of the Pharma Industry and Universities undertaking various projects.

Recently the library was presented with the following published books:

**Early Pharmacy Teaching in Port Elizabeth**
The story of the Diploma in Pharmacy
By Professor Peter Loyson, NMMU Chemistry Department.

The book tells the story of pharmacy education in the Port Elizabeth Technical College, Chemistry Department from 1928 till the end of 1982. In 1983 the first students registered at the University of Port Elizabeth for the degree course and post graduate studies.

Professor Loyson acknowledges the assistance he received from our library, especially in tracing the contribution of Chris Price to pharmacy education at the Technical College and the University.

**Antimicrobial Stewardship**
Published by the Oxford University Press, 2016
Edited by Matthew Laundy, Mark Gilchrist, and Laura Whitney.

This book was presented by Mr. Laundy, the father of Matthew Laundy who explained that Matthew obtained his B.Pharm. and MB BCh. at the University of the Witwatersrand and went on to obtain his FRCPath at Oxford. He is currently a consultant in Medical Microbiology and the Clinical Lead for Antimicrobial Stewardship. He is a Senior Lecturer, at the Institute for Infection Control and Immunity, St George’s University of London.

To access books in the Reference Library
Pharmacists are welcome to study the books in the library or alternatively to take out a book for a two week period.

Contact:-Ray Pogir at e-mail raypogir@pssasg.co.za
Introduction

Overactive bladder (OAB) is a common condition affecting people worldwide, especially the elderly population. The condition is characterised by urgency and frequency of urination. Urgency of urination is defined as the sudden need to urinate and frequency is having to urinate more than eight times in 24 hours. In some cases, urge incontinence (urine leakage) may occur with OAB. The prevalence of OAB increases with age and its symptoms can significantly affect the quality of life of patients.

Although the initial management of OAB involves bladder training, fluid management and in some cases, weight loss, drug therapy is often needed when patients fail to respond to non-drug interventions. For many years, anticholinergic medications such as oxybutynin and tolterodine have been the mainstay for treating OAB. While these agents have been used successfully, cognitive dysfunction has been a concerning side effect, particularly in the elderly population. Although ongoing assessments are needed, studies have also shown that anticholinergic agents may be linked to increased mortality and cardiovascular risk.

Further understanding of the pathophysiology of OAB has led to drug development targeting the beta-adrenoceptors. Mirabegron is the first beta3-receptor agonist (bladder muscle relaxant) to be approved for the treatment of OAB and represents an alternate treatment option for patients.

Mirabegron

Composition and Indication

Betmiga® is available as 25 mg or 50 mg tablets containing the active ingredient, mirabegron. It is indicated for the symptomatic treatment of urgency, increased urinary frequency and/or urgency incontinence in adult patients with overactive bladder syndrome.

Dosage and administration

<table>
<thead>
<tr>
<th>Recommended dose (adults and elderly)</th>
<th>50 mg once daily</th>
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<tbody>
<tr>
<td>Administration</td>
<td>The tablet is to be taken once a day, with liquids, swallowed whole and should not be chewed, divided, or crushed.</td>
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</tbody>
</table>
Who should not use it?

Patients with the following conditions should not receive Betmiga®:

- allergy to any of the active ingredients or excipients of Betmiga®
- severe end-stage renal impairment with eGFR < 15 ml/min/1.73m²
- severe uncontrolled hypertension (systolic blood pressure ≥180 mm Hg and/or diastolic blood pressure ≥110 mm Hg)
- severe hepatic impairment (Child-Pugh Class C).

Key information

- Mirabegron appears to be well tolerated, with a lower incidence of dry mouth, constipation, and blurred vision than the anticholinergic agents?
- Mirabegron has little or no effect on:
  - Contraceptive pill
  - Warfarin
  - Metformin
  - Digoxin
- Use with caution in patients with congenital or acquired QT prolongation
- Due to a lack of safety information, mirabegron should not be used in pregnant or breastfeeding patients.
- Mirabegron may cause elevation in blood pressure and if patients experience sudden, migraine-like headaches, they should be referred to the doctor as these may be signs of increase in blood pressure.
- Common side effects which may affect up to 1 in 10 people include:
  - Tachycardia
  - Urinary tract infections
  - Nausea
  - Constipation
  - Headache
  - Diarrhoea
  - Dizziness
- Mirabegron is metabolised through the cytochrome P450 pathway, therefore caution should be exercised when using concomitant medication also metabolised via this pathway.

Betmiga® tablets, have been available in South Africa from March 2017.

References

In the early 1600’s doctors and pharmacists (then known as apothecaries) realised that grocers and herbalists in England were growing in numbers, importing and selling medicinal plants and herbs to the general public. There were no standards for identifying classifying, or establishing the efficacy of what was being sold. The result was that a number of professional bodies started publishing reference books of standards for the identification and preparation of medicines.

The first reference to establish legal control of the standards of medicines and compounds by a competent authority is in the Medical Act, Great Britain, of 1858, section 54. This granted the General Council of Medical Education and Registration in the UK (The General Council) the exclusive right to publish a book, to be called “The British Pharmacopoeia” (BP) containing the list of medicines, and compounds together with true weights, measures, methods by which they were to be prepared, and other matters relating thereto. A subsequent Act in 1862 (THE ACT) states that the BP shall supersede the Pharmacopoeia’s of Scotland, and Ireland and others. This then had the effect of establishing the BP, as the one official reference for all medicines prescribed and prepared throughout the UK.

It is interesting to note that The General Council had members who were appointed by the Apothecaries’ Society of London and the Apothecaries’ Hall of Ireland amongst the other appointments who were mainly from the universities with medical faculties.

In the library we have a London Pharmacopoeia dated 1834, 183 years ago, which predates the 1862 Act by 28 years. The first BP to be published under the authority of THE ACT was published in 1864 and caused great dissatisfaction amongst the practitioners of that time. They were unhappy about the various formulations and other descriptions of the entries. The next BP of 1867 was the result of a complete revision and was accepted by practitioners as the accepted standard.

The 1834 London Pharmacopoeia in the photograph has 197 pages, the 1898 BP has 445 pages and the current BP consists of 6 volumes with some 3000 monographs. An illustration of how pharmaceutical science has grown over the years.