The Golden Mortar

Newsletter of the Southern Gauteng Branch of the Pharmaceutical Society of South Africa and associated Sectors.

Edition 3/May 2016

SAAPI Conference 2016

Report by Val Beaumont, - Southern Gauteng Branch/SAAPI

SAAPI conference 2016 was held on the 13th and 14th of April at the CSIR in Pretoria. The conference theme, "Success through Synergy", embraced topics related to National Health Insurance, registration of medical devices, IVDs and complementary medicines, pharmacovigilance, medicine registration harmonisation and a host of subjects reflecting the speciality subjects of medicine registration and clinical research.

Some key points arising from the opening address

Mr Ivan Kotzé

The opening address was presented by the Executive Director of the Pharmaceutical Society of SA (PSSA), Ivan Kotzé. He highlighted challenges which the proposed National Health Insurance (NHI) model will present in the supply of medicines in the public and private sectors and some of the shifts that may be experienced. Mr Kotzé noted in particular that one could anticipate a shift from the dispensing of chronic medicines to the collection of medicines by patients at pickup points, where the medicines will be dispensed at a central chronic medicine dispensing unit and distributed through a system of pickup points such as schools, churches and contracted community pharmacies. This system focusses on the supply of medicines only thereby missing the opportunity to make greater use of community pharmacies in ensuring the correct utilisation of medicines.

While the NHI white paper does give limited detail on how pharmaceutical services will work, there is a lack of information for pharmacists and perhaps there are more questions than answers. He sees the pharmacy sector as having all the ingredients needed to support an NHI environment and called for cooperation between the profession and the Department of Health.

He embraced the inclusion of a session in the meeting, on complementary medicines, and expressed his concern over the lack of regulatory control of this group of products, many of which fall into the definition of medicines and should be properly controlled in terms of the Medicines and Related Substances Act (Act 101).

..../continued on page 2

INDEX	PAGE

He alluded to the WHO traditional medicines strategy which has been put in place in some countries to support and strengthen the use of traditional medicines. He called for increased regulation of products, practitioners and processes in the complementary medicine field.

Harmonisation of regulatory requirements globally, throughout Africa and within the Southern African Development Community (SADC) is receiving increased attention and he reported on a concurrent meeting where the harmonisation and review of medicines labelling and GMP practices in SADC were being reviewed.

He drew the attention of the audience to provisions in the amended "Act 101" with respect to dispensing licenses for Allied Health Care practitioners and Veterinarians. These changes to section 22C(a) imply that these two groups of professionals will need in future to obtain dispensing licenses and will need to comply with requirements for dispensing fees for licenced providers. The requirements of the single exit price legislation will also have to apply.

National Health Insurance (NHI) – Dr Anban Pillay
Dr Anban Pillay, Deputy Director General of the Department of Health, gave an excellent presentation on "the road ahead" for NHI and not only reviewed the bigger picture but paid specific attention to pharmaceutical issues and the role of the pharmacist and the provision of medicines in an NHI environment.

The objective of the NHI initiative is to ensure that all South Africans have access to quality health care irrespective of social-economic means. It is intended that health services are delivered equitably and that the population does not pay for accessing health services at the point of use. Further, it aims to provide the population with financial risk protection against catastrophic health expenditure. It is important to note that the NHI is not a medical scheme but a funding mechanism that is aimed at consolidating funding resources to ensure equity.

<u>The NHI Fund and a single funding environment:</u>
The NHI is a financing mechanism that also attempts to change the way healthcare services are delivered. An NHI fund will be established, independently of the Department of Health, to manage the financial arrangements of National Health Insurance, including revenue collection, risk pooling and strategic purchasing.

The framework envisaged for NHI is that the South African Revenue Services (SARS) will collect funds from taxes and special levies. It is intended that individuals will not pay more for healthcare than they are paying at present and the grounding principles of the scheme will be based on social solidarity. Procurement of healthcare services will be managed through a central fund created through the pooling of resources into a single fund for the strategic purchasing of healthcare services. This risk pooling will ensure that the financial risk associated with health expenditure is borne by all members of the population rather than by individual contributors. The strategic purchasing will involve the allocation of resources to healthcare delivery for the entire population and will involve the setting of incentives for providers to deliver high quality services at reasonable cost.

Dr Pillay recognised that the public health care environment required substantial reform before the NHI dream would be realised. He noted also that the South African initiative to create universal access to healthcare preceded the UN position of universal health care as a human right. NHI is about creating universal access to quality health care.

In his overview of the NHI, Dr Pillay emphasised the need to integrate the provision of health care into a single system, and to move away from the notion of a public and private sector for the provision of health care. In the proposed NHI system, patients will be able to obtain healthcare from either public providers or private providers to the fund, underpinned by the principal that they are funded from the NHI fund and this would follow the patient. There will no longer be a clear distinction between the public and the private sectors and practitioners in each sector will compete with each other for quality of service.

Health care providers, including pharmacists supplying services in an NHI environment would be dependent on the fund to procure their services on behalf of a particular community, but the pharmacists themselves would not be employed by government. Further, the fund will not be responsible for costs of managing the business or reimbursing professional services on a fee for service basis but will rather contract for the delivery of specific services, probably through a capitation fee which will also include the cost of consumables.

<u>Purchasing private health care services:</u>
A primary objective of the NHI will be to assess population needs for health services and ensure the availability of those services. Providers will be identified that deliver efficient accessible high quality health care and their performance incentivised on efficiency and quality. These will need to be accredited and specifically contracted. Gatekeeping of the services delivered at primary, secondary and tertiary levels will be implemented. Key resources will be procured centrally.

…./continued on page 3

Incentivisation mechanisms that are being explored include salaries, capitation programs at primary health care level and Diagnosis – Related Group classification for payments for hospital care.

The pharmaceutical supply chain will change in nature with the introduction, centrally, of an efficient procurement system. This will include an Office of Health Products Procurement known as OHPP, which will be responsible for vendor and contract management and payment. The OHPP will also have oversight over tertiary services, donations, risk management, financial management, high cost devices and equipment and selection and product list.

The Price Determination, Economic Evaluation and High Technology Assessment (HTA) unit will be responsible for the determination of a national framework to inform mechanisms for purchasing healthcare services. This unit will determine capitation rates for primary health care services and the level at which the Diagnosis Related Groups (DRGs) will be reimbursed in hospitals. It will also determine the prices of health products in the Essential Drug List (EDL) and apply various strategies to obtain fair prices, access to innovation and a secure supply of medicines. A Technical Assistance team will provide advice on goods that should be on the National Product Catalogue (NPC) at each level (primary to tertiary), prioritise products on the national product catalogue and manage prices and negotiations. Health technology assessment, price determination and economic evaluation will be important to the decision-making processes.

The founding blocks for NHI will be the registration of the population per community. This will involve a declaration of health conditions, and assessment of the burden of disease of the community and take account of disease prevalence and preventative measures needed. It will also involve the mapping out of current providers to each community, and their health care provision capacity. The intention is that healthcare services needed by a community will be free at the level of patient care.

Pharmacists offering services to an NHI environment will establish and manage their own practice but will charge the NHI fund for the services that they deliver. The NHI fund will incentivise providers using an outcomes-based approach to drive performance management. By way of example, Dr Pillay explained that a healthcare provider will not be reimbursed for multiple patient visits where the patient's treatment outcomes are not positive. Patients will be discouraged from going directly to specialists and the core of the NHI will be a primary care approach.

Dr Pillay highlighted certain risks associated with the procurement of medicines, including:

- Selection - making assumptions about the practice environment and prices that will be realised in a competitive environment
- Quality - expiry of stock, the need for accurate forecasting, good wholesaling practice and appropriate procurement deadlines.
- Volume forecasts - to avoid the pitfalls of the tender system
- Competition - unknown dynamics.

<u>Certification and contracting of providers</u>

The Office of Health Standards Compliance (OHSC) is another important link to the NHI fund. This office is responsible for certification and contracting of service providers to the fund and specific criteria will be applied in licensing providers. These include:

- licensing by statutory councils,
- certification by the OHSC,
- range of services offered at each level of care,
- human capital,
- adherence to treatment protocol and guidelines and the NHIF formulary,
- initiating care at the primary care level and
- adherence to referral pathways
- submission of information for performance monitoring
- adherence to pricing policies.

<u>Medicines specifics;</u>

Medicines, in the NHI environment, will be procured at a central level and the tender system is likely to fall away. Decentralised ordering of medicines at facility level will be controlled and limited and the fund will pay a price for a medicine which has been negotiated with the manufacturer. The intention is to keep as many manufacturers as possible supplying medicines to the NHI fund and moving away from the tender system where only contracted manufacturers can participate in the market, a strategy which mitigates against the competitive pharmaceutical market.

With respect to access to medicines, Dr Pillay described an environment where patients would have access to a mix of medicines although the benefit packages had not yet been described. Pharmacoeconomics assessments will inform the choice of medicines and a unit similar to the UK NICE units will be established. There is currently an agreement in place for the sharing of know-how on setting up a NICE-like unit (UK) in SA. The NHI structures will independently assess the value of Health Technology (HTA).

…./continued on page 4

The National Health Insurance fund will be an independent body and it is anticipated it will have a range of units and will attract skills from the medical schemes environments.

An important question for the pharmaceutical sector, both manufacturers and pharmacist healthcare providers, is the question of which drugs will be available, how this will be regulated, and what the impact on manufacturers will be of products that are not included in the central procurement process. In this respect Dr Pillay reported that the NHI would identify diseases that would be reimbursed by the NHI fund and the drugs that would be used in the treatment protocols for treating these diseases. Selection of drugs will follow an evidence-based approach following WHO principles and be open to public debate. Selection would take account also of the quality, the volume and competition in the market and will be governed by the Office of Health Products Procurement (OHPP). The NHI fund will do its own inspections and audits. A drug not on the selection list will not be funded by the NHI but, if a company wishes to sell this product and it is registered within the country it can be sold but not paid for by the NHI. What is anticipated is that companies will naturally focus more on marketing commonly used products. The fact that there will no longer be a tender system keeps the options more open for companies.

The NHI implementation is projected to be a 14 year process.

Pharmacists in the delivery of Primary Health Care (PHC)

In answer to the question of whether or not a pharmacist would have a role over and above that of dispensing and have the opportunity to participate in the provision of primary care, Dr Pillay replied that in order to deliver the level of care that was required and ensure access of all South Africans to quality healthcare, it would be necessary for all healthcare professions to participate, and that everyone was needed on board. However, notwithstanding the accepted principle that pharmacists would be involved in the provision of primary care, Dr Pillay acknowledged that tension exists with other professionals in achieving a balance. He related the example of a specific project in Mamelodi where GPs have established multidisciplinary teams which include pharmacists and which are working extremely successfully. In this scheme the capitated fee covers the role of all professionals and the practitioners working within that environment are reporting good earnings. This experience illustrates that there is a case to be made for the capitation of multidisciplinary teams for PHC involving pharmacists with GPs and other healthcare professionals.

Building Development

54 Glenhove Road as 22 April 2016

The exciting finishing stage to 54 Glenhove Road has been reached - plans have been transformed into reality and the first tenants are expected to take up occupation shortly.

1ST NATIONAL SYMPOSIUM FOR COMMUNITY PHARMACISTS IN SOUTH AFRICA - 14 MAY 2016.

"Shaping the future of Community Pharmacists"

David Sieff, FPS

The key note speaker will be the Chairman of the Board of the Canadian Pharmacists Association, Mr Carlo Berardi. He will describe the expanded scope of community pharmacy practice in Canada in the areas of prescriptive authority, medication and chronic disease management and other new clinical, pharmacist-led services such as immunisations. These aspects are pertinent to the South African situation, so we can gain valuable learning from his presentation.

New and advanced services being offered by pharmacists have led to improvements in timely access to primary health care, patient safety and desirable outcomes. Examples of best practices and processes will be presented along with pharmacy service compensation and business models, which are evolving to align the needs of community pharmacy closer to those of the patient.

Other presenters will include:

- Mr Gavin Steele – National Department of Health (NDOH).
  "Access to medicine – partnerships with community pharmacists".
- Ms Inge Cunningham– Western Cape Health Department (WCHD).
  "Providing Primary Health Care (PHC) services on behalf of government: A Western Cape experience".
- Adv Elsabe Klinck - Elsabe Klinck Consulting cc
  "Nurses in pharmacies – are there any unintended consequences?"
- Mr V Mokoena – SA Pharmacy Council.
  "Safe systems of work: Challenges facing Responsible Pharmacists (RPs), including recording of CPD events."
- Young Pharmacists Group (YPG) of the PSSA
  under the guidance of Ms Mariet Eksteen who will host a workshop –
  "To be successful and competitive, community pharmacists will require the necessary "emotional intelligence".

Venue: Birchwood Hotel and Conference Centre on 14 May 2016. For more information and to register visit www.saacpsymposium.co.za

Carlo Berardi

A strong advocate for the Pharmacist Profession

Carlo Berardi, B.Sc.Phm., MBA

Carlo Berardi is the Chair of the Board of the Canadian Pharmacists Association (CPhA) for the 2015-2016 term.

The pharmacist-owner of an independent community pharmacy in the Sudbury area for the past 26 years, Carlo is an active member of the community and strong advocate for the pharmacist profession. As a CPhA Board member since 2014 and Past Chair and current Board member of the Ontario Pharmacists Association, Carlo has played a key role representing the profession before governments and stakeholders, advocating for an expanded role for pharmacists in the delivery of health care in Canada.

With the goal of advancing the health and well-being of Canadians through excellence in pharmacist care, Carlo will be working with the Board of Directors to ensure the successful implementation of CPhA's new mission, vision and strategic plan. This new and revitalized direction will ensure a stronger and more united national voice for the pharmacist profession in Canada and chart a clear course for CPhA's future, focused on the health of Canadians and the provision of world-class pharmacy leadership. As Chair of CPhA, Carlo is committed to ensuring that pharmacists are provided with the tools and supports they need to provide better health and better care to all Canadians, and better value to the health care system.

DIRK MEERKOTTER

Pharmacist and Internationally acclaimed Artist.

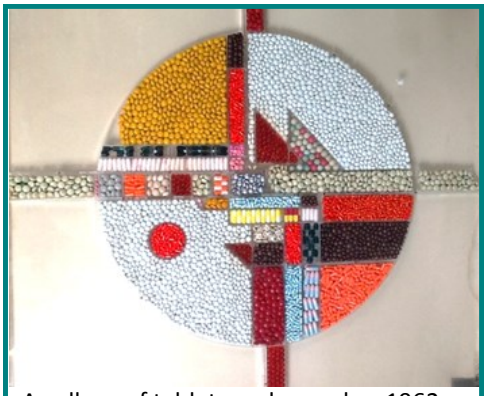
Ray Pogir, FPS, Curator, National Pharmacy Museum

Dirk Meerkotter was born in Pietersburg in 1922. Both of his parents were graduates of the Music school in Amsterdam and were music teachers. He grew up in a home filled with the appreciation of music and art and showed a talent as an artist at a young age.

He matriculated in 1940 and studied pharmacy at the Pharmacy School at the Technical College in Johannesburg and qualified in 1944.

Starting in the early 1950's he held 87 solo exhibitions in South Africa, the most recent two were held in Pretoria (2005) and Stellenbosch (2009). He also participated in the Florence International Graphic Biennial in 1972 and in 1974. Over the years he had a number of works featured in group shows in countries such as Europe, Canada, Peru, Argentine and Rhodesia (Zimbabwe). His art works have been acquired by municipal museums in South Africa and by private collectors in Europe, the USA and South Africa.

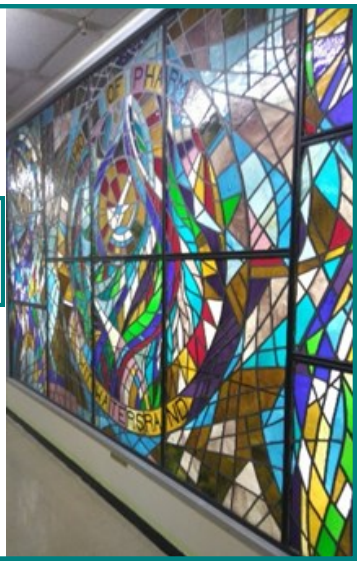
The photographs with this article feature three examples of works by Meerkotter which were produced in commemoration of various milestones in the history of pharmacy and the PSSA, and also of the large stained glass panel which was placed at the entrance to the Pharmacy School at the Wits Technical College. It is now at the entrance to the Pharmacy School at Wits University.



A collage of tablets and capsules, 1962, which mark the transition of prescriptions from "secundum artem" to manufactured products.

A ceramic plaque described by Meerkotter as a ceramic tablet with an emblematic design which features symbols such as the mortar and pestle, a scale, a cup shaped measuring cylinder and a microscope to symbolize progress. The snake, an age-old symbol of healing, connects the symbols and fills the otherwise slightly static subject matter with rhythm and force. The whole is bound together with the benzene ring.

The stained glass panel at the entrance to the Pharmacy School.



…./continued on page 8

A graphic artwork, 1985, of which 250 were printed to commemorate the 100th year from the 1st meeting of pharmacists on the 13th June 1895 at which it was moved that a South African Pharmaceutical Association be formed.

Extract from the Minutes follows:

Minutes of a meeting of the Chemists of the Eastern Province held on Saturday the 13th of June, 1885, at the Public Library, Kingwilliamstown.

Present: - Messrs Hucklow, Mc Jannet, Tucker, Lumsden, Braums, Abbott and Cook.

Mr. Hucklow having been voted to the Chair, Mr. Cook Hon Secretary, protem, explained the reasons why the meeting was called and its objects.

It was moved and carried unanimously that an Association be formed and thereupon a discussion arose as to the rules to be adopted.

It was resolved that the name of the Association be "The South African Pharmaceutical Association"

It was announced that replies favourable to the formation of an Association for the protection of the rights and interests of the Chemists in the Colony had been received from the following Chemists viz Messrs Lennon, Tucker, Dutton, Smit, Mc Jannet, Mager, Hamlin, Russell, James, Billingham, Austen, Broadhead, Wells, and H. L. Bell.

Mr. Cook then showed that it was desirable that a new "Pharmacy Act" be framed and passed, also that a change be made in the present Constitution of the Medical Board in Cape Town.

Mr. Hucklow spoke in favour of a total repeal of the existing Law and more particularly with regard to the Poison Act. He was in favour of assimilating as far as possible the Pharmacy Act of Great Britain to the requirements of the Colony. Other speakers concurred and it was the unanimous opinion of the meeting that the Chairman had fully expressed the views of the Chemists of the Eastern Province.

More benefits for members of the Pharmaceutical Society of SA (PSSA)

Recently announced in a PSSA Newsletter, pharmacist members of the Pharmaceutical Society of SA now have access to free membership of the Commonwealth Pharmacists Association. Membership benefits offered by the CPA include:

1. Free and newly introduced online accredited courses on evidence based management of diabetes and patient safety available through the CPA website.
2. Network with International pharmacy practice, particularly the range of practice across commonwealth countries.
3. Access to leading articles on key pharmaceutical topics.
4. Preferential rates for the CPA biennial conference.
5. Access to the CPA Members Forum, an interactive discussion board where members share their views and experience on a variety of topics.
6. Access to NHS choices, a reliable source of information providing support for health and social care professionals in their daily work.
7. Links to relevant wider sources of information.

To register go to the CPA website at www.commonwealthpharmacy.org/amember/signup

Your coupon code is C1C10DAA. Note that the coupon code is valid until 28 February 2017 after which a new code will be issued.

& Ethics

Contributed by Val Beaumont, FPS

Mr. Amos Masango

Update on pharmacy Council issues. Key points of general interest to pharmacists from presentation by the Registrar of the Pharmacy Council, Amos Masango, at the Southern African Pharmaceutical Regulatory Affairs Association (SAPRAA) meeting, 8 April, 2016.

The Registrar invited the audience to register for the 2nd National Pharmacy Conference, 21-24 October, 2016 to be held in Durban.

Inspections

The Registrar reported the Council's inspection results for the previous year, emphasising that the 18% of grade C inspections (Major shortcomings) in community pharmacy were attributable largely to non-compliance with the conditions under which a pharmacy should be conducted. He reminded us that pharmacy inspection schedules are determined by the outcomes of previous inspections as follows; grade A pharmacies are inspected once in 3 years, grade B once in two Years, grade C once each year. Grade D inspections result in closure.

He also urged that pharmacists familiarise themselves with the conditions under which a pharmacy shall be conducted; (Chapter VII of the Regulations Relating to the Practice of Pharmacy, regulations 20 to 23)

Pharmacists must conform with the Council requirements for:

⇒ good pharmacy practice,
⇒ the code of conduct published as rules for pharmacy and
⇒ provisions applicable to the legislation.

Scheduled medicines in a pharmacy may only be handled by a pharmacist or by a pharmacist interns and support staff under the direct personal supervision of a pharmacist (Pharmacy Practice Regulations, Chapter VII, regulation 20). The dispensary must therefore not be accessible to the public and the schedule one and two area must be under the continuous supervision of a pharmacist.

Every pharmacy must be conducted under the direct personal supervision of a responsible pharmacist (RP). Exceptions must be determined by Council and the name of the responsible pharmacist must be displayed conspicuously over the main entrance of the pharmacy.

The Responsible Pharmacist (RP) is ultimately responsible for the pharmacy. In the absence of an RP, the owner in the private sector and the head of pharmaceutical services in the public sector has specific responsibilities in terms of Practice Regulation 28.

⇒ continuous supervision of the pharmacy
⇒ have appropriate qualifications and experience and ensure that persons practising Scope of Practice in pharmacy are appropriately registered with Council
⇒ notify Council on termination of his/her services as Responsible Pharmacist
⇒ take corrective measures relating to inspection reports
⇒ ensure no unauthorised access to scheduled medicines
⇒ establish policies and procedures
⇒ ensure safe and effective storage/keeping of medicines
⇒ correct and effective record keeping of medicines sales, purchases, possessions, storage, and returns of medicines.

…./continued on page 10

Sale of HIV test kits in pharmacies – recent changes

The SAPC resolution of 2014 removed the prohibition on pharmacists from selling test kits and standards have been published. Pharmacies wishing to sell HIV test kits need to comply with this standard. Pharmacists, interns and support staff must be adequately trained to counsel purchasers before the sale of the test kits. Pharmacists must supply information to purchasers on where to access follow-up and support services and training on performing the test and on the interpretation of the results. HIV kits that claim to diagnose cannot be sold by pharmacies.

Education and Competencies

Mid-level workers

Significant changes are taking place in the qualification of mid-level workers. Training provisions for Basic and Post-basic support staff have been extended to June 2018 and the following changes have been proposed and are awaiting approval by the Minister of Health.

The basic qualification to move to NQF 4 and the post basic qualification to NQF 5, both with no change in scope of practice. The new pharmacy technician is at NQF 6 and a new scope of practice is being developed. Regulations to amend these NQF levels are with the Minister of Health for approval.

There will be two training frameworks for support staff, the Council of Higher Education (CHE) framework and the QCTO (qualifications of the trades organisation). The new framework facilitates web-based training for work place learning. Training of pharmacy technicians can go through the CHE route or through the QCTO route with on the job training.

Competence standards for pharmacists

The competency standards for pharmacists are being updated and it is envisaged that a new qualification will come into place in 2018. The profession will be involved in the formal process of creation of the new competency standards.

Specialities in Pharmacy

There are two existing categories of specialist pharmacist, radio-pharmacist and pharmaco-kineticist. The qualifications for three new specialities are currently being finalised. These are Clinical Pharmacist, Public Health Pharmacist and Industrial Pharmacist.

The specialist qualification for Industrial Pharmacists will be presented to the Council in May and then will be open to wider consultation.

Continuing Professional Development (CPD)

The CPD regulations are with the National Department of Health (NDoH) awaiting finalisation but in the interim all pharmacists are expected to be doing CPD.

A similar presentation was made by the Registrar of the SA Pharmacy Council at the SA Association of Hospital and Institutional Pharmacists (SAAHIP) AGM and Conference held during March 2016.

A REMINDER

The Pharmaceutical Society of South Africa
71st Annual General Meeting

Notice in terms of the Constitution – Section 22.2

To:
All members of the General Council of the Pharmaceutical Society of South Africa

You are hereby notified that the 71st Annual General Meeting of the General Council will take place at the Birchwood Hotel and OR Tambo Conference Centre, Boksburg on Friday, 13 May 2016 commencing at 14:00

Hypertension and the PCDT pharmacist

Johan Moolman, MPS, Community Pharmacist

While World Hypertension Day is scheduled for 17th May this year, hypertension is for many people a chronic condition which requires continual careful management. Community Pharmacists are well placed to fill this role. The author, a licensed PCDT pharmacist, describes the routine approach that a PCDT pharmacist follows to ensure positive outcomes for these patients who attend his clinic.

Approximately 4 in every 10 adults older than 25 years have hypertension. The unfortunate part is around 50% of these people are unaware of their condition. Of those who are aware half of them do not take any action to control their blood pressure either through lifestyle modification or medication.

This means 75% of the world's hypertensive population are at risk and are potential candidates for heart disease, stroke or kidney disease or even sudden death.

If I compare the number of patients testing positive for HIV compared to Hypertension in my pharmacy clinic I can see a major shift in the number of patients having hypertension. The worst part is that about 80 % of the patients I find with a problem with their blood pressure live in denial and find something to blame or to make out its nothing to be concerned about and think their body will reset itself.

How do I approach hypertension as a PCDT pharmacist in my pharmacy?

According to the EDL list of conditions a PCDT pharmacist may treat a much wider scope of practice versus the old R10.00 blood pressure measurement that is done in most pharmacy clinics. The PCDT pharmacist may now at a fee continue treatment if initiated by a doctor with close monitoring for six months after which the patient should be referred to the doctor. The pharmacist will only repeat if the patient remains within target range of blood pressure.

What does this close monitoring mean? Does it mean that the patient comes in to the pharmacy and takes his blood pressure and if it shows normal the PCDT pharmacist writes out a repeat prescription and off the patient goes for the next six months? For sure not!

I think the Department of Health had more in mind when they took the step to allow the PCDT pharmacist to take control of the patient's blood pressure for a further six months. To be allowed to do this the PCDT pharmacist should take control of the patient's blood pressure for the first 6 months already before a further 6 months can be prescribed.

A very important factor is the record keeping involved in this process. What we need to remember is that should you decide to repeat the prescription, you take responsibility for the control of the patient's blood pressure for the next 6 months. If you take a single reading before you repeat the medication and nothing else and anything goes wrong with the patient, you might have some explaining to do. Everything that you do should be well documented and proper record kept on a clinic system. Hypertension is a serious condition. Make sure you have a clinic program that enables you to record everything and that can be referred to easily.

What does chronic management for the PCDT pharmacist mean?

1. When you take a chronic hypertension patient into your care it should be explained to the patient what this service entails. It should not be marketed as a service to save the patient a visit to his doctor after the first six months of treatment. It is a 12 month treatment plan initiated by the PCDT pharmacist.
2. An initial consultation must be done to understand the lifestyle of the patient and it must be explained to the patient that doing certain things during their normal lifestyle can affect their blood pressure e.g. high salt diet, misuse of certain over the counter medication etc. A full history should be taken. Make sure you know what your risk factors are before you just accept the responsibility.

…./continued on page 12

3. Document all these on the patient profile for future reference.
4. Look for bad lifestyle habits e.g. excessive smoking or coffee intake, lack of exercise, over-weight.
5. Explain to the patient that they will have to visit the clinic before they get their chronic prescription to make sure their treatment is effective. I have seen a number of patients in my clinic that received a prescription from a cardiologist and assumed because their medication was prescribed by a cardiologist they could safely accept their blood pressure would be under control. Often I have found the opposite and a quick call to his or her specialist resulted in other medication being prescribed and the doctor also requesting that the patient visit the clinic regularly to monitor that the BP is controlled and that the clinic updates the doctor on progress. This does wonders for your relationship with the prescribing doctors.
6. Make sure you know the full diagnoses of the patient. Patients often omit to tell you that they have other chronic conditions. If a patient suffers diabetes their blood pressure is of cardinal importance. Kidney function should be monitored, for protein in the urine, for diabetic patients who also suffer from hypertension. Notify the doctor immediately should you find protein in the patient's urine and no signs of infection.
7. Patients on chronic pain medication should also be monitored. Recent studies showed that patients on chronic NSAIDS must be monitored for an increase in blood pressure. An increase in blood pressure could be an indication of the cardiac side effect of NSAIDS especially COX2 inhibitors. The patient's doctor should be notified should this be the case and possibly a calcium channel blocker will be added to stabilize his/her blood pressure.
8. If the patient has their own blood pressure machine at home, let them regularly record the measurements, and show you the records.
9. Do not just take the patient's blood pressure. Use with the stethoscope for any abnormal heart sounds.
10. Listen to lungs and ask the patient if they have any difficulty to breath or have a chronic cough when they lie down.
11. If they complain of a cough check for an ACE-inhibitor bradikinin cough.
12. Check cholesterol and blood sugar levels on a regular basis. These can affect the patient's blood pressure if not controlled.
13. Explain to the patient that certain OTC medications can result in an increase of their blood pressure and they should always consult you first before they just take something for example for flu or cold medication.
14. If the patient had a heart attack, they should avoid the use of any NSAIDS for the next 6 months. Using these could result in a next myocardial infarction (MI)
15. Get the patient to do mild exercise.
16. Advise the patient to limit salt intake as a general rule.
17. Always check the hydration of the patient if they are on diuretics. I have often found that patients visit the clinic during the warm summer months in a dehydrated state and complain that they have no energy but severe headaches. In the mean-time they still use diuretics in a dehydrated state. Adding rehydration therapy to their chronic medication does wonders for these patients.
18. Patients complaining of low energy, headaches and chronic fatigue should be tested for anaemia.
19. In a hypertensive emergency the patient must be given an Amlodipine 10mg stat and **must** then be referred to a hospital immediately. Make sure the hospital knows you gave the patient the Amlodipine 10mg as an emergency treatment.

The opportunity is now to show the control we can bring and the impact we can have on the health of our patients. The golden rule remains that if you suspect anything is abnormal refer or contact the patient's doctor immediately. Do not try and change patient's treatments without the consent of their doctor. All responsibility of this patient might end on your head if anything goes wrong. It should always be a team effort with the other healthcare providers involved.

Biologicals & BIOSIMILARS

David Sieff, FPS

In a recent Continuing Professional Development presentation, medicine and health strategist Ms Val Beaumont, conducted a PSSA inter-sectoral workshop on the REQUIREMENTS FOR REGISTRATION, PRESCRIBING AND DISPENSING AND POST MARKETING OF BIOLOGICAL MEDICINES AND BIOSIMILARS.

Val Beaumont's introduction to the topic included an outline of the differences in the manufacture, clinical performance, and legal implications for dispensing and prescribing of this growing class of complex medications. With the current range of excellent chemical molecules for common chronic diseases, new developments have slowed down, and small advances are too costly, allowing an opportunity for the industry to change to biotechnology, involving cell biology, new target sites, and expensive, risky genomic research.

Biotechnology harnesses cellular and biomolecular processes to develop new technologies and products. Modification and genetic reprograming of living organisms or their parts, produce complex therapeutic proteins, mostly by recombinant DNA techniques. About 250 health products and vaccines are now available to patients - the oldest of which is insulin – addressing many unmet medical needs, and benefitting about 350 million patients worldwide.

New mechanisms of action disrupt, trigger, or replace complex interactions in a patient's body, targeted towards specific causes or debilitating systems of a disease, not a generalised effect. The disease entities being highly researched include multiple sclerosis, rheumatoid arthritis, allergy and eczema, various cancers, hepatitis B and C, and septic shock. Examples of biologicals for various treatments include vaccines, insulins, interferons, interleukin, growth factors, and herceptin, all with significant treatment benefits.

The dynamics have changed for stakeholders, including medicines regulators, patients, funders, manufacturers, and doctors and pharmacists – therapeutic decisions are more complex, there can be no switching or substitution. Prescribing and patient management have to be product specific, as are management and reporting of adverse drug reactions, and cost vs patient benefit assessments are at a new level.

The comparison of *BIOSIMILA*R products vs *ORIGINATOR* biologicals reveals that although similar, they are not generics; each product has to be supported by it's own research data and distinct regulatory standards and tests. Biosimilars have different chemical names from the originators, and are not interchangeable with other medicines of the same class. Prescribing must be specific to each product and indication. Biosimilars are also not clones.

Val Beaumont summarised the topic to conclude her informative presentation, and accepted discussion and questions from the floor.

Sanofi Pharmaceuticals were thanked for their kind sponsorship of the event.

The Chairman of the Editorial Board is David Sieff and the members are Doug Gordon, Neville Lyne, Ray Pogir, Miranda Viljoen, Val Beaumont, Gary Kohn & Jan du Toit. All articles and information contained in The Golden Mortar of whatsoever nature do not necessarily reflect the views or imply endorsement of the Editorial Board, the Branch Committee, the PSSA, its Branches or Sectors. The Editorial Board and the afore-said cannot therefore be held liable. Every effort is made to ensure accurate reproduction and The Golden Mortar is not responsible for any errors, omissions or inaccuracies which may occur in the production process.
We welcome all contributions and as space permits, these will be published, abridged and edited if necessary.

The Golden Mortar
P O Box 2467, Houghton, 2041
Tel: 011 442 3615, Fax: 011 442 3661
nevillel@pssasg.co.za

Your SG Branch Chairman Lynette Terblanche

Your PSSA Southern Gauteng Branch Sector representatives are:

Community Pharmacy: Tshifhiwa Rabali & Winny Ndlovu

Hospital Pharmacy: James Meakings & Jocelyn Manley

Industrial Pharmacy: Yolanda Peens & Mario Botha

Academy Paul Danckwerts & Deanne Johnston

Contact them through the Branch Office: Tel: 011 442 3615

The Editorial Board acknowledges, with thanks, the contributions made by the SAACP Southern Gauteng Branch to the production of this newsletter.