The Golden Mortar

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

Edition 1/FEBRUARY 2021

MESSAGE FROM THE NEW CHAIRMAN OF THE PHARMACEUTICAL SOCIETY, SOUTHERN GAUTENG BRANCH.

Lynette Terblanche

It is with honour and humility that I accept my election as the incoming Chairperson of the Southern Gauteng SG Branch of The Pharmaceutical Society of South Africa. It is indeed an honour to be nominated to serve the PSSA members in this branch of the PSSA in this capacity once more. I would like to express my gratitude for entrusting me with an enormous responsibility which I intend fulfilling with total commitment.

I would like also to congratulate the Deputy Chairperson, Stephanie de Rapper, and the Treasurer Rubina Shaikh, on their election as Honorary Officers of the Branch Committee. I would like to thank Thanushya Pillaye for all the hard work as Chairperson of the Committee during 2020.

I am aware that I shall be able to discharge this responsibility only by working closely with all Committee members as well as the SG membership, to ensure that members of this Branch receive benefits enabling all members to be the best possible professionals they can be in these uncertain times. **We have so much talent that exists in our membership, that if channelled purposefully, can translate to a better life for all our people.**

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Pharmacists in this Branch must take their rightful position as reliable partners and deserving members of the healthcare profession, because it is only if we reach our full potential, contributing towards optimal healthcare for all in a rapidly changing environment, that we will command the respect we deserve of other players in the provision of healthcare.

In pursuance of this objective, as a Branch, we will continue to build on the work of those who came before us and we will continue to work with other organisations and the National body to seek out opportunities to achieve our collectively defined priorities.

We must do everything possible to ensure that pharmacy is positioned as a unified profession for the good of patients in our country.

One of the challenges we face is to ensure that transformation and succession continues to receive the attention it deserves. We have a dynamic young pharmacist group in the Branch and one which is continuing to grow rapidly. We must therefore ensure that our young pharmacists are suitably mentored and skilled to eventually lead the profession.

For us to achieve the objectives of the Branch, we require a strong Committee, united by a commitment to serve our members with professionalism and loyalty. I am certain that all the members of Committee 2021 are committed to these values.

I am reminded of the inspirational words of Ms Cecilia Molokwane, President of Netball SA, during our recent AGM, that leaders must know what their people want.

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I would therefore request you as PSSA members in this Branch to use the existing communication channels to let us, your Committee, know if there are specific aspects of the profession that you would like us to address in one way or another.

Together we can make a difference in 2021!

ANNUAL GENERAL MEETING

SOUTHERN GAUTENG BRANCH OF THE PSSA

By Cecile Ramonyane

The 76th AGM of the PSSA SG Branch was held on Thursday 4 February 2021. The keynote address was delivered by the President of Netball South Africa, Mrs. Cecilia Molokwane, who gave an inspirational talk on "The incredible Power of Believing in Yourself."

Cecilia Molokwane

Cecilia encouraged members to believe in themselves, because no one will do it for someone else.

Cecilia mentioned the following points of encouragement in leadership:

- Go for your goals and objectives. Even if it takes time, be patient and you will succeed.
- Leave fear behind if you want to achieve, only fear God and He will give directive.
- The word "Impossible" should be taken out of our vocabulary if we want to win. Accept that you might fail in your attempts but do not fail to try - difficult times do not last.
- Believe that you can. "Refill your glass," and always ask God to give you strength and wisdom in dealing with situations.
- Know your worth.
- Always have a sense of humour. Be friendly and approachable.
- Introspection.
- Believe that you will be the best in what you do.
- Compete with yourself but compete with others in a healthy way instead of spiting, and leave a good legacy that people can re-member you by. Complement each other more than competing.
- Let your work speak for you, not negative criticism.
- God is the only one to give us validation.
- You have been placed where you are for a purpose, not by mistake. You owe everything to yourself.
- In everything you do remember that we all have one life. Dream like you are going to live forever.

"Leaders must know what their members want"

In closing, Cecilia emphasised that leaders must know what their members want.

I hope that as PSSA SG we will take something home from Cecilia's talk to build our interaction with others.

NEW PSSA SG BRANCH COMMITTEE
Congratulations to the new Branch Committee

Honorary Officers

Chairman:	Lynette Terblanche
Vice-Chairman:	Stephanie De Rapper
Treasurer:	Rubina Shaikh

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Committee Members

- Val Beaumont
- Cazandra Da Silva
- James Meakings
- November Nkambule
- Gina Partridge
- Thanushya Pillaye - Immediate Past Chairman - *Ex officio*

Honorary Life Members

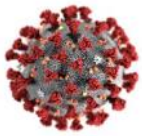
- Gary Kohn
- Raymond Pogir
- David Sieff

Sector Representatives

SAAHIP: Tabassum Chicktay and Rashmi Gosai
SAAPI: Tammy Maitland-Stuart and Thavashini Pather
SAACP: Richard Barry and Winny Ndlovu
Academy: Zelna Booth and Muhammed Vally

The Branch encourages members to participate in pharmacy affairs through the Branch Office to address challenges. The future of the Branch depends on experienced members and new ideas from our young pharmacists.

TRIBUTE TO OUR FALLEN HEROES



We pay tribute to the many healthcare workers and everyone who has been taken from us far too soon during this devastating Covid-19 pandemic.

Any death is too many in a situation like this. There have been so many who have lost their lives while caring for and protecting patients, and who still had so much to give.

The frontline healthcare professionals and workers have given their dedication, professionalism and passion in caring for patients with compassion and skill, and for this they are recognised and immensely appreciated.

Deepest and heartfelt condolences are extended to their grieving families and friends.

May they rest in peace.

SAACP SG Branch Committee

The SAACP SG Branch is a financial contributor to The Golden Mortar.
Please visit our website: www.saacpsg.co.za as well as our Facebook page: South African Association of Community Pharmacists - SG
You are also able to view The Golden Mortar Editions on the website as well as to provide input to the following email address:
info@saacpsg.co.za

THE MISSING LINK IN THE PREVENTION AND SUPPLEMENTARY TREATMENT OF COVID-19 IN COMMUNITY PHARMACY

By Gary Kohn, Responsible Pharmacist, SAM NUTRITIONAL PRODUCTS

As one of the essential frontline healthcare workers, as pharmacists, we have rendered unstinting service during this period of COVID-19 exposure with treatment delivery that affected pharmacists and patients alike, even causing the ultimate loss of customers and colleagues, that have sadly passed away.

We have seen the rush by patients buying large quantities of vitamins and minerals and immune boosters [see examples below], and often expressing their fear and concern for this pandemic with which we are all challenged.

We have seen the doctors prescribing a cocktail treatment of some of the following: acetylcysteine, zinc, vitamin D3, ascorbic acid, colchicine, azithromycin, cortisone, aspirin, and thiamine.

VITAMIN C

Vitamin C (ascorbic acid) shortens the duration and alleviates the common cold, and prevents colds under specific conditions.

'Pneumonia is the most common severe infection, which is usually caused by bacteria or viruses,'

There are significant effects of Vitamin C against pneumonia and viral respiratory infections,

It is effective against pain caused by herpes zoster. and safeguards the integrity of connective tissue.

Vitamin C may protect against stress caused by cold and hot environments.

Heavy physical stress leads to elevation of oxidative stress, therefore vitamin C might have beneficial effects on people who are under physical stress.

It also contributes to cell protection from free radical damage, and maintains the normal function of the immune system during and after intense physical stress; it also contributes to collagen formation for the normal function of blood vessels.

Ascorbic acid is an antioxidant that assists in the maintenance of general good health, and it may, in addition, alleviate or prevent infections caused by bacteria, viruses, and protozoa,

VITAMIN D3

Maintaining an adequate vitamin D3 level by regular intake is also important in protection against the Covid-19 Virus, and lower levels of vitamin D3 increase the risk of Covid-19 infections; a daily intake of at least 1000iu should be taken - while increased Body Mass Index (BMI) will require an increased daily dosage.
Vitamin D contributes to normal cell division and to the normal function of the immune system.

SELENIUM

Selenium contributes to the protection of cells from oxidative stress and to the normal function of the immune system as well. and It acts as an antioxidant for the maintenance of good health.

A French Scientists Dr. Laurent Hifler, explains SELENIUM versus COVID-19 in an article in the Journal 'Frontiers in Nutrition' from September 2020

"The use of an essential mineral known as selenium that has possibly been overlooked up to now, should be included as an immune booster and supplement to restore the depleted selenium stores used up by the COVID-19 RNA virus in its unchecked 'mutations, replications and virulence in attaching to the ACE2 receptors.' Intense viral replication would induce a selenium deficiency in the host cells; an adequate external

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supply and presence of selenium would restore the patient's stores, which is essential for the recovery and antioxidant defence. Selenium might be beneficial via such restoration.

Selenium deficiencies are associated with higher susceptibility to RNA viral infections and more severe disease outcomes.

The elderly, especially those with comorbidities, are more prone to selenium deficiencies and oxidative stress, which explains the worst outcome in the elderly compromised population.

COVID-19 has been associated with thrombotic events such as large vessel clots, deep vein thrombosis, pulmonary embolism and microvascular thrombosis, platelet activation and inflammation, and also with an increasing incidence of strokes. Selenium's antithrombotic properties in this regard are also recognised.

The selenium status becomes important, 'the lower the selenium status in a population the lower the recovery rate from Covid-19.'

'The lowest serum selenium levels were strongly associated with mortality'.

"The higher the selenium intake, the recovery rate from Covid-19 was almost triple the average" and offered a protective benefit against the detrimental effects of the viral infection.

"Having a higher-than-normal selenium status may offer a protective benefit ....

A dosage of 200 mcg daily given to the elderly for years has given positive results in lowering viral infections and reducing cardiovascular mortality."

The above article, in supporting the use selenium, does not profess to treat Covid-19 but to supplement an essential mineral as an immune booster, a restoration of optimum selenium levels, and for its role in reducing oxidative stress.

We take note of a recent announcement that the USA has placed a travel ban on RSA visitors because of the identification of a more virulent strain of Covid-19 in South Africa.

ZINC

Zinc has proven antiviral action against some viruses; increased intracellular zinc concentrations efficiently impair viral replication. Lower plasma levels at hospital admission are associated with mortality in Covid-19 cases.

It is a trace element with immunoregulatory and antiviral properties. assisting in the maintenance of the immune function and good health. and is vital in DNA synthesis.

Zinc is a factor in the maintenance of good health, and contributes to protection from oxidative stress.

Notwithstanding temperature checks and monitoring, COVID-19 protective screen partitioning in front of the required counseling area, social distancing, hand sanitisation, the wearing of face masks and facial visors, and even recent Government restrictions and controls, patients are still vulnerable and can contract the COVID-19 virus. Some pharmacies have even been forced to close and their staff placed under quarantine.

Covid-19 is a systemic disease with respiratory symptoms and with possible secondary complications that include heart problems like myocarditis and systemic micro-thromboses, a symptom of haemorrhagic fever viruses and blood clotting.

Our older, immunocompromised, diabetic and cancer patients, cardiac/high blood pressure, overweight patients with high BMI, are more at risk of being infected with the Covid-19 virus.

REFERENCE PAPERS

Selenium and RNA virus interactions: Potential implications for SARS-CoV-2 infections (Covid-19)

1. Laurent Hifler and Benjamin Rakotoambinina. Independent researchers: Lagnry-Marne, France. This paper is available on request.
2. Vitamin C and infections by Harri Hemilla. Department of Public Health, University of Helsinki. Accepted 15TH March 2017.
3. SAHPRA: Complementary Health Supplements, Safety and Efficacy.


Africa
10 - 12 MARCH 2021
CANCELLED
We are disappointed to inform you that we have made the decision to cancel SARCDA Africa 2021, due to the ongoing Covid-19 restrictions.
We have prepared a proposal for the City JOC (the Joint Operations Committee, which is tasked with ensuring that all events held in Johannesburg are safe) explaining the safety precautions that SARCDA is taking and will continue to lobby them to secure permission for SARCDA Christmas 2021 to take place. The exhibition industry as a whole will also continue to lobby government for permission to open the industry up.
The SARCDA team would like to thank you from the bottom of our hearts for your ongoing support in these most difficult of times – we cannot wait to see you in person at an exhibition again. Fingers crossed, that this will come to pass at SARCDA Christmas 2021. Until then, stay safe and healthy!
SARCDA online
A platform connecting Suppliers and Buyers to help grow businesses.
Easy to use Search Capabilities
Buyers deal directly with Exhibitors
View product images & descriptions
Exhibitor Information
A-Z
A-Z Exhibitor listing

DRY EYES IN PHARMACY

By Leshasha Mashabela & Nasiphi Mkatshane - BPharm Students Wits

Nasiphi Mkatshane

INTRODUCTION

Dry Eye Syndrome is a common condition that occurs when tears are not able to provide enough lubrication for the eyes.

A normal tear film consists of three important components:

- An oily (lipid) component produced by meibomian glands in the eyelids.
- A watery (aqueous) component produced by lachrymal glands located behind the outer aspect of the upper eyelids.
- A mucous-like (mucin) component produced by goblet cells in the conjunctiva that covers the white of the eye.

Tear lipids help keep tears from evaporating too quickly and increase lubrication, while mucin spreads the tears across the surface of the eye.

The aqueous component provides the disinfecting and immune defence role of tears. Any incompetence with these secretions may result in tear instability and dry eyes.

WHO IS AT RISK?

Risk factors for dry eye include advanced age, female gender, and extended screen use.
Dry eye syndrome affects 15-33 % of those aged over 65 years and the prevalence increases with age. It is 50 % more common in women.
Individuals more susceptible to dry eyes include:

- Women experiencing hormonal fluctuations as associated with pregnancy, oral contraceptive use or menopause;
- Those taking decongestants or drugs with anticholinergic activity, such as antihistamines and certain antidepressants;
- Those with medical conditions such as allergies, arthritis, diabetes, or thyroid problems;
- Those working in dry environments or exposed to smoke or wind;
- Contact lens wearers and those who have recently had eye surgery.

CAUSES OF DRY EYE

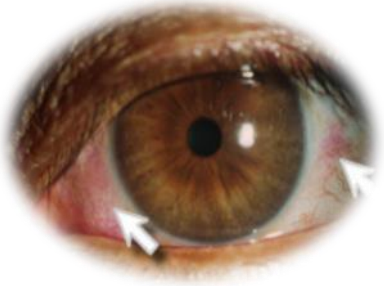
Dry eyes can arise as a result of insufficient tear production, excess tear loss, abnormalities of eyelids and blinking, or changes in tear film composition.

Insufficient tear production may be the result of:

- Sjögren's syndrome - an autoimmune disease causing incompetence of the lachrymal glands.
- Adverse effects of certain drugs, e.g. antihistamines and antidepressants.
- Allergic conjunctivitis.

Excess tear loss may be the result of:

- Low humidity from air conditioning or high wind conditions;
- Low blink rate, wide lid aperture;
- Prolonged use of screens;
- Smoking;
- Allergic conjunctivitis;
- Vitamin A deficiency;
- Preservatives in eye drops;
- Contact lens wear.



PREVENTION

Simple dry eye prevention measures include:

- Avoid air blowing directly onto the face from fans, heaters or a hair-dryer.
- Wear sunglasses, preferably the wrap-around type, for maximum eye protection when outdoors.

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- Avoid smoke, whether it is coming from a cigarette or a fireplace.
- Use a humidifier to add moisture to the environment, if appropriate.
- Reduce the amount of time spent wearing contact lenses.

Leshasha Mashabela

TREATMENT

Treatment for dry eye aims to supplement the natural production of tears or to decrease the loss of tears as a result of evaporation.

Several tear substitutes containing e.g. hydroxypropylmethylcellulose and lanolin anhydrous, are available for the management of dry eye symptoms. Contact lens wearers should avoid products that contain preservatives as the preservative may adhere to the lenses and lead to toxicity. Patients who are using ophthalmic ointments should be advised to apply the ointment at night because ointments may lead to temporarily blurred vision.

The use of omega-3 fatty acid supplements may help produce a healthy tear oil layer and also has anti-inflammatory effects.

Second-line treatment for more serious dry eye conditions may include topical ciclosporin, a topical integrin antagonist (e.g. lifitegrast) or a topical glucocorticoid.

WHEN TO REFER

Patients should be referred to the doctor immediately if a serious underlying condition is suspected, e.g. acute glaucoma, a corneal ulcer, or inflammation of the iris or cornea. Children with any dry eye symptoms and patients who complain about a discharge and difficulty with vision also require referral.

Patients who do not respond to the tear supplements and the non-pharmaceutical therapy after a week should be referred, preferably to an ophthalmologist,

CONCLUSION

Dry eye syndrome is a common condition seen in the pharmacy. If mild, it can be treated with over-the-counter artificial tears, nutritional supplements, and environmental coping strategies.

REFERENCES AVAILABLE ON REQUEST

BACK TO BASICS

THE ROLE OF THE PHARMACIST IN THE COVID-19 VACCINE ROLL-OUT

By Tabassum Chicktay

At the beginning of February 2021, South Africa received its first batch of the Astra Zeneca-University of Oxford Covid-19 vaccines.

Long before this, pharmacists in all sectors were already hard at work in preparation for the Covid-19 vaccine roll out.

Of course, as pharmacists, our sheer tenacity and specific skills set, make us the quintessential people to implement this mammoth task. Immunisation services are not a new service provided by pharmacists, however, this kind of mass vaccination campaign will require the pharmacy workforce to shift into another level of due diligence.

Back to the basics, my fellow colleagues, refer Good Pharmacy Practice (GPP) (2010) section 2.14:-

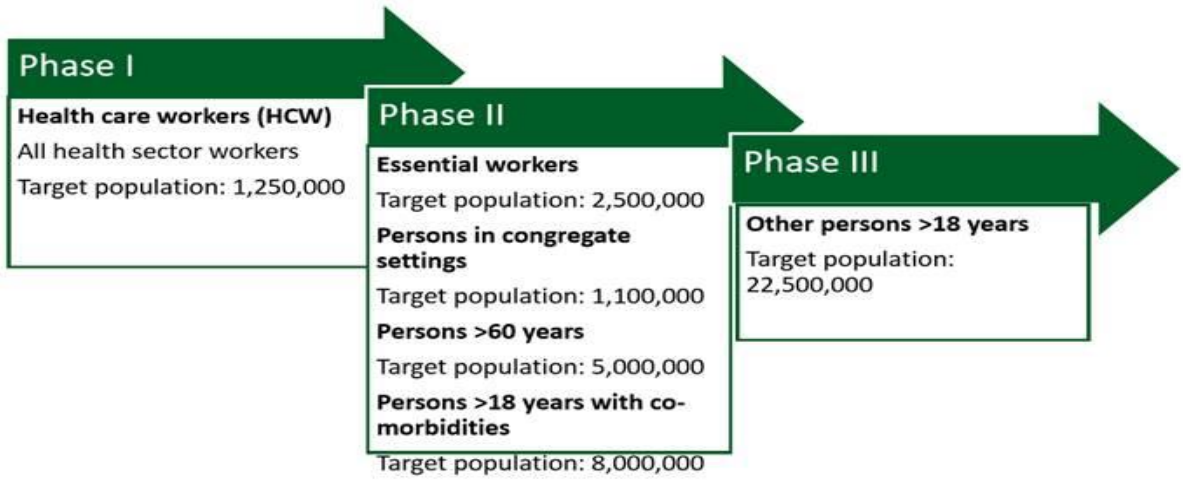
MINIMUM STANDARDS FOR IMMUNISATION SERVICES

"Although the pharmacist's involvement with immunisation varies with each practice setting, the pharmacist can be actively involved in the following activities:

- educating the public and other healthcare professionals about immunisation;
- advocating paediatric immunisation;
- providing immunisation for international travel;
- screening patients who are at risk of preventable infectious diseases by occupation, lifestyle, or an underlying disease state;
- administering immunisation agents;
- recording immunisation data;
- using the immunisation database to generate reminder letters for booster doses.

In Gauteng, pharmacists have led and supported the entire process of quantifying the demand that would be required as well as the procurement and distribution supply chain processes.

TEN THINGS PHARMACISTS SHOULD KNOW ABOUT THE COVID-19 VACCINE ROLL OUT

1. Provincial Coordinating Committees appointed by Heads of Departments (HODs) with representation from the Expanded Programme for Immunisation (EPI), Communicable Disease Cluster (CDC), Medicines Supply Chain Management (SCM), Information Systems, Human Resources for Health (HRH), Primary Health Care (PHC), Monitoring and evaluation, and the provincial private sector Coordinating Committee, were established. A private health sector Coordinating Committee which includes medical schemes, private hospital associations, pharmacies' groups, general practitioner and specialist associations, nursing associations, allied health professions associations, and logistics providers was established.
2. 

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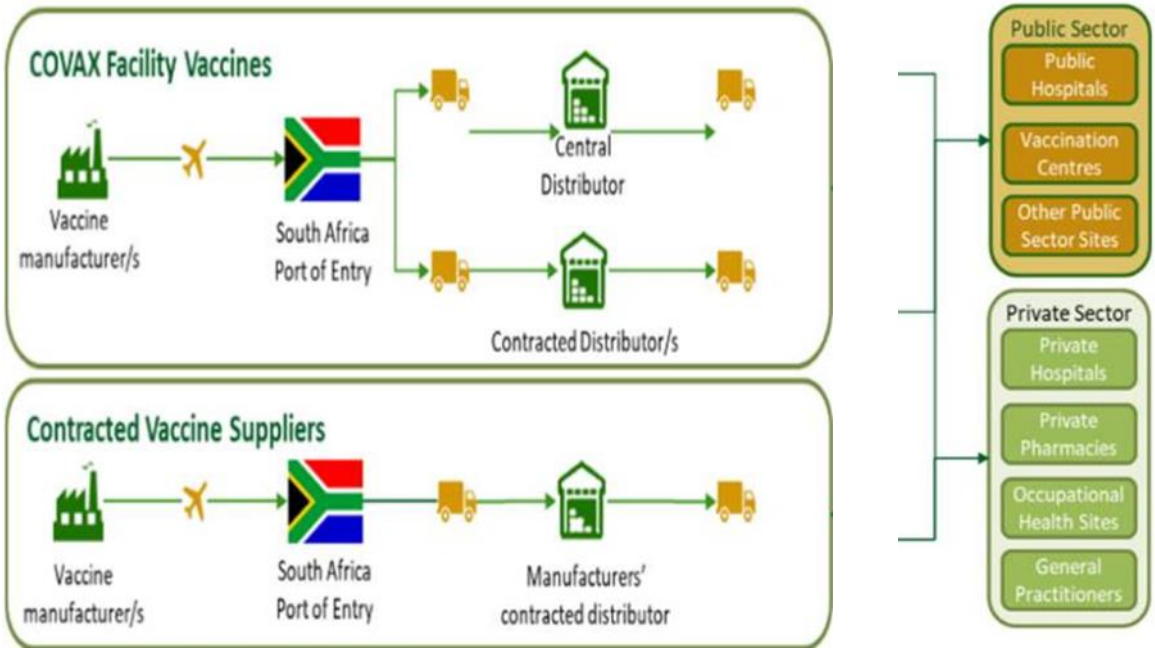
3. **Phase Number 1 will target all Health Care workers.** During this phase, Health Care Workers (HCWs) will be divided into risk categories, with those in the first and second categories being the first to receive their vaccinations.

CATEGORY OF HCWs	DESCRIPTION OF CATEGORY
Category 1	Those carrying out and are involved in aerosol generating activities and procedures such as intubation, ventilation, suctioning process and COVID 19 specimen collections.
Category 2	Those in direct contact with known or suspected COVID 19 patients.
Category 3	Those in contact with patients who are not known or suspected COVID 19 patients
Category 4	Those not in contact with patients

4. **The Astra Zeneca- University of Oxford Covid-19 vaccine was very recently found to be ineffective against the Covid-19 501Y.V2 variant**. Therefore, the planned roll-out of the vaccine will continue with the Johnson and Johnson vaccine.
5.



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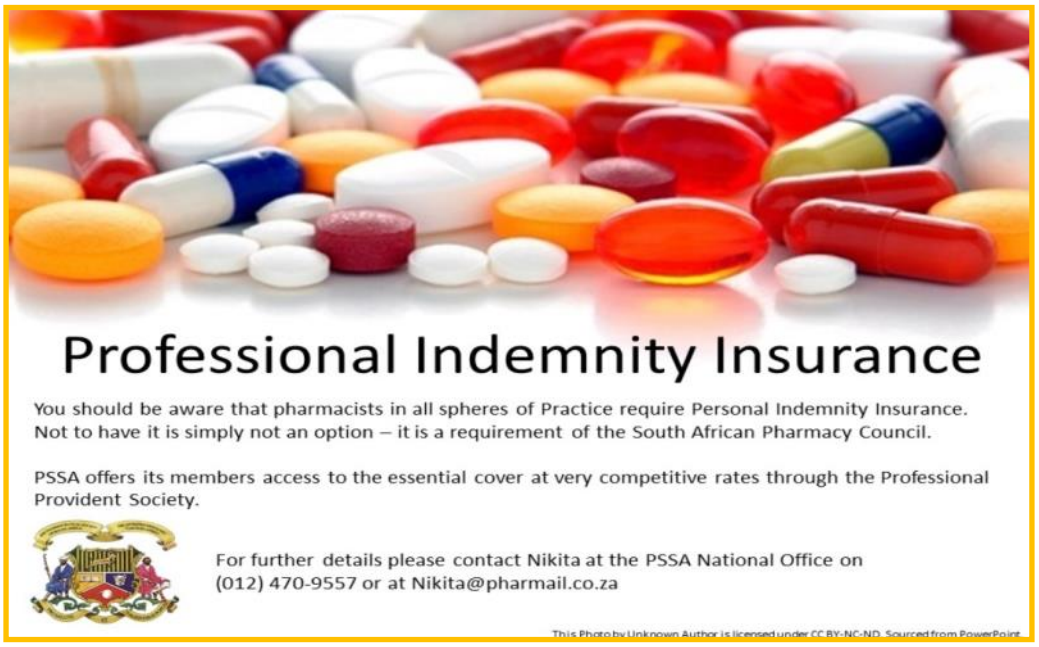
7. **Frontline healthcare workers are encouraged to enroll on the Electronic Vaccination Data System (EVDS).** Follow the self-registration link, http://vaccine.enroll.health.gov.za/ This includes both public and private, clinical and non-clinical workers.
8. **EVDS must support collection and provision of the following information:**
    - Patient information (including demographics, number of doses, etc.)
    - Health establishment where service is accessible (name and type, e.g. clinic)
    - Vaccine administered (manufacturer, batch number, etc.)
    - Safety information as part of a pharmacovigilance plan (Adverse Events Following Immunization – AEFI)
    - A record of vaccination issued to individuals where appropriate and required.
9. **As pharmacists, we play a key role in ensuring that the vaccines cold chain is managed 100%.** GPP!!! GPP!!! GPP!!! As I said, "Back to basics," colleagues.
    - Products to be stored in a temperature-regulated environment per manufacturer's product label;
    - NO domestic fridge shall be deemed suitable;
    - Large enough to allow orderly arrangement and air circulation;
    - Kept clean. Internal air temperature distribution must be mapped: i. On installation while empty. ii. When fully stocked. iii. Annually, under conditions of normal use.
    - All storage areas to be properly maintained to ensure factory standards. Proof of maintenance must be provided;
    - WHO approved/compliant temperature recording devices must be installed;
    - Temperature must be monitored and recorded at least twice daily;
    - Large commercial fridges and Walk-in-Fridges (WIF)/Cold rooms must be monitored with an electronic temperature recording device that measures the load in more than 1 location;
    - The storage area must be connected to a standby generator.
10. **As pharmacists, we are well equipped to educate and promote the usage of this vaccine to all.** Vaccine hesitancy is a global threat, and the Covid-19 pandemic has sparked fear and anxiety in many people. Know your facts when assisting someone with their decision to choose vaccination. Never force them to comply. Understand your patients' concerns. Counter any misinformation. Know that you are the most trusted information source.

2021 has started off with a bang and coming off a very difficult year in 2020, Pharmacists have experienced all kinds of emotional ups and downs, paired with physical exhaustion.
I would like to once again thank you for all your continued hard work and true passion and dedication in ensuring that we win the fight against this pandemic.

Remember social distancing, washing your hands and wearing your masks, ALWAYS.

STAY SAFE AND IF WE PLAY OUR PART IN THIS VACCINE ROLL-OUT, WE WILL ALL SOON BE TOGETHER AGAIN.



South African Pharmacy Council

2021 Annual Declarations by registered Pharmacists should be made from 1 January 2021

Registered Pharmacists are required to make an annual declaration indicating whether they are practising or non-practising every year. Failure to make this declaration will result in an auto-designation as a practising pharmacist and result in an expectation to comply with CPD requirements. From 1 January 2021, pharmacists are urged to make their annual declaration by signing-in to their secure profile on the SAPC website. Without this declaration, pharmacists will not be able to access certain functionality on the SAPC website, such as viewing their 2020 CPD entries.

The need for a patient to be switched from one antidepressant to another is not uncommon.

The most common reasons for switching antidepressants include:

- An inadequate response to initial therapy. It is estimated that approximately half of patients do not respond to their initial antidepressant.
- Intolerable adverse effects.

It is important to keep in mind that there is a potential risk of an interaction between the two agents, as well as a risk of withdrawal side-effects from the first drug being replaced.

SWITCH STRATEGIES

The procedure to follow when switching from one antidepressant to the next will depend on the antidepressant the patient is currently taking and the antidepressant that the patient will be switching to, including:

- The pharmacodynamic and pharmacokinetic properties of both antidepressants
- How urgent it is to switch the drug
- The dose of the current antidepressant
- The duration of treatment with the first antidepressant

Gradual taper, washout period and then switch

A conservative approach to switching antidepressants involves tapering the current antidepressant over several weeks, (usual recommended period is 4 weeks), applying a washout period (period where no drug is taken), then

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starting with the new antidepressant. As a rule of thumb, one can calculate the amount of time taken for a drug to be eliminated from the body by multiplying its half-life by 5 (5 X t1/2).

This method, while being the safest option with respect to drug interactions, is not always feasible for the following reasons:

- It may take a long time to withdraw the initial drug, followed by a washout period where no drug is taken, which may be detrimental to the health of a severely depressed patient
- A patient may have to abruptly discontinue an antidepressant due to a severe adverse reaction to the initial antidepressant

A moderate approach would be to reduce the washout period to approximately 2-4 days if necessary, then gradually introduce the new drug. The risk of drug-drug interactions may be increased but is still considered to be low. The gradual taper, washout period and then switch method would then be the preferred method employed, (for example when switching to a monoamine oxidase inhibitor (MAOI)).

Cross-Tapering

Cross-tapering involves gradually withdrawing the first drug and at the same time, starting the new drug at a low dose and tapering up. When the first drug is stopped, the second drug is increased to its therapeutic dose. There is an overlap of the two drugs normally for one or two weeks during the cross-tapering process, but in certain instances, where a patient is showing discontinuation symptoms, the cross-tapering may be extended over three or four weeks.

This method of switching antidepressants is contraindicated in instances where the two antidepressants interact severely with one another.

Direct switch

In certain cases, the first antidepressant may be stopped, and the next antidepressant started the following day. This method of switching antidepressants, while simple and rapid, may only be considered in certain cases, e.g.

- When switching to an antidepressant with a similar mode of action, (such as when switching from one short half-life selective serotonin reuptake inhibitor (SSRI) to another)
- Or if the first antidepressant has been taken for less than 6 weeks (less risk of withdrawal side-effects)

This method of switching antidepressants has the potential of increased risk of withdrawal symptoms from the first drug, which may be misconstrued as side-effects from the second drug being introduced.

TYPE OF ANTIDEPRESSANTS AND SPECIAL SWITCHING PRECAUTIONS

Selective Serotonin reuptake inhibitors (SSRIs)

(Examples include: citalopram, escitalopram, fluoxetine, fluvoxamine, sertraline)

- **Risk of serotonin syndrome when switching to another serotonergic antidepressant or MAOI**
- **Fluoxetine has a long half-life and caution should be exercised when switching from fluoxetine to other antidepressants (recommended gap of 4-7 days). A washout period of 5-6 weeks is recommended when switching to a MAOI**
- **SSRIs (especially fluvoxamine, fluoxetine, and paroxetine) inhibit metabolism of tricyclic antidepressants (TCAs)**

Serotonin-norepinephrine reuptake inhibitors (SNRIs)

(Examples include: desvenlafaxine, duloxetine, venlafaxine)

- **Fluoxetine and paroxetine strongly inhibit CYP2D6, which metabolises duloxetine and venlafaxine. Therefore,patients switching from fluoxetine and paroxetine to duloxetine or venlafaxine should start the SNRI at low doses**
- **At low doses, direct switch from one SNRI to another is possible. However, at higher doses, cross-tapering is recommended**

Tricyclic antidepressants (TCAs)

(Examples include: amitriptyline, desipramine, doxepin, imipramine, nortriptyline, clomipramine)

- **Clomipramine and venlafaxine or duloxetine should not be co-administered due to high risk of serotonin syndrome**

Non-selective monoamine oxidase inhibitors (MAOIs)

(Examples include: phenelzine, tranylcypromine)

- **Mandatory washout period necessary, as there is a high risk of drug-drug interactions, including hypertensive crisis or serotonin syndrome**

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- 2-week washout period is needed when switching from a non-selective MAOI to another antidepressant (3 weeks when switching to imipramine and clomipramine)
- Gap of 5-6 weeks is recommended when switching from fluoxetine to non-selective MAOI

Atypical agents

Examples include: bupropion, mirtazapine, trazodone, agomelatine, vortioxetine

- Agomelatine and fluvoxamine should not be co-administered

Quick Reference Guide for Switching Between Antidepressants

Table 1

FROM ↓ / **TO** →	**SSRIs** Citalopram Escitalopram Paroxetine Sertraline	**Fluoxetine**	**SNRIs** Desvenlafaxine Duloxetine Venlafaxine	**TCAs** (clomipramine separate)	**MAOIs** Phenelzine Tranylcypromine	**Atypical agents** Mirtazapine Agomelatine Vortioxetine Bupropion
SSRIs Citalopram Escitalopram Paroxetine Sertraline	Taper drug, start alternative SSRI at low dose*	Taper drug, start fluoxetine at low dose*	Taper drug, then start SNRI at low dose*	Cross taper cautiously with very low dose TCA (except clomipramine) **Clomipramine**: Taper and stop, then start clomipramine at low dose the following day	Taper and stop drug for 7 days, then start MAOI at low dose	**Mirtazapine**: Withdraw before starting mirtazapine cautiously* **Agomelatine**: Taper drug, start agomelatine* **Bupropion**: Taper & stop then bupropion. * **Vortioxetine**: Taper drug, then start vortioxetine at low dose. Direct switch possible, (caution if paroxetine is used)
Fluoxetine	Stop fluoxetine, wait 4-7 days, then start new SSRI at low dose and increase slowly	-	Stop fluoxetine, wait 4-7 days, then start new SNRI at low dose and increase very slowly	Stop fluoxetine, wait 4-7 days, then start TCA (except for clomipramine) at low dose and increase very slowly **Clomipramine**: Stop fluoxetine- wait 2 weeks- then start clomipramine at low dose and increase very slowly	Stop fluoxetine, wait 5-6 weeks for washout, then cautiously start with low dose MAOI	**Mirtazapine**: Stop fluoxetine, wait 4-7 days, start mirtazapine cautiously* **Agomelatine**: Stop fluoxetine, start agomelatine* **Bupropion**: Stop fluoxetine, wait 4-7 days, start bupropion **Vortioxetine:** Stop fluoxetine, wait 4-7 days, start vortioxetine at low dose with caution
SNRIs Desvenlafaxine Duloxetine Venlafaxine	Cross-taper cautiously with low dose of SSRI*	Cross-taper cautiously with low dose of fluoxetine*	Taper and stop, then start new SNRI at low dose **Duloxetine-> venlafaxine**: Stop duloxetine and start venlafaxine at low dose the	Cross-taper cautiously with very low dose of TCA (except clomipramine) **SNRI -> clomipramine**: Taper	Taper and stop, wait 1 week then start MAOI cautiously at low dose	**Mirtazapine:** Taper SNRI and then start at low dose **Agomelatine:** Cross-taper cautiously **Bupropion:** Taper and stop, then start

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SNRIs Desvenlafaxine Duloxetine Venlafaxine	Cross-taper cautiously with low dose of SSRI*	Cross-taper cautiously with low dose of fluoxetine*	next day **Venlafaxine -> duloxetine**: Direct switch possible	and stop, start low dose clomipramine the next day	Taper and stop, wait 1 week then start MAOI cautiously at low dose	bupropion cautiously **Vortioxetine**: Taper SNRI, start vortioxetine at low dose. Direct switch possible*
TCAs (clomipramine separate)	Slowly decrease dose by up to 50% & then start SSRI at normal starting dose (withdrawing TCA over a few weeks) **Clomipramine**: Taper gradually, then stop, then start SSRI at low dose the following day	Slowly decrease dose by up to 50% & then start fluoxetine at normal starting dose (withdrawing TCA over a few weeks) **Clomipramine**: Taper gradually, then stop, then start fluoxetine at 10mg the following day	Cross-taper cautiously, start SNRI at low dose **Clomipramine:** Taper and stop clomipramine, then start SNRI at low dose	Switching is of questionable benefit Cross-taper cautiously **Clomipramine**: Cross-taper cautiously	Taper & stop, wait 14 days (21 days for imipramine), then start MAOI **Clomipramine**: Taper and stop, then wait 21 days before starting MAOI	**Mirtazapine:** Taper drug, start new drug at low dose* (clomipramine: cross-taper cautiously) **Agomelatine**: Taper drug, start new drug at low dose* (clomipramine: cross-taper cautiously) **Bupropion:** Taper & stop (or to low dose), then start bupropion cautiously* **Vortioxetine:** Halve dose of TCA, start vortioxetine at 5mg, then slowly withdraw TCA (**Clomipramine-> vortioxetine**: Discontinue drug gradually, then stop-start vortioxetine at low dose the following day)
MAOIs Phenelzine Tranylcypromine	Taper and stop MAOI, then wait 14 days for washout before starting SSRI	Taper and stop MAOI, then wait 14 days for washout before starting fluoxetine	Taper and stop MAOI, then wait 14 days for washout before starting SNRI	Taper and stop MAOI, then wait 14 days for washout before starting TCA **Clomipramine**: Taper and stop MAOI, then wait 21 days for washout before starting clomipramine	Taper and stop MAOI, wait 14 days for washout before starting other MAOI	**Mirtazapine:** Taper and stop MAOI, then wait 14 days for washout before starting mirtazapine **Agomelatine**: Taper and stop MAOI, then start agomelatine **Bupropion:** Withdraw MAOI, then wait 14 days for washout before starting bupropion **Vortioxetine**: Taper and stop MAOI, then wait 14 days for washout before starting vortioxetine

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Atypical agents Mirtazapine Agomelatine Vortioxetine Bupropion	**Mirtazapine**: Taper drug, then start SSRI* **Agomelatine**: Stop, then start SSRI **Bupropion**: Withdraw, then start SSRI* **Vortioxetine**: Taper drug, then start SSRI at low dose*	**Mirtazapine**: Taper drug, then start fluoxetine **Agomelatine**: Stop, then start fluoxetine **Bupropion**: Withdraw, then start fluoxetine **Vortioxetine**: Taper and **stop**, then start fluoxetine at 10mg	**Mirtazapine**: Taper, then start SNRI* **Agomelatine**: Stop agomelatine, then start SNRI **Bupropion**: Taper and stop, then start SNRI at low dose and increase slowly **Vortioxetine**: Taper, then start SNRI at low dose	**See table 2**	**Mirtazapine**: Taper and stop, wait 14 days washout, then start low-dose MAOI cautiously **Agomelatine**: Stop, then start MAOI **Bupropion**: Withdraw and wait 7 days, then start MAOI **Vortioxetine**: Taper and stop, wait 21 days washout before starting MAOI (at low dose) cautiously	**See table 3**

*Safest option is to apply a washout period between drugs

Table 2

FROM / **TO**	**TCA's** Amitriptyline Imipramine Nortriptyline Doxepin Dothiepin Trimipramine	**Clomipramine**
Mirtazapine	Cross-taper cautiously*	Taper, then start clomipramine at 25mg*
Agomelatine	Stop agomelatine, start TCA the next day at low dose	Stop agomelatine, start clomipramine the next day
Vortioxetine	Cross-taper cautiously with low-dose TCA	Taper and stop vortioxetine, start clomipramine at 25mg
Bupropion	Taper and stop, then start TCA at a low dose and increase slowly	-

Table 3

FROM / **TO**	**Mirtazapine**	**Agomelatine**	**Vortioxetine**	**Bupropion**
Mirtazapine	-	Taper drug, start agomelatine cautiously	Taper drug, start vortioxetine cautiously	Withdraw, then start bupropion cautiously
Agomelatine	Stop agomelatine, start mirtazapine the following day	-	Stop agomelatine, start vortioxetine the following day	-
Vortioxetine	Taper vortioxetine, then start mirtazapine at low dose	Taper vortioxetine, then start agomelatine at 25mg	-	-
Bupropion	Withdraw bupropion, then start mirtazapine cautiously	-	-	-

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CONCLUSION

A patient switching from one antidepressant to another will need to be individually assessed in order to determine which approach will be the safest and most effective for the patient. The switch will need to be carefully monitored by the physician. Patients should be counselled, where applicable, of the signs and symptoms of serotonin syndrome, as well as the possible discontinuation side-effects of the antidepressant being switched.

REFERENCES AVAILABLE ON REQUEST

Explainer: How South Africa Regulates Medicines and Vaccines

By Andy Gray
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theconversation.com / The Saturday Star

Andy Gray

COVID-19 has raised public awareness about the role of national medicines regulatory authorities in enabling access to safe, effective and quality-assured medicines. This includes vaccines.

In South Africa, the pandemic has also exposed a number of important misperceptions, among the public and health professionals.

The South African Health Products Regulatory Authority (SAHPRA) is responsible for monitoring, evaluating, investigating, inspecting and registering all health products. These include medicines for human and animal use, medical devices and diagnostic tests. The authority is an independent structure, located outside the Department of Health and the public service. Funded by a combination of user fees and fiscal allocation, with a small contribution from donors, it is accountable to the Minister of Health.

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Regulatory bodies vary around the world, but the structure of the South African authority is now closer to those of other major regulators. The decision-making power is vested in the Chief Executive Officer (CEO), WHO can appoint a range of technical advisory committees to make recommendations to inform regulatory decisions. Members of the advisory committees are drawn from academia and private practice.

Examples of regulatory decisions include:

- Registration of a medicine or vaccine. Registration is required before a medicine can be marketed.
- Approval to conduct a clinical trial in human volunteers of an investigational vaccine.
- Approval of compassionate access to an unregistered medicine. This is done on the basis of motivation by an authorised prescriber or the Department of Health.

National medicines regulatory authorities can also be proactive. For example, they can provide advice on regulatory standards. The authorities can also engage with applicants as they develop new products. For example, regulators have communicated in advance about the targets for the efficacy of COVID-9 vaccines.

The South African authority has also contributed to global regulatory efforts. And it is doing rolling reviews of two COVID-19 vaccines (Novavax; Johnson and Johnson) and is assessing a dossier for another (Pfizer). It has also approved imports of the vaccine (Oxford/AstraZeneca) which is being manufactured in India even though it hasn't yet been registered. It's awaiting submission of a full dossier on the vaccine.
The Astra Zeneca- University of Oxford Covid-19 vaccine was very recently found to be ineffective against the Covid-19 501Y.V2 variant.

THE SOUTH AFRICAN AUTHORITY

By law, the South African Health Products Regulatory Authority is constrained to consider only three factors when it makes decisions: quality, safety and efficacy.

Quality refers to the batch-to-batch reliability of the regulated product. This takes into account how it is made, packaged and distributed. Quality must be demonstrated at the time of registration. It must also be assured throughout the lifecycle of the health product. Lifecycle refers to the entire time that a product is marketed.

Every medicine is associated with desired and undesirable effects. The safety assessment relates to the undesired, adverse effects, and whether they are proportional to the proposed use. For example, a treatment for a severe and potentially fatal disease may be associated with serious adverse effects. But, on balance they may be considered acceptable.

On the basis of safety considerations, medicines can be restricted to prescription-only access, or pharmacist-initiated sale, or placed on the market for general sale.

In some cases, a formal post-registration obligation is placed on the applicant. Examples include research on use in children. But most post-registration safety data comes from spontaneous reporting by health professionals and patients. Anything reported to the manufacturer must be reported to the regulator.

Efficacy data describe whether the medicine achieves its proposed purpose in preventing or treating a disease or symptom. The data also shows whether there are important differences in effect between patient groups. For example, it is affected by age or sex.

Importantly, there are certain things the regulator is excluded from factoring in. These include:

- the price of a medicine
- its cost-effectiveness to the health system, or
- its affordability.

This responsibility lies with the Minister of Health and a pricing committee.

THE PROCESS

In the case of medicines and vaccines, the starting point for the regulator's assessment is the dossier submitted by the applicant. This is a comprehensive and exhaustive submission of the evidence of quality, safety and efficacy.

After initial screening, the elements of the common technical document are referred to specific evaluators. These are often external people, or technical advisory committee members. Their assessments, after peer review and sometimes committee deliberations, inform the eventual regulatory decisions.

The final decision to issue a certificate of marketing authorisation is accompanied by:

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- specific conditions,

- approval of the professional information and patient information leaflets, and
- an approved proprietary (brand) name for the product.

Lastly, each batch of biological medicines, such as vaccines, is tested at the National Control Laboratory for Biological Products.

Many of the assessments conducted by the South African regulator may have been done by one in another country. To avoid duplication, and speed up decision-making, regulators engage in what is called "reliance". They enter into agreements to share information and co-operate in making regulatory decisions.

In a minority of applications, South Africa's regulator can "rely" on prior decisions taken by well-resourced and mature regulators, and focus its efforts only on issues that are specific to circumstances in the country.

The South African Health Products Regulatory Authority's response to COVID-19 has been questioned.

Advocates for medicines that are unregistered in South Africa have accused the body of not being proactive in bringing such products to market and approving their use. But an applicant is needed to provide a quality–assured product and to be held accountable for meeting those standards. The authority can't approve a product in the absence of an appropriate applicant.

The body has also been criticised for not conducting the necessary clinical trials to provide the needed evidence of safety and efficacy. Again, its role is to regulate such trials, not to conduct or fund them.

MEETING MANDATES

National medicines regulatory authorities are gatekeepers that protect the public from unnecessary harm from health products. They do so in the best tradition of the injunction to "do no harm". But in doing so, regulators must necessarily restrict the freedom to make, sell or use such products.

As prominent political scientist Daniel Carpenter described, the most powerful of these agencies, the US Food and Drug Administration *is venerated in one corner and bemoaned in another; it is targeted for expansion by one voice, for evisceration by a second.*

The South African Health Products Regulatory Authority is no less buffeted in a time of extraordinary clinical need and risk. It can only respond by being true to its mandate, transparent in its decision-making and scrupulously reliant on the scientific evidence.

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Your COVID-19 vaccination journey

6 steps to getting vaccinated

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2. Apply to Sisonke Vaccine Programme at https://sisonke.samrc.ac.za/
3. Receive vaccination voucher number
4. Attend vaccination site for vaccination
5. Get the vaccine
6. Receive final SMS with vaccination proof code

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"THIS IS ONLY FOR HEALTHCARE WORKERS"

The Southern Gauteng Branch of PSSA cordially invites you to attend our March CPD

COVID-19 Therapeutics What has Changed in the Past Year

Date: 23 March 2021
Time: 19h00
Venue: **Virtual** via Microsoft Teams

Presenter: Mr. Muhammed Vally
Lecturer: Head of Division of Clinical Pharmacy

THE LINK WILL BE SENT IN DUE COURSE

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