



## Determining the preparedness of the SA pharmacy profession to vaccinate during a pandemic

Since March 2020, the COVID-19 pandemic dominated our lives. Initial strategies were to pause life as much as possible, to allow governments and global leadership the opportunity to develop strategies for the way forward and giving the healthcare systems time to prepare for the increased burden and to prevent the collapse of the healthcare systems. We had to adapt to the new life with masks, hand washing, physical distancing, curfews, working from home, virtual events, and much more. The rest of 2020 was occupied by the different adjusted levels and our freedom of movement based on the daily number of infections.

As everyone was looking forward to a new year in 2021 and the possibility of life without a pandemic, the new focus on vaccination was on our shores. It is said to be the single largest public health initiative ever, with the aim to reach herd immunity on a global level. Although details on which product will be best suited for the (current) South African variant is yet to be finalised; it does not change the massive task ahead of nationwide vaccination roll out.

In order to vaccinate more than 40 million South African citizens, the government is pressured to use every healthcare worker who is allowed to immunise, to assist in achieving this goal in the shortest possible duration. This includes pharmacists, as the World Health Organization has determined that pharmacists are the first point of contact for patients within the healthcare system<sup>1</sup> and as a result, the most accessible healthcare professional and the geographical distribution of private sector community pharmacies in this country allows for reach in almost every corner of the country.

The International Pharmaceutical Federation's (FIP) forum for professional regulators developed a self-assessment tool to identify strengths and areas for improvement in order to inform pandemic planning efforts ahead of current and future waves of COVID-19. The checklist is based on the desired function to deploy pharmacists and pharmacies to increase access to vaccination and testing services, provide supportive care for patients with chronic medication needs, and offer treatment for minor symptoms when the patient's viral conditions is considered minor. In South Africa, where pharmacists have vaccination rights, the PSSA used this tool to support further expansion of this role within the current pandemic.

This tool is divided into four sections, which focus on vaccination, testing, prescribing and supply chain management. For each of the following aspects, the PSSA evaluated the requirements as either "in place" or "not in place", based on the situation in South Africa. In the case of requirements that are not in place, the "Estimated time needed to implement" was predicted as well as the "Risk level" which indicates, from a public protection perspective, the impact should the task not be completed or be delayed unduly or unnecessarily.

### Vaccination

In the Regulations relating to the practice of pharmacy,<sup>2</sup> the provision of immunisation is listed under services pertaining to the scope of practice of a pharmacist and which may therefore be provided in a community or institutional pharmacy. In addition, the Rules relating to the services for which a pharmacist may levy a fee and guideline for levying such a fee or fees<sup>3</sup> includes both the administration of an intramuscular or subcutaneous inject as well as administration of immunisation. These services must be provided in accordance with the Good Pharmacy Practice (GPP) rules<sup>4</sup> relating to the Minimum standard for immunisation services (rule 2.14). It is important to remember that the definition of a pharmacy, as included in the Pharmacy Act,<sup>5</sup> means any (registered) place wherein or from which any service specially pertaining to the scope of practice of a pharmacist is provided, thus allowing for pharmacists to participate in off-site vaccination campaigns.

The National Department of Health (NDoH) offered intense training for healthcare workers on the vaccination roll out strategy through their Knowledge Hub from 15 January to 3 February 2021. The training consisted of seven modules, including distribution and storage, vaccination session management, adverse events following immunisation (AEFI), record and monitoring, communication, and ethical principles.

To complement this clinical training, the PSSA offered a webinar series of eight episodes on vaccines back-to-basics, which not only assisted the pharmacy workforce to revisit and refresh their knowledge on pharmacology, pharmaceuticals and pharmacy practice, but further empowered them to be able to answer

questions and queries from patients and the public in the build-up to nationwide vaccination scheduled for later this year. This training is in addition to webinars offered during 2020 to members on COVID-19.

The provision of immunisation is included in the services pertaining to the scope of practice of a pharmacist and should therefore be included in the BPharm degree. The extent to which this training is offered by the nine pharmacy schools in the country may differ.

The so-called ethical rules<sup>6</sup> prescribed by the South African Pharmacy Council (SAPC) state that it would be deemed unethical or unprofessional conduct to perform any professional acts for which (s)he is inadequately trained or have insufficient experience. If additional training is desired, it can take place either in the workplace through learning from peers or by accessing formal training in the form of a course in immunisation and injection techniques.

Recordkeeping of vaccinations is currently achieved through hardcopy records, such as the Road to Health card or Yellow Fever vaccination card. For the COVID-19 vaccine and beyond, the NDoH developed the centralised Electronic Vaccination Data System (EVDS) which will assist with vaccination records. This is much more comprehensive and sustainable than the current paper-based records.

If the NDoH envisages that over 40 million people will be immunised in 18 months, this mammoth task will require every available health resource, and pharmacists are ideally placed to assist.<sup>7</sup>

All pharmacy professionals, irrespective of whether their practice setting is selected as a national vaccination centre or not, or whether they are currently working on the frontline or not, are encouraged to participate in this effort. Pharmacists may volunteer as vaccinators at other facilities selected as vaccination centres, outside of their remunerated working hours. Pharmacist interns, pharmacy support personnel and pharmacy students can volunteer and participate as administrators, assisting with data capturing and management of the vaccination session.

The PSSA will focus on this over the next few months, as the risk associated with *not* achieving this strategic objective will result in a much longer time frame needed to vaccinate the nation, during which time unnecessary infections and deaths may continue.

## Testing

Nasal swabbing falls into the scope of practice of pharmacists, which may be performed if the pharmacist is trained to perform such a service. In the hospital pharmacy setting, this service was provided by other healthcare professionals and not by the pharmacy staff.

Some community pharmacies have offered this service to patients, but it remained a risk for the pharmacy to bring possible COVID-19 positive patients into the pharmacy, thereby increasing the risk of

staff and other patients to contract the virus. Since most pharmacy clinics do not have extractor fans and are in a confined space, the pharmacies that offered these services did so on premises outside of the pharmacy and used other healthcare professionals employed by the pharmacy, such as professional nurses, rather than pharmacists.

With the introduction of antibody and antigen rapid tests, the South African Health Products Regulatory Authority (SAHPRA) provided conditions for the use of COVID-19 serological test kits.<sup>8</sup> All serology test results must be recorded and must contribute to the national database. Further to this all results should be reported to the National Health Laboratory Service (NHLS) utilising the web-based application.

## Prescribing

With the commencement of the pandemic and the associated adjusted level 5 lockdown in the country, many patients had difficulty in accessing their prescribers for repeat chronic prescriptions. Section 22A(6)(l)<sup>9</sup> allows a pharmacist, in an emergency, to sell Schedule 3 or 4 substances on a non-recurring basis for a period not exceeding 30 days in accordance with the original prescription in order to ensure that therapy is not disrupted, and only if the pharmacist is satisfied that an authorised prescriber initiated the therapy, with the intention that the therapy be continued.

During this time, the Minister of Health, on the recommendation of SAHPRA, published an exclusion of Schedule 2, Schedule 3 and Schedule 4 substances from the requirement in section 22A(6)(f) of the Act that such substances may be dispensed for no longer than six months.<sup>10</sup> Unfortunately, the intention of this exemption was not followed by all colleagues in the profession, which led to misuse and possible abuse thereof, which was not in the interest of the patient.

As a result, an updated exemption was published on 20 November 2020,<sup>11</sup> instructing the pharmacist to first confirm the intention of the prescriber to continue therapy before dispensing another repeat. The current state of affairs is that pharmacists cannot initiate continuing supply of chronic medicines independently during the pandemic.

All vaccines included in the NDoH's Expanded Programme on Immunisation (EPI)<sup>12</sup> are listed as Schedule 2, and are accessible to pharmacists through pharmacist-initiated therapy (PIT) without a prescription from a medical practitioner. Included in the list of Schedule 2 vaccines are those vaccines against the Human Papilloma Virus, combined Measles, Mumps and Rubella, and annual flu vaccine. Other prescription-only vaccines only available on prescription from an authorised prescriber includes Varicella-Zoster, Pneumonia, Meningococcal and Tetanus (for adults). A special permit is needed to prescribe and dispense prescription-only vaccines for travel vaccination which includes typhoid, hepatitis A, rabies, and yellow fever.<sup>13</sup>

The schedule, or lack thereof, of the COVID-19 vaccine is at this stage not yet finalised. Similar medicines categorised as Biologicals

are currently listed in Schedule 4, requiring a prescription from an authorised prescriber. It is anticipated that a Primary Care Drug Therapy (PCDT) pharmacist with a valid section 22A(15) permit will be able to prescribe the COVID-19 vaccine given their current permit conditions.

Pharmacists working in community or hospital pharmacies with relevant training in immunisation and injection techniques will have access to prescribing the COVID-19 vaccine through PIT, as used to access Schedule 1 and 2 medicines for the treatment of minor symptoms. The professional nurse working in community pharmacies will have access to the COVID-19 vaccine through the abovementioned pharmacist.<sup>14</sup> The scheduling of the COVID-19 vaccine, and associated access for pharmacists, remains a priority to the PSSA.

### Supply chain management

Section 22C of the Medicines Act<sup>15</sup> requires that manufacturer, wholesaler or distributor of a medicine, scheduled substance, medical device or IVD must be licensed to manufacture, import,

export, act as a wholesaler of or distribute upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing and distribution practices as the Authority may determine.

This legislation will still be enforced during the importation and distribution of the COVID-19 vaccine, as stated in the “Request for proposals for the provision of importation and logistics services for COVID-19 vaccines to the NDoH”,<sup>16</sup> specifying that all warehousing facilities must be appropriately licensed in terms of the Medicines Act as pharmaceutical warehouses.

The South African Good Wholesaling Practice for Wholesalers<sup>17</sup> offers guidelines on the return of medication but highlights the need for a “No Returns” policy in the event of cold-chain items. This sentiment is echoed in the NDoH’s request for proposals document, where it is specified that no product must be accepted for returns from any delivery site unless such return is instructed in writing by the NDoH.

The importation agreement<sup>18</sup> between the South African government and the potential service provider confirms that the

Factors	Legislative/regulatory requirement	In place	Not in place	Estimated time needed to implement change	Risk level	Priority
<b>Vaccination</b>						
1. There is enabling legislation to allow pharmacists to be vaccinators during a pandemic	<i>A pharmacist who meets the qualifications set out in the regulations may, subject to any restrictions or conditions set out in the regulations and in the course of the practice of pharmacy, engage in the act of administering medicines or vaccines that are designated in the regulations.</i>	X				
2. There is comprehensive and clear regulations describing the conditions under which pharmacists can be vaccinators	<i>A pharmacist may administer vaccines through intradermal, subcutaneous, intramuscular injection or other routes only if he or she holds a current certification to do so. A pharmacist may administer a vaccine that is prescribed by an authorised practitioner to a person or may administer a vaccine without a prescription to a person as part of an approved immunisation programme.</i>	X				
3. Education and training programmes are available and required for pharmacists to be vaccinators	<i>A pharmacist must be certified / recognised to administer a vaccine by injection through successfully completing the required education and training requirements approved by the regulator. Certification can occur during the undergraduate programme or through accredited continuing education.</i>	X				
4. There is a centralised vaccination reporting database system in place and/or patient personal vaccination booklet system	<i>A pharmacist who plans to administer a vaccine to a patient must check with the centralised vaccination patient data to confirm the vaccination has not already taken place and, once the vaccination is completed, report the details of the administration to the patient vaccination database.</i>	X				
5. Pharmacists may administer vaccines offsite from the pharmacy, to reach homebound patients and those living in remote and underserved areas, in other community locations such as care or nursing homes, workplaces, schools, etc.	<i>Pharmacists certified in administration may administer vaccines outside the community pharmacy as long as they are following all the requirements of vaccine storage and administration and do so safely to readily address emergency patient response situations and monitor patients after administration.</i>	X				
6. Pharmacists must have an understanding of the risk when a pandemic is declared and act as educators of the public regarding the value of mass vaccination programmes during times of pandemic	<i>Pharmacists must be knowledgeable in the value and impact of mass vaccination programmes on population health and provide factual information to the public in support of the science of vaccines and mass vaccination programmes.</i>	X				
7. There is enabling legislation to allow trained personnel (e.g., nurse technicians, pharmacy technicians) to be vaccinators during a pandemic	<i>Personnel qualified by suitable training should be able to administer vaccines — freeing up nurses and medical doctors to treat COVID patients.</i>		X	2–4 months	High	Second

NDoH is in the process of sourcing and procuring vaccines from global manufacturers and that the service provider (to whom the tender will be awarded) will conclude the procurement agreements with the various manufacturers around the world and import into South Africa.

## Conclusion

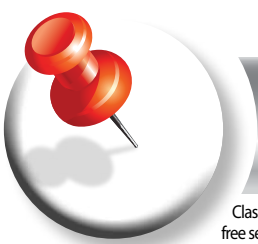
As a country, South Africa made provision for all aspects associated with preparation for a pandemic, including the nationwide roll out of the COVID-19 vaccine.

Pharmacy-based vaccination, testing and prescribing is possible through current legislation. *Only two aspects from the self-assessment tool require the PSSA's continuous attention, namely the scheduling of the vaccine to allow PIT and access by pharmacists without prescriptions, as well as to support current legislation and efforts to ensure sufficient qualified pharmacy professionals, including support personnel, to serve at vaccination centres as vaccinators or administrators, either through employment or volunteering.* The PSSA through its National Executive Committee (NEC) will implement actions to realise these two shortcomings.

Testing						
There is enabling legislation to allow pharmacists to perform virus screening tests and provide test results during a pandemic	<i>A pharmacist who meets the qualifications set out in the regulations may, subject to any restrictions or conditions set out in the regulations and in the course of the practice of pharmacy, engage in the act of: (a) performing point-of-care screening tests of appropriately regulated quality to support the diagnosis of disease cases in the community; (b) interpreting patient-administered automated tests that are designated in the regulations; (c) ordering and receiving reports of screening and diagnostic tests that are designated in the regulations.</i>	X				
Education and training programmes are available and required for pharmacists to perform tests related to the pandemic	<i>A pharmacist must be certified to perform tests through successfully completing the education and training requirements approved by the professional regulator. Certification can occur during the undergraduate programme or through accredited continuing education.</i>	X				
There is a centralised testing reporting database system in place	<i>A pharmacist who administers a test to a patient must check with the centralised patient data to confirm the last time a test was performed and the result and, once the test is completed, report the details of the test into the centralised patient database.</i>	X				
Mitigate the community-transmission risk through testing services provided to patients and staff and enhance their understanding of containment responsibilities and activities	<i>Pharmacists must be knowledgeable in the value and impact of testing services as it relates to pandemic containment and key activities to decrease the spread of the virus and provide the information to patients and pharmacy staff.</i>	X				
Prescribing						
There is enabling legislation to allow pharmacists to prescribe vaccinations during a pandemic	<i>A pharmacist who meets the qualifications set out in the regulations may, subject to any restrictions or conditions set out in the regulations and in the course of the practice of pharmacy, engage in the act of prescribing vaccines that are designated in the regulations.</i>	X	2-4 months	High	First	
There is enabling legislation to allow pharmacists to prescribe continuing chronic medicines during a pandemic	<i>In order to continue patients on current chronic medication that was previously prescribed, a pharmacist who meets the qualifications set out in the regulations may, subject to any restrictions or conditions set out in the regulations and in the course of the practice of pharmacy, engage in the act of prescribing drugs that are designated in the regulations.</i>	X				
There is enabling legislation to allow pharmacists to prescribe treatment for minor symptoms of patients with the pandemic virus	<i>In order to meet the needs of patients with a pandemic virus, a pharmacist who meets the qualifications set out in the regulations may, subject to any restrictions or conditions set out in the regulations and in the course of the practice of pharmacy, engage in the act of prescribing medicines, as designated in the regulations, for symptomatic treatment of the minor symptoms associated with the viral conditions up to a point when referral to another healthcare professional or hospital admission is warranted.</i>	X				
Supply chain management						
There is legislation requiring the registration and licensure of manufacturers and wholesale pharmaceutical distributors (for vaccine distribution to retail settings and/or healthcare providers in licensed facilities)	<i>Any person or business engaged in the distribution of medicines and vaccines to licensed facilities or healthcare professionals for the purpose of administration to a member of the public must be licensed and comply with all applicable statutes and regulations.</i>	X				
Legislation prohibits risky return and redistribution activities	<i>Licensed pharmaceutical distributors cannot accept for redistribution any medicine or vaccine from a licensed facility or healthcare professional unless the distributor originally supplied that exact vaccine, as confirmed through lot number and expiry date, to the facility or healthcare professional and can be assured the quality of the vaccine has been maintained.</i>	X				
Legislation requires integrity of the vaccine to be distributed	<i>Licensed pharmaceutical and vaccine distributors must ensure vaccines are obtained from legitimate sources and are required to keep accurate records of acquisitions and visually examine vaccines for the possibility of being falsified vaccines or having been subject to improper storage or damage.</i>	X				

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