

## ***Pharmaceutical News Summary of Highlights***

### ***SA's role in the race for a COVID-19 vaccine***

#### ***SA joins measles vaccine trial in Covid-19 fight***

Researchers are preparing to launch the SA leg of an international trial investigating whether the well established measles, mumps and rubella (MMR) shot used in childhood immunisation programmes can protect front-line healthcare workers from Sars-CoV-2, the virus that causes COVID-19. The SA arm of the study is expected to receive final approval from the SA Health Products Regulatory Authority shortly and will enrol about 5 000 volunteers in sub-Saharan Africa.

More than 170 potential C-19 vaccines are being developed worldwide, but only nine are in late-stage phase 3 efficacy trials, and none has yet been approved by regulators, according to the World Health Organisation.

#### ***Wits launches SA's second Covid-19 vaccine trial***

In August, Wits University launched its second COVID-19 vaccine trial, testing an experimental shot made by US biotech company Novavax, supported in part by a \$15-m (about R261-m) grant from the Bill & Melinda Gates Foundation.

The phase 2b trial of the shot, called NVX-CoV2373, will enrol about 2 900 adult volunteers, including 240 who are HIV-positive,” reported *Times Live* (19 August 2020).

#### ***SA's first C-19 antibody tests now available***

On August 24, *News24* reported that South Africans can now pay for private medical screenings – antibody tests – to detect if they have been exposed to the coronavirus.

This, after SAHPRA has already announced five months earlier that the tests would be “expedited” as key armaments in the fight against C-19,

#### ***Using remdesivir to treat COVID-19 still controversial.***

In August the DoH issued new treatment guidelines for the Covid-19 medicine *remdesivir*, citing the medicine's “high cost and marginal benefit” as reasons for its decision not to recommend it.

However, by the end of August the pharmaceutical company, Cipla SA, has already sold 25 000 units of the drug to the private sector. The Charlotte Maxeke Johannesburg Academic Hospital, a public facility, has ordered 500 vials of *remdesivir*, from Cipla. *Remdesivir* is not registered for use in SA but Cipla has obtained a license from the SA Health Products Regulatory Authority (SAHPRA) to import it.

Although study results for *remdesivir*'s efficacy are inconsistent, Cipla SA's CEO, Paul Miller, said the demand for the drug is soaring in some countries. An analysis of seven international trials found that treating critically ill COVID-19 patients with corticosteroid drugs, like *hydrocortisone*, *dexamethasone* and *methylprednisolone*, reduces the risk of death by 20%, reported *Reuters* (2 September 2020).

#### ***Regulator approves trial on MMR vaccine***

In October the SA health Products Regulatory Authority (SAHPRA) approved the local arm of an international clinical trial to investigate whether the childhood vaccine for measles, mumps and rubella (MMR) can protect healthcare workers from Covid-19. 30 000 healthcare workers around the world took part in the trial. There is mounting evidence that some vaccines provide broader benefits than simply protecting people from the disease they target.

### ***J&J vaccine deal to boost Aspen's global profile***

The COVID-19 vaccine deal Aspen has secured with Johnson & Johnson will position SA as a major player in the international pharmaceutical industry and provide Aspen with a higher international profile to secure further deals, reported *Business Times* (8 November 2020). Aspen invested R3.4-bn in a facility in Port Elizabeth for the creation of anaesthetic products. This will now also be used to manufacture the 300-m COVID-19 doses a year.

### ***Pfizer set to produce vaccines in SA***

Pharmaceutical company Pfizer is increasing its manufacturing capacity for vaccines in SA, but it will not manufacture a COVID-19 vaccine in the country, reported *Business Times* (27 September 2020). Rhulani Nhlaniki, the cluster lead for sub-Saharan Africa and country manager for SA at Pfizer in SA the group, is working with the Biovac Institute to manufacture the pneumococcal conjugate vaccine. He said Biovac has not been tasked with the production of the COVID-19 vaccine and SA will need to rely on it being imported from the US and Europe. He estimates that by the end of 2020, depending on the outcome of the phase 3 trials and regulatory approval, Pfizer and its manufacturers in the US and Europe will have manufactured 1.3-bn doses of the COVID-19 vaccine.

### ***Research warns against putting inoculation on hold***

A study by the London School of Tropical Medicine (published in *The Lancet*) estimates that up to 702 000 children, and more than 18 000 in SA, could die before the age of five because of temporary lockdown suspensions of immunisation.

According to the study “the benefit of sustaining routine childhood immunisation in Africa far outweighs the excess risk of C-19 deaths during the child’s vaccination visit, particularly for the vaccinated children”. According to the study 84 deaths would be prevented by vaccinating children under five years for every one C-19 possible death.

Immunisation via inoculation against hepatitis B, influenza type B and pneumonia and diarrhoea could avert about 471 000 deaths. The first dose of vaccination for measles, rubella and yellow fever in some African countries is estimated to avert about 220 000 deaths.

## ***TB***

### ***Study to evaluate new TB diagnostic tests and treatments***

**In September Biz Community** reported that a grant of R128-m from the US National Institutes of Health (NIH) will help fund a five-year multinational research study that Stellenbosch University is undertaking to investigate new tuberculosis (TB) tests. The trials will comprise 4 000 participants and seven novel tests, that will be evaluated for diagnosing active TB; for TB treatment response outcomes; and, for predicting those at risk of progressing to active TB.

### ***TB meds side-effects crisis***

According to a study, published by the Human Sciences Research Council (HSRC), the inadequate reporting of the side-effects of drug-resistant TB (DR-TB) were one of main reasons for patients defaulting on medication. Gastrointestinal reactions, peripheral neuropathy and hepatitis abnormalities, are the 14 common side-effects associated with drug-resistant TB medication. HSRC’s Dr Razia Gaida said while many cases of TB could be cured with six months’ antibiotic treatment, DR-TB does not respond to one or more antibiotics and, in some cases, can be difficult to cure.

Many patients stop taking therapy before they have completed the six months course, or by not taking the medication correctly. This could also lead to further mutations and patients could develop resistance to multi drug resistant TB, which makes further treatment options very difficult.

## ***HIV***

### ***HIV prevention shot outperforms daily pills***

**In November *Business Day*** reported that an international HIV prevention trial comparing ViiV Healthcare's long-acting cabotegravir injections with a daily regimen of Gilead Science's Truvada pill in women has proved so successful that it has been stopped early. The HPTN 084 trial, which includes SA volunteers, found women who received a shot of cabotegravir every two months were nine times less likely to get HIV than those who were directed to take a daily pill.

Sinead Delany-Moretlwe, research director at Wits Reproductive Health and HIV Institute, said this is a real step forward for the HIV prevention field