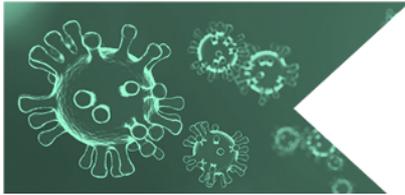


✉ Share this with those who need to know



SAMED COVID-19 NEWS

south african medical technology industry association

COVID-19 news from SAMED, Government and Abroad.

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SAMED ON COVID-19

The [SAMED Library](#) is a dedicated resource for all COVID-19 related updates, regulations, notices and news. All SAMED COVID-19 updates and related information can be found [here](#).

PLEASE PARTICIPATE: BSA COVID-19 products and company information portal.

This effort is part of the broader SAMED collaboration with the Minister of Health via Business Unity South Africa's "Business for South Africa" initiative (BSA). During the current pandemic, up-to-date information is critical to ensure all key stakeholders in the value chain make the best-informed decisions at the right time.

The information collected on the covid19manager.co.za platform will be used to ensure supplier verification, regulatory compliance, product availability, reasonable pricing and providing the accurate and most up-to-date logistical information to the procurement department division at BSA to place orders from you and/or assist with ramping up local production. It is an automated process to help facilitate the overwhelming demand currently being experienced in South Africa during the weeks to come. The SAMED office, IDC, the dti, Minister of Health and the BSA procurement team will have access to the data. No data will be shared with other suppliers.

NOTE: THIS IS A LIVE SYSTEM SO PLEASE UPDATE YOUR STOCK QUANTITIES AND LEAD TIME AS AND WHEN THEY CHANGE.

Please see the following [link to the video](#) for an explanation of how to use the portal and click on <https://covid19manager.co.za/> to add your company and product information.

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measure. The BSA procurement team will always supply you with your security code that only you have access to on the portal. See the video for reference as to where to find this code. Please never share or read this code to anyone but only have them read it back to you for validation. If at any point you feel your security code is compromised please let Tanya Vogt (tanya@samed.org.za) know and it will be reset.

We are extremely appreciative of the support and commitment of our members in fighting this pandemic.

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DO YOU HAVE A COVID-19 QUESTION OR QUERY?

Please visit the [FAQ Section](#) of our library as it provides answers to many of the frequently asked questions we receive.

Frequently Asked Questions (FAQs) relating to Essential Goods, clearance and movement of goods and service rendered by customs under the COVID-19 lockdown

- What is the difference between critical supplies and essential goods?
- What do we need to know about the importation of critical supplies or essential goods to the national state of disaster (COVID-19 pandemic)?
- Do I need to apply for the VAT exemption under rebate item 412.11?
- Where can I find the certificate issued in terms of Schedule 1(8) of the Value Added Tax Act, 1991, item 412.11/00.00/01.00 (RE: SARS Essential Goods List)?

Find the answer to these and other questions [here](#).

Disaster Management Tax Relief FAQ's for Employees' Tax, ETI and Provisional Tax

- Who are qualifying taxpayers?
- What are the requirements to claim the tax relief?
- What is the Employment Tax Incentive (ETI) tax relief?
- What is the Employees' Tax Deferral?

Find the answer to these and other questions [here](#).

COVID-19 UPDATES, NOTICES, LEGISLATION AND REGULATIONS

REGULATIONS: New under the Disaster Management Act

The new set of regulations repeals the previous set of regulations in its totality. This set of regulations will now apply until the end of the State of Disaster.

The Regulations, R480 of 29 April 2020, GG No 43258, include the following:

- Definitions - no more "essential services" or "essential goods" in the regulations, although the definition of essential services are now included in Annexure D and references the designation of such by the Essential Services Committee - see below
 - 'permitted goods' means Part E in Table 1:
 - 'permitted goods for export' means the goods listed in Annexure C:
 - 'permitted services' means the services permitted in Table 1
- The levels are no longer called "lock-down levels" but "alert levels".
- It empowers the Various ministers to issue Directions (Reg 4), e.g:
 - The Minister of Health to issue directions on human resources (similar to what as previously released as a Directive - see our update email of 8 April 2020)
 - The Minister of Trade, Industry and Competition to issue on competition, and the security & availability of the supply of goods & services
 - Any Minister can issue directions on emergency procurement procedures - details of this is in Reg 11.
 - The Minister of Health may designate services that are necessary for essential health

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- special measures for those over 60; disclosure of co-morbidities and higher risk.
- Reg 6 deals with persons refusing testing care, etc. for COVID-19 for whom a warrant of arrest could be issued;
 - Reg 7 persons must comply with instructions from doctor, nurse or enforcement officer to quarantine or travel to a health facility;
 - Reg 8 deals with tracking & tracing, incl. the surveillance under the authority of Judge O'Regan;
 - Various government departments must release resources (human and funding) under Reg 9;
 - Before litigation on the Regulations, parties can agree to mediation, or even before a judgement is handed down (Reg 13);
 - Penalties of 6 months imprisonment or a fine under Reg 14.
 - Alert Level 4 (previously proposed as Lockdown level 4) - Reg 15 to 33:
 - Applies from 1 May till when next level is declared;
 - Persons can move to perform an essential or permitted service as allowed in level 4;
 - Obtain services permitted in Table 1, see below.
 - Only children returning to school, persons returning to work or for funerals can one travel across provincial borders, once-off;
 - All employers must have a phased-in return to workplaces, a COVID-19 compliance officer - this plan is prescribed in **Annexure E** of the Regulations; must also have health protocols in place (Reg 16);
 - Directions will be issued on transport;
 - Essential goods may be imported and permitted goods may be exported, **Annexure B** lists the essential goods for import, namely: medical supplies, medicines, equipment and PPE but excludes cloth face masks; chemicals and packaging. For Export it lists ONLY agricultural products and only manufacturing products under directions of the Minister of Trade.
 - There is a list of closed places on Reg 24;
 - Visits at health facilities will be controlled according to health protocols (Reg 25);
 - Reg 28 deals with "operation of economic sectors", as set out in **Table 1**:
 - Manufacturing: "all other" up to 30% under strict health protocols; [This does not seem to cover pharmaceutical or device importers that do not do any manufacturing]
 - Wholesale & Retail: medical supplies, medicine, equipment, PPE; and all chemicals and packaging used in these products [i.e. thereof for local manufacturing];
 - Business services [e.g. voluntary associations, advisories, etc.] medical schemes administration, banking, but excluded is debt collecting services and all professional services must work from home, if not possible only to support other open level 4 businesses.
 - Supply Chain: Production, manufacturing, supply, logistics, transport, delivery and critical maintenance/repair of goods and services permitted.
 - Live-in staff to care for the sick, mentally ill, elderly, persons living with a disability, children.
 - Health, Social & Personal Services: Medical and veterinary services, social work, counselling and care & relief; trade union essential staff
 - **Annexure A, Form B** is the same Permit as under the previous set of Regulations to allow staff to travel - however, the address of the workplace and the place of residence of the Employee must now be indicated.
 - **Annexure D** now clarifies the reference to s213 of the LRA on essential services and refers to not only the definition as before but to the designation of services under s71 of the LRA as essential. [This is a new development, as it now clarifies who falls within that definition. Designated under s71 are:
 - SANBS
 - Old age homes & child centres
 - PUBLIC SECTOR: ER, medical & paramedical services, nursing (and related services such as clinical engineering, waste removal, laundry, etc.), [THIS DOES NOT SOLVE THE ISSUE OF WHETHER PRIVATE SECTOR PROVIDERS ARE INCLUDED IN TABLE 1 - however, as Table 1 is IN the regulations, and this is only an Annexure (the opposite as how it was under the previous set of Regulations, one could argue that the main provisions override these. There are, however, other interpretation rules that could lead to a different result. The question is whether it could have been the intention of the legislature to exclude the private sector from being an essential service - this seems inconceivable]
 - Computer systems relating to PERSAL, and hospital systems.]
 - In spite of the above, Annexure D lists "Medical, Health (including Mental Health), Laboratory and Medical services and the National Institute for Communicable Diseases" and "Care services and social relief of distress provided to older persons, mentally ill, persons with disabilities, the sick, and children"

What you must do: NEW Disaster Management Regulations

The new Disaster Management Regulation is now referred to as the “**Risk-adjusted Strategy Regulations**” and ONLY pertains to Level 4.

These are some of the conclusion (although the split between what is in Table 1 “permitted services” and what is in Annexure D “essential services” and when what would apply is not completely clear):

- Re-opening or wider opening of **permitted services (Table 1)** and
- What all people can travel/move around for (Reg 16(3)) **outside of the curfew**, namely for Services listed in **Annexure D** or for “**security or medical emergency**” - last night we missed that this only applies to movement from 20:00 to 05:00.

The following actions need to be considered:

1. For all businesses and practices and support entities (e.g. society office staff):

If you re-open or are already open - Table 1

a) ensure you have **new Permits** for your staff or existing permits that include both the place of work and the place of residence (Reg16(2)(b)). Why the permits must change: #level4lockdown: your permit to travel for work **MUST** change. If it only says, “essential services”, it refers to overnight work only under the new regs. If you’ll work during the day it must say “Permitted services” so that it will include Table 1, 05:00- 20:00 work!

b) ensure that you have a **Workplace Plan** that covers the issues set out in Annexure E & designate a Covid-19 compliance officer - this also applies to small businesses and small practices (Reg 16(6) and Annexure E), all persons must return to work in a phased manner

c)it is not clear if new “essential services” **CIPC certificates** would be needed in light of services now being described in Table 1as “Permitted Services”.

d)pharma and device companies: Follow the **new health and safety Directions** issued yesterday (GG sent as signed but not yet published yesterday), separate **rules will be issued for practices & hospitals**

(e) all services that **can be rendered by work from home, must be so done** (e.g. telehealth, legal/compliance, etc.) - introduction to **Table 1**.

2. For healthcare practices and hospitals:

(a) **Permitted services** are listed in Table 1 (Reg 16(2)(d)): “To obtain services that are allowed to operate” from **05:00 to 20:00: “Medical and veterinary services”**. There are no definitions of what is included in here, and in the absence of the envisaged Health & Safety Guidelines, it is not yet clear how operations should commence complying.

(b) Professional services (Part H.9 of Table 1), e.g. professional societies may only operate only where work from home is not possible and to support level 4 permitted services and trade union staff (Part P.7) only as essential staff for level 4 workers, subject to Directions.

(c) From **20:00 to 05:00** only **Essential Services** may be rendered, which is, as we pointed out, narrowly defined D (as per the LRA designations that again limits the list) and lists the level 5 list of services as per the previous Regs, namely:

“1. Medical, Health (including Mental Health), Laboratory & Medical Services, NICD”,

“9. Care services and social relief of distress ... older persons, mentally ill, persons with disabilities, the sick and children”,

“24. Transport services for those rendering essential services and goods, transportation of patients”,

3. For pharma/device companies:

(a) **Importation** of goods listed in Annexure B, Reg 22(1), namely:

“6. Medical and hospital supplies, medicine, equipment and PPE (excluding cloth face masks)”

“10. Chemicals, packaging ... products used in ... production”

(b) **Export** of goods listed in Annexure C, Reg 22(1)(e):

“2. Manufacturing products ... permitted under level 4 table, subject to Directions...”

[we could not find the general export permission referred by my Minister Zuma last night, nor the import and export via bonded warehouse to neighbouring countries, referred to by Min Patel on Saturday etc.]

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(d) **Wholesale and Retail:** "E.7. Medical and hospital supplies, medicine, equipment and PPE" and the chemicals, packaging, etc, associated with it (E.14.)

Download the regulations [here](#).

Download a short "To-Do" [here](#).

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Occupational Health & Safety Directive for all non-HCP businesses

There are now Occupational Health & Safety Measures that all businesses, apart from health facilities and practices, must adhere to. This applies to those who have been supplying essential goods this far, as well as those that may partially re-open from level 4 and down (those regulations are still being awaited).

For health facilities and HCPs: As physical distancing can, for example, not be practised when attending to a patient, a separate set of rules are expected. However, it is anticipated that many of the rules in the attached will, in any event, be applicable.

Download the OHS directive [here](#).

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SAHPRA Medical Device Hotline

SAHPRA has launched a COVID-19 Medical Device Hotline to deal with COVID-19 related queries.



The graphic is a white rounded rectangle with a blue border. At the top center is the SAHPRA logo, which consists of the word "SAHPRA" in large blue letters, with "South African Health Products Regulatory Authority" in smaller blue text below it. Below the logo is the title "SAHPRA COVID-19 Medical Device Hotline" in bold blue text. Underneath the title is the text "Commencing on Tuesday 14 April 2020," followed by "The SAHPRA Medical Device Hotline will be active. Direct all COVID-Related queries relating to Medical Devices to the following Hotline numbers." Below this text are three phone numbers listed vertically: "084 220 8037", "072 993 2273", and "078 281 6334". Below the numbers is the text "Hours of Operation: (Excluding weekends and public holidays)" followed by "08:00 – 16:00". At the bottom center is a blue circular icon containing a white headset with a microphone.

Download this notice, [here](#).

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National Treasury Emergency Procurement Response to the National State of Disaster

National Treasury has published the COVID-19 Disaster Management Central Emergency Procurement Strategy for PFMA Organs of State. This document is to provide instruction for a disaster management central emergency process for PPE. In light of the lockdown, emergencies may occur where normal procurement practices are impractical and, moreover, where there is high demand within a short time frame for good or services and special arrangements with service providers with proven capabilities can capacity to assist need to be made. Given the current global situation, it is clear that countries need to centralise their procurement for local and imported health products, not only to develop scales and

Download the procurement response [here](#).

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COVID-19 PPE Price List

The following price list was issued on 28 April 2020 with regards to personal protective equipment. Surgical masks for healthcare workers, gowns, biohazard bags, body bags and gloves (examination or surgical, sterile) can only be procured by the National Health Department.

Download the price list [here](#).

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Updated Recommended Guidelines for Fabric Face Masks

The Department of Trade, Industry and Competition has released an updated guideline on fabric face masks.

- In line with the Republic of South Africa's Industrial Policy Action Plan10 (IPAP) and the Clothing, Textile, Footwear and Leather (CTFL) Master Plan's policy objectives it is highly recommended that manufacturers source textiles made locally, by local manufacturers, when making fabric/cloth face masks.
- All textile/fabric quality recommendations for making fabric face masks, found within the guidance document, are qualities found in textiles that are locally made in the Republic of South Africa.
- It is imperative that fabric/cloth face mask manufacturers ensure that efforts to manufacturer masks are done within the broader context of supporting South Africa's Clothing and Textile Industry, and our government's efforts to ensure localisation of value-chains and boarder economic prosperity – in keeping with our country's developmental objectives and Industrial Policy.
- Using three layers, selecting a non-woven (or similar) fabric with strong filtering capability (barrier efficiency) as the middle layer (with the accompanying inner and outer layers providing comfort, structure, and some additional protection) is recommended.
- The primary function of the middle layer is to trap or stop particles 5 microns and larger. It should have a barrier efficiency of at least 75%.
- If a filter layer is not used, the combination of the two layers must provide a 5-micron particle barrier efficiency of at least 75%.
- A user-guide MUST be supplied with a mask on how to wear and how to care for it.

Download the updated guidelines [here](#).

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BSA Update: Minister of Health thanks BSA and SMMEs

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"We express appreciation to Business for South Africa which has acquired 41 million pieces of PPE and has an order book to the value of R1 billion rand. We thank the myriad of small and medium enterprises that have come forward with PPE stock and manufacturing."

Dr. Zweli Mkhize
Minister of Health

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The Solidarity Fund uniting South Africa against COVID-19

The Solidarity Fund provided more details on its purpose and mandate of mobilising and coordinating efforts and resources from all South Africans and the international community to assist most vulnerable South Africans to deal with the impact of Covid19 and the consequences of measures intended to slow its rate of infection. One of its key focus areas is a Health Response with direct support for the healthcare system, augmenting both the private and government healthcare sectors to ensure they have what they need, as well as enabling emergency supplies.

Details on how to donate are available on the Fund's website www.solidarityfund.co.za

For more information email info@solidarityfund.co.za

For offers of supply of Medicines and Medical Devices send

to covid19supplies@businessresponsecovid19.co.za

If you are seeking PPE for your hospital, clinic, or NGO please email your request

to covid19requests@businessresponsecovid19.co.za

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COVID-19 RELATED PRODUCT REQUESTS

Request for infrared digital thermometers

If you are a supplier of infrared digital thermometers and currently have stock, please contact James Meakings on the details below. This device is required for screening staff.

Contact James Meakings, Azochem Laboratories Pty Ltd: 083 651 2320

or james.meakings@azochem.co.za

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COVID-19 EVENTS

BSA Risk Assessment Presentation

Business for SA has performed a comprehensive risk assessment of the significant strategic risks arising from the COVID-19 crisis. The risk assessment has gone beyond the conventional two-dimensional approach to depicting risk and has taken a four-dimensional view by including considerations of risk interconnectedness and velocity. This enables consideration of the contagion effect of risks and will assist to identify and highlight those risks which, when addressed, will have the greatest effect on mitigating the other risks. To view the full document, [click here](#).

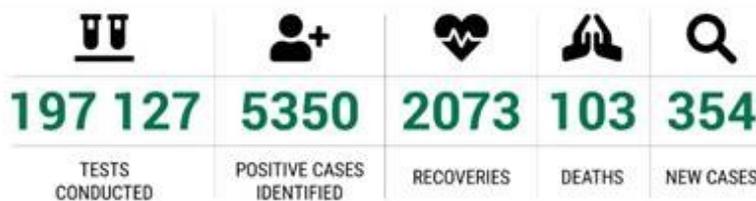
Subscribe	Past Issues	Translate ▼
Tues, 05 May; 07:30 to 08:30am	Tues, 12 May; 07:30 to 08:30am	
Wed, 06 May; 07:30 to 08:30am	Wed, 13 May; 07:30 to 08:30am	
Thurs, 07 May; 07:30 to 08:30am	Thurs, 14 May; 07:30 to 08:30am	

To enrol for any of the above sessions please contact: Daniella de Gouveia: +27 66 307 0846 or Daniella.de.Gouveia@businessresponsecovid19.co.za

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COVID-19 DEVELOPMENTS

TRACKING THE PANDEMIC South Africa



The official media release by the Department of Health noted that the total number of confirmed COVID-19 cases in South Africa was 5 350 as at 29 April and this represented a one-day increase of 354 cases.

The department commented: "This is the highest number of cases in a 24-hour cycle recorded to date and represents a 73% increase relative to the day before. While this is well noted, the interpretation of the rate of spread is more reasonably assessed by studying trends over time.

"The total number of tests conducted to date is 197 127, of which 11 630 were done in the last 24 hours. This is the highest number of tests done in a 24-hour period, representing a 66% percent increase relative to the previous day's tally. Additionally, we have recorded the highest COVID-positive result yield from a 24-hour cycle of testing at 3%."

The new deaths recorded were mostly among older people. Among those who have died is a nurse.

Global figures

Number of cases
3 089 013

Number of deaths
217 551

Number of recoveries
888 091

POLICY DEVELOPMENTS

The regulations governing a Level 4 lockdown, which come into effect on Friday 1 May, are published in the Government Gazette today and several Cabinet members briefed the media on the contents last night. In many respects, they confirmed the President's outline of Stage 4 a few days ago. In some instances they provided more detail and in a few instances indicated a change in direction as a result of public submissions that had been taken into account.

The thrust of Level 4 is getting the economy moving cautiously under strict conditions of physical distancing. Types of work that cannot be done with distancing have generally been excluded unless they are considered critical to the functioning of the country. For details on the full range of sectors permitted to operate, please consult the regulations.

Here are a few points of interest:

Cigarettes may still not be sold – contrary to the President's earlier announcement

Health 24 reports: "The U-turn comes after government received over 2 000 submissions from the public opposing the sale of tobacco products, Minister of Cooperative Governance and Traditional Affairs Nkosazna Dlamini-Zuma said. "Initially government had proposed that the sale of cigarettes would be allowed at level four, but government had received submissions from the public opposing it on the grounds that it posed a health risk, Dlamini-Zuma said. "Besides the effects of tobacco on lungs and the way tobacco is shared, it does not allow for social distancing and encourages the spread of the virus."

The minister specifically raised concerns about spreading the virus in saliva, when the paper of a "zol" (handrolled cigarette) is sealed with saliva.

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allowed through the ports, including wine. The wine and grape industry contributes about R49bn to GDP annually. In addition, other liquor products – such as Amarula – may now be transported for purposes of export. (Fin24)

Exercise in public streets is permitted but under specific conditions

Running, walking and cycling along public roads is permitted between the hours of 6am and 9am, provided individuals wear face masks and maintain social distancing. Parks remain closed.

Companies will have to meet back-to-work conditions

According to Business Insider SA, there are numerous requirements for companies going back to work while the Covid-19 state of disaster is still in place. Companies of different sizes have different responsibilities in terms of the new regulations.

A Covid-ready Workplace Plan must be developed prior to the reopening of an enterprise employing persons or serving the public. Regulations include general injunctions to minimise the number of workers through shift rotation and remote working, and companies are called on to "minimise contact between workers as well as between workers and members of the public".

There are also very practical rules that companies will have to follow or they may face sanctions:

- Employees must either be 1.5 metres apart or must have "physical barriers" between them.
- Those showing symptoms of Covid-19 may not be allowed to work.
- The employer must phone the national Covid-19 hotline in case of a suspected case.
- Employees must have cloth masks that comply with specifications. Two per worker and the employer must launder masks.
- Everyone must have access to soap and water, and sanitiser that can be used on workstations as well as hands.
- Employees must be made to wash and sanitise and required to disinfect workstations regularly.

Measures "may include dividing the workforce into groups or staggering break-times to avoid the concentration of workers in common areas".

Companies must screen workers when they report for work for "any of the observable symptoms associated with Covid-19".

Companies are obliged to report to both the department of health and the department of employment and labour if an employee is diagnosed with Covid-19. They must then investigate the cause of infection, "including any control failure" in the workplace.

(NOTE: this is no substitute for reading the regulations!)

HEALTH-RELATED DEVELOPMENTS

Decline in TB testing in SA despite an estimated 63 000 deaths a year

The specialist publication, Spotlight, reports that there has been a decline in TB testing since the Covid-19 pandemic hit South Africa and at least one TB ward has been being turned into a Covid-19 ward.

According to the World Health Organisation, TB caused around [63 000 deaths](#) in South Africa in 2018. So far, about 100 people are confirmed to have died of Covid-19 in the country, although this number is expected to shoot up in coming months.

"It's really important that we don't forget how bad TB is," says Prof Harry Hausler, CEO of HIV/TB Care (an NGO), and a member of the World Health Organisation's civil society task force. Patients with TB are likely more vulnerable to severe Covid-19 and there is a risk of dual-disease, which will put further strain on the national healthcare system.

Actuarial Society estimates death toll of 46 000 to 88 000

Tamar Kahn of Business Live reports on the modelling on the possible magnitude of coronavirus burden undertaken by the Actuarial Society of SA (Assa). This is still work in progress and anticipated impacts vary according to the assumptions in the model. These relate mainly to the number of undetected (but still infectious) cases of Covid-19, the degree of infectiousness and the success of the lockdown.

Among the ASSA estimates are the following:

- Death toll: Possibly between 46 000 and 88 000.
- Total number of cases: 588 000 and 2.3 million
- Peak demand for hospital beds: Up to 78 000 beds and up to 14 800 intensive care beds.

ECONOMIC DEVELOPMENTS

Further sovereign downgrade by S&P

Fin24 reports: "S&P Global Ratings has lowered South Africa's sovereign credit rating further into non-investment grade, or junk, citing the impact of the coronavirus on the country's already struggling economy. On Thursday evening the rating agency announced it had downgraded SA's long-term foreign-currency credit rating to 'BB-', or the third tier of non-investment grade. The outlook is stable. In a note, S&P said that SA's "already contracting economy will face a further sharp Covid-19-related downturn in 2020". It now expects SA's economy to shrink by 4.5% this year, which is still more bullish than the [6.1% contraction](#) projected by the SA Reserve Bank. "

RESEARCH & SCIENTIFIC DEVELOPMENTS

Trials show remdesivir reduces recovery time

BBC reports that a clinical trial at hospitals around the world has shown that the drug remdesivir cut the duration of coronavirus symptoms from an average of 15 days to 11 days. Remdesivir was originally developed as an Ebola treatment. It is an antiviral and works by attacking an enzyme that a virus needs in order to replicate inside our cells.

The trial was run by the US National Institute of Allergy and Infectious Diseases (NIAID) and 1 063 people took part. Some patients were given the drug while others received a placebo (dummy) treatment.

Dr Anthony Fauci who runs the NIAID said: "The data shows remdesivir has a clear-cut, significant, positive effect in diminishing the time to recovery." He said the results prove "a drug can block this virus" and were "opening the door to the fact that we now have the capability of treating" patients.

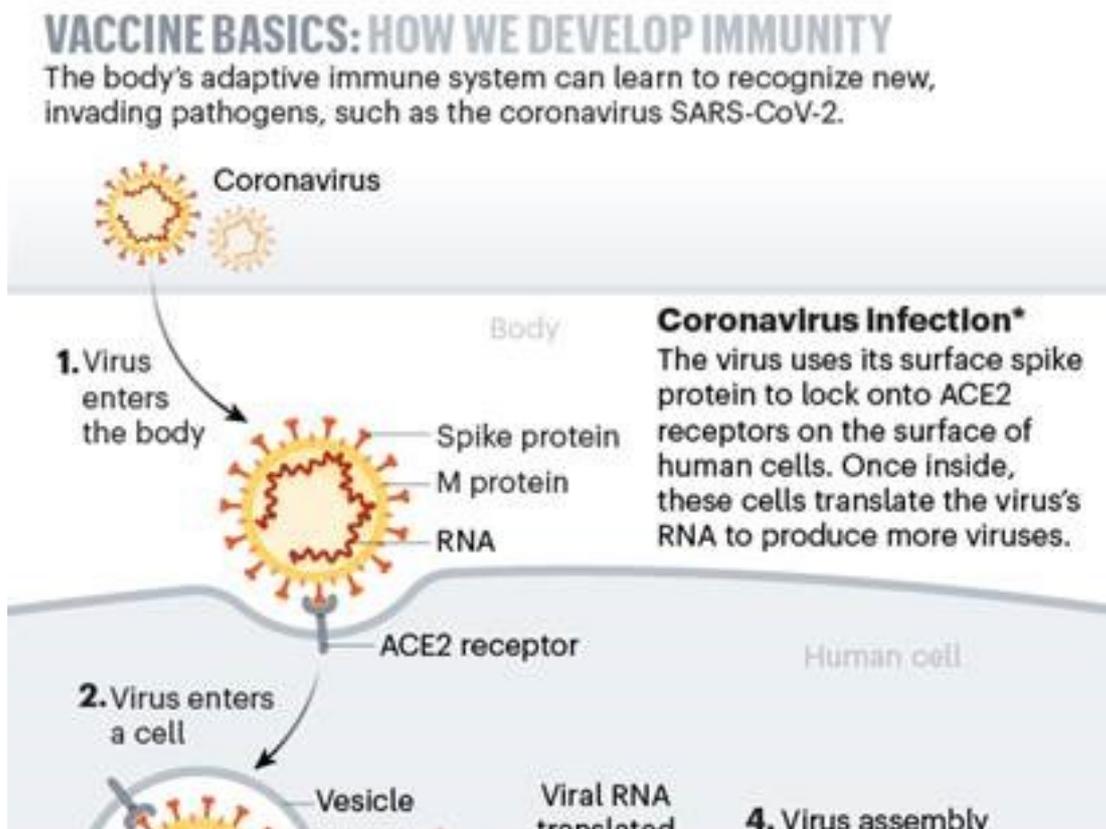
The impact on deaths is not as clear cut. The mortality rate was 8% in people given remdesivir and 11.6% in those given a placebo, but this result was not statistically significant.

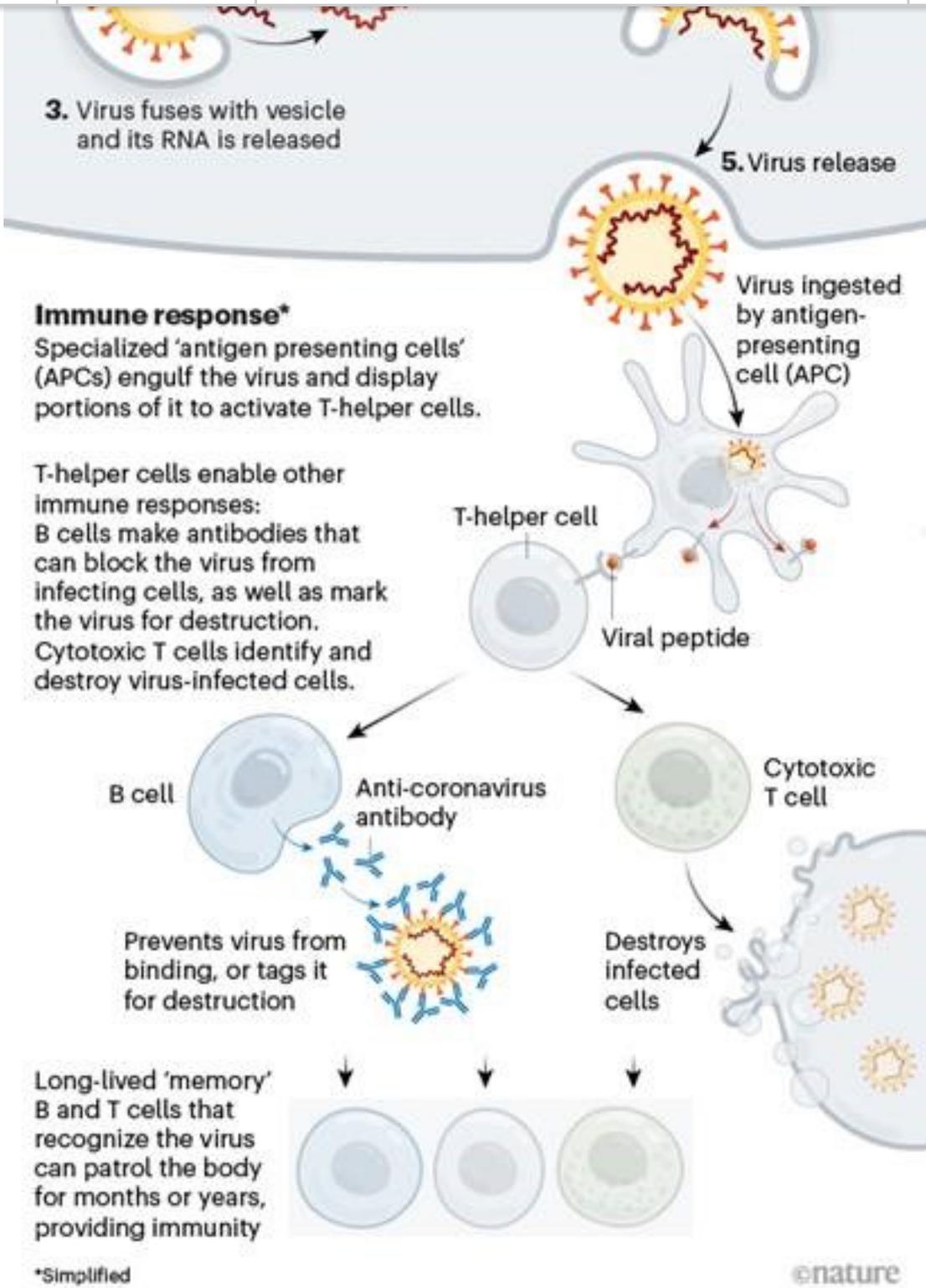
The rundown on vaccine research in progress

Ewen Calloway reports in the journal, Nature, that more than 90 vaccines are being developed against SARS-CoV-2 by research teams in companies and universities across the world. Researchers are trialling different technologies, some of which hasn't been used in a licensed vaccine before. At least six groups have already begun injecting formulations into volunteers in safety trials; others have started testing in animals.

For those who want to understand the different approaches [click here](#).

Others may find the following graphic from Nature interesting.





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