Path to regulatory approval of the Covid-19 vaccine in SA

By Zareenah Rasool, Rui Lopes and Darryl Bernstein

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The ongoing, global Covid-19 pandemic has led to an obvious need for clarity regarding the regulatory approvals that must be satisfied before a vaccine can be rolled out. In anticipation of the vaccine being developed and readied for wide-scale clinical use, pharmaceutical companies and Non-Governmental Organisations (NGOs) have sought to clearly define the necessary procedures for expedient approval of a candidate vaccine. This need has been amplified in recent weeks, given the latest promising developments in vaccine trials. Pfizer and BioNTech have confirmed that an early analysis of trial data has showed that their vaccine prevented 90% of Covid-19 symptomatic infections, making the vaccine strongly effective. As a result, we could see a first roll-out of the vaccine, to a limited number of high-risk individuals, before the end of the year. This news gives hope to late-stage trials being conducted worldwide, that an effective and successful vaccine may be within reach, critical to global health.

South Africa has a comprehensive and well-defined drug-regulatory framework, which has been developed by the Medicines and Related Substances Act, 101 of 1965 (Medicines Act), the National Health Act, 61 of 2003, and the South African Good Clinical Practice Guidelines (Clinical Guidelines). The Medicines Act established the South African Health Products Regulatory Authority (SAHPRA), which is the body tasked with ensuring efficient, effective and ethical evaluation, registration and control of all clinical trials, medicines and other healthcare products in South Africa. The Clinical Guidelines detail further scientific and ethical standards that must be satisfied in the context of clinical trials conducted on human beings. Trials cannot be conducted, and medicines cannot be prescribed, sold or marketed in South Africa, without prior SAHPRA approval. The SAHPRA does not undertake ethical or safety trials in its own capacity as regulator, but rather approves those conducted by pharmaceutical researchers and manufacturers, in order to ensure that safety standards have been complied with and are being maintained.

The process to approve a clinical trial

The following streamlined steps must be followed before a clinical trial may be conducted in South Africa:

Medical Control Council approval

First, the pharmaceutical company or other organisation responsible for the launch, management and/or financing of the trial (Sponsor), or a South African-based scientist accountable for the undertaking and reporting of the trial (Principal Investigator), must apply to the Medical Control Council to approve the trial being conducted on human participants. The Medical Control Council has a statutory responsibility to confirm that drugs available in the country meet safety, quality and efficacy standards. To clarify, the SAHPRA is secretariat to the Medical Control Council.

Ethical approval

Second, all clinical trials to be undertaken in South Africa, including multinational trials, must apply for, and receive, ethical approval from an accredited research ethics committee based in the country.

Ethics committees are responsible for safeguarding the human rights of all trial participants and inspection of the scientific relevance of the trial within the South African context. Ethics committees are required to pay additional attention to certain, named categories of trials, including trials involving "innovative therapy or intervention". In these circumstances, additional measures are imposed on the trial to ensure that the welfare of participants are protected. These measures may include more frequent or stringent review standards.

All Covid-19-related clinical trials will fall within the category of "innovative therapy or intervention".

Registration

Once a trial protocol has received Medical Control Council and ethical approval, the Sponsor must submit an application to register the trial, together with all relevant trial information, to the Department of Health. Within two business days of the application being received, the trial will be recorded on the South African National Clinical Trial Register and will be awarded a unique number. The trial may only begin once this number is received by the Sponsor or Principal Investigator.

Monitoring

The Sponsor should develop a monitoring plan to provide for the methods, responsibilities and requirements in respect of periodic review and monitoring of the clinical trial. It must be noted that should a regulatory or ethical authority find that a trial is being conducted in a manner inconsistent with the approved protocol, or in any manner that does not satisfy or that breaches imposed and industry standards, approval can be withdrawn and the trial will be discontinued or suspended.

Clinical trials are a lengthy process and may take anywhere between two to five years, or any such longer period as may be necessary. However, SAHPRA has confirmed that it will "expedite the review" of Covid-19 treatments, although it will not amend processes or compromise standards to do so.

The process to approve the roll-out of a vaccine

Once a vaccine has been successfully developed, it must be registered with the SAHPRA before it may be prescribed, administered or sold in South Africa. At the point where a Covid-19 vaccine is readied for wide-scale roll out, it is likely that the vaccine will have already received approval from a foreign drug-regulatory authority, however SAHPRA approval will still be required irrespective of whether such offshore approval has been granted. If offshore approval has been granted by a stringent regulatory authority, which SAHPRA recognises as being particularly thorough, such as the Food and Drug Administration in the United States, SAHPRA may accelerate local approval.

In order to register the vaccine, an application must be made to SAHPRA, accompanied by all required documentation, whereafter the Biological Medicines Evaluation and Research Unit will evaluate the application to register the biological medicine, together with any recommendations of expert committees, and will make a determination in respect of whether the medicine satisfies all required standards. Only once registration has been confirmed may the vaccine prescribed, administered, sold or marketed in South Africa.

The pathway to obtaining regulatory and ethical approval in South Africa is clearly defined. This is of key importance to pharmaceutical companies and NGOs, given this will ensure the vaccine will be rolled out efficiently and expeditiously once developed, simultaneously minimising costs and prioritising the welfare of the South African population.

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