



SAHPRA urges medical doctors to stop anticipatory and irrational prescribing of medicines for COVID-19

In addition to licensing medicines that are safe, effective and of good quality, SAHPRA is also responsible for monitoring the use and misuse of medicines that are already on the market. One form of medicine misuse is the prescribing of medicines to patients in the absence of an actual medical indication, particularly if these medicines are prescribed for an unproven or off-label indication.

Chloroquine is a medication previously used to prevent and treat malaria. It is a Schedule 2 antimalarial agent when used in combination with proguanil for malaria prevention, and Schedule 4 when used for malaria treatment. Recent reports suggest that chloroquine (among various other treatments) may have some benefit in treating patients with severe manifestations of COVID-19. It is important to note that these reports of benefit are based on small studies that need to be verified with formal clinical trials assessing both efficacy and safety.

It has come to SAHPRA's attention that medical doctors are prescribing chloroquine-containing products to their patients in anticipation of a potential COVID-19 infection, presumably in response to the early reports on potential efficacy, combined with public fears of contracting COVID-19. This anticipatory prescribing to patients, in the absence of a confirmed COVID-19 infection, supports fear based stockpiling of potentially life-saving medicines, and is a serious misuse of important therapeutic resources. **It is strongly discouraged.**

On a large scale, anticipatory prescriptions could lead to dire consequences in terms of limiting access to potentially life-saving medicines when they are actually needed. There are other important risks – both to the individual and the societal level response to the pandemic. Self-treatment of COVID-19, without notification to a health professional, undermines the extraordinary efforts being made by health professionals nationally, aimed at minimising the spread through contact tracing and patient monitoring. Moreover, chloroquine is associated with a host of side effects, special precautions and contraindications, all of which that need to be carefully considered as part of a risk-benefit assessment before prescription.

SAHPRA wishes to emphasize that the use of chloroquine and other treatments for the management of coronavirus, mentioned in the media and other early reports, is **still investigational**. Both the benefits and the potential risks of these treatments to patients are still being carefully studied. An international clinical trial, called the Solidarity Trial, is being conducted under the aegis of the World Health Organization to accumulate as much evidence as possible, as quickly as possible, about the merit of chloroquine as well as

other medicines for the management of the more severe forms of COVID-19. There are several sites in South Africa that are contributing to the Solidarity trial, which will comply with international ethical and clinical standards of care.

Clinicians are also reminded that the **vast majority (approximately 80%) of patients** who become infected with coronavirus will only present with **mild symptoms** and will make a full recovery. It is therefore imperative that adequate stocks of these investigational treatments are always easily available for those who do in fact progress to the more severe forms. Over-prescribing chloroquine and other investigational treatments for COVID-19 could have important negative public health consequences including limiting our ability to effectively respond to this international crisis. To avoid the potential need for extraordinary restrictive measures, which bring their own adverse consequences, medical practitioners are strongly urged to cease these practices immediately.

Sincerely.

Dr Boitumelo Semete-Makokotlela

SAHPRA CEO

23 March 2020