South African Health Products Regulatory Authority
Private Bag X828
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Date: 20 March 2020

Chief Executive Officer

Dr. Boitumelo Semete-Makokotlela

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Object: Availability of hydroxychloroquine in the context of the COVID-19 pandemic.

Dear Sir, Dear Madam,

By the present letter, we would like to draw your attention to the high number of questions that Sanofi is receiving from healthcare professionals (general practitioners, pharmacists and hospitals) regarding potential off-label use of our hydroxychloroquine-containing product the management of COVID-19.

Please note that hydroxychloroquine is currently not a registered product by the South African Health Products Regulatory Authority (SAHPRA).

Despite preliminary findings from independent clinical studies that give a first signal of a potential antiviral activity of hydroxychloroquine in COVID-19 infection, further analysis and more robust and larger clinical studies need to be conducted to assess the patient benefit/risk profile of hydroxychloroquine in COVID-19 to ensure patient safety.

To date there are insufficient clinical data to draw any final conclusions over the clinical efficacy or safety of hydroxychloroquine in the management of COVID-19.

Any use of this medicine in the management of COVID-19 is considered an off-label use (i.e. in absence of a marketing authorization for that indication).

As a committed healthcare player, Sanofi is willing to support any clinical research that has been or will be authorized and validated by Health Authorities and for which the protocol follows the good clinical practices and all other relevant requirements validated by the competent authorities.

Sanofi is willing to provide hydroxychloroquine, if specifically requested by the Health Authorities or Governments.

Sanofi will address any official request received from health authorities or Governments on a case by case basis and will assess the number of doses we can progressively provide based on current globally available supplies and production capacity, while preserving necessary stock to ensure supply continuity in countries where hydroxychloroquine is approved for other indications.
However, to date, Sanofi is already facing a high number of demands from hospitals and Health Authorities globally for use in COVID-19 patients.

To date, given the limited and confirmation-pending scientific evidence, Sanofi would like to ensure that any off-label use of hydroxychloroquine is carefully notified, monitored and controlled.

Sanofi is asking Health Authorities to communicate a clear position regarding current lack of robust clinical data for the use of hydroxychloroquine in the management of COVID-19, emphasizing that such use will be off-label, and to communicate the known serious adverse events associated with hydroxychloroquine, namely the contraindications in patients with known hypersensitivity to 4-aminoquinoline compounds; with pre-existing maculopathy of the eye; below 6 years of age (200mg tablets not adapted for weight <35 kg) and the risk of retinal toxicity, hypoglycemia and cardiac toxicity reported in patients treated with hydroxychloroquine.

We also request that all off label use is communicated to Sanofi affiliate pharmacovigilance teams at ZA.drugsafety@sanofi.com, whether or not the patients suffer adverse events.

We also welcome guidance or recommendations from the Health Authorities that will help us define appropriate allocation of the product.

In the meantime, we confirm that we are currently carefully monitoring the orders we receive globally and remain attentive to the ones we can't answer in the absence of a clear regulatory frame, which we expect to be defined shortly by competent health authorities, and in the best interest of healthcare professionals and patients.

In the current context, we thank you in advance for any ad-hoc measures you intend to put in place to address the above and remain at your entire disposal to discuss further.

Sincerely,

Graeme James

Graeme James
Country Head of Regulatory
Responsible Pharmacist

Alicia McMaster
Country Head of Medical

Thibault Crosnier Leconte
Country Chair and RX GM