25 March 2020

Dear Healthcare Professional,

Availability of hydroxychloroquine (Plaquenil®) in the context of the COVID-19 pandemic

Sanofi is experiencing a high volume of questions from healthcare professionals regarding our hydroxychloroquine-containing product Plaquenil® (AUST R 50055). In addition, we are experiencing a high demand from wholesalers & hospitals and we are observing increased sales at pharmacy of Plaquenil®.

In Australia, Plaquenil® is authorised by the TGA for use in the following indications:

- Rheumatoid arthritis
- Mild systemic and discoid lupus erythematosus;
- The suppression and treatment of malaria

It is important that these patients can continue to fill their normal prescription and we have been actively discussing this with patient associations, healthcare professional groups, the Department of Health and Government.

Sanofi welcomed the TGA's rapid action (on 24 March 2020) to make changes that support on label prescribing of this product. These changes mean that:

- Initiation of hydroxychloroquine is now restricted to the following medical specialties as per the Medical Board list: dermatology; intensive care medicine; paediatrics and child health; physician; and emergency medicine.
- General practitioners and other medical practitioners (e.g. hospital Resident Medical Officers (RMOs) and doctors in training) can continue to prescribe repeats for hydroxychloroquine to patients in line with the registered indications for patients in whom the medication was prescribed prior to 24 March 2020.
- General practitioners and doctors in training can prescribe these medicines for continued treatment of patients where treatment was previously initiated by one of the specialists.

Our Australian supply team is continuing to work across Sanofi's global network to secure ongoing deliveries of Plaquenil ®. We are also actively assessing orders and will allocate existing stock to wholesalers and customers to support appropriate distribution.

Sanofi has also been made aware of cases of off-label use of Plaquenil® for the management of COVID-19. Any use of Plaquenil® in the management of COVID-19 is considered an off-label use (i.e. in absence of a marketing authorisation for that indication). To date there are insufficient clinical data to draw any conclusions on the clinical efficacy or safety of hydroxychloroquine in the management of COVID-19.

There are known serious adverse events associated with Plaquenil®, 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.

Sanofi does not encourage or endorse the off-label use of medicines. We would like to ensure that any off-label use of Plaquenil® is carefully notified, monitored and controlled and **request that all off label use is communicated to the Sanofi affiliate pharmacovigilance team via ae@sanofi.com, whether or not the patients suffer adverse events.**

We appreciate your understanding of this current situation and we thank you for your cooperation in ensuring the appropriate use of this medicine.

Sincerely,

James Scott

Medical Operations & Portfolio Manager, General Medicines

Sanofi

References:

Plaquenil (hydroxychloroquine) Product Information, December 2019