HSA facilitates the development and access of therapeutic products for COVID-19 patients

June 2020

Dear Chief Executive Officers, Managing Directors and General Managers of Pharmaceutical Companies

I trust that you are all keeping safe and healthy at work and at home.

As a community, we are dealing with unprecedented challenges brought about by the COVID-19 pandemic. HSA is constantly adapting with regulatory agility to ensure that we are effective and nimble, to manage the challenges and demands arising from the global health crisis. HSA remains committed in ensuring that we expedite the access to essential and promising health products, with reasonable safeguards, to protect public health and safety. Some of the measures that are implemented to facilitate clinical trials, development and approval of therapeutic products for COVID-19 are highlighted in this communication.

HSA grants conditional approval for remdesivir for the treatment of COVID-19 infection caused by SARS-CoV-2 in adult patients

HSA has granted a conditional approval for remdesivir for the treatment of COVID-19 infection based on an expedited review of the current available data for remdesivir. The review was conducted in a reduced timeline given the urgent public health need during this pandemic. The conditional approval will facilitate access to remdesivir for our patients outside of clinical trials. As the data is limited at this point of time, this conditional approval requires post-approval submission of full data from the on-going manufacturing and clinical studies to ensure the continued safety, quality and efficacy of the product. Please refer to this link for further information on the conditional approval of remdesivir.

HSA steps up regulatory consultations for COVID-19 therapeutics and clinical trials

HSA has stepped up in providing scientific and regulatory advice to researchers and companies with promising therapeutic products for COVID-19 treatment. This is done with the aim to enable promising medicines to reach patients as soon as possible, initially in the clinical trial setting, and eventually to the market. To date, HSA has expeditiously authorised 7 clinical trials to fast-track therapeutics development for the potential treatment and prophylaxis of COVID-19.

HSA issues guidance on the conduct of clinical trials during COVID-19 pandemic

HSA recognises the difficulties faced by sponsors and investigators in managing clinical trials during the COVID-19 situation. These may be due to trial participants being unable to visit trial sites due to travel restrictions, interruption of Investigational Product supply chain or challenges in conducting on-site monitoring visits by sponsors. HSA has published a guidance to provide general considerations to sponsors and investigators to ensure the safety of trial participants, compliance with the clinical trials regulations and guidelines, and minimise risks to trial integrity.

HSA embarks on virtual inspections of manufacturing, importing and wholesaling facilities

HSA has embarked on virtual inspections, in lieu of onsite inspections, through online video platforms and "google glass" technology as an innovative approach during this COVID-19 pandemic period. This helps to ensure the continued governance of good manufacturing and distribution standards at manufacturing and warehouse facilities. This also facilitates the approvals of new manufacturing, importing and wholesaling facilities for COVID-19 needs and the continued supply of good quality therapeutic products.

HSA joins global efforts to advance the development of COVID-19 therapeutics and vaccines

The unprecedented speed of global research and development efforts has generated a remarkable list of innovative and repurposed therapeutic and vaccine candidates for COVID-19. HSA joins international regulators to prioritise the most promising therapeutics and expedite their development and access to patients. HSA participates actively in the World Health Organisation Global Research and Innovation Forum (Vaccines Working Group), International Coalition of Medicines Regulatory Authorities, ACSS (Australia, Canada, Singapore, Switzerland) Consortium, to collaborate and contribute to COVID-19 response on accelerated reviews of promising therapeutics and vaccines. HSA also works closely with regulatory agencies that have confidentiality or Memorandum of Understanding arrangement with us, to share COVID-related information.

During this period, HSA's priority will be to ensure that Singapore has continued access to critical and good quality health products to deal with the pandemic. We endeavour to maintain our service delivery standards. Nonetheless, given our priorities related to COVID-19 balanced against current manpower resourcing, we seek industry's understanding if the expected turnaround times for some of the more routine applications are impacted during this pandemic.

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cc: Regulatory Affairs Managers

For further information pertaining to clinical trials approved by HSA, please refer to this link.