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HSA APPROVES NEW STORAGE CONDITION FOR THE PFIZER-BIONTECH COVID-19 VACCINE AT REFRIGERATOR TEMPERATURE FOR UP TO 31 DAYS

The Health Sciences Authority (HSA) has on 20 May 2021 approved the new storage condition for the Pfizer-BioNTech COVID-19 vaccine to be stored at refrigerator temperature (2 to 8 degrees Celsius) for up to 31 days. This will greatly facilitate the transportation and local distribution of this vaccine to vaccination centres, as well as their storage and use at the centres, which is important in ensuring the steady progress of our vaccination programme and protect more Singaporeans.

2 The new storage condition was approved after a thorough review of the application and supplemental data submitted by Pfizer. HSA has determined that the thawed, undiluted COVID-19 vaccine remains stable when stored at standard refrigerator temperatures (2 to 8 degrees Celsius) for 31 days. The long term storage of the vaccine remains at minus 70 degrees Celsius.

Previous Storage Conditions Authorised by HSA

3 HSA's initial authorisation of the Pfizer-BioNTech vaccine on 14 December 2020 had approved its long term storage at minus 70 degrees Celsius and temporary storage after thawing at 2 to 8 degrees Celsius for up to 5 days. On 25 February 2021, HSA had authorised a change to indicate that the vaccine can be stored at standard freezer temperature (minus 20 degrees Celsius) for up to two weeks.

4 "The newly approved extended storage condition at refrigerator temperature for up to 31 days is a significant improvement over the existing storage conditions," said Dr Choong May Ling, Mimi, Chief Executive Officer of HSA.

5 "HSA's evaluators will continue to conduct rigorous and efficient assessments of evolving scientific and real-world data, to facilitate Singapore's continued access to critical COVID-19 vaccines and medicines and support our nation's battle against the COVID-19 pandemic," added Dr Choong.

6 The <u>Singapore prescribers' factsheet</u> has been updated to reflect the new storage condition.

About the Health Sciences Authority (HSA)

The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services and Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. As the national blood service, it is responsible for providing a safe and adequate blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit http://www.hsa.gov.sg/.

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About HSA's Health Products Regulation Group

The Health Products Regulation Group (HPRG) of HSA ensures that drugs, innovative therapeutics, medical devices and health-related products are wisely regulated and meet appropriate safety, quality and efficacy standards. It contributes to the development of biomedical sciences in Singapore by administering a robust, scientific and responsive regulatory framework.