FDA Updates: Use of Electronic Means of Prescription for Drugs and Registration of Drug Products under Emergency Use

With the enactment of Republic Act No. 11494, or the Bayanihan to Recover as One Act ("**Bayanihan Act 2**") and the periodic changes on the quarantine status of different localities, the Food and Drug Administration ("**FDA**") reissued and extended its existing guidelines on: (*a*) implementation of the use of electronic means of prescription for drugs and (*b*) registration of drug products under emergency use ("**DEU**") for COVID-19.

Electronic Means of Prescription for Drugs

Last March 17, 2020, the FDA issued guidelines which allowed the electronic means of prescribing drugs and ordered drugstores, pharmacies, and similar outlets to honor electronic prescriptions (the "**Guidelines on Electronic Prescription**"). Previously, pharmacists and owners of drugstores, and other drug-dispensing establishments are only allowed to dispense drugs if there is a written prescription issued by a licensed physician or dentist. The electronic prescription helps ensure that individuals who are vulnerable to COVID-19 will have unrestricted access to ther prescription and maintenance medicines despite the community quarantine.

The Guidelines on Electronic Prescription is for the benefit of and covers all individuals vulnerable to COVID-19 which include senior citizens, persons with disability, and people with chronic illnesses or immuno-compromised conditions.

All licensed physicians are authorized to issue electronic prescriptions which refer to optical electronic data (captured image in pdf, jpeg, or other photo file format) which is generated, sent, received or stored through email and messaging applications (i.e. WhatsApp, Viber, Line, and Messenger, among others). The electronic prescription shall contain the name of the individual, medicine, dosage, and other information which are also required to be in a written prescription. The physician shall also digitally sign the electronic prescription indicating his or her license number, name, and professional tax receipt, if applicable.

Drugstores, pharmacies, and other drug establishments shall recognize the validity and effectivity of the electronic prescription. They shall treat electronic prescriptions similarly to written prescriptions for all intents and purposes. The physical presence of the vulnerable individual named in the electronic prescription is not required for the dispensing of the drugs. Instead, a representative, with the identification card of the vulnerable individual and authorization letter, may purchase the drugs.

The FDA, through the issuance of FDA Circular No. 2020-007-B, extended the validity of the Guidelines on Electronic Prescription until December 31, 2020, regardless of the classification of the quarantine imposed in the area.

Registration of DEU for COVID-19

The Bayanihan Act 2 authorizes the necessary and proper exercise of powers to ensure the availability of medicine and minimal disruption in the supply chain. Through the issuance of FDA Circular No. 2020-028 dated September 22, 2020 (the "**Circular**"), the FDA updated the guidelines on registration of DEU products with the objective of streamlining the requirements and expediting the process.

The Circular shall be applicable to all marketing authorization holders ("**MAHs**") who intend to manufacture, import, or distribute the drug products listed in the Philippine Society for Microbiology and Infectious Diseases Clinical Practice Guidelines on the Interim Management Guidelines for COVID-19 ("**PSMID Guidelines**").

The Circular only recognizes *Tocilizumab*, currently, with the prescribed dosage form and strength, as the product eligible for DEU registration. The DEU shall be locally manufactured or imported and distributed for the management of COVID-19 patients, in line with the PSMID Guidelines

New applications for the registration for *Chlorquine, Hydroxychloroquine, and Lopinavir + Ritonavir* under DEU registration shall no longer be accepted. Current stocks at the manufacturing level of products with existing Certificates of Product Registration ("CPR") shall be exhausted for their approved indications within the given validity. The FDA will not grant further extensions.

There shall be no need for the scheduling of submission of applications, and applications shall be under "Emergency Use" classification and shall be submitted at the Food and Drug Action Center ("**FDAC**"). Submission of the applications may be done manually to the FDAC or through e-mail: fdac.pacd.cdrr@fda.gov.ph.

Approved applications shall be issued a CPR which will have a validity of one (1) year under emergency use registration status and will not be subject to renewal registration. The CPR shall be automatically revoked at the end of the pandemic.

MAHs are also ordered to abide by the post-approval compliance processes and requirements, such as post-approval stability data of commercial batches for products without stability data submitted upon its registration, submission of commercial sample from first batch of manufacture to FDA, and post-market surveillance with the assistance of health institutions and healthcare professionals. Guidelines on post-market surveillance shall be the subject of a separate issuance.

Electronic signatures in the applications for DEU registration will be accepted. The requirement for notarized documents shall be suspended but the applicant shall submit a commitment letter on the subsequent submission of the notarized documents.

The Circular on the registration guidelines of DEU shall be in effect until December 31, 2020, regardless of the level of the quarantine restrictions imposed in the area.

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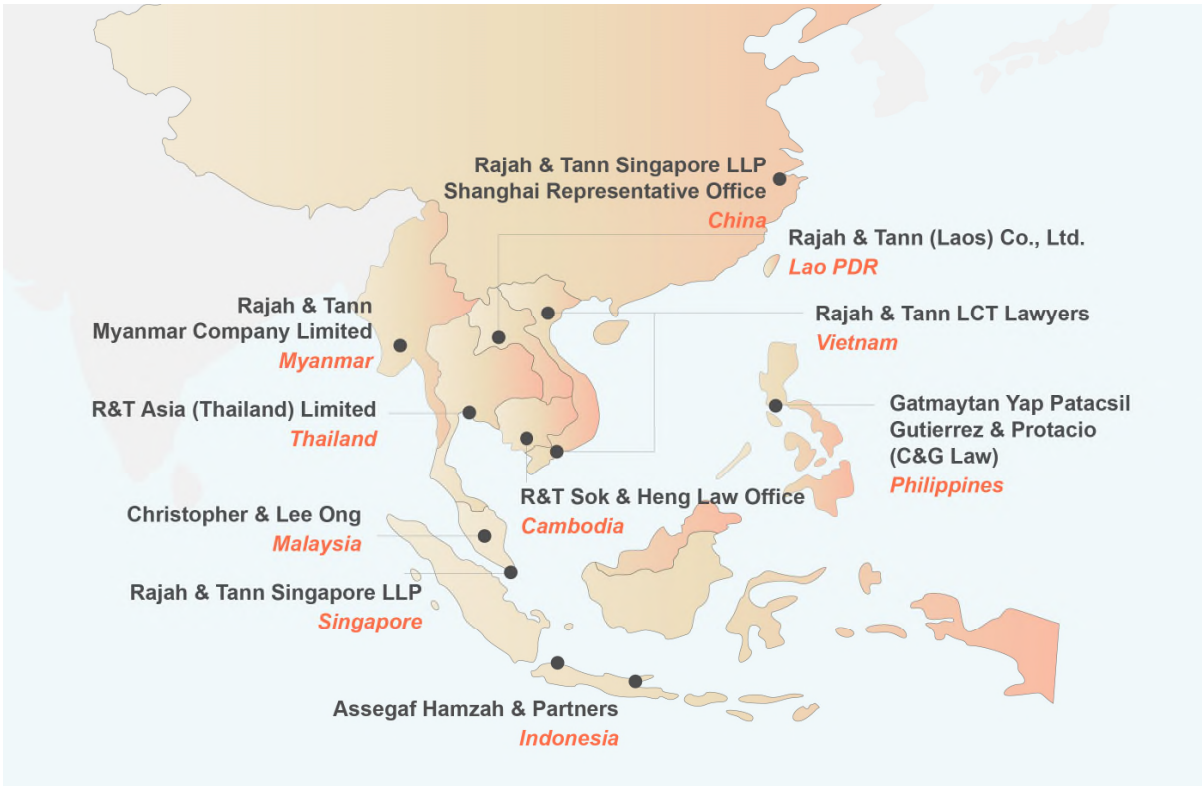

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