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COMBATING COVID-19: LEGAL REQUIREMENTS AND PROCEDURES FOR THE IMPORTATION OF VACCINE INTO MALAYSIA

Introduction

On 11 March 2020, the World Health Organization ("**WHO**") declared the COVID-19 outbreak as a pandemic. Until today, COVID-19 has affected 203 countries and territories around the world and 2 international conveyances (Diamond Princess cruise ship and MS Zaandam cruise ship). In order to stop the spread of COVID-19 virus, a nationwide movement control order has been implemented in Malaysia effective from March 18 to April 14. Notably, not only the government of each country has set up protection measures, many pharmaceutical companies and research laboratories around the world are working at full tilt on vaccine clinical trials. If these clinical trials are successful in other countries, Malaysia may consider to import vaccine from other country(ies) to treat its patients. This article will solely focus on the legal requirements and procedures of vaccine importation into Malaysia.

Registration for Imported Vaccine Products

In Malaysia, we have the Control of Drugs and Cosmetics Regulations 1984 ("**CDCR 1984**") which were promulgated under the Sale of Drugs Act 1952 ("**SDA 1952**"). The Drug Control Authority ("**DCA**") was established under Regulation 3 of the CDCR 1984 to ensure the quality, safety and efficacy of medicinal products.

The DCA shall consist of the following members:

1. The Director-General of Health as chairman;

2. The Senior Director of Pharmaceutical Services as alternate chairman;

3. The Director of the National Pharmaceutical Regulatory Agency ("NPRA"); and

4. 8 other members to be appointed by the Minister.

The DCA is responsible for the registration, quality control, inspection, licensing and post-registration activities while the NPRA acts as the secretariat to the DCA. The NPRA, formerly known as the National Pharmaceutical Control Bureau (NPCB), was set

up in October 1978 under the quality control activity of Pharmacy and Supply Programme. This institution was established to implement quality control on pharmaceutical products. The infrastructure and facilities were designed to meet the requirements for testing and quality control activities.

Regulation 7(1) of the CDCR 1984 states that:

“Except as otherwise provided in these Regulations, no person shall manufacture, sell, supply, import or possess or administrator any product unless-

a) the product is a registered product; and

b) the person holds the appropriate licence required and issued under these Regulations.”.

“Product” is defined under Regulation 2 as “a drug in a dosage unit or otherwise, for use wholly or mainly by being administered to one or more human beings or animals for a medicinal purpose” or “a drug to be used as an ingredient of a preparation for a medicinal purpose”.

Further, Section 2 of the SDA 1952 defines “drug” to include any substance, product or article intended to be used or capable, or purported or claimed to be capable, of being used on humans or any animal, whether internally or externally, for a medicinal purpose. For “medicinal purpose”, one of definitions under Section 2 is “alleviating, treating, curing or preventing a disease or a pathological condition or symptoms of a disease”.

Based on the above provisions, it can be concluded that vaccine for COVID-19 would fall within the definition of “Product” and thus, it shall be dealt in accordance with the CDCR 1984 and approved by the DCA (by way of registration). Therefore, in order to import vaccine for COVID-19 from other countries, it has to be registered. Nonetheless, if the vaccine for COVID-19 is imported solely for the purpose of treatment of any person suffering from a life-threatening disease such as COVID-19, exemption for registration can be made pursuant to Regulation 15(6) of the CDCR 1984.

Vaccine approval process in Malaysia is regulated by the NPRA which ensures the safety, effectiveness and availability of vaccines through its comprehensive regulatory review mechanisms.

Procedure for Registration

The applicant for product registration must be a locally incorporated company, corporate or legal entity, with permanent address and registered with the Companies

Commission of Malaysia. If a foreign company intends to import the vaccine into Malaysia, it shall appoint a local agent in Malaysia to be the product registration holder of the said vaccine to be registered in Malaysia. Being the product registration holder, the local agent shall bear all responsibilities pertaining to the product registered in its name.

Product registration can only be done via online submission through QUEST at https://www.npra.gov.my/index.php/en/. For first time user, the applicant must register for a membership to get a USB token before the applicant can proceed with the product registration. According to the "Drug Registration Guidance Document ("**DRGD**")"[1], the processing and analysis fees of a new drug product are as specified below:

Processing Fee	Analysis Fee	Total Fees
RM1,000	Single active ingredient: RM3,000	RM4,000
	Two or more active ingredients: RM4,000	RM5,000

Under Regulation 8(3) of the CDCR 1984, it states that the DCA will charge any costs as it may incur for the purpose of carrying out any evaluation or investigation prior to the registration of any product. Applications without the prescribed fees will not be accepted and are not refundable.

Upon confirmation of payment, the application with the submitted data shall be evaluated. Review of applications shall follow a queue system. According to the DRGD, priority review may be granted for new product intended for unmet medical needs with no treatment options locally available such as new vaccines. An application for priority review should be submitted via a formal letter addressed to the Director of NPRA. The timeline for evaluation under priority review for new drug products is 120 working days. Hence, to speed up the importation of COVID-19 vaccine, an application for priority review can be submitted to the NPRA.

Under Regulation 10(1) of the CDCR 1984, the DCA may also require any product registration holder to furnish a written declaration made by or on behalf of the manufacturer of the imported product that all requirements governing the manufacture of the product imposed by the law of the country of manufacture have been complied with.

Vaccines Lot Release

The "Guidance Document for Vaccines Lot Release in Malaysia"[2] laid down the procedures of vaccines lot release in Malaysia. The procedures for general cases and exceptional cases (such as pandemic) are different. Since COVID-19 is a pandemic, it falls under the exceptional case.

Hence, the procedure will be as follows:

1. Applicant submits application form and documents via email to CQC (vaccineCQC@npra.gov.my).

2. NPRA will respond to the email by providing confirmation on the amount of fee to be paid as listed below:

Type of Vaccine	Cold Chain Inspection and Evaluation of Lot Summary Protocol		Cold Chain Inspection for Lot Summary Protocol has been Evaluated	
	West Malaysia	*East Malaysia*	*West Malaysia*	*East Malaysia*
Monovalent Vaccine	RM300/vaccine lot	RM600/vaccine lot	RM200/vaccine lot	RM500/vaccine lot
Polyvalent Vaccine	RM500/vaccine lot	RM800/vaccine lot		
Combination Vaccine	RM1000/vaccine lot	RM1300/vaccine lot		

3. Before the product's arrival, applicant makes payment to NPRA.

4. Evaluation of summary protocol is conducted.

5. Within 2 working days after the arrival of vaccines at warehouse, NPRA's officer will conduct cold chain inspection and verify physical appearance of the vaccines.

6. NPRA will issue lot release certificates if all the requirements have been fulfilled, within 6 working days after the product's arrival at warehouse.

Licensing

According to Regulation 7 of the CDCR 1984, an import licence is required in order to import vaccines for COVID-19 into Malaysia. Regulation 12(1) further provides that the Director of Pharmaceutical Services may issue an import licence in Form 5 in the Schedule, authorising the licensee to import and sell by wholesale or supply the registered products from the address of the premises specified in the licence. Hence, an application for an import licence shall be submitted online with a processing fee of RM500.[3] An import licence shall be valid for one year.[4]

Storage and Transportation of Vaccine from Importer to User

Medicinal products like vaccines are commonly handled by specific personnel and finally administered to the patient through healthcare professionals. Vaccines imported from overseas usually reach through Kuala Lumpur International Airport Cargo and are transferred straight to the Central Store. From the Central Store, the vaccines will be distributed to the Regional Store followed by the District Store and finally to the Health Centres. Dedicated transports like refrigerated trucks are used during the distribution of the vaccines between the centres and stores. This series of cold chain handling has to be strictly controlled to ensure that the vaccine is still in acceptable condition before it

can be administered to the patient. As such, all storage and transportation of the vaccine for COVID-19 are subject to the requirements set out in "Guideline on Good Distribution Practice"[5].

Conclusion

All in all, in order for a local company to import vaccine for COVID-19 into Malaysia, the vaccine product has to be registered under the CDCR 1984 and vaccine lot release has to be applied for. However, since COVID-19 has been declared by WHO as a pandemic and if the vaccine is imported solely for the purpose of treatment of any person suffering from a life-threatening disease, the registration for it can be waived. Nevertheless, vaccine lot release and import licence have to be applied for.

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1. "Drug Registration Guidance Document", 2nd Edition, 2016 (Revised 2020) <https://www.npra.gov.my/easyarticles/images/users/1047/Complete-DRGD-Revised-Jan-2020-final.pdf>
2. "Guidance Document for Vaccines Lot Release in Malaysia", 3rd Edition, 2016 <https://www.npra.gov.my/images/Guidelines_Central/Guidelines-vaccine-lot/2016/Guidance_Documents_for_Vaccine_Lot_Release_in_Malaysia_3rd_edition_1_Dec_2016.pdf>
3. Control of Drugs and Cosmetics Regulations 1984, Regulation 13(1)
4. Control of Drugs and Cosmetics Regulations 1984, Regulation 12(4)
5. "Guideline on Good Distribution Practice", 3rd Edition, 2018 <https://www.npra.gov.my/images/Guidelines_Central/Guidelines_on_Regulatory/2018/GUIDELINE_ON_GDP_3rd_Edi_2018.pdf>

Important Information

Azmi & Associates has set up Azmilaw Covid Task Force to look into all issues arising from COVID-19 and MCO. Clients are welcomed to contact their usual Partner who will bring their issues to Azmilaw Covid Task Force for our further action.

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We hope the above discussion is of assistance to you and your company. If your company's operations or contractual obligations are affected by the COVID-19 outbreak, we are ready to assist you on any queries you have.

Corporate Communication
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