KEMENTERIAN KESIHATAN MALAYSIA
(*Ministry of Health Malaysia*)
Bahagian Regulatori Farmasi Negara (NPRA)
Lot 36, Jalan Universiti
46200 Petaling Jaya
Selangor
MALAYSIA

No. Telefon : 03 - 7883 5400
No. Faksimili : 03 - 7956 2924
Portal Rasmi : http://www.npra.moh.gov.my
E-mel Rasmi : npra@npra.gov.my

Our Reference : NPRA.600-1/9/13 (9)
Date : 14 December 2020

PRODUCT REGISTRATION HOLDERS

RELEVANT ASSOCIATIONS

Sir/ Madam,

CONTROL OF DRUGS AND COSMETICS REGULATIONS 1984
DIRECTIVE NO.18/2020 BY DIRECTOR OF PHARMACEUTICAL SERVICES
DIRECTIVE ON THE IMPLEMENTATION OF FAST-TRACK CONDITIONAL REGISTRATION FOR PHARMACEUTICAL PRODUCTS DURING DISASTER

I refer to the above matter.

2. Please find enclosed the Directive No. 18/2020 by Director of Pharmaceutical Services: Directive on the implementation of fast-track conditional registration for pharmaceutical products during disaster for your information and attention.

3. Please be advised to comply with the above requirements.

Thank you.

"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,

(DR. HASENAH BINTI ALI) RPh 1517
Director
Bahagian Regulatori Farmasi Negara (NPRA)
Ministry of Health Malaysia

SAB/NB/PKPSR/NPRA/10122020
SAB/nb
✉ suhailah@npra.gov.my / nurhidayah@npra.gov.my
☎ +603 – 7883 5463 / 5465

DIRECTIVE IN ACCORDANCE WITH REGULATION 29,
CONTROL OF DRUGS AND COSMETICS REGULATIONS 1984

NO. 18 / 2020

DIRECTIVE ON THE IMPLEMENTATION OF FAST-TRACK CONDITIONAL REGISTRATION OF PHARMACEUTICAL PRODUCTS DURING DISASTER

BACKGROUND

1.1 In accordance with Regulation 8, Control of Drugs and Cosmetics Regulations 1984 (CDCR 1984), the Drug Control Authority (DCA) in the **351st** meeting on **3rd December 2020** has agreed with the implementation of fast-track conditional registration of pharmaceutical products during disaster.

1.2 Therefore, this directive is issued by the Director of Pharmaceutical Services in accordance with Regulation 29, CDCR 1984 to inform product registration holders regarding the implementation of fast-track conditional registration of pharmaceutical products during disaster.

IMPLEMENTATION

2.1 Please refer to the *Guidance and Requirements on Conditional Registration of Pharmaceutical Products During Disaster* (Attachment A) regarding the implementation of fast-track conditional registration for pharmaceutical products during disaster.

2.2 Among the main points outlined in the guideline:

2.2.1 Objective of fast-track conditional registration during disaster

To provide expedited access to pharmaceutical products for treatment or prevention during disasters without compromising aspects of quality, safety and efficacy using a risk-based approach.

2.2.2 Eligibility conditions for applications for fast-track conditional registration during disaster

i. The disease for which the product is intended is **serious or immediately life threatening** and has the potential to cause an outbreak, epidemic or pandemic; **AND**

ii. Existing registered products (medicine or vaccine) have not been successful in eradicating the disease or preventing outbreak, epidemic or pandemic; **AND**

iii. The product should be at least in an **on-going Phase III clinical study** that has preliminary data on safety and efficacy based on at least one well-planned Phase III clinical study that clearly demonstrates the safety and efficacy of the product; **AND**

iv. The product must be registered or have been given emergency use authorization by national regulatory authorities of country of origin **OR** any DCA reference agencies **OR** the World Health Organization (WHO).

2.2.3 Scope of fast-track conditional registration during disaster

New pharmaceutical products for use during a disaster.

2.2.4 Procedure for fast-track conditional registration during disaster

The current registration procedure still applies where the registration application shall be submitted online through the QUEST3+ system. Registration requirements are according to the current *Guideline on Conditional Registration for New Chemical Entities and Biologics in Malaysia.* However, to expedite access to these phamaceutical products, the applicant may submit the dossier through rolling submission and obtain technical advice and support through the pre-submission meeting.

2.2.6 Regulatory requirements for fast-track conditional registration during disaster

The list of regulatory requirements are as stated in the *Guidance and Requirements on Conditional Registration of Pharmaceutical Products During Disaster* (Attachment A).

2.2.7 Processing timeline for fast-track conditional registration during disaster

All registration applications for pharmaceutical products during disaster that fulfill the eligibility conditions shall be automatically given priority review status and shall be processed within **120 working days** from the date the complete application is received.

2.2.8 Validity of fast-track conditional registration during disaster

A fast-track conditional registration for the pharmaceutical product is valid for **one (1) year** from the date the product is registered. Thereafter, the conditional registration may be renewed **for a one (1) year** up to **two (2) times** through renewal application.

EFFECTIVE DATE

3.1 This directive will be in force **WITH IMMEDIATE EFFECT.**

"BERKHIDMAT UNTUK NEGARA"

(DATIN DR. FARIDAH ARYANI BINTI MD YUSOF) **(RPh 1197)**
Director of Pharmaceutical Services
Ministry of Health Malaysia
SAB/NB/PKPSR/NPRA/04122020

cc 1. Director
Bahagian Regulatori Farmasi Negara (NPRA)
Ministry of Health Malaysia

2. Director
Pharmacy Enforcement Division
Ministry of Health Malaysia

3. Director
Pharmacy Practice & Development Division
Ministry of Health Malaysia

4. Director
Pharmacy Policy & Strategic Planning Division
Ministry of Health Malaysia

5. Legal Advisor
Ministry of Health Malaysia