Guidelines on Conditional Registration for New Chemical Entities and Biologics MALAYSIA

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Objectives

1	**To allow promising new medicines to reach patients with unmet need earlier based on phase II clinical data to support the efficacy and safety.**
2	**To provide guidance on the application necessary for implementation of conditional registration**
3	**To ensure that appropriate measures are in place to manage the risks inherent as additional data are still required.**

SCOPE

New registration applications NCEs & Biologics

Early clinical data - phase II based on fully validated surrogate endpoints or other early data relevant to the medicine's safety and efficacy

Comprehensive quality and non-clinical safety data as required in the Drug Registration Guidance Document

At the point of submission, the product must be registered in at least two DCA reference country
The approval of addition indication with less than comprehensive clinical data may be decided on case-to-case basis

Request for Conditional Registration

Request by PRH

- Notify NPRA about the intention for a conditional registration during the registration submission

Justifications

- Show that the medicinal product falls within the **scope and requirements** of conditional registration are fulfilled
- PRH's proposal for completion of ongoing or new studies, or the collection of pharmacovigilance data

Products scope

- medicinal products for seriously debilitating or life threatening disease; or
- medicinal products to be used in emergency situation; or
- orphan medicinal products

Justification for Conditional Registration

+ risk benefit

- **Risk benefit balance should be positive based on less than comprehensive clinical data**

clinical data

- **Able to provide comprehensive clinical data** explaining how the comprehensive data can be provided post-registration.

Public Health

- **Benefits to public health in the context of immediate availability outweigh the inherent risks of limited data**

Unmet needs

- **Unmet medical need that it is necessary to introduce new methods or that it is necessary to provide a major improvement on existing methods**

Granting Approval & Renewal

Timeline

Standard time line for NCEs and Biologics unless priority review is granted upon request

Validity

2 years - may be renewed with the possibility of 2 extension (2 year each)
Additional renewal beyond 2 times will be considered on case-to-case basis based on justifications

Renewal

Six months before expiry
Documents to be submitted

i) updated Package Insert
ii) interim / full clinical report for confirmatory trial
iii) Latest PBRER

- NPRA will assess the renewal application on the basis of the risk-benefit balance and formulate an opinion whether the specific conditions or their timeframes need to be retained or modified
- Product will be granted full registration once the conditions have been fulfilled

Cancellation

DCA may cancel the conditional registration of a product or cancel the approved indication under the conditional registration if:

- **A trial required to verify the predicted clinical benefit of the product fails to verify such benefit.**
- **Other evidence demonstrates that the product is not shown to be safe or effective under the conditions of use.**

THANK YOU

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