APPENDIX 12

PRIORITY REVIEW

1. Priority review may be granted for new product application (in the category of New Drug Products, Biologics and Generics) which fulfils either one of the following conditions;

   a) Product which is intended for:
      (i) Unmet medical needs (e.g. medicines for rare diseases, new vaccines, etc.) with no treatment options locally available,
      (ii) Life-saving such as for treatment/ prevention of serious medical conditions (e.g. anticancer, antiretroviral, etc.) with no treatment options locally available,
      (iii) Treatment/ prevention in pandemic/ endemic situations, for the interest of public health,
      (iv) Emergency supply/ crucial for treatment purpose according to the current needs in the country,
      (v) Supply to the Ministry of Health Malaysia under circumstances where alternative product with the same active ingredient is unavailable,
      (vi) Population's specific needs (e.g., religious purpose)

   b) Product which involves a change in the formulation due to the decision/ instruction by the Drug Control Authority (DCA), for the purpose of formulation improvement with appropriate scientific justification(s),

   c) New application for products that have been registered with the same active ingredient for which the registration has been cancelled/ withdrawn due to issues other than safety issues. Priority review will be considered based on individual/ case to case basis and involves product that is crucial for treatment purpose.

   d) Product which is the first *generic/ biosimilar product, or the first three locally manufactured generic/ biosimilar product.

      **No generic/ biosimilar product has been registered by DCA at point of consideration on granting Priority Review*

      **During product evaluation, the priority review status granted can be cancelled in the event that the condition (d) is no longer fulfilled.*

e) New Chemical Entity (NCE) or biologics product with a phase III global, multicentre pivotal clinical trial conducted locally in Malaysia for the treatment of diseases of public health significance (e.g., hepatitis, HIV, COVID-19, etc.). A minimum of 5% of the total number of randomised subjects are subjects in the clinical studies conducted at study sites in Malaysia.

2. An application for Priority Review should be submitted via a formal letter to the Director of NPRA within one month after the payment has been confirmed.

3. The approval of Priority Review is subjected to the decision of the Drug Evaluation Committee Meeting upon submission of complete product registration documentation and does not exempt applicant from any product registration requirements.

4. The timeline for evaluation for product granted Priority Review is as below;

No.	**Product Category**	**Duration** (Starting from the date of approval of Priority Review)
(A)	**Full Evaluation**	
1.	New Drug Products	120 working days
2.	Biologics	120 working days
3.	Generics (Scheduled Poison)	100 working days
4.	Generics (Non-Scheduled Poison)	100 working days