MINOR VARIATION NOTIFICATION FORM FOR PHARMACEUTICAL PRODUCTS

Please read the following instructions before filling in the form.

1) This notification form is for Product Registration Holder (PRH) to notify National Pharmaceutical Control Bureau (NPCB) on the implementation of MiV-Notification (MiV-N) as per Malaysian Variation Guideline (MVG). The timeline for NPCB to acknowledge the variation notification is within 20 working days following receipt of a notification.
2) Please refer to the MVG for the conditions and supporting documents required.
3) Submission of relevant revised draft of package insert and labeling is subject to current regulatory requirements as per the latest Drug Registration Guidance Document (DRGD) and Circulars from NPCB. In the event that the revised draft of package insert and labeling does not meet the current regulatory requirements, please submit under Minor Variation Prior Approval (MiV-PA) or Major Variation (MaV).
4) PRH must submit this notification form together with the online submission through the Quest 2 system as the approval will only be notified via online submission. For submission online, please scan this form and attach together with the revised draft of package insert and labeling as a single file.
5) A MiV-N application may be rejected in specific circumstances with the consequence that the PRH must cease to apply the already implemented variation.
6) The completed form must be submitted to :
   Pusat Pendaftaran Produk, Biro Pengawalan Farmaseutikal Kebangsaan, Kementerian Kesihatan Malaysia,
   Lot 36, Jalan Universiti, 46200 Petaling Jaya, Selangor. (Fax No: 03-79581312)

Product Name: Product Category: ☐NCE ☐Biotech ☐Prescription ☐OTC	Name and address of product registration holder:
Reference Number:	Tel. No.:
Registration Number:	Fax No.:
Date of online submission in Quest System:	Email address:

Variation No.	Minor Variation (Notification)	Please tick (√) *Multiple selection is allowed*
MiV-N1	Change of details of product registration holder	
MiV-N2	Change of importer and/or store address	
MiV-N3	Change of product owner	
MiV-N4	Change in ownership of manufacturer	
MiV-N5	Change of the name or address (for example: postal code, street name) of the manufacturer of drug product	
MiV-N6	Change of the name or address (for example: postal code, street name) of the company or manufacturer responsible for batch release	
MiV-N7	Change of the name and/or address (for example: postal code, street name) of a manufacturer of the drug substance	
MiV-N8	Withdrawal/deletion of the alternative manufacturer(s) for drug substance	
MiV-N9	Renewal of European Pharmacopoeial Certificate of Suitability (CEP)	
MiV-N10	Change of specifications of the drug product and/or drug substance and/or excipient, following the updates in the compendium	
MiV-N11	Deletion of pack size for a product	

I hereby notify NPCB on the minor variation by notification for the product(s) above and declare that

- ✓ There is no other change except for the proposed variation;
- ✓ The change(s) will not adversely affect the quality, efficacy and safety of the product;
- ✓ All conditions for the variation concerned are fulfilled;
- ✓ The required supporting documents as specified for the variation in MVG have been submitted; and
- ✓ The proposed change has been checked in reference with the currently approved data in the system & there are no discrepancies.

Name	Signature	Date
_____	_____	_____