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://npra.moh.gov.my
E-mel Rasmi : npra@npra.gov.my

Ruj. Kami : (4) dlm. BPFK/PPP/01/03 Jld. 4
Tarikh : 23 APR 2019

SEMUA PEMEGANG PENDAFTARAN

SEMUA PERSATUAN BERKENAAN
(SEPERTI DI SENARAI EDARAN)

Tuan/ Puan,

MAKLUMAN BERKENAAN PERUBAHAN PROSEDUR KERJA BEBERAPA KATEGORI VARIASI *MINOR VARIATION (PRIOR APPROVAL)* DAN *MAJOR VARIATION* KEPADA *MINOR VARIATION (NOTIFICATION)* 'DO & TELL'* UNTUK PRODUK FARMASEUTIKAL, SUPLEMEN KESIHATAN DAN PRODUK SEMULAJADI

Dengan segala hormatnya perkara di atas adalah dirujuk.

Pihak Berkuasa Kawalan Dadah (PBKD) dalam mesyuaratnya kali ke **333** pada **4 April 2019** mengambil maklum dan bersetuju dengan perubahan prosedur kerja beberapa kategori variasi *Minor Variation (Prior Approval)* (MiV-PA) dan *Major Variation* (MaV) kepada *Minor Variation (Notification)* 'Do & Tell'* (MiV-N* 'Do & Tell') untuk produk farmaseutikal, suplemen kesihatan dan produk semulajadi.

2. Permohonan variasi 'MiV-N* 'Do & Tell' ini membawa maksud pemegang pendaftaran boleh meneruskan perubahan pada produk selepas penghantaran permohonan variasi yang berkaitan sementara menunggu kelulusan daripada pihak Bahagian Regulatori Farmasi Negara (NPRA). Mohon rujuk Lampiran A untuk kategori variasi yang terlibat.

3. Jangka masa penilaian dan bayaran fi pemprosesan tidak berubah dan masih mengikut kategori asal jenis variasi tersebut. Semua permohonan juga perlu memenuhi keperluan dan dokumen sokongan (*conditions and supporting documents*) sebagaimana yang digariskan dalam *Malaysian Variation Guideline for Pharmaceutical Products* dan *Malaysian Variation Guideline for Traditional Medicine and Health Supplement Products.*

4. Adalah menjadi tanggungjawab pemegang pendaftaran untuk membatalkan semua perubahan yang telah dilakukan ke atas produk berkenaan sekiranya didapati permohonan variasi MiV-N* 'Do & Tell' tersebut tidak memuaskan dan ditolak oleh pihak NPRA. Pemegang pendaftaran perlu mematuhi prosedur panggil balik (*recall*) sepertimana yang dinyatakan dalam *Guideline on Good Distribution Practice* untuk kelompok baharu yang telah dipasarkan / dikilangkan dengan perubahan variasi tersebut.

5. Tarikh kuat kuasa arahan ini ialah mulai **1 Mei 2019.**

6. Pemegang pendaftaran produk adalah dimohon untuk mengambil maklum tentang perkara ini.

Sekian, terima kasih.

"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,

SITI AIDA BINTI ABDULLAH (RPh 1028)
Timbalan Pengarah
b/p Pengarah
Bahagian Regulatori Farmasi Negara
Kementerian Kesihatan Malaysia

AAG/nb/ppp/NPRA/080419

AAG/nb/sr

azizahag@npra.gov.my / nurhidayah@npra.gov.my / seetha@npra.gov.my
+603 – 7883 5521/5526/5520
+603 - 7958 1312

s.k. 1. Pengarah Kanan Perkhidmatan Farmasi
Kementerian Kesihatan Malaysia.

2. Pengarah
Bahagian Penguatkuasa Farmasi
Kementerian Kesihatan Malaysia.

3. Pengarah
Bahagian Amalan dan Perkembangan Farmasi
Kementerian Kesihatan Malaysia

LAMPIRAN A

Senarai variasi *Minor Variation-Prior Approval* (MiV-PA) dan *Major Variation* (MaV) sedia ada yang akan diproses sebagai MiV-N* '*Do & Tell*'

1) Senarai Variasi Untuk Produk Farmaseutikal

No.	Variation Type	Variation Title
1.	MiV-PA2(a)*	Change of product labeling (in accordance to country specific labeling requirement) Includes: (i) Change of POSITION of existing graphic design & product info (ii) Change of colour of existing graphic (iii) Change of box size (iv) Add barcode/ 'halal' logo
2.	MiV-PA3(a)*	Update of approved patient information leaflet
3.	MiV-PA5*	Change and/or addition of alternative manufacturer/site of drug substance [where European Pharmacopoeial Certificate of Suitability (CEP) is available]
4.	MiV-PA7(a)*	Change of in-process controls applied during the manufacture of the drug substance [including tightening and where European Pharmacopoeial Certificate of Suitability (CEP) is not available]
5.	MiV-PA9(a)*	Change of the specification of drug substance (a) Specification limits are tightened
6.	MiV-PA13*	Revision of European Pharmacopoeial Certificate of Suitability (CEP) of drug substance
7.	MiV-PA14*	Change of batch size of non-sterile drug product
8.	MiV-PA20(a)*	Change of in-process controls applied during the manufacture of the drug product (tightening)
9.	MiV-PA22(a)*	Change of the specification of an excipient (a) Specification limits are tightened
10.	MiV-PA25(a)*	Change of release and shelf-life specifications of the drug product (a) Specification limits are tightened
11.	MiV-PA31*	Change of pack size/fill volume and/or change of shape or dimension of container or closure for non-sterile product
12.	MiV-PA32*	Change of outer carton pack sizes for a drug product
13.	MiV-	Change in any part of the (primary) packaging material not in contact

	PA33(a)*	with the finished product formulation such as colour of flip-off caps, colour code rings on ampoules, change of needle shield (different plastic used), without affecting product labeling/packaging insert.
14.	MiV-PA35*	Reduction of shelf-life of the drug product (a) As a package for sale and/or (b) After first opening and/or (c) After dilution/reconstitution

2) Senarai Variasi Untuk Produk Semulajadi dan Suplemen Kesihatan

No.	Variation Type	Variation Title
1	MaV-2(a)*	Change of product labeling (in accordance to country specific labeling requirement) Includes: (i) Change of POSITION of existing graphic design & product info (ii) Change of colour of existing graphic (iii) Change of box size (iv) Add barcode/ 'halal' logo
2	MaV-12(a)*	A reduction of shelf life of the drug product
3	MiV-PA2(a)*	Update of approved patient information leaflet
4	MiV-PA4(a)*	Change of the specification of drug substance (a) Tightening of limits
5	MiV-PA6(a)*	Change of specification of the drug product (a) Tightening of limits
6	MiV-PA8(a)*	Change of in-process controls applied during the manufacture of the drug product (tightening)
7	MiV-PA9*	Change of batch size of drug product
8	MiV-PA13*	Change of pack size/fill volume and/or change of shape or dimension of container or closure for non-sterile product
9	MiV-PA14*	Change in secondary packaging or any part of the primary packaging material not in contact with the finished product formulation such as colour of flip-off caps

**subtype variation: only relevant fields are opened in Quest 3+ variation module*