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Tarikh : 10 Julai 2020

SEMUA PEMEGANG PENDAFTARAN

SEMUA PERSATUAN BERKENAAN
(SEPERTI DI SENARAI EDARAN)

Tuan/Puan,

PEKELILING BERKENAAN PENGEMASKINIAN SENARAI KATEGORI VARIASI *MINOR VARIATION (PRIOR APPROVAL)* DAN *MAJOR VARIATION* YANG DIPROSES SEBAGAI *MINOR VARIATION (NOTIFICATION) 'DO & TELL' UNTUK PRODUK FARMASEUTIKAL, SUPLEMEN KESIHATAN DAN PRODUK SEMULAJADI**

Adalah saya merujuk perkara di atas dan pekeliling dengan nombor rujukan (4) dlm. BPFK/PPP/01/03 Jld.4 bertarikh 23 April 2019.

2. Sepertimana tuan/ puan sedia maklum, beberapa kategori variasi *Minor Variation (Prior Approval)* (MiV-PA) dan *Major Variation* (MaV) telah diproses sebagai *Minor Variation (Notification)* (Asterisk) *'Do & Tell'* (**MiV-N* *'Do & Tell'***) melalui pekeliling dengan nombor rujukan (4) dlm. BPFK/PPP/01/03 Jld.4 bertarikh 23 April 2019. Senarai kategori variasi yang telah diluluskan sebelum ini merangkumi 14 kategori bagi produk farmaseutikal dan 9 kategori bagi produk semulajadi dan suplemen kesihatan.

3. Dimaklumkan bahawa Bahagian Regulatori Farmasi Negara (NPRA) akan melaksanakan pengemaskinian melalui penambahan serta peluasan skop beberapa kategori variasi yang diproses sebagai MiV-N* *'Do & Tell'* kepada 21 kategori bagi

produk farmaseutikal dan 15 kategori bagi produk semulajadi dan suplemen kesihatan seperti di **Lampiran A**.

4. Pelaksanaan variasi *MiV-N* 'Do & Tell'* adalah seperti berikut :

4.1 Permohonan variasi *MiV-N* 'Do & Tell'* bermaksud pemegang pendaftaran boleh meneruskan perubahan pada produk selepas penghantaran permohonan variasi yang berkaitan sementara menunggu kelulusan daripada pihak NPRA.

4.2 Melalui sistem QUEST3+, jenis variasi *MiV-N* 'Do & Tell'* akan dilabelkan dengan simbol **(Asterisk).*

4.3 Jangka masa penilaian dan bayaran fi pemprosesan tidak berubah dan masih mengikut kategori asal variasi tersebut.

4.4 Semua permohonan perlu memenuhi keperluan dan dokumen sokongan *conditions and supporting documents* seperti yang dinyatakan dalam *Malaysian Variation Guideline for Pharmaceutical Products* dan *Malaysian Variation Guideline for Natural (Traditional Medicine and Homeopathy) and Health Supplement Products (Abridged Evaluation)* mengikut kategori MiV-PA dan MaV sedia ada.

4.5 Sekiranya didapati permohonan variasi MiV-N* 'Do & Tell' tersebut tidak memuaskan dan ditolak oleh pihak NPRA, pemegang pendaftaran bertanggungjawab untuk :

4.5.1 membatalkan semua perubahan yang telah dilakukan ke atas produk berkenaan.

4.5.2 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. Pelaksanaan ini adalah terpakai bagi permohonan yang diterima mulai **1 Ogos 2020** dan pekeliling ini akan menggantikan pekeliling sedia ada dengan nombor rujukan (4) dlm.BPFK/PPP/01/03 Jld.4 bertarikh 23 April 2019.

6. Sekiranya tuan/ puan mempunyai pertanyaan lanjut, sila berhubung dengan seksyen berkaitan. Pihak pemegang pendaftaran dinasihatkan agar mengambil maklum mengenai perkara di atas.

Sekian, terima kasih.

"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,

(DR HASENAH BINTI ALI) RPh 1517
Pengarah
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Kementerian Kesihatan Malaysia

2. Pengarah
Bahagian Penguatkuasaan Farmasi
Kementerian Kesihatan Malaysia

3. Pengarah
Bahagian Amalan dan Perkembangan Farmasi
Kementerian Kesihatan Malaysia

4. Semua Timbalan Pengarah
Bahagian Regulatori Farmasi Negara (NPRA)

LAMPIRAN A

SENARAI VARIASI *MINOR VARIATION-PRIOR APPROVAL* (MIV-PA) DAN *MAJOR VARIATION* (MaV) YANG 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-PA4*	Replacement of the company or party responsible for batch release # Changes in the labels strictly for updating the batch release information ONLY
4.	MiV-PA5*	Change and/or addition of alternative manufacturer/site of drug substance [where European Pharmacopoeial Certificate of Suitability (CEP) is available]
5.	MiV-PA7*	Change of in-process controls applied during the manufacture of the drug substance [including tightening and addition of new in process test and where European Pharmacopoeial Certificate of Suitability (CEP) is not available]
6.	MiV-PA9(a)*	Change of the specification of drug substance (a) Specification limits are tightened
7.	MiV-PA13*	Revision of European Pharmacopoeial Certificate of Suitability (CEP) of drug substance
8.	MiV-PA14*	Change of batch size of non-sterile drug product
9.	MiV-PA15*	Reduction or removal of overage # no other changes to the formulation can be made
10.	MiV-PA18*	Change of the colouring/flavouring agent of the product [addition, deletion or replacement of colourant(s)/flavour(s)]
11.	MiV-PA20*	Change of in-process controls applied during the manufacture of the drug product (including tightening and addition of new in process test)

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No.	Variation Type	Variation Title
12.	MiV-PA22(a)*	Change of the specification of an excipient (a) Specification limits are tightened
13.	MiV-PA25(a)*	Change of release and shelf-life specifications of the drug product (a) Specification limits are tightened
14.	MiV-PA26(a)*	Change of imprints, bossing or other markings on tablets or printing on capsules including addition or change of inks used for product marking (a) Imprints, bossing or other markings on tablets or printing on capsules # Proposed marking/imprint should not be of misleading logo/wordings and changes in the labels strictly for updating the new description ONLY. (b) Removal of score/break-line that was included initially for cosmetic purposes is allowed
15.	MiV-PA29*	Change in primary packaging material for non-sterile product a) Qualitative and quantitative composition and/or b) Type of container and/or c) Inclusion of primary packaging material # For upgrading purpose(reference paper to support the material upgrading is needed)
16.	MiV-PA30*	Replacement of a manufacturer for secondary packaging # Changes in the labels strictly for updating the secondary packaging site information ONLY
17.	MiV-PA31*	Change of pack size/fill volume and/or change of shape or dimension of container or closure for non-sterile product
18.	MiV-PA32*	Change of outer carton pack sizes for a drug product
19.	MiV-PA33(a)*	Change in any part of the (primary) packaging material not in contact 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.

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No.	Variation Type	Variation Title
20.	MiV-PA34*	Addition or replacement of measuring device for oral liquid dosage forms and other dosage form # as long as the device is not an integrated part of the primary packaging
21.	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

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

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(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-8(a)*	Qualitative or quantitative change of excipient – Change of the colouring/flavouring agent of the product [addition, deletion or replacement of colourant(s)/flavour(s)]
3.	MaV-10(a)*	Change in primary packaging material for non-sterile product a) Qualitative and quantitative composition and/or b) Type of container and/or c) Inclusion of new primary packaging material # For upgrading purpose(reference paper to support the material upgrading is needed)
4.	MaV-12(a)*	A reduction of shelf life of the drug product
5.	MiV-PA2(a)*	Update of approved patient information leaflet
6.	MiV-PA4(a)*	Change of the specification of drug substance (a) Tightening of limits
7.	MiV-PA5*	Replacement of the company or party responsible for batch release # Changes in the labels strictly for updating the batch release information ONLY
8.	MiV-PA6(a)*	Change of specification of the drug product (a) Tightening of limits
9.	MiV-PA8*	Change of in-process controls applied during the manufacture of the drug product (including tightening and addition of new in process test)
10.	MiV-PA9*	Change of batch size of drug product
11.	MiV-PA10(a)*	Change of imprints, bossing or other markings on tablets or printing on capsules including addition or change of inks used for product marking

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No.	Variation Type	Variation Title
		(a) Imprints, bossing or other markings on tablets or printing on capsules # Proposed marking/imprint should not be of misleading logo/wordings and changes in the labels strictly for updating the new description ONLY. (b) Removal of score/break-line that was included initially for cosmetic purposes is allowed
12.	MiV-PA12*	Replacement of a manufacturer for secondary packaging/repacker # Changes in the labels strictly for updating the secondary packaging site information ONLY
13.	MiV-PA13*	Change of pack size/fill volume and/or change of shape or dimension of container or closure for non-sterile product
14.	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
15.	MiV-PA15*	Addition or replacement of measuring device for oral liquid dosage forms and other dosage form # as long as the device is not an integrated part of the primary packaging

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