KEMENTERIAN KESIHATAN MALAYSIA
(*Ministry of Health Malaysia*)
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Rujukan : Bil (6) dlm. NPRA/PPPK/01/04
Tarikh : 14 Julai 2022

SEMUA PEMEGANG PENDAFTARAN PRODUK

SEMUA PERSATUAN BERKENAAN
(SEPERTI DI SENARAI EDARAN)

Tuan/Puan,

PEKELILING BERKENAAN PENAMAAN SEMULA PROSEDUR *'DO & TELL'* KEPADA 'TELL & DO' DAN PENGEMASKINIAN SENARAI JENIS VARIASI *MINOR VARIATION (PRIOR APPROVAL)* DAN *MAJOR VARIATION* YANG DIBENARKAN UNTUK DIPROSES MELALUI PROSEDUR INI UNTUK PRODUK FARMASEUTIKAL, SUPLEMEN KESIHATAN DAN PRODUK SEMULAJADI

Saya dengan hormatnya merujuk kepada perkara di atas dan pekeliling dengan rujukan NPRA.600-1/9/12 (2) bertarikh 10 Julai 2020 serta pekeliling dengan rujukan (4) dlm. BPFK/PPP/01/03 Jld.4 bertarikh 23 April 2019 adalah berkaitan.

2. Sepertimana tuan/ puan sedia maklum, beberapa jenis variasi *Minor Variation (Prior Approval)* (MiV-PA) dan *Major Variation* (MaV) telah dibenarkan untuk diproses sebagai *Minor Variation (Notification)* *(Asterisk)* *'Do & Tell'* (MiV-N* *'Do & Tell')* melalui pekeliling dengan rujukan NPRA.600-1/9/12 (2) bertarikh 10 Julai 2020 dan pekeliling dengan rujukan (4) dlm. BPFK/PPP/01/03 Jld.4 bertarikh 23 April 2019. Senarai jenis variasi yang telah diluluskan sebelum ini merangkumi 21 jenis perubahan bagi produk farmaseutikal dan 15 jenis perubahan bagi produk semulajadi dan suplemen kesihatan.

3. Bahagian Regulatori Farmasi Negara (NPRA) telah memutuskan untuk menamakan semula prosedur ini untuk menggambarkan proses kerja yang sebenarnya dengan lebih tepat. Prosedur ini akan dikenali sebagai ***'Tell & Do'*** di mana **selepas permohonan variasi dikemukakan*(Tell)***, pemegang pendaftaran boleh **meneruskan perubahan pada produk (*Do*)** sementara menunggu kelulusan daripada pihak NPRA. Penamaan semula ini adalah juga untuk mengelakkan kekeliruan kerana istilah *Do & Tell* adalah merujuk kepada jenis variasi *Minor Variation (Notification)* berdasarkan *ASEAN Variation Guideline (AVG)* & *Malaysian Variation Guideline (MVG)* dan tidak melibatkan jenis variasi MiV-PA dan MaV.

4. Selain itu, NPRA telah melaksanakan pengemaskinian kepada jenis variasi yang dibenarkan untuk diproses sebagai ***'Tell & Do'*** bagi produk farmaseutikal berdasarkan pengkelasan semula jenis variasi di peringkat NPRA dan ASEAN. Senarai baru ini merangkumi 23 jenis perubahan bagi produk farmaseutikal dan 15 jenis perubahan bagi produk semulajadi dan suplemen kesihatan seperti di **Lampiran A**.

5. Pelaksanaan variasi *'Tell & Do'* adalah seperti berikut :

5.1 Melalui Sistem Quest, jenis variasi *'Tell & Do'* akan dilabelkan dengan simbol **(Asterisk)*.

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

5.3 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 jenis MiV-PA dan MaV sedia ada.

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

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

5.4.2 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.

6. Pelaksanaan ini adalah terpakai bagi permohonan yang diterima mulai **1 Ogos 2022** dan pekeliling ini akan menggantikan pekeliling sedia ada dengan rujukan NPRA.600-1/9/12 (2) bertarikh 10 Julai 2020 dan rujukan (4) dlm.BPFK/PPP/01/03 Jld.4 bertarikh 23 April 2019.

Sekian, terima kasih.

"WAWASAN KEMAKMURAN BERSAMA 2030"

"**BERKHIDMAT UNTUK NEGARA**"

Saya yang menjalankan amanah,

(DR. ROSHAYATI MOHAMAD SANI) RPh.1449
Pengarah
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Rujukan : Bil (6) dlm. NPRA/PPPK/01/04

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

2. Pengarah
Bahagian Penguatkuasaan Farmasi
Kementerian Kesihatan Malaysia

3. Pengarah
Bahagian Amalan dan Perkembangan Farmasi
Kementerian Kesihatan Malaysia

Rujukan : Bil (6) dlm. NPRA/PPPK/01/04

SENARAI EDARAN

1. Presiden
   Pharmaceutical Association of Malaysia (PhAMA)
   C-18-2, Two Square (Dataran 3 2)
   No.2, Jalan 19/1
   46300 Petaling Jaya, Selangor.

2. Presiden
   Persatuan Industri Farmaseutikal Malaysia (MOPI)
   Global Business & Convention Centre
   Mezzanine Floor, Block A
   No. 8, Jalan 19/1, Section 19
   46300 Petaling Jaya, Selangor.

3. Presiden
   Malaysian Association of Pharmaceutical Suppliers (MAPS)
   c/o Medispec (M) Sdn Bhd
   B-1-07, Block B,
   Jalan SS25/22, Mayang Avenue,
   Taman Mayang
   47301 Petaling Jaya, Selangor.

4. Presiden
   Direct Selling Association of Malaysia (DSAM)
   Unit 1702,17th Floor
   Blok A, Damansara Intan
   No. 1, Jalan SS20/27
   47400 Petaling Jaya, Selangor.

5. Presiden
   Malaysian Direct Distribution Association (MDDA)
   Unit 709, Block A, Level 7
   Kelana Business Centre
   97, Jalan SS 7/2, Kelana Jaya
   47301 Petaling Jaya, Selangor.

6. Presiden
   Malaysian Dietary Supplement Association (MADSA)
   Axis Tower Level 3
   2 Jalan 51A/223, Seksyen 51A
   46100 Petaling Jaya, Selangor.

7. Presiden
   Persatuan Pengeluar Ubat Cina Malaysia (PPUCM)
   Lot 41, Jalan BRP 9/2B
   Kawasan Perindustrian, Taman Bukit Rahman Putra
   47000 Sungai Buloh, Selangor.

8. Presiden
   Federation of Chinese Physicians and Medicine Dealers Associations of Malaysia (FCPMDAM)
   10-11, 13th Floor, Sun Complex
   Jalan Bukit Bintang,
   55100 Kuala Lumpur.

9. Presiden
   Malaysian Chinese Medical Association (MCMA)
   Persatuan Tabib Tionghua Malaysia
   No.2, Jalan Hang Jebat,
   50150 Kuala Lumpur.

10. Presiden
Persatuan Pengeluar-Pengeluar Ubat Tradisional Melayu Malaysia (PURBATAMA)
Lot 292, Jalan Shahab 1, Shahab Perdana
Jalan Sultanah Sambungan
05150 Alor Setar, Kedah.

11. Presiden
Pertubuhan Perubatan Tradisional India Malaysia (PEPTIM)
Darshan Ayurvedic Centre
No. 32, Queen Street
10200 Pulau Pinang.

12. Presiden
Majlis Perubatan Homeopathy Malaysia (MPHM)
Unit B07-4, Taman Dagang Business Centre,
Jalan Dagang Besar,
68000 Ampang Selangor.

LAMPIRAN A

SENARAI JENIS VARIASI YANG DIBENARKAN DIPROSES MELALUI PROSEDUR 'TELL & *DO*'

(1) Senarai Variasi Minor Variation-Prior Approval (MiV-PA) untuk Produk Farmaseutikal

No.	Variation Type	Variation Title
1.	**MiV-PA3***	Change of patient information leaflet (PIL)
2.	**MiV-PA5***	Addition/Replacement of manufacturer/site of drug substance [where European Pharmacopoeial Certificate of Suitability (CEP) is available]
3.	**MiV-PA7***	Change of in-process controls applied during the manufacture of drug substance [including tightening and addition of new in process test and where European Pharmacopoeial Certificate of Suitability (CEP) is not available]
4.	**MiV-PA9(a)***	Change of specifications of drug substance (a) Specification limits are tightened *Note: This applies for specification changes* *- between non-compendial* *- from non-compendial to compendial* *- from one compendium to another*
5.	**MiV-PA9(b)***	Change of specifications of drug substance (b) Addition of new test parameter and limits (following compendium) *Note: This applies for specification changes* *- from non-compendial to compendial* *- from one compendium to another*
6.	**MiV-PA9(c)***	Change of specifications of drug substance (c) Specification limits are widened following compendium *Note: This applies for specification changes* *- from non-compendial to compendial* *- from one compendium to another*

7.	**MiV-PA9(d)***	Change of specifications of drug substance (d) Deletion of test parameter and limits following compendium *Note: This applies for specification changes* *- from non-compendial to compendial* *- from one compendium to another*
8.	**MiV-PA13***	Revision of European Pharmacopoeial Certificate of Suitability (CEP) of drug substance
9.	**MiV-PA14***	Change of batch size of non-sterile drug product (up to 10-fold)
10.	**MiV-PA15***	Reduction/Removal of overage of drug substance *Note: No other changes to the formulation can be made*
11.	**MiV-PA18***	Change of colouring agent/flavouring agent/capsule shell colour of drug product
12.	**MiV-PA20***	Change of in-process controls applied during the manufacture of drug product (including tightening and addition of new in-process test)
13.	**MiV-PA22(a)***	Change of specifications of non-compendial excipient (a) Specification limits are tightened
14.	**MiV-PA25(a)***	Change of release and/or shelf life specifications of drug product (a) Specification limits are tightened *Note: This applies for specification changes* *- between non-compendial* *- from non-compendial to compendial* *- from one compendium to another*
15.	**MiV-PA25(b)***	Change of release and/or shelf life specifications of drug product (b) Addition of new test parameter and limits (following compendium) *Note: This applies for specification changes* *- from non-compendial to compendial* *- from one compendium to another*

16.	**MiV-PA25(c)***	Change of release and/or shelf life specifications of drug product (c) Specification limits are widened following compendium *Note: This applies for specification changes* *- from non-compendial to compendial* *- from one compendium to another*
17.	**MiV-PA25(d)***	Change of release and/or shelf life specifications of drug product d) Deletion of test parameter and limits following compendium *Note: This applies for specification changes* *- from non-compendial to compendial* *- from one compendium to another*
18.	**MiV-PA26***	Change of imprints, embossing/debossing or other markings (including break/score-line) on tablets or printing on capsules including addition/change of inks used for product marking (a) Imprints, embossing/debossing or other markings on tablets or printing on capsules *Note: Proposed imprints/markings 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
19.	**MiV-PA29***	Change in primary packaging material for non-sterile drug product a) Type of container b) Addition of primary packaging material c) Qualitative and quantitative composition *Note: For upgrading purpose (reference paper to support the material upgrading is needed)*
20.	**MiV-PA31***	Change/Addition of pack size/fill volume and/or change of shape or dimensions of container or closure for non-sterile drug product
21.	**MiV-PA32***	Change of drug substance submission option
22.	**MiV-PA34***	Addition/Replacement of measuring device for oral liquid dosage forms and other dosage forms *Note: As long as the device is not an integrated part of the primary packaging*

23.	**MiV-PA35***	Reduction of the shelf life of drug product a) As a package for sale b) After first opening c) After dilution/reconstitution

**Subtype variation: Only relevant fields are opened in the online QUEST system*

(2) Senarai Variasi *Minor Variation-Prior Approval* (MiV-PA) dan *Major Variation* (MaV) 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 *Note: 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 *Note: Changes in the labels strictly for updating the batch release information ONLY*

No.	Variation Type	Variation Title
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 (a) Imprints, bossing or other markings on tablets or printing on capsules *Note: 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 *Note: 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 *Note: As long as the device is not an integrated part of the primary packaging*

Subtype variation: Only relevant fields are opened in the online QUEST system