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

Ruj. Kami : NPRA.600-1/9/12 (4)
Tarikh : 21 Julai 2020

SEMUA PEMEGANG PENDAFTARAN

SEMUA PERSATUAN BERKENAAN
(SEPERTI DI SENARAI EDARAN)

Tuan/ Puan,

PEKELILING BERKENAAN PERUBAHAN PROSEDUR KERJA BEBERAPA KATEGORI VARIASI *MINOR VARIATION* (*PRIOR APPROVAL*) KEPADA *MINOR VARIATION (NOTIFICATION) "DO & TELL"* BAGI PRODUK FARMASEUTIKAL VETERINAR

Adalah saya merujuk perkara di atas.

2. Dimaklumkan bahawa Bahagian Regulatori Farmasi Negara (NPRA) akan melaksanakan perubahan prosedur kerja perubahan prosedur kerja beberapa kategori variasi *minor variation (prior approval)* kepada *minor variation (notification) "Do & Tell"* bagi produk farmaseutikal veterinar. Prosedur kerja ini telah dibentangkan dan diambil maklum oleh Pihak Berkuasa Kawalan Dadah (PBKD) dalam mesyuaratnya kali ke **346** pada **9 Julai 2020** .

3. Seperti yang tuan/puan sedia maklum, 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 NPRA. Sila rujuk Lampiran 1 untuk kategori variasi yang terlibat.

4. 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*) seperti yang diterangkan dalam kategori MiV-PA sedia ada walaupun setelah dipinda kepada kategori MiV-N 'Do & Tell'.

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

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

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.

6. Tarikh pelaksanaan prosedur ini adalah **SERTA MERTA** mulai tarikh pekeliling ini.

7. Sekiranya tuan/ puan ingin mendapatkan maklumat lanjut, sila hubungi Seksyen Ubat Veterinar, Pusat Penilaian Produk dan Kosmetik, NPRA. 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
Bahagian Regulatori Farmasi Negara
Kementerian Kesihatan Malaysia

SAB/NB/PKPSR/NPRA/10072020

SAB/nb

- suhailah@npra.gov.my / nurhidayah@npra.gov.my
+603 – 7883 5563/5474

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

4. Pengarah
Bahagian Dasar dan Perancangan Strategik Farmasi
Kementerian Kesihatan Malaysia

5. Semua Timbalan Pengarah
Bahagian Regulatori Farmasi Negara
Kementerian Kesihatan Malaysia

LAMPIRAN 1

The list of 'Do & Tell' Variation for Veterinary Pharmaceutical Products

Notes

*(a) * : to create additional field*

** : to maintain the field (TO CHANGE TO DO & TELL)*

No.	Variation Type	Variation Title	Remarks	Fields to be open in Quest 3+ system
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) inclusive of font size	To create additional field	D1, D2, D3 ,E14 C1,C2,C3,C4,C5, C6,C7
2.	MiV-PA5*	Change and/or addition of alternative manufacturer/site of drug substance [where European Pharmacopoeial Certificate of Suitability (CEP) is available]	Rename existing variation title (add *)	S1.1,S1.2,S1.3, S2.1,S4.1,S4.4, S4.4.1,E14
3.	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]	To create additional field	S2.4,S4.1,S4.4, S4.4.1,E14
4.	MiV-PA9(a)*	Change of the specification of drug substance (a) Specification limits are tightened	To create additional field	S2.1,S4.1,S4.4, S4.4.1, E14
5.	MiV-PA13*	Revision of European Pharmacopoeial Certificate of Suitability (CEP) of drug substance	Rename existing variation title (add *)	S2.1,S4.1,S4.4, S4.4.1,E14

6.	MiV-PA14*	Change of batch size of non-sterile drug product	Rename existing variation title (add *)	B1.1,B3,P3.1,P3.2, P3.3,P3.4,P3.5, P5.4,P5.4.1,P8, E14
7.	MiV-PA20(a)*	Change of in-process controls applied during the manufacture of the drug product (tightening)	To create additional field	P3.2,P3.3,P3.4, P5.1,P5.2,P5.4, P5.4.1,E12,E14
8.	MiV-PA22(a)*	Change of the specification of an excipient (a) Specification limits are tightened	Rename existing variation title (add *)	P4.1,P4.2,P4.3, P4.4,E14
9.	MiV-PA25(a)*	Change of release and shelf-life specifications of the drug product (a) Specification limits are tightened	To create additional field	E12,E14,P5.1, P5.2,P5.4,P5.4.1, P5.5,P5.6,P8
10.	MiV-PA31*	Change of pack size/fill volume and/or change of shape or dimension of container or closure for non-sterile product	Rename existing variation title (add *)	C1,C2,C3,C4,C5, C6,C7,D1,D2,D3, P3.2,P3.3,P7,P8, E14
11.	MiV-PA32*	Change of outer carton pack sizes for a drug product	Rename existing variation title (add *)	C1,C2,C3,C4,C5, C6,C7,D1,D2,D3, P3.2,P3.3,P7,E14
12.	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.	To create additional field	C1,C2,C3,C4,C5, C6,P7,E14
13.	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/recontitution	Rename existing variation title (add *)	A20,A21,A22,D1, D2,D3,E14,P5.1, P8