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POS BERDAFTAR

Ruj. Kami : NPRA.600-1/9/12 (13)
Tarikh : 10 Jun 2022

SEMUA PEMEGANG PENDAFTARAN PRODUK

SEMUA PERSATUAN BERKENAAN
(SEPERTI DI SENARAI EDARAN)

Tuan/ Puan,

PEKELILING BERKENAAN PELUASAN SKOP PERMOHONAN PERTUKARAN TAPAK PENGILANG/*CHANGE OF MANUFACTURING SITE* (COS) *TYPE III* DAN *TYPE IV*

Saya dengan hormatnya merujuk kepada perkara di atas.

2. Pihak Berkuasa Kawalan Dadah (PBKD) dalam mesyuaratnya kali ke-**373** pada **2 Jun 2022** telah bersetuju dan mengambil maklum berkenaan peluasan skop permohonan pertukaran tapak pengilang (COS) *Type III* dan *Type IV* untuk kategori produk **ubat baru, biologik, ubat generik, ubat veterinar** seperti berikut :

2.1 Pertukaran berikut dibenarkan diproses melalui permohonan *COS Type III* dan *Type IV* :

2.1.1 Tapak pengilang kontrak luar negara kepada tapak pengilang kontrak luar negara yang baru;

2.1.2 Tapak pengilang tempatan kepada tapak pengilang luar negara *(its own/subsidiary);*

2.1.3 Tapak pengilang tempatan kepada tapak pengilang kontrak luar negara.

3. Selain itu, definisi pertukaran tapak pengilang (COS) *Type III* dan *Type IV* dalam *Drug Registration Guidance Document* (DRGD) akan dipinda seperti berikut:

Type of COS		***Description***	
		Definisi sedia ada dalam *DRGD 3rd Edition, 2nd Revision January 2022*	**Pindaan yang telah dipersetujui**
Type III	*Change of manufacturing site located outside Malaysia*	*Change of location of the site of manufacture to manufacturing facilities located outside Malaysia.* *This may be due to a merger or rationalization of manufacturing sites in line with multinationals' manufacturing strategies.*	*Change of location of the site of manufacture to manufacturing facilities located outside Malaysia.* *a) From a manufacturer to its own/ subsidiary manufacturing premise* ➢ *This may be due to a merger or rationalization of manufacturing sites in line with manufacturing strategies.* ➢ *Applicable for all product categories.* *b) From a manufacturer (its own/ subsidiary/ contract) to a contract manufacturing premise.** *c) From a local manufacturing site (in Malaysia) to manufacturing facilities located outside Malaysia (its own/subsidiary/contract).** **Applicable <u>only</u> for the following product categories:* *i. New drug products* *ii. Biologics* *iii. Generic products containing scheduled and non-scheduled poisons* *iv. Veterinary products*

Type of COS		***Description***	
		Definisi sedia ada dalam *DRGD 3rd Edition, 2nd Revision January 2022*	**Pindaan yang telah dipersetujui**
Type IV	*Change of manufacturing site for sterile products*	*i) Transfer of manufacturing of an aseptically processed sterile product to a:* *a) newly constructed or refurbished aseptic processing facility or area;* *b) an existing processing facility or area that does not manufacture similar approved products.* *(For example, transferring the manufacture of a lyophilized product to an existing aseptic process area where there is no approved lyophilized product is manufactured).* *ii) Transfer of a finished product sterilized by terminal processes to a newly constructed facility at a different manufacturing site.*	*Change of location of the site of manufacture for sterile products:* • *within Malaysia* • *from outside Malaysia to a location in Malaysia* • *from Malaysia to manufacturing facilities located outside Malaysia* • *between sites located outside Malaysia* *a) From a manufacturer to its own/ subsidiary manufacturing premise* ➢ *This may be due to a merger or rationalization of manufacturing sites in line with manufacturing strategies.* *b) From a manufacturer (its own/ subsidiary/ contract) to a contract manufacturing premise*

4. Tarikh kuat kuasa perkara ini adalah mulai **15 Jun 2022.**

5. Untuk makluman, maklumat berkaitan perkara ini akan dikemaskini dalam *Drug Registration Guidance Document (DRGD)*, *Third Edition, 3rd Revision, July 2022*.

6. Sekiranya tuan/puan ingin mendapatkan maklumat lanjut, sila hubungi seksyen berkaitan di Pusat Penilaian Produk dan Kosmetik, NPRA. Pihak tuan/puan adalah diarahkan untuk mengambil maklum dan mematuhi perkara tersebut di atas.

Sekian, terima kasih

"WAWASAN KEMAKMURAN BERSAMA 2030"

"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,

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s.k. 1. Pengarah Bahagian Regulatori Farmasi Negara, Kementerian Kesihatan Malaysia (KKM)

2. Pengarah Bahagian Penguatkuasaan Farmasi, KKM

3. Pengarah Bahagian Amalan dan Perkembangan Farmasi, KKM

4. Pengarah Bahagian Dasar dan Perancangan Strategik Farmasi, KKM

5. Semua Timbalan Pengarah, NPRA, KKM