APPENDIX 21

SPECIAL CONDITIONS FOR REGISTRATION OF A PARTICULAR PRODUCT OR GROUP OF PRODUCTS

NO.	PRODUCTS
1.	**BLOOD PRODUCTS**
2.	**HUMAN GROWTH HORMONE** (Somatotropin, Somatropin)
3.	**KETOCONAZOLE**
4.	**MAGNOLIA OFFICINALIS**
5.	**MIDAZOLAM**
6.	**PARACETAMOL IN COMBINATION WITH CAFFEINE**
7.	**PARACETAMOL INTRAVENOUS INJECTION**
8.	**RETINOIDS INDICATED FOR THE TREATMENT OF SKIN DISEASES (ORAL)**
9.	**VACCINES**

NO.	SPECIAL CONDITIONS/ REQUIREMENTS
1.	**BLOOD PRODUCTS** a) Each batch of product must comply with WHO requirements for the product. b) The following documents must be enclosed with each bath of the product imported into Malaysia: i. Batch Release Certificate from the relevant authority in the country of manufacture ii. Certificate confirming that the blood or plasma used in the production of the lot is tested and found to be negative for HIV antibody, HbsAg, and HCV, and that high-risk donors were excluded iii. Certificate of analysis
2.	**HUMAN GROWTH HORMONE** (Somatotropin, Somatropin) A proper record of product supplied stating the product name, product registration number, name, address and contact number of purchaser (prescriber) shall be kept and submitted to the Authority upon request.
3.	**KETOCONAZOLE** Oral products containing ketoconazole are restricted for hospital use only.
4.	***MAGNOLIA OFFICINALIS*** a) *Magnolia officinalis* is **only allowed** for products that comply with Chinese Traditional medicine formulation based on recognized references such as *Pharmacopeia of the People's Republic of China*, *Taiwan Herbal Pharmacopeia*, etc. b) Product Registration Holder shall ensure that the product is sold or supplied to Registered Traditional Chinese Medicine Practitioners only. c) Manufacturers or Importers and Wholesalers shall ensure that the product is manufactured or imported and sold wholesale or supplied to Registered Traditional Chinese Medicine Practitioners only. Reference: ***NPRA.600-1/9/12 (11)*** *Pekeliling Berkenaan Pengemaskinian Status Bahan Aktif Magnolia Officinalis Dalam Drug Registration Guidance Document (DRGD)*
5.	**MIDAZOLAM** Products containing midazolam in tablet form are restricted for use in government and private hospitals and specialist clinics only.

NO.	SPECIAL CONDITIONS/ REQUIREMENTS
6.	**PARACETAMOL IN COMBINATION WITH CAFFEINE** a) For products containing a combination of paracetamol and caffeine: Dose unit of caffeine for adults is 65mg and maximum dose of caffeine is 520mg per day Dose unit for paracetamol is 500mg with the maximum dose of 4,000mg per day or 8 tablets daily. b) Products containing caffeine for pediatric patients are not allowed. c) Allowable packing size should not exceed 20 tablets/ capsules.
7.	**PARACETAMOL INTRAVENOUS INJECTION** Products containing paracetamol in the form of intravenous injection are restricted for hospital use only.
8.	**RETINOIDS INDICATED FOR THE TREATMENT OF SKIN DISEASES (ORAL)** a) The product registration holder shall ensure that the product shall only be sold or supplied to, and prescribed by: i. Dermatologists registered in the National Specialist Register; or ii. Dermatologists serving in any government health facilities. b) The product registration holder shall submit a proper record containing the following information to the Authority upon request. i. Name of product; ii. Product registration number; iii. Date & quantity of product manufactured/ imported and supplied; and iv. Name, address & contact number of purchaser (prescriber). c) The prescriber shall keep and maintain proper patient records for audit purpose, if any. **Reference:** Directive No. 17, 2020. *NPRA.600-1/9/13 (8) Direktif Berkenaan Pindaan Syarat Pendaftaran Khas Bagi Produk Yang Mengandungi Oral Retinoid Yang Diindikasikan Untuk Rawatan Penyakit Kulit* (14 September 2020)
9.	**VACCINES** a) Each batch of the product must comply with WHO requirements for the product. b) A batch release certificate must be enclosed with each batch of the product imported into Malaysia.