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WARTA KERAJAAN PERSEKUTUAN

FEDERAL GOVERNMENT GAZETTE

PERINTAH PERANTI PERUBATAN (PENGECUALIAN) 2024

MEDICAL DEVICE (EXEMPTION) ORDER 2024

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AKTA PERANTI PERUBATAN 2012

PERINTAH PERANTI PERUBATAN (PENGECUALIAN) 2024

PADA menjalankan kuasa yang diberikan oleh seksyen 77 Akta Peranti Perubatan 2012 [*Akta 737*], Menteri membuat perintah yang berikut:

Nama

1. Perintah ini bolehlah dinamakan **Perintah Peranti Perubatan (Pengecualian) 2024**.

Tafsiran

2. Dalam Perintah ini—

"demonstrasi pemasaran" ertinya suatu aktiviti pemasaran termasuklah promosi, pameran, simposium saintifik atau tinjauan, yang tidak melibatkan penggunaan peranti perubatan ke atas manusia;

"kajian klinikal" ertinya apa-apa penyiasatan sistematik atau kajian yang menentukan keselamatan dan keberkesanan ubat-ubatan, peranti, produk diagnostik, tatacara perubatan dan regimen rawatan yang diniatkan dalam atau pada satu atau lebih subjek manusia, dalam persekitaran klinikal manusia yang mencukupi;

"kegunaan peribadi" ertinya peranti perubatan yang dibawa masuk ke dalam Malaysia bagi kegunaan seorang individu tertentu sahaja dan tidak boleh diletakkan dalam pasaran atau digunakan ke atas pihak ketiga;

"pendidikan" ertinya proses mengajar, melatih atau mendidik orang ramai yang bukan bagi maksud promosi atau pemasaran, dan tidak digunakan apa-apa peranti perubatan ke atas manusia;

"peranti perubatan akses khas" ertinya peranti perubatan bagi kegunaan pengamal perubatan dalam situasi kecemasan atau dalam keadaan apabila rawatan perubatan konvensional gagal, tidak tersedia atau tidak sesuai;

"peranti perubatan usang" ertinya peranti perubatan sedia ada di kemudahan dan perkhidmatan jagaan kesihatan Kerajaan dan swasta, pusat kesejahteraan atau mana-mana kemudahan berkaitan yang sudah lapuk dan tidak lagi dibuat disebabkan oleh perubahan reka bentuk atau perkembangan teknologi baharu;

"peranti perubatan yang dibuat khas" ertinya peranti perubatan yang telah direka bentuk dan dibuat mengikut preskripsi bertulis daripada seorang pengamal perubatan yang berkelayakan untuk kegunaan tunggal seseorang pesakit tertentu tetapi tidak termasuk peranti perubatan yang dibuat secara pukal yang perlu disesuaikan untuk memenuhi kehendak khusus pengamal perubatan atau mana-mana pengguna profesional lain;

"peranti perubatan yang dihentikan" ertinya peranti perubatan sedia ada di kemudahan dan perkhidmatan jagaan kesihatan Kerajaan dan swasta, pusat kesejahteraan atau mana-mana kemudahan berkaitan yang tidak lagi diedarkan;

"peranti perubatan yatim" ertinya peranti perubatan sedia ada di kemudahan dan perkhidmatan jagaan kesihatan Kerajaan dan swasta, pusat kesejahteraan atau mana-mana kemudahan yang berkaitan apabila pembuat atau wakil diberi kuasa telah terhenti beroperasi.

Pengecualian daripada pendaftaran peranti perubatan

3. (1) Menteri mengecualikan apa-apa peranti perubatan daripada pendaftaran di bawah seksyen 5 Akta jika peranti perubatan itu adalah—

(a) bagi maksud kegunaan peribadi;

(b) bagi maksud demonstrasi pemasaran;

(c) bagi maksud pendidikan;

(d) bagi maksud kajian klinikal;

(e) bagi maksud penilaian prestasi peranti perubatan;

(f) bagi maksud eksport sahaja;

(g) bagi maksud import untuk dieksport semula;

(h) peranti perubatan yang dibuat khas;

(i) peranti perubatan akses khas;

(j) peranti perubatan yatim;

(k) peranti perubatan usang; atau

(l) peranti perubatan yang dihentikan.

(2) Pengecualian di bawah subperenggan (1) adalah tertakluk kepada syarat yang berikut:

(a) mana-mana orang yang mengimport, mengeksport, membuat atau meletakkan dalam pasaran apa-apa peranti perubatan di bawah subsubperenggan (1)*(b)*, *(c)*, *(d)*, *(e)*, *(f)*, *(g)*, *(h)* atau *(i)* hendaklah membuat permohonan pengecualian kepada Pihak Berkuasa dalam bentuk dan cara sebagaimana yang ditentukan oleh Pihak Berkuasa;

(b) peranti perubatan yang dikecualikan di bawah subsubperenggan (1)*(a)*, *(j)*, *(k)* dan *(l)* hendaklah diuruskan dalam bentuk dan cara sebagaimana yang ditentukan oleh Pihak Berkuasa.

Pengecualian daripada lesen establismen

4. Menteri mengecualikan seseorang yang mengimport atau mengeksport mana-mana peranti perubatan yang disebut dalam perenggan 3 kecuali peranti perubatan akses khas daripada kehendak lesen establismen di bawah subseksyen 15(1) Akta.

Pengecualian daripada penilaian pematuhan bagi peranti perubatan Kelas A

5. Menteri mengecualikan suatu peranti perubatan Kelas A daripada tatacara penilaian pematuhan oleh badan penilaian pematuhan di bawah seksyen 7 Akta.

Pembatalan dan kecualian

6. (1) Perintah Peranti Perubatan (Pengecualian) 2016 [*P.U. (A) 103/2016*] dibatalkan.

(2) Apa-apa pengecualian yang dibuat di bawah Perintah Peranti Perubatan (Pengecualian) 2016 sebelum tarikh permulaan kuat kuasa Perintah ini hendaklah, pada tarikh permulaan kuat kuasa Perintah ini, terus berkuat kuasa sehingga dipinda atau dibatalkan.

Dibuat 20 Februari 2024
[KKMMDA(S)100/1-1-1; PN(PU2)711/V]

DATUK SERI DR. HAJI DZULKEFLY BIN AHMAD
Menteri Kesihatan

MEDICAL DEVICE ACT 2012

MEDICAL DEVICE (EXEMPTION) ORDER 2024

IN exercise of the powers conferred by section 77 of the Medical Device Act 2012 [*Act 737*], the Minister makes the following order:

Citation

1. This order may be cited as the **Medical Device (Exemption) Order 2024**.

Interpretation

2. In this Order—

"demonstration for marketing" means a marketing activity which includes promotions, exhibitions, scientific symposia or surveys, which do not involve the use of medical device on human;

"clinical research" means any systematic investigation or study that determines the safety and effectiveness of medications, devices, diagnostic products, medical procedures and treatment regimens intended in or on one or more human subjects, in an adequate human clinical environment;

"personal use" means a medical device which is brought into Malaysia for the use of a particular individual only and not to be placed in the market or be used on a third party;

"education" means the process of teaching, training or educating the public not for the purpose of promoting or marketing, and not to be used any medical device on human;

"special access medical device" means a medical device for the use of medical practitioners in emergency situations or in the event that conventional medical treatment has failed, is unavailable or unsuitable;

"obsolete medical device" means an existing medical device in a Government and private healthcare facilities and services, wellness centres or any related facilities which is outdated and no longer being manufactured due to design changes or evolution of new technologies;

"custom-made medical device" means a medical device that has been designed and manufactured in accordance with a written prescription from a qualified medical practitioner for the sole use of a particular patient but not including mass produced medical devices which need to be adapted to meet the specific requirements of the medical practitioner or any other professional user;

"discontinued medical device" means an existing medical device in a Government and private healthcare facilities and services, wellness centres or any related facilities that is no longer in the distribution;

"orphaned medical device" means an existing medical device in a Government and private healthcare facilities and services, wellness centres or any related facilities where the manufacturer or authorized representative has ceased operation.

Exemption from registration of medical devices

3. (1) The Minister exempts any medical device from the registration under section 5 of the Act if the medical device is—

(a) for the purposes of personal use;

(b) for the purposes of demonstration for marketing;

(c) for the purposes of education;

(d) for the purposes of clinical research;

(e) for the purposes of performance evaluation of medical device;

(f) for the purposes of export only;

(g) for the purposes of import for re-export;

(h) a custom-made medical device;

(i) a special access medical device;

(j) an orphaned medical device;

(k) an obsolete medical device; or

(l) a discontinued medical device.

(2) The exemption under subparagraph (1) is subject to the following conditions:

(a) any person who imports, exports, manufactures or place in the market any medical device under subsubparagraph (1)*(b)*, *(c)*, *(d)*, *(e)*, *(f)*, *(g)*, *(h)* or *(i)* shall make an application for an exemption to the Authority in the form and manner as determined by the Authority;

(b) the exempted medical devices under subsubparagraphs (1)*(a)*, *(j)*, *(k)* and *(l)* shall be dealt in the form and manner as determined by the Authority.

Exemption from establishment licence

4. The Minister exempts a person who imports or exports any medical device referred to in paragraph 3 excluding a special access medical device from the requirement of an establishment licence under subsection 15(1) of the Act.

Exemption from conformity assessment for Class A medical device

5. The Minister exempts a Class A medical device from the conformity assessment procedures by a conformity assessment body under section 7 of the Act.

Revocation and saving

6. (1) The Medical Device (Exemption) Order 2016 [*P.U. (A) 103/2016*] is revoked.

(2) Any exemption made under the Medical Device (Exemption) Order 2016 before the date of coming into operation of this Order shall, on the date of coming into operation of this Order, continue to be in force until amended or revoked.

Made 20 February 2024
[KKMMDA(S)100/1-1-1; PN(PU2)711/V]

DATUK SERI DR. HAJI DZULKEFLY BIN AHMAD
Minister of Health