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WARTA KERAJAAN PERSEKUTUAN

FEDERAL GOVERNMENT GAZETTE

PERATURAN-PERATURAN PERANTI PERUBATAN (PENGIKLANAN) 2019

MEDICAL DEVICE (ADVERTISING) REGULATIONS 2019

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AKTA PERANTI PERUBATAN 2012

PERATURAN-PERATURAN PERANTI PERUBATAN (PENGIKLANAN) 2019

PADA menjalankan kuasa yang diberikan oleh perenggan 79(2)*(h)* Akta Peranti Perubatan 2012 [*Akta 737*], Menteri membuat peraturan-peraturan yang berikut:

Nama dan permulaan kuat kuasa

1. (1) Peraturan-peraturan ini bolehlah dinamakan **Peraturan-Peraturan Peranti Perubatan (Pengiklanan) 2019**.

(2) Peraturan-Peraturan ini mula berkuat kuasa pada 1 Julai 2020.

Syarat pengiklanan

2. (1) Tiada seorang pun boleh mengiklankan mana-mana peranti perubatan berdaftar tanpa kelulusan daripada Pihak Berkuasa.

(2) Mana-mana orang yang melanggar subperaturan (1) melakukan suatu kesalahan dan boleh, apabila disabitkan, didenda tidak melebihi dua ratus ribu ringgit atau dipenjarakan selama tempoh tidak melebihi dua tahun atau kedua-duanya.

(3) Permohonan bagi kelulusan untuk mengiklankan suatu peranti perubatan berdaftar hendaklah dibuat secara bertulis kepada Pihak Berkuasa dan hendaklah disertakan dengan—

(a) sesalinan iklan yang dicadangkan bagi peranti perubatan berdaftar itu;

(b) fi pemprosesan sebanyak satu ribu ringgit; dan

(c) suatu surat pelantikan daripada establismen yang atas permohonannya peranti perubatan itu didaftarkan, jika pemohon

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dilantik oleh establismen itu untuk mengiklankan peranti perubatan itu.

(4) Pihak Berkuasa boleh, secara bertulis, pada bila-bila masa selepas menerima suatu permohonan di bawah subperaturan (3), meminta pemohon supaya memberi Pihak Berkuasa, dalam tempoh yang ditetapkan dalam permintaan itu, apa-apa butiran, maklumat atau dokumen lain.

Kandungan iklan

3. Suatu iklan untuk mengiklankan suatu peranti perubatan berdaftar hendaklah mengandungi maklumat yang berikut:

(a) suatu perakuan yang peranti perubatan itu telah didaftarkan di bawah Akta; dan

(b) nombor pendaftaran yang diberikan kepada peranti perubatan berdaftar itu oleh Pihak Berkuasa.

Dibuat 3 September 2019
[KKM.PUU/PU2/MDA/3(17); PN(PU2)711/IV]

DATUK SERI DR. DZULKEFLY BIN AHMAD
Menteri Kesihatan

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MEDICAL DEVICE ACT 2012

MEDICAL DEVICE (ADVERTISING) REGULATIONS 2019

IN exercise of the powers conferred by paragraph 79(2)*(h)* of the Medical Device Act 2012 [*Act 737*], the Minister makes the following regulations:

Citation and commencement

1. (1) These regulations may be cited as the **Medical Device (Advertising) Regulations 2019**.

(2) These Regulations come into operation on 1 July 2020.

Conditions for advertising

2. (1) No person shall advertise any registered medical device without the approval from the Authority.

(2) Any person who contravenes subregulation (1) commit an offence and shall, on conviction, be liable to a fine not exceeding two hundred thousand ringgit or to imprisonment for a term not exceeding two years or to both.

(3) An application for an approval to advertise a registered medical device shall be made to the Authority in writing and shall be accompanied by—

(a) a copy of the proposed advertisement for the registered medical device;

(b) a processing fee of one thousand ringgit; and

(c) a letter of appointment from an establishment on whose application the medical device is registered to, if the applicant is appointed by the establishment to advertise the medical device.

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(4) The Authority may, in writing, at any time after the receipt of an application under subregulation (3), request the applicant to give to the Authority, within the period specified in the request, any other particulars, information or documents.

Contents of advertisement

3. An advertisement to advertise a registered medical device shall contain the following information:

(a) a certificate that the medical device is registered under the Act; and

(b) the registration number assigned to the registered medical device by the Authority.

Made 3 September 2019
[KKM.PUU/PU2/MDA/3(17); PN(PU2)711/IV]

DATUK SERI DR. DZULKEFLY BIN AHMAD
Minister of Health

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