The Medical Device (Advertising) Regulations 2019

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HEAD OF SURVEILLANCE & ENFORCEMENT SECTION

MEDICAL DEVICE AUTHORITY

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Presentation Outline

- Background
- Advertisement Regulation
- Code of Advertisement
- Application Procedure
- Implementation

BACKGROUND

Background - Provisions of Act 737

Section 44

- (1) No person shall advertise a medical device unless the medical device has been registered and complied the requirements of the Act
- (2) No person shall make any misleading or fraudulent claims in respect of a medical device in any advertisement
- (3) contravention of (1) or (2) is an offence and shall, on conviction be liable to a fine not exceeding RM300,000 or to imprisonment for a term not exceeding 3 years or to both

Section 79

- (1) The Minister may make such regulations as may be expedient or necessary for the better carrying out provisions of the Act
- (2) without prejudice to the generality of (1), regulations may be made for the purpose:
  - (h) To prescribe matters relating to the contents of and conditions for advertising of medical devices

MEDICAL DEVICE (ADVERTISEMENT) REGULATION 2019

Medical Device (Advertisement) Regulations 2019

Overview

- Published in the Gazette on 15 Nov 2019
- Listed as P.U. (A) 317
- Commenced on 1 July 2020

The contents:

- Citation & Commencement
- Condition of Advertising
- Content of Advertising

https://portal.mda.gov.my/documents/regulation/1312-medical-device-regulations-advertising-2019/file.html

15 November 2019
15 November 2019
P.U. (A) 317

WARTA KERAJAAN PERSEKUTUAN

FEDERAL GOVERNMENT GAZETTE

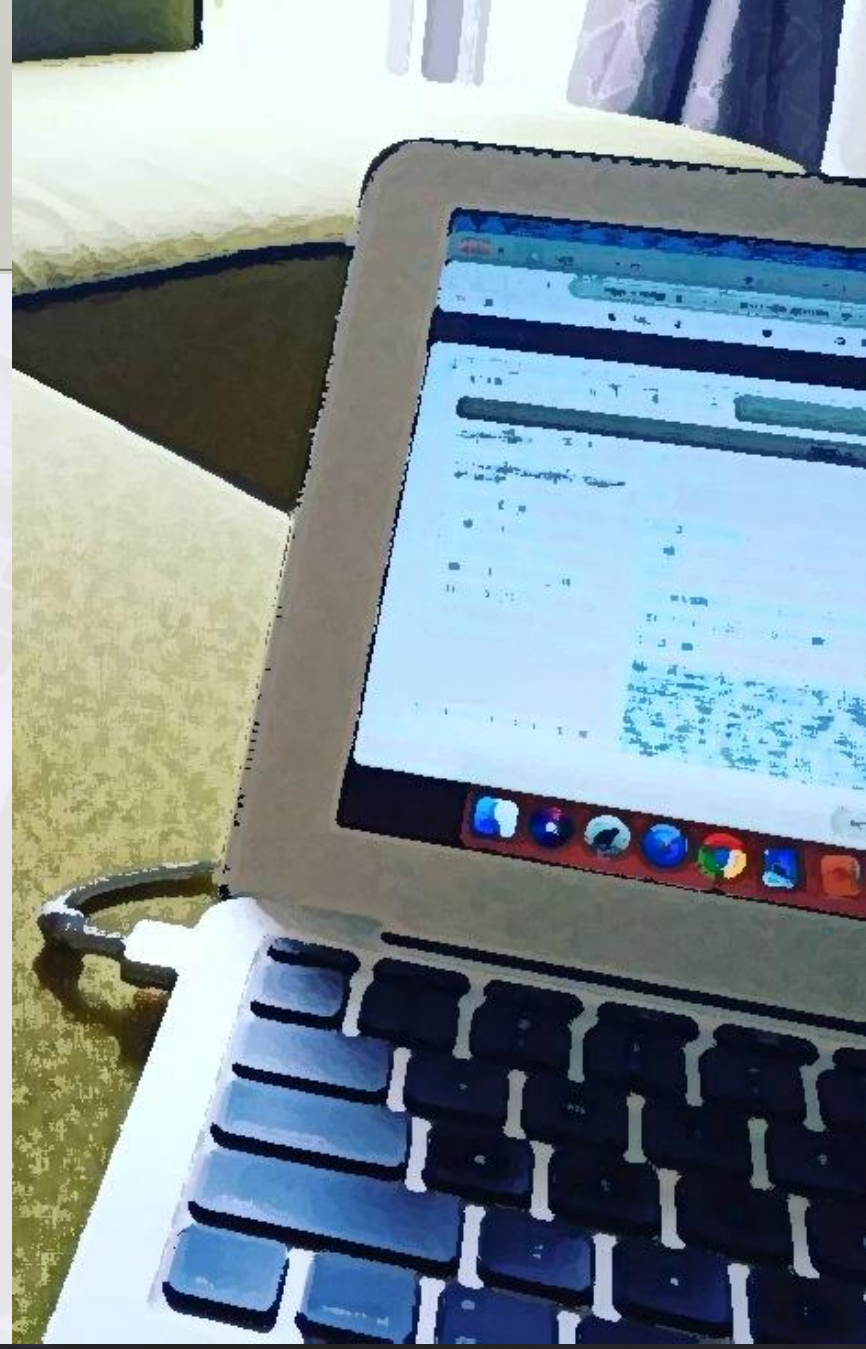
PERATURAN-PERATURAN
PERANTI PERUBATAN (PENGIKLANAN) 2019

MEDICAL DEVICE (ADVERTISING) REGULATIONS 2019

DISIARKAN OLEH/
PUBLISHED BY
JABATAN PEGUAM NEGARA/
ATTORNEY GENERAL'S CHAMBERS

Medical Device (Advertisement) Regulations 2019

- Prescribing condition and contents of advertisement for medical devices
- Cited as Medical Device (Advertisement) Regulations 2019
- Come into operation on 1 July 2020



Conditions for Advertising

2(1) Approval for advertisement

No person shall advertise any registered medical device without the approval from the Authority

2(2) Offence & Penalty

Any person contravenes (1) commit and offence and shall, on conviction be liable to a fine not exceeding RM200,000 or to imprisonment for a term not exceeding 2 years or to both

2(3) Application for approval

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 proposed advertisement
b) A processing fee of RM1000
c) A letter of appointment from an establishment on whose the medical device is registered to, (applicable for advertising agency/service provider)

2(4) Additional Information

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

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

CODE OF ADVERTISEMENT

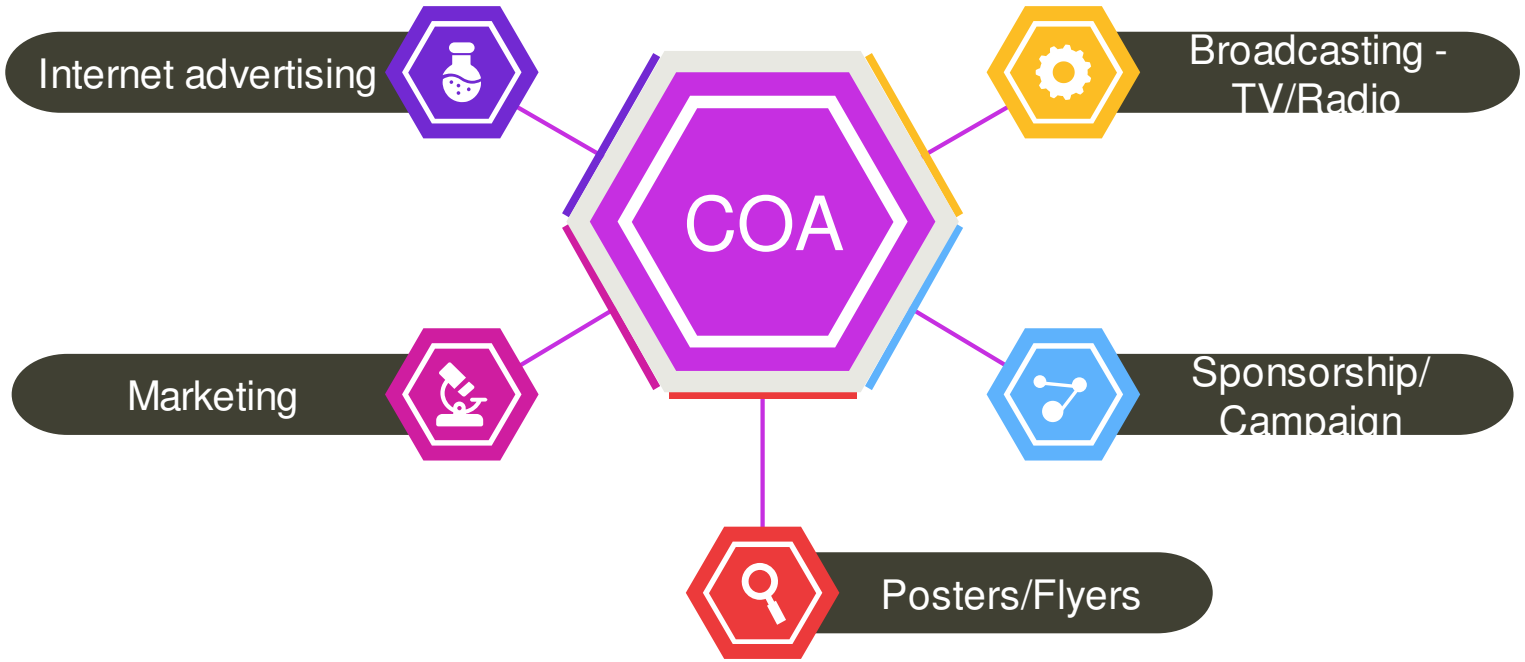
CODE OF ADVERTISEMENT (COA)

Promotes the standards for the ethical advertising of medical device without regulating the following activities:

- Pricing or other trade terms for the supply of devices i.e. commercial policies and/or practices of medical device industry players.

- Provision of non-promotional information such as:
  - community messages;
  - announcement on clinical trial and investigational testing recruitment
  - corporate messages

Code of Advertisement (COA) - Coverage



Standard of Promotion – the basic rules

- Advertisements shall contain information that is reliable, accurate, truthful, informative, fair, objective, unambiguous, balanced, up-to-date and be capable of substantiation.
- Advertisements shall not contain any statement or visual presentation which, whether directly or by implication, is likely to mislead the consumer about any device.
- An advertisement shall present information which is factually correct and not exaggerated.
- Advertisements shall not lead to self-diagnosis or inappropriate treatment of potentially serious diseases.
- Advertisements should take into account peoples' legitimate desire for information and encourage the correct and proper use of a medical device.
- Cautionary statements are encouraged for medical devices, and all required statements etc. should appear clearly in the advertisements.

Device claims

- shall be consistent and in line with the intended use of a medical device as registered
- shall not promote a medical device outside its approved intended users or patient groups
- shall not be stronger than scientific evidence warrants, and every effort should be made to avoid ambiguity

- [X] Therapeutic claims
- [X] Claims relating to ageing and premature ageing
- [X] Claims concerning the brain, memory and concentration
- [X] Claims relating to immunity against specific disease(s)
- [ ] Claims relating to stress
- [ ] Claims relating to performance in sports and studies
- [X] Claims concerning weight management
- [X] 'Before' and 'after' claims
- [X] Claims related to device origin
- [ ] Natural claims
- [ ] Device novelty claims
- [ ] Safety claims

Ethical values

Acts of violence or illegal activities

Dangerous practices or disregard for safety

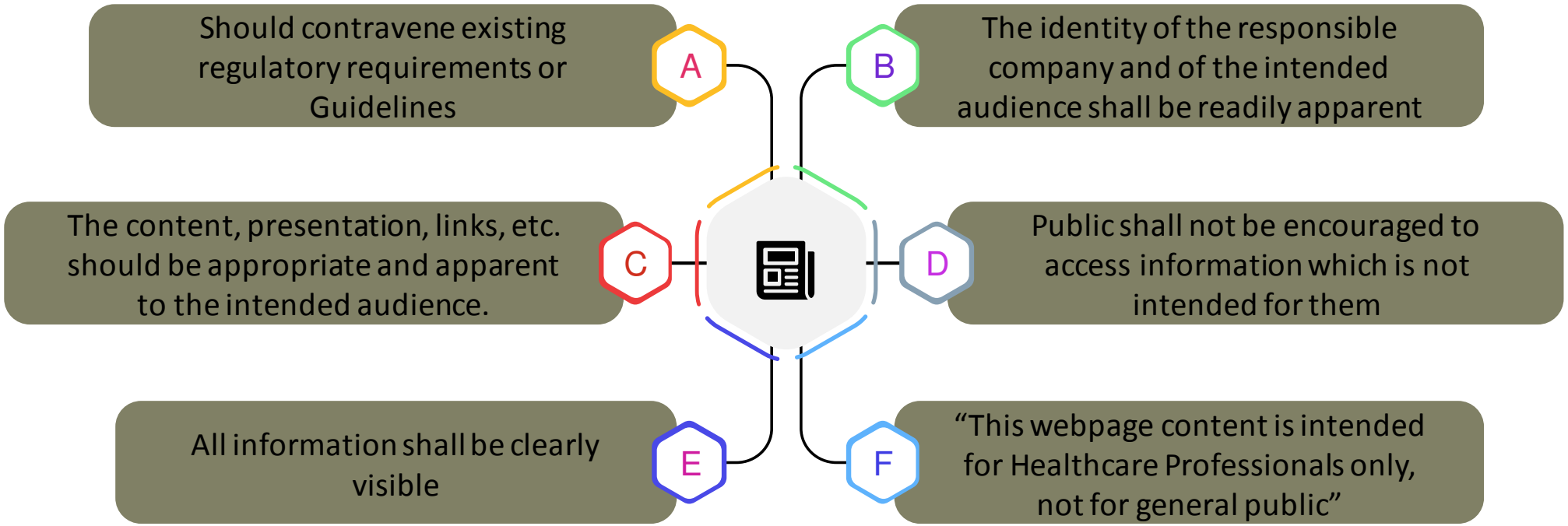
Standard of morality or decency

Disparagement

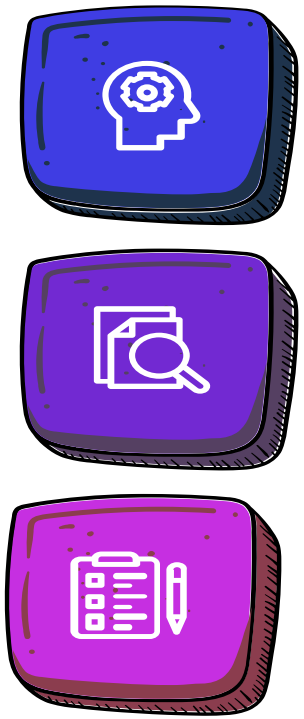
Use of statistical data

Fear and superstition

Advertising on the internet



Social Responsibility



Advertisement aimed at specific population

Advertising of medical device for healthcare professional use only

Terms and conditions

- Pregnant or lactating women
- Children
- Senior citizens
- People with disabilities

Other promotional activities

APPLICATION PROCEDURE

General Requirements

1. Only medical devices registered with the Authority may be advertised.
2. There shall be no misleading or fraudulent claims in respect of the medical device in any advertisement.
3. All advertisement of medical device shall comply with the **Code of Advertisement** as stated under Clause 5.
4. All advertisement of medical device shall obtain approval from the Authority **except**:
   a) materials that only contain product pictorial representation, brand and/or company name and/or logo that do not consist of any product claims or descriptions
   b) materials which only contain exact replica of the packaging (not size but shape and content) approved by the Authority
   c) medical device advertisements aimed at **healthcare professionals** including personnel involved in procurement, or administration in a healthcare facility
   d) Advertorials
   e) Disease awareness and health education campaigns
   f) Contests and competitions
   g) Sponsorship

Approval is required for advertisement aimed for general public and home use medical devices.

Application procedure

- Application shall be made using the 'Application Form for Medical Device Advertisement'.
- Advertisement approval can be applied in **one application** and/or **multiple applications.**
- Advertisement in other languages besides Bahasa Malaysia and English, a translated version endorsed by translation body recognised by Authority shall be provided.
- Each application shall be subjected to RM 1,000.00 processing fee and the payment shall be made via a bank draft.
- The processing fee will not be refunded regardless any decision by the Authority.
- A complete application form with supporting documents and bank draft shall be submitted to the Authority by post or by hand.

Supporting documents

- Copy of proposed advertisement for the registered medical device (such as story board/art work),
- Copy of translated advertisement (if the advertisement is in other language apart from Bahasa Malaysia and English),
- Authorisation Letter from the manufacturer or Authorised Representative,
- RM1000 Bank Draft,
- Supporting documents to support all claims in an advertisement.

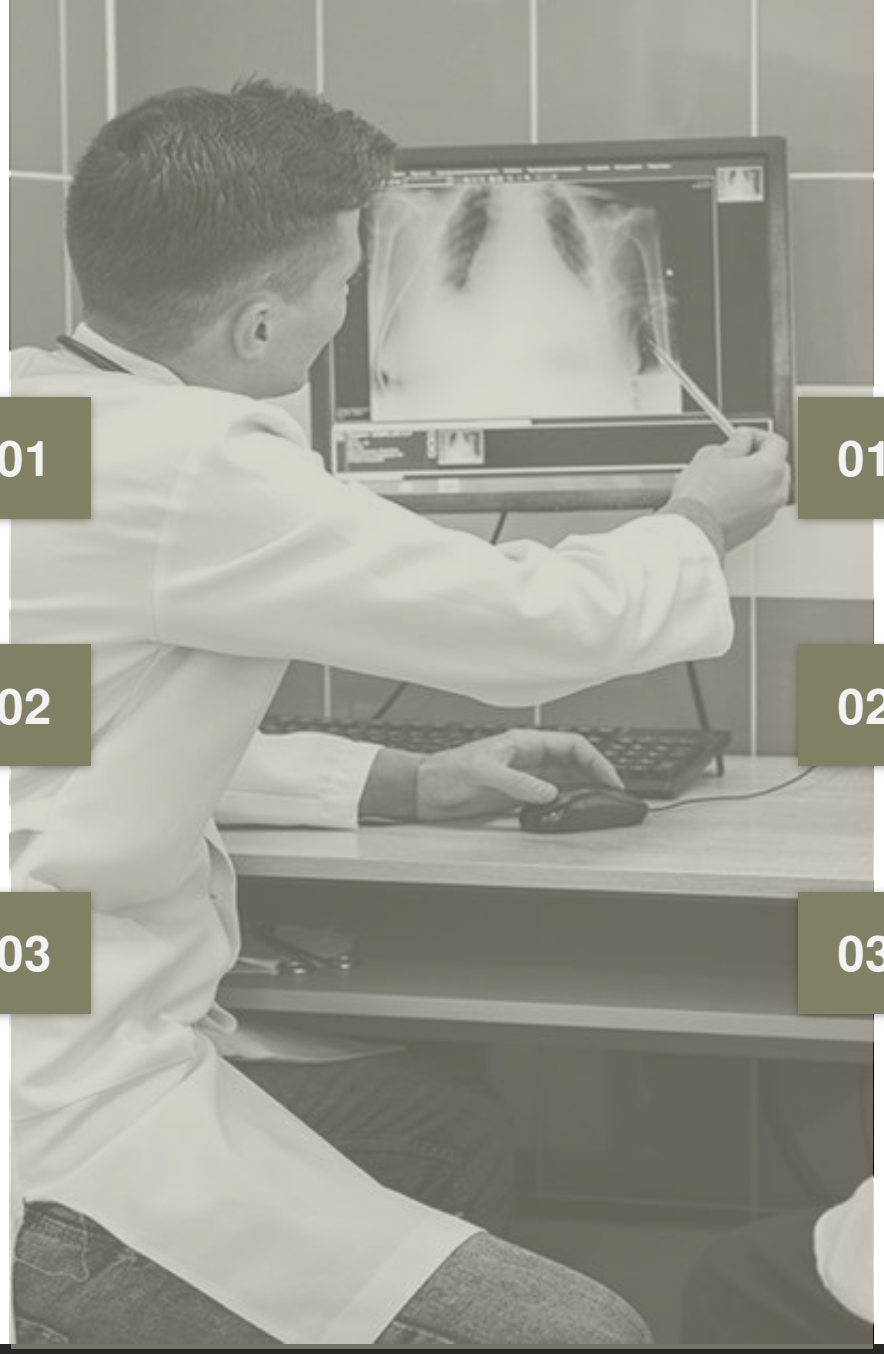
Issuance of Approval for Medical Device Advertisement

01 A letter of approval and assign an approval number

02 Approval conditions shall be imposed

03 Approved advertisement to be posted, displayed or broadcasted shall include:

statement “registered under Act 737” √
medical device registration number √
advertisement approval number √



Revocation of Approval for Medical Device Advertisement

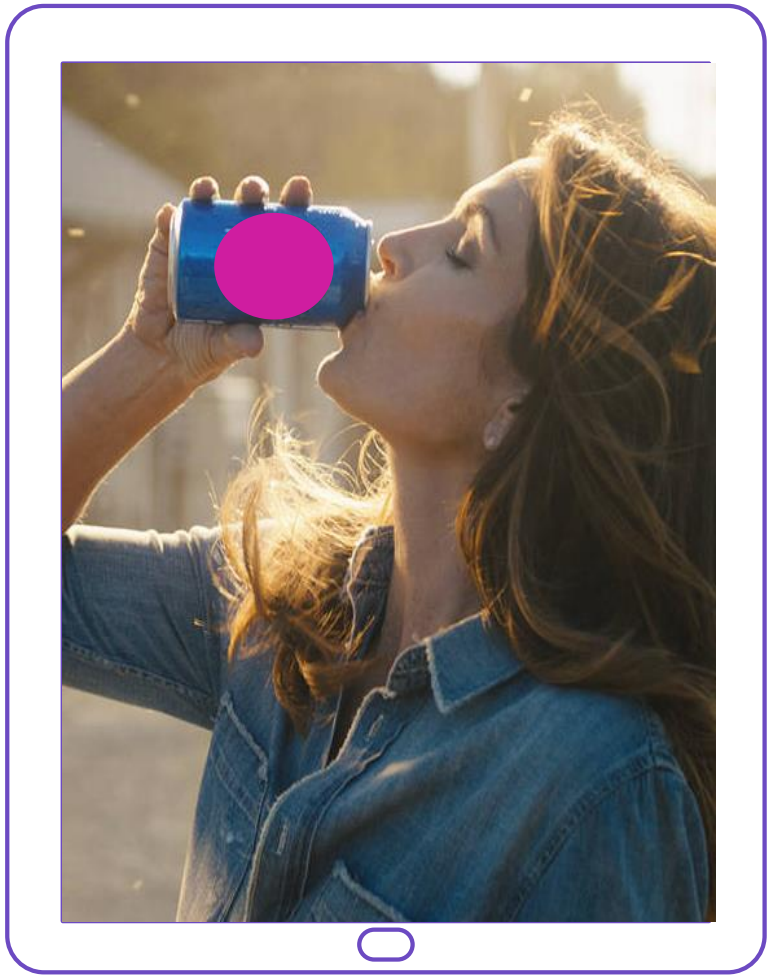
01 the medical device registration if expired

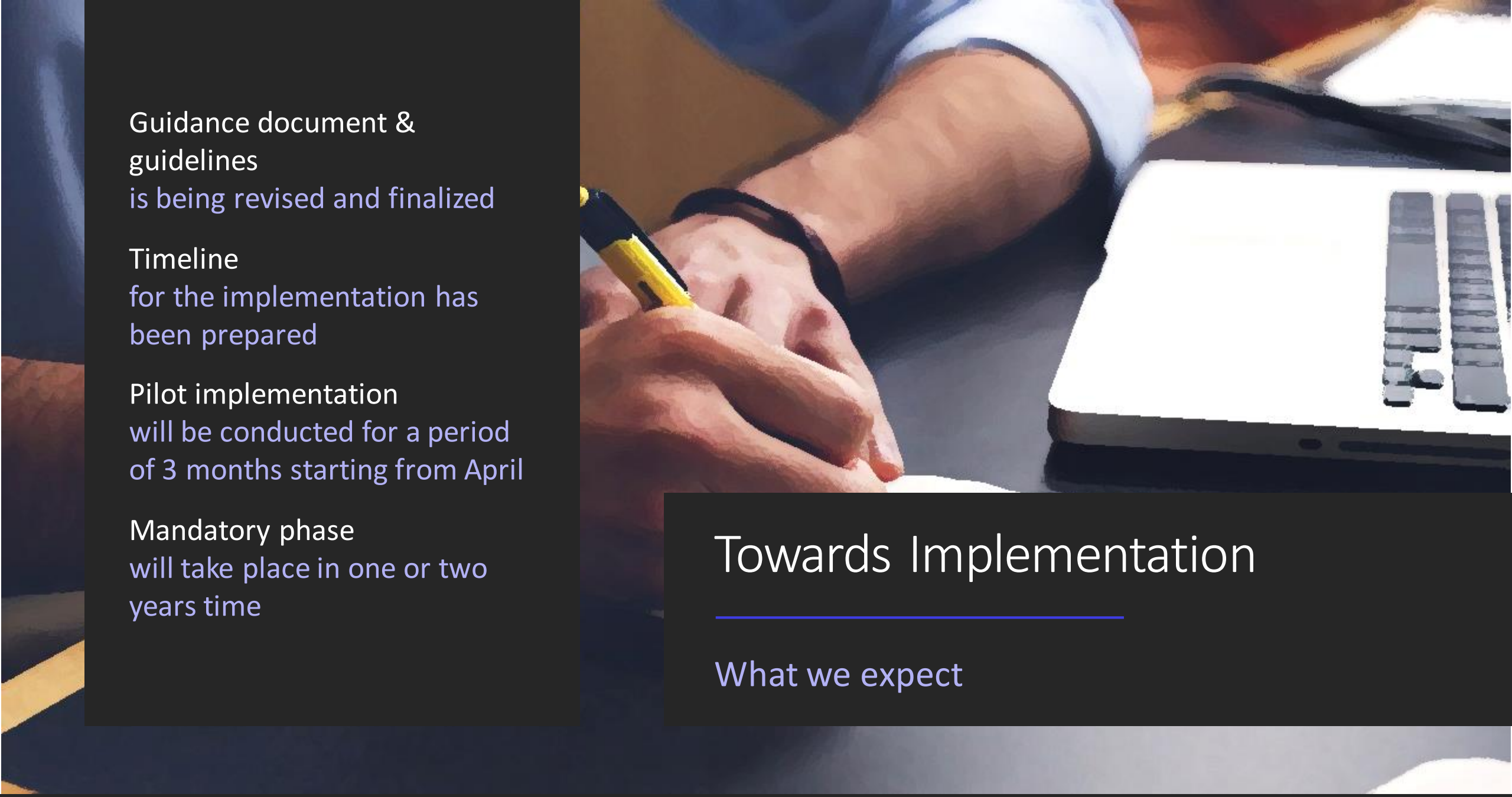
02 changes in the intended use or indication of the medical device as per the registration information

03 changes in the content of advertisement that alter the substantive meaning of the advertising material or claims

Changes after approval

- any change in the content of advertisements or any new issuance of the same advertisement using other languages requires for a new application for approval
- **editorial changes & change of pictures** do not require a new application
- if the changes are related to pictorial change that delivers a different message or claim, a new application shall be submitted





Towards Implementation

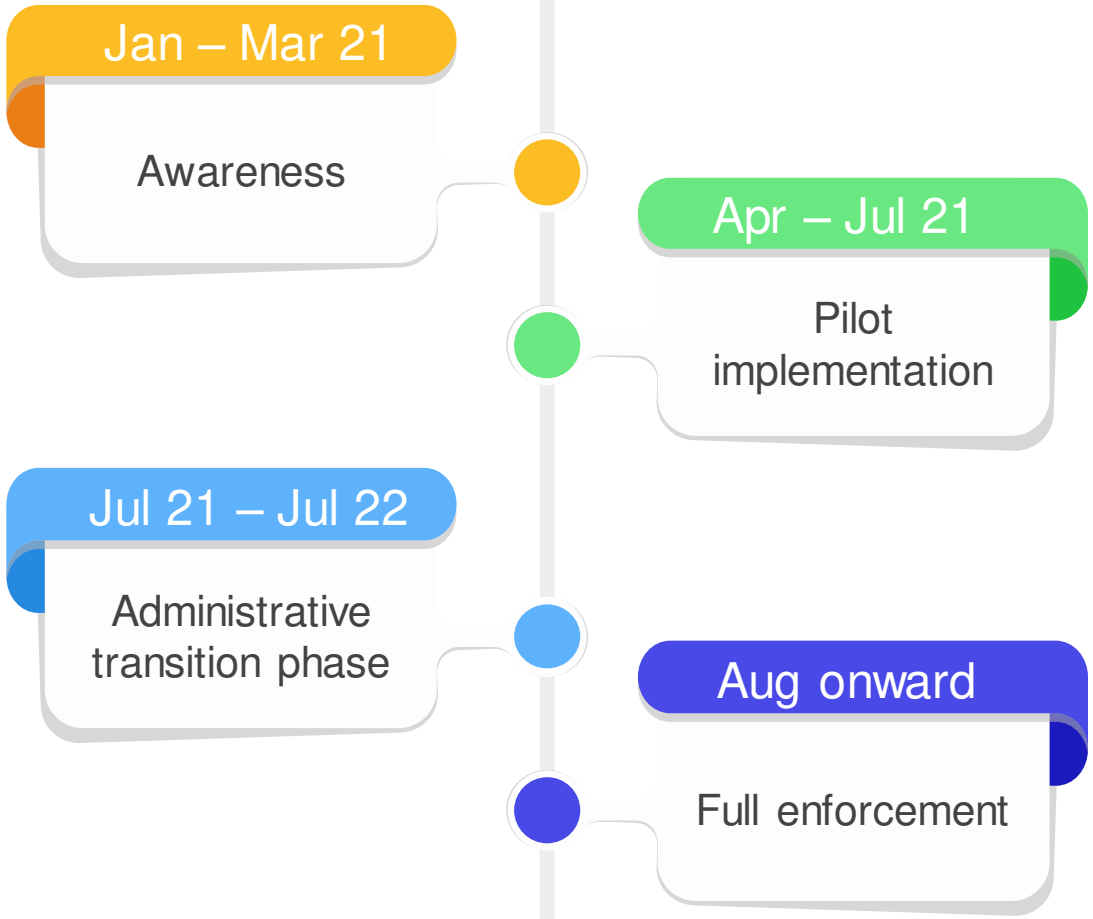
What we expect

Guidance document & guidelines
is being revised and finalized

Timeline
for the implementation has been prepared

Pilot implementation
will be conducted for a period of 3 months starting from April

Mandatory phase
will take place in one or two years time



Timeline for Implementation of Medical Device (Advertisement) Regulations 2019

*Subject to change

Thank You!

For your commitment & attention.

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