Effective Communication With Industries For Fast And Proper Access To Patients

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CORPORATE COMMUNICATION UNIT
MEDICAL DEVICE AUTHORITY MALAYSIA
MINISTRY OF HEALTH MALAYSIA

01.

WHO IS MDA

BACKGROUND

• Medical Device Authority Malaysia (MDA) is the government agency entrusted to serve the Malaysia medical device's industry.

• It is a federal statutory agency under the Ministry of Health Malaysia to implement and enforce the Medical Device Act 2012 ; Act 737 and Act 738.

•To protect the public health and safety through ensuring that medical devices in Malaysia are of high quality, effective and safe.

OUR FUNCTION

Any medical device that is imported, exported or placed in the Malaysia market **MUST** be registered with MDA and WE issuance licensing to establishments.

Vision

To become an internationally recognized medical device regulatory body by providing world-class services, and be the leading medical device hub for a safe and effective healthcare environment in Malaysia by 2023.

OUR MISSION

MISSION 1

Effective Control and Enforcement.

MISSION 2

Driven by technology and human resource competencies towards customer satisfaction

MISSION 3

Stakeholders and customers engagement

MISSION 4

Establish and strengthen international relations.

02. EFFECTIVE COMMUNICATION

WHAT IS EFFECTIVE COMMUNICATION

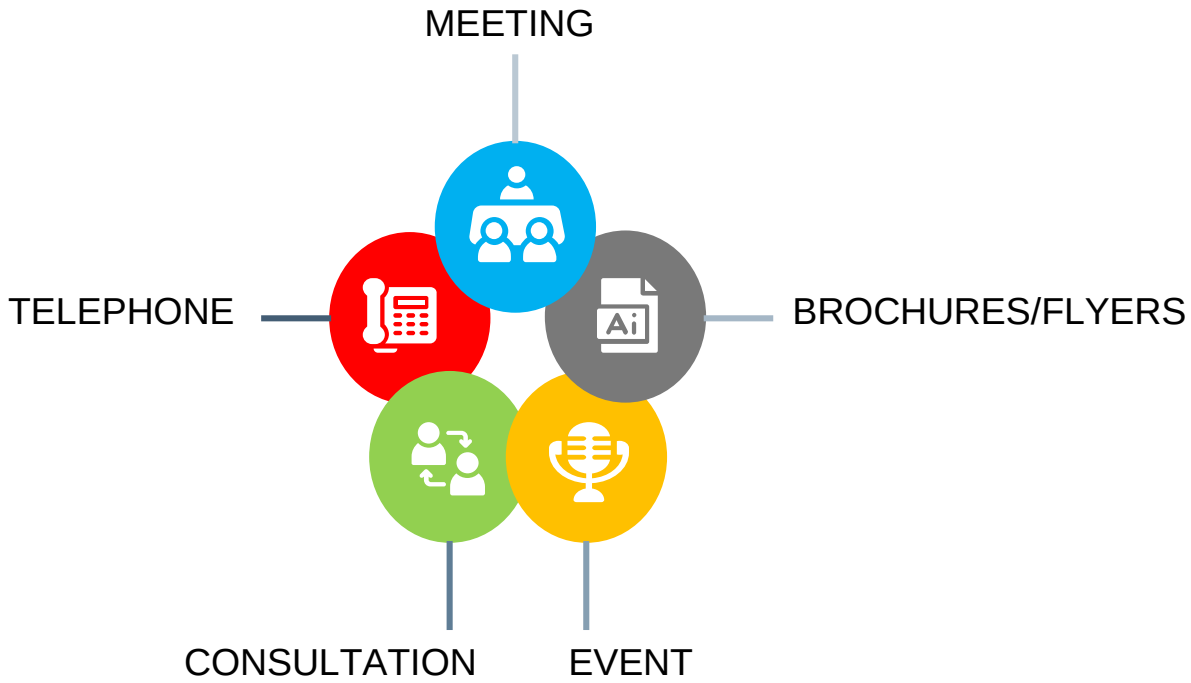
DEFINITION

An **Effective Communication** is a communication between two or more persons wherein the intended message is successfully delivered, received and understood.

Sources: https://businessjargons.com/effective-communication.html

2 TYPES OF COMMUNICATION CHANNELS

EXAMPLE OF OFFLINE COMMUNICATION



MEETING:

Board Meeting

- MDA held board meeting every 2 months in a year (6 times)
- YBhg. Tan Sri Dato' Seri Dr. Noor Hisham Bin Abdullah (Director – General of Health Malaysia) is our chairman.
- According to Act 738 Medical Device Authority Malaysia under Section 4(1) e has stated; "not more than five (5) **persons with expertise and experience in medical device** matters to be appointed by the Minister".

MEETING:

MICC

- MICC or Medical Device – Industry Collaborative Committee is a meeting that **involve medical device industries and MDA (regulators).**
- This meeting is chair by CEO MDA and co chair by Industries.
- The purpose of MICC meeting has been created is **to have discussion among industries** in terms of compliance with regulatory requirements, collaboration programs, international engagement training such as meetings, conferences and exhibitions related to the medical devices.

TELEPHONE:

- MDA **mainline number** is +603 – 8230 0300
- **Industries** or public **can contact directly** with **MDA officers** by **find** the **contact information/ staff directory** in our **website.**

CONSULTATION:

- MDA provide **consultation service** in an **effort to assist the medical device industries to understand and comply** with Malaysian medical device regulatory requirements.
- MDA gives consultation to industries through face to face (walk in to MDA) or Online consultation (when only physical consultation is not possible such as during Pandemic Covid 19) and also includes ad – hoc (by calling).
- Any inquries regarding consultation, industries can email to **consultation@mda.gov.my.**

HOW TO BOOK CONSULTATION:

Visit at portal.mda.gov.my

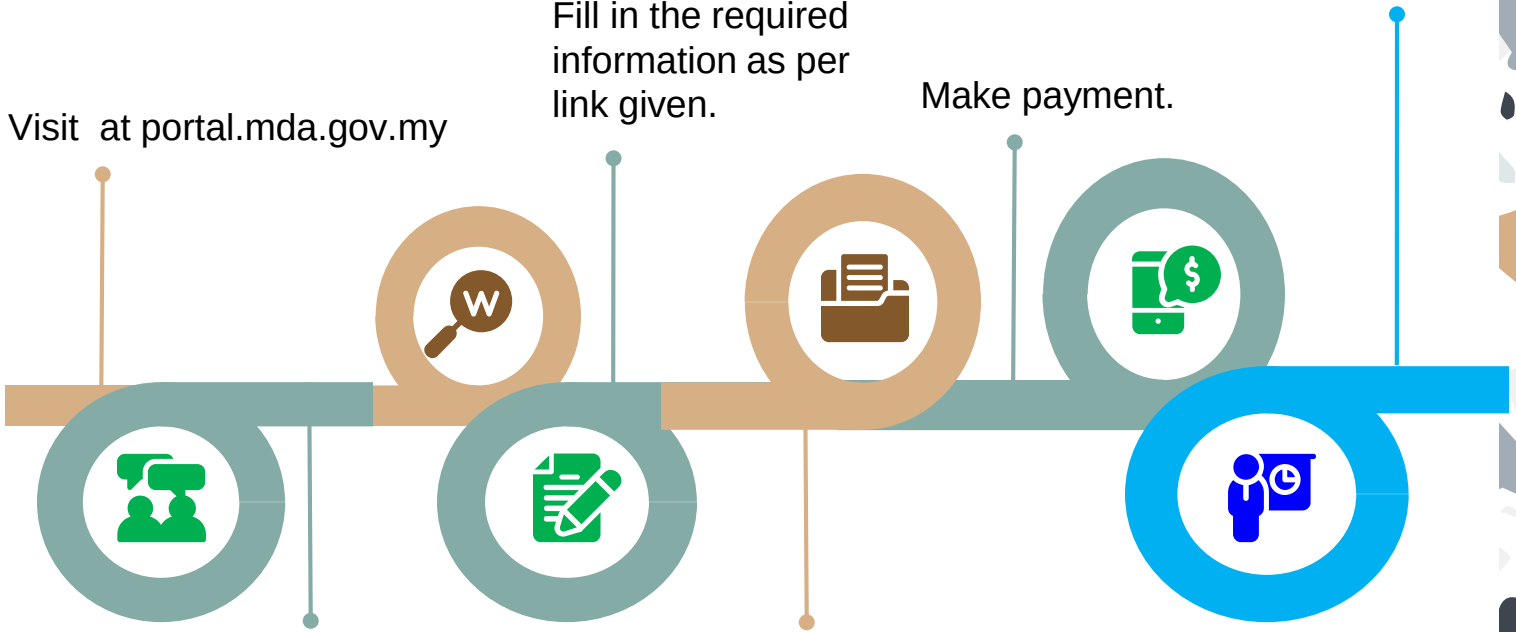
Find INDUSTRY and you may see at the bottom right there is CONSULTATION.

Fill in the required information as per link given.

Wait for invoice to be emailed.

Make payment.

Once payment is cleared, an appointment will be scheduled.



EVENTS:

IMDC

- MDA organized international events such as IMDC (International Medical Device Conference).
- Where it started in 2017 in Penang and it was a very successful event and the latest event was held in 2019 at MITEC (Malaysia International Trade and Exhibition Centre) Kuala Lumpur. It was officiated by Malaysia former prime minister YB Tun Dr Mahathir Mohammad.
- **In the future if MDA held conference please join us and don't miss out MDA event as we together can explore medical device trends, sharing knowledge , build and solidify relationship!**

IMDC EVENTS 2019:

EVENTS:

- **SEMINAR WITH INDUSTRY**
  This program purpose to give a talk to medical device industry people to make them understand regarding requirement needed in Act 737 and Act 738.

- **AWARENESS PROGRAM FOR USER**
  The target group is for healthcare institutions.

BROCHURE AND FLYERS:

FUNCTION OF CORPORATE COMMUNICATION UNIT

To ensure the board meeting is properly prepared with meeting's files, documentations, venue, rsvp, invitations and other relevant matters.

To organize and manage the Medical Device Authority (MDA) website with certain matters such as information checking, updates and manage basic ICT tasks.

To manage the fundamental matters related to Corporate Communication Unit (CCU) such as handling meetings, documentations, memo preparation, communication with other agencies, ministry, establishments, industries, and users.

To coordinate communication between Ministry of Health (MOH) parliament unit and Medical Device Authority (MDA) to ensure any Medical Device issues that was raised during parliament session was given the necessary feedback.

Act as a secretariat and coordinate with all units to ensure the annual report is published and circulated within the deadline set by Ministry of Health (MOH).

Manage various kinds of feedback received from the public related to Medical Device complaints, appreciations, inquiry and suggestions and ensure all feedbacks are replied within the deadline.

Manage various kinds of feedback received from the public that includes complaints, appreciations, inquiry, and suggestions and make sure that all the feedbacks are accomplish replied within the period given.

Organize events such as Awareness Programs, seminars and trainings. CCU also assists in other unit events in terms of protocol and logistics.

To help disseminate update information regarding events, programs, training, announcement, festival season and many more that are required by the MDA's Facebook page.

FUNCTIONS OF INTEGRITY UNIT

The six (6) main functions and roles of the Unit are as follows:

1. **Administrative Management**
   - Planning, managing and do all the programs to enhance and ensure the best of good governance practices implemented;
2. **Consolidation of Integrity**
   - Planning, managing and ensure all the programs implemented are following the good cultures and institutions of best integrities within MDA;
3. **Detection and Authentication**
   i. To detect and confirm the complaints about misconduct, any activities against the good etiquette and also all crime activities must be taken further actions.
   ii. To lodge a report on any crimes activities within MDA to the authorities.
4. **Complaint Management**
   - To receive and take actions to all complaint/information regarding misconduct activities, crime activities and violation of good etiquettes.
5. **Compliance**
   - Planning programs related to compliance monitoring such as internal examinations and spot check regarding property and assets, financial records and others to make sure all the daily tasks are comply with the regulations and follows procedures.
6. **Disciplinary Actions**
   - Implementing and presence as the secretary of MDA Disciplinary Board and Appeal Board.

FUNCTIONS OF THE TECHNICAL EVALUATION

Generally, BPT contribute in the development of medical devices regulatory program through activities based on information technology, scientific and academic for:

- To manage and coordinate technical study
- To develop programmes with regards to exempted medical device
- To manage and coordinate ICT system development
- To manage and coordinate information

FUNCTIONS OF MANAGEMENT AND SERVICE UNIT

Functions of Management and Service Unit in general are as follows:

- Manage staffing MDA.
- Designing, developing and implementing training and development of personnel competence.
- Manage and counseling services.
- Manage the financial, procurement and construction.
- Manage administrative and logistical MDA.
- Coordinate the implementation of computer applications such as HRMIS.
- As the secretariat to the Committee of Human Resources Management, Financial Management and Accounts Committee Meeting, Part MDA, MDA Promotion Committee, Joint Department Council and the Human Resources Development Panel.

FUNCTIONS OF LEGAL ADVISER OFFICE

Functions performed by the Office of The Legal Adviser MDA are as follows:

- To provide legal advice related to the Ministry verbally or in writing.
- To draft or amend primary legislation includes any regulations for MDA.
- To examine all documents and agreements by examining the related legal implications.
- To act on behalf of MDA in a civil claim under the jurisdiction of the Legal Adviser and file action for MDA as the claimant, and
- To act on behalf of MDA for prosecution cases as a result of non-compliance to Act 737 and the regulations.

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MEDICAL DEVICE AUTHORITY

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8. HOW LONG IS THE LICENSE VALIDITY AND WHEN WE CAN START TO RENEW?

The validity is 3 years and an establishment can start to renew the license 1 year prior to expiry date.

9. AMENDMENT OF ESTABLISHMENT LICENSE

Introduction

Amendment of establishment license is divided into two categories which are amendment major and amendment minor. If an establishment intends to amend the details of establishment license, establishment shall submit the request application via online application Medcast 2.0.

1. **Amendment Major**
   - There are 3 types of amendment major:
   1) Change of Establishment Name
   2) Change of Establishment Address
   3) Change of Person Responsible Name & IC/Passport
2. **Amendment Minor**
   - There are 5 types of amendment minor:
   1) Change of Establishment telephone, fax and company website
   2) Change of Contact Person Details
   3) Change of Person Responsible Details except Name & IC/Passport
   4) Change of QMS Details
   5) Additional of Letter of Authorization (LOA)

10. CHANGE OF OWNERSHIP APPLICATION

Change ownership of medical device registration is required for reasons such as:

a) Manufacturer outside Malaysia who has set up a company in Malaysia and intends to obtain the ownership of medical device registration from AR.
b) Replacing of existing AR to new AR by the manufacturer to place the medical device in the market
c) Merging and acquisition activities
d) Existing AR closed its business

The Fee

The new AR will be required to pay the service/processing fee RM500 per medical device registration ID.

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HOW TO GET YOUR ESTABLISHMENT LICENSE?

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BROCHURE AND FLYERS:

6. APPLICATION AND REGISTRATION FEES

Every application and registration shall be accompanied by the prescribed fees as specified in the Table of Fees-Fifth Schedule of the MDR 2012.

(a) Application Fee - RM 1,500.00

(b) Registration Fee - RM 8,000.00

7. SUMMARY

For the purpose of registering the medical device and licensing the establishment, the four (4) elements of conformity assessment must be conducted by a REGISTERED CAB as prescribed in Part III-Third Schedule of the MDR 2012. The elements are -

(a) conformity assessment of quality management system;

(b) conformity assessment of post-market surveillance system;

(c) conformity assessment of technical documentation; and

(d) declaration of conformity.

The CAB shall be registered under the Act 737 by the Authority for the duration of three (3) years and been awarded with a certificate of registration.

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REGISTRATION OF CONFORMITY ASSESSMENT BODY (CAB) UNDER THE MEDICAL DEVICE ACT 2012 (ACT 737)

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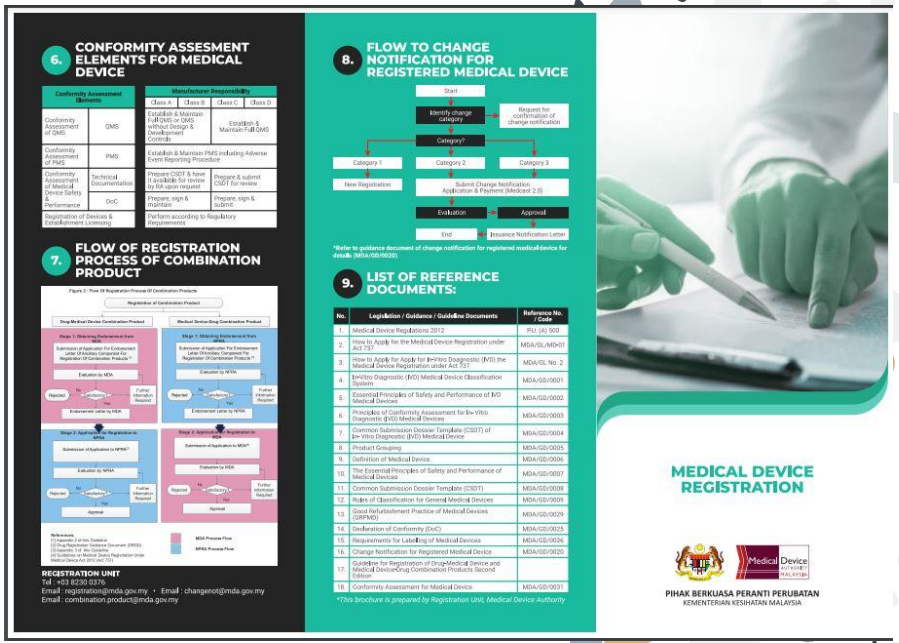

6. CONFORMITY ASSESMENT ELEMENTS FOR MEDICAL DEVICE

Conformity Assessment Elements		Manufacturer Responsibility			
		Class A	Class B	Class C	Class D
Conformity Assessment of QMS	QMS	Establish & Maintain FUR QMS or QMS without Design & Development Control		Establish & Maintain FUR QMS	
Conformity Assessment of PMS	PMS	Establish & Maintain PMS including Adverse Event Reporting Procedure			
Conformity Assessment of Medical Device Safety & Performance	Technical Documentation	Prepare CSDT & have it available for review by RA upon request		Prepare & submit CSDT for review	
	DoC	Prepare, sign & maintain		Prepare, sign & Submit	
Registration of Devices & Establishment Licensing		Perform according to Regulatory Requirements			

7. FLOW OF REGISTRATION PROCESS OF COMBINATION PRODUCT

Figure 2 : Flow Of Registration Process Of Combination Products

Registration of Combination Product

Drug-Medical Device Combination Product | Medical Device-Drug Combination Product

Step 1: Obtaining Endorsement from

Submission of Application For Endorsement Letter Of Ancillary Component For Registration Of Combination Products™

Evaluation by MDA / Evaluation by NPRA

Rejected / Further Information Required / Yes

Endorsement Letter by MDA / Endorsement Letter by NPRA

Step 2: Application for Registration to NPRA / Step 2: Application for Registration to MDA

Submission of Application to NPRA™ / Submission of Application to MDA™

Evaluation by NPRA / Evaluation by MDA

Rejected / Further Information Required / Yes

Approval

MDA Process Flow

NPRA Process Flow

REGISTRATION UNIT
Tel : +03 8230 0376
Email : registration@mda.gov.my • Email : changenot@mda.gov.my
Email : combination.product@mda.gov.my

8. FLOW TO CHANGE NOTIFICATION FOR REGISTERED MEDICAL DEVICE

*Refer to guidance document of change notification for registered medical device for details (MDA/GD/0023)

9. LIST OF REFERENCE DOCUMENTS:

No.	Legislation / Guidance / Guideline Documents	Reference No. / Code
1.	Medical Device Regulations 2012	PU. (A) 500
2.	How to Apply for the Medical Device Registration under Act 737	MDA/GL/MD-01
3.	How to Apply for Apply for In-Vitro Diagnostic (IVD) the Medical Device Registration under Act 737	MDA/GL No. 2
4.	In-Vitro Diagnostic (IVD) Medical Device Classification System	MDA/GD/0001
5.	Essential Principles of Safety and Performance of IVD Medical Devices	MDA/GD/0002
6.	Principles of Conformity Assessment for In-Vitro Diagnostic (IVD) Medical Devices	MDA/GD/0003
7.	Common Submission Dossier Template (CSDT) of In-Vitro Diagnostic (IVD) Medical Device	MDA/GD/0004
8.	Product Grouping	MDA/GD/0005
9.	Definition of Medical Device	MDA/GD/0006
10.	The Essential Principles of Safety and Performance of Medical Devices	MDA/GD/0007
11.	Common Submission Dossier Template (CSDT)	MDA/GD/0008
12.	Rules of Classification for General Medical Devices	MDA/GD/0009
13.	Good Refurbishment Practice of Medical Devices (GRPMD)	MDA/GD/0029
14.	Declaration of Conformity (DoC)	MDA/GD/0025
15.	Requirements for Labelling of Medical Devices	MDA/GD/0026
16.	Change Notification for Registered Medical Device	MDA/GD/0020
17.	Guideline for Registration of Drug-Medical Device and Medical Device-Drug Combination Products Second Edition	
18.	Conformity Assessment for Medical Device	MDA/GD/0031

*This brochure is prepared by Registration Unit, Medical Device Authority

MEDICAL DEVICE REGISTRATION

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EXAMPLE OF ONLINE COMMUNICATION

EMAIL

FEMES

ONLINE TRAINING/VIDEO CONFERENCE

REGULATORY INFORMATION SUBSCRIPTION

CUSTOMER SATISFACTION SURVEY

WEBSITE

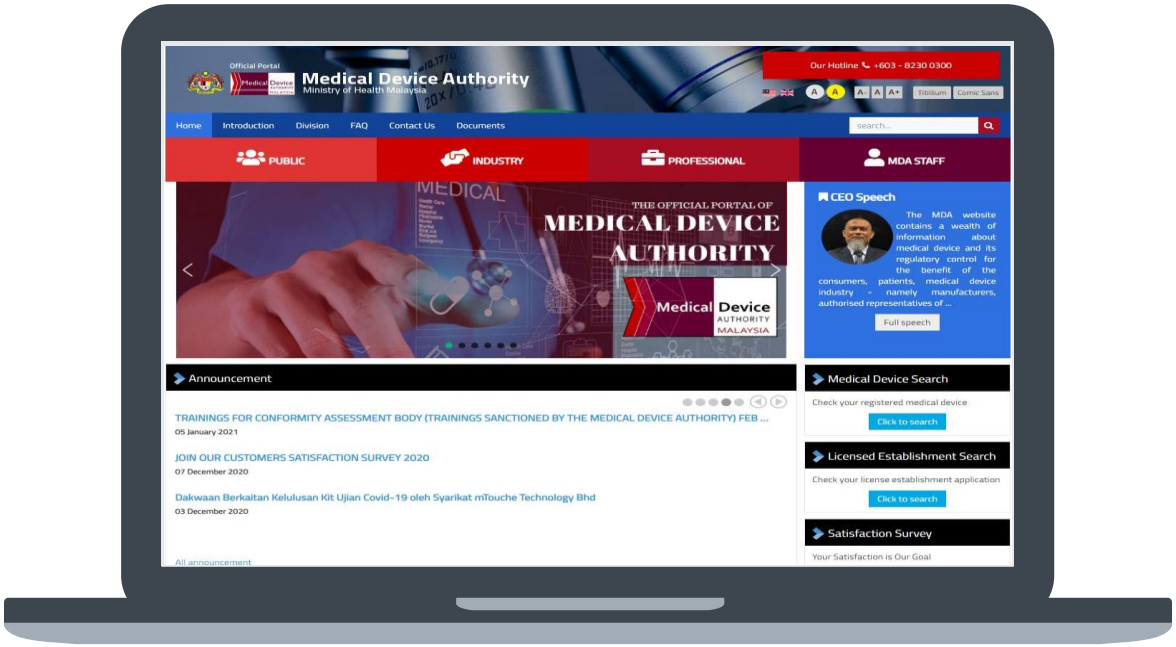
SOCIAL MEDIA

PUBLIC COMMENTS METHOD

EMAIL

- General email at **mdb @mda.gov.my**
- **Each department/division in MDA** has **specific email** in terms of processing documentation or inquiries or matters to related field such as **mpr @ mda.gov.my** (to report for Mandatory Problem/Incident /Adverse Event Reporting)
- **Industries** and public also **has been provided** with **personal emails (work)** of **each officer** to make them convenient to contact with related officer .
- We display **all the emails or contact numbers** in our official **website**.

WEBSITE



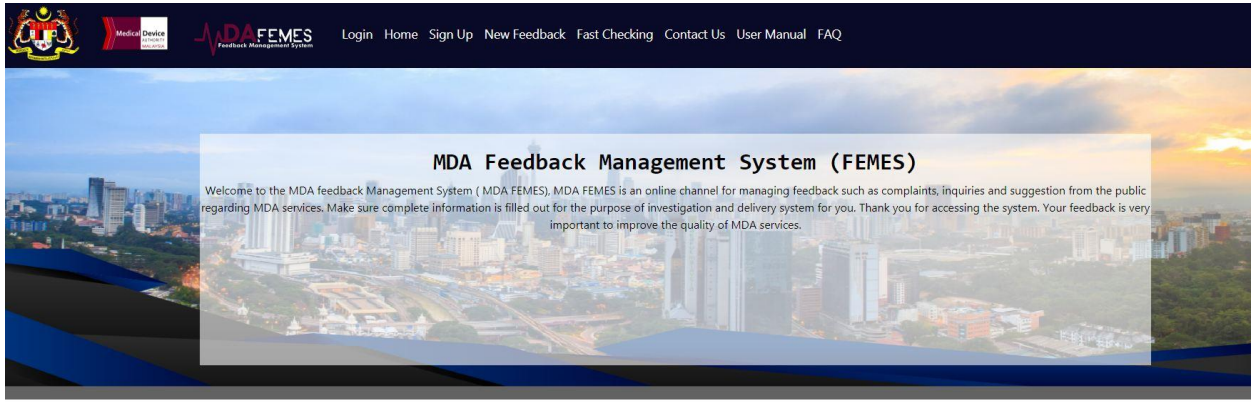
- Find us at portal.mda.gov.my

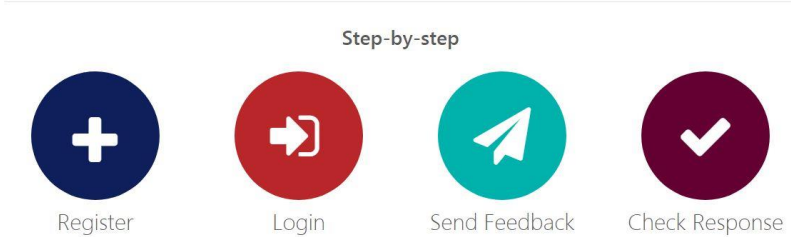
FEMES

- FEMES - MDA Feedback Management System was launched in April 2019.
- MDA FEMES is an online channel for **managing feedback** such as complaints, inquiries and suggestions **from the industries** or public **regarding medical device or MDA services**.
- The development of this system is part of MDA's ongoing efforts **to improve the quality of services and delivery of feedback to the industries.**

MDA FEMES
Feedback Management System

FEMES

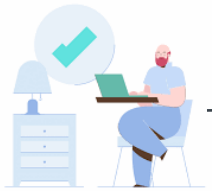

Login Home Sign Up New Feedback Fast Checking Contact Us User Manual FAQ
MDA Feedback Management System (FEMES)
Welcome to the MDA feedback Management System (MDA FEMES). MDA FEMES is an online channel for managing feedback such as complaints, inquiries and suggestion from the public regarding MDA services. Make sure complete information is filled out for the purpose of investigation and delivery system for you. Thank you for accessing the system. Your feedback is very important to improve the quality of MDA services.


Step-by-step
Register
Login
Send Feedback
Check Response

OVERVIEW OF THE PROCESS

Step 2 – The Gatekeeper (Admin) identify the inquiry and channel it to the relevant department.

Step 4 – Customer receive the feedback via email notification.



Step 1 – Customer make an inquiry using MDA FEMES.

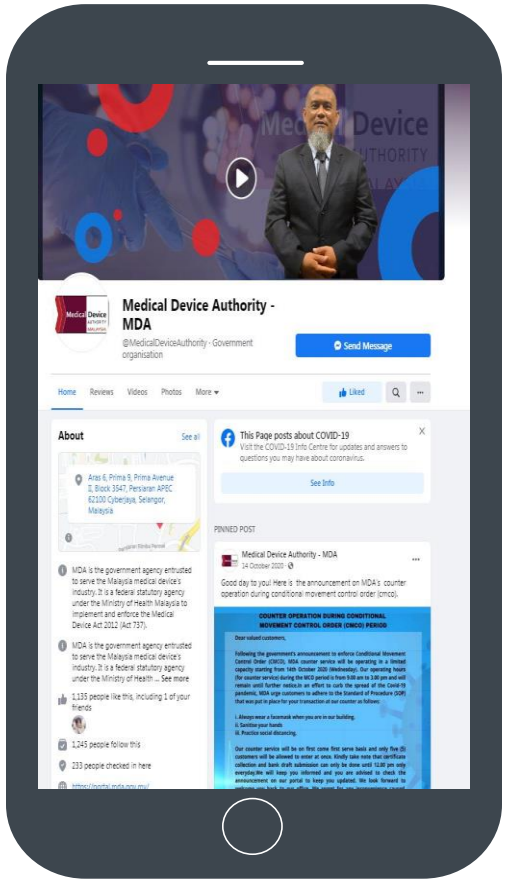
Step 3 – The relevant dept. receive the assignment and compose the feedback to customer.

SOCIAL MEDIA

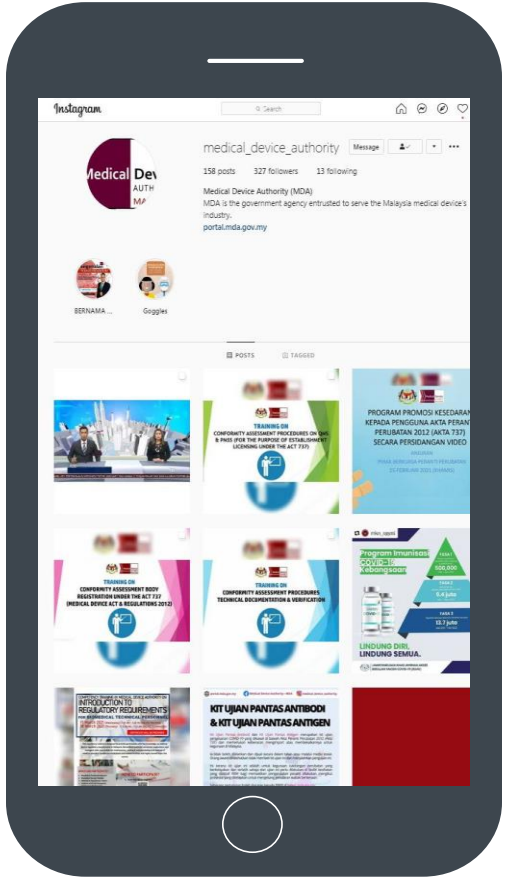
- MDA official Facebook page is **Medical Device Authority – MDA**

- MDA official Instagram page is **medical_device_authority**

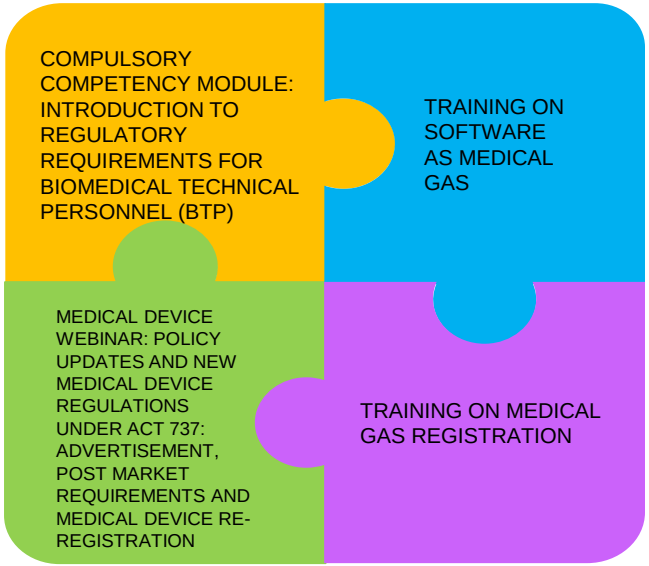
SOCIAL MEDIA



SOCIAL MEDIA



ONLINE TRAINING/ VIDEO CONFERENCE



To those who wish to join this online training programs please call **Training Secretariats**:
MR. FEZRI BIN AZIZ at 03 8230 0395 or fezriaziz@mda.gov.my
MS.NUR RASIDAH BINTI NGASBON at 03 8230 0211 or nurrasidah@mda.gov.my

PUBLIC COMMENTS METHOD

- MDA request public comment on the guidance document because the public has a vested interest in the medical device that regulates, and because the input provides critical insight into the effects of the ACT and Regulation on the public. The comments is to present the "real world" concerns related to the guidance documents.

PUBLIC COMMENTS METHOD : How we do it?

Once the draft of the guidance document deliberate in the task group,

Secretariat of the task group will post draft guidance documents together with public comment template via MDA website

2 weeks will be given for them to provide the comment to the secretariat of the task group.

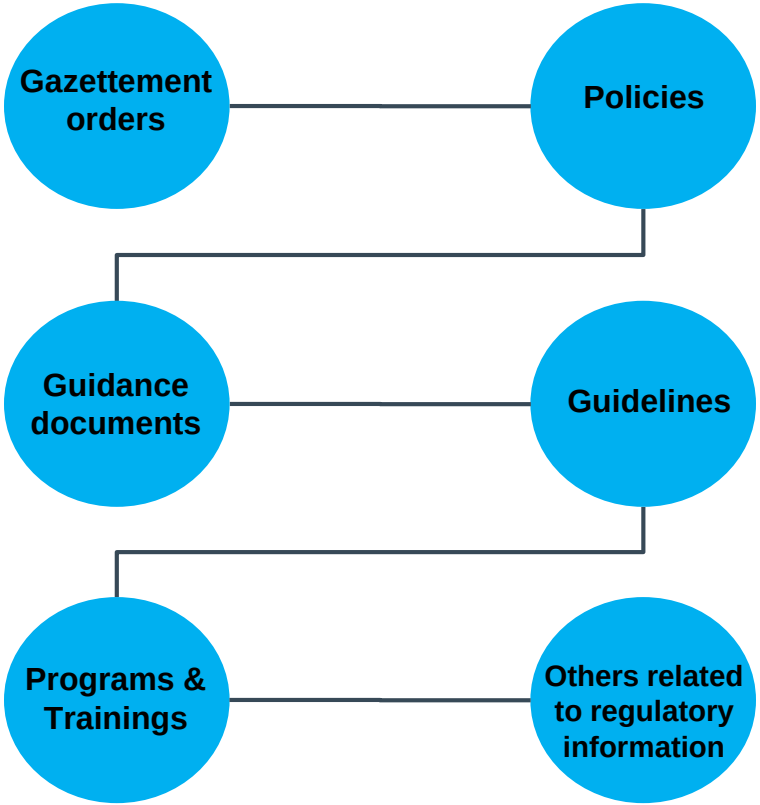
The task group will discuss again on each and every single comment before finalise the draft for approval.

REGULATORY INFORMATION SUBSCRIPTION

- This program of **e-mail notification** subscription is an initiative of MDA to provide the latest information to stakeholders and the general public who wish to subscribe to this service.
- This is **one of the initiatives that MDA is offering to promote effective dissemination of information to individuals and companies** that value on time and direct access to pertinent regulatory information and activities related to medical devices.

REGULATORY INFORMATION SUBSCRIPTION

- Example of information the industries received if they subscribe with this email system:



CUSTOMER SATISFACTION SURVEY

- It is a tool used by MDA to determine the rate of satisfaction from customers towards MDA.
- Customers refers to any individual or organization that have any experience in dealing with MDA directly or indirectly.
- This survey can also be used to measure the quality of service provided by MDA towards its customers.

CUSTOMER SATISFACTION SURVEY

03. CONCLUSION

CONCLUSION

We need to combine these two methods in order to ensure the communication process become efficiency and success.

For future plan, MDA will have TWITTER and YOUTUBE as to widen our communication channels.

We hope that with these information will help industries understand and assist you to get the right direction.

THANKS!

Does anyone have any questions?

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