

Experience Sharing on Enforcing Regulatory Requirements to Ensure Continuous Compliance (Malaysia)

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ENFORCEMENT ACTIVITIES

Intelligence, Investigations
and Raiding Operations



1.

INTRODUCTION

Intelligence & Investigation Branch,
Post-Market & Enforcement Division



MEDICAL DEVICE AUTHORITY

- ▶ Headquarters in Cyberjaya
21 officers
- ▶ Receive complaints and
initiate the investigations

2.

MEDICAL DEVICE ACT 2012 (ACT 737)

An overview of Part 5 Act 737

SECTION 48

Authorization - Before enforcement can be carried out, the officer must be authorized by the Minister



SECTION 49

The authority card must be given to the officer (Sect. 49) to show powers to be exercised by him/her.



SECTION 50

Power of Investigation



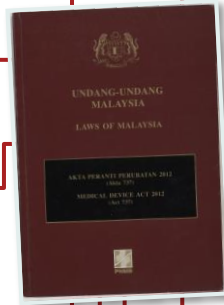
SECTION 51 & 52

Search and Seizure (with or without warrant)



SECTION 53

Access to computerized data



SECTION 60

Power to Require attendance of persons acquainted with case



SECTION 61

Examination of persons acquainted with case



SECTION 64

Power of Arrest



SECTION 65

Power to take Sample



SECTION 66

Appointment of Analyst



ACTION FRAMEWORK

ENFORCEMENT	ADMINISTRATIVE	LEGAL
Receiving and evaluating complaints	Issuance of notice, reminder, or warning	Compound
Investigating complaints	Recall Instruction	Cancellation of registration
Carrying out inspection and intelligence	Instruction to stop sale	Suspension or revocation of license or permit
Conducting seizure and seals	Instruction to remove advert from advertisement & online selling platform	Imprisonment & Penalty

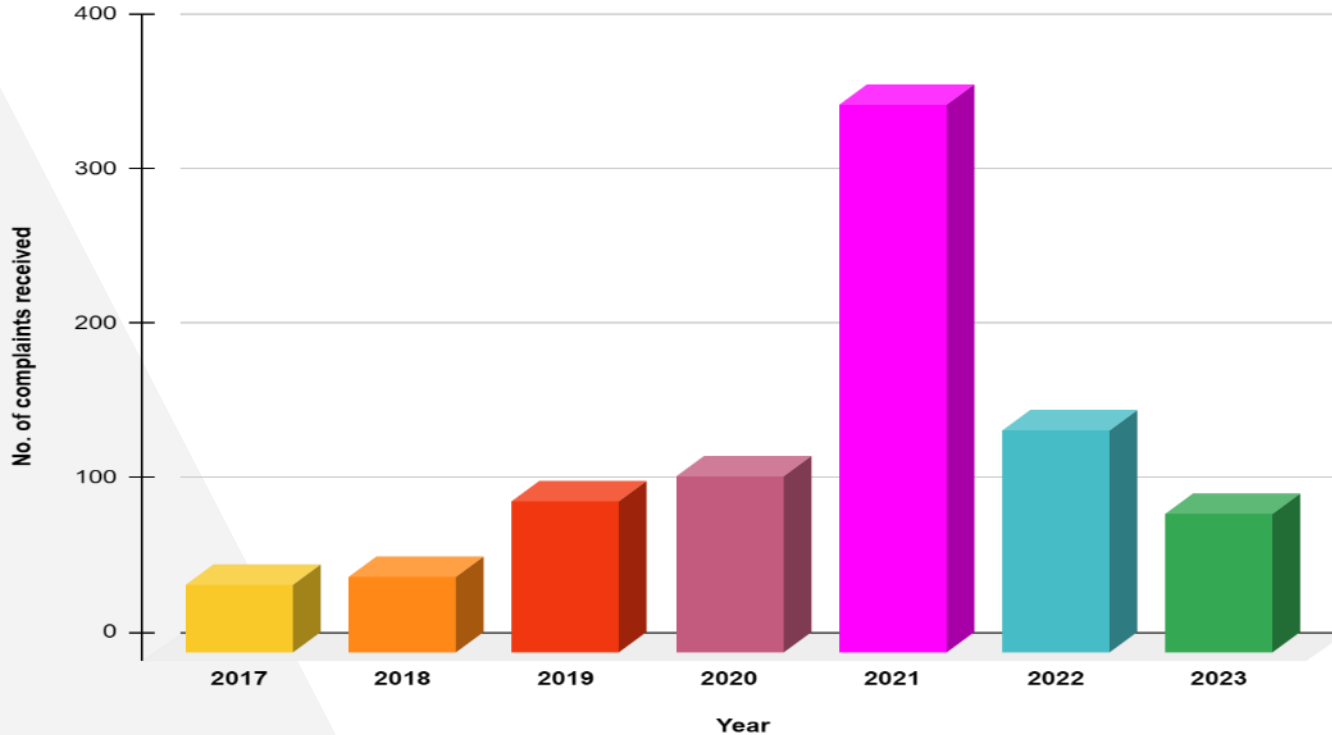
3.

COMPLAINTS TRENDING

Number and type of complaints over the years

TREND NUMBER OF COMPLAINTS RECEIVED BY MDA

Number of Complaints Received vs Year



4.

ENFORCEMENT ACTIVITIES

Intelligence, Investigations and Raid Operations

Syarikat tiada lesen diserbu, MDA rampas peralatan perubatan RM300,000



PHIL: Sebuah van diserbu ke atas sebuah pejabat yang mengedarkan peralatan perubatan tidak berdaftar dari 1 unit lesen di Batu Pahat.

View on desktop version: 14 Jul 2021 8:46 pm.



BATU PAHAT: Cara-cara mengedarkan peralatan perubatan tidak berdaftar selain tidak mempunyai lesen, sebuah syarikat yang beroperasi di daerah ini diserbu Pihak Berkuasa Peranti Perubatan (MDA) hari ini.

Ketua Unit Risikan dan Operasi MDA, Dery Akmal Abdul Rahman berkata, serbuan dilakukan hasil risikan selama enam bulan oleh pihaknya setelah menerima aduan daripada orang ramai.

Antara peranti perubatan yang dirampas ialah kit ujian kandungan, 'blood lancet', pelitup muka perubatan dan 'first aid' bernilai kira-kira RM300,000 yang dijual di farmasi serta klinik di seluruh negara.

MDA seizes unregistered medical devices worth over RM1 million

Bername Oktober 6, 2021 23:07 MYT



MDA, KKM | Syarikat Jual Peranti Perubatan Tidak Berdaftar Diserbu Sebuah syarikat di Batu Pahat, Johor diserbu Pihak Berkuasa Peranti...

Batal lesen jika jual peranti perubatan tidak sah - MDA

oleh MOHAMMAD HUSYAMUDDIN AYUB 14 Julai 2021 12:45pm Masa membaca: 3 minit



Iskandarhan (tengah) menunjukkan peranti perubatan berharga kemudi tidak sah yang dirampas di Sungai Petani, Kedah pada Khamis.



999 TV3: Peranti Perubatan Tidak Berdaftar Tun Hizami Hashim (999 TV3)

THANK YOU!

Any questions?

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