ORIGINAL ARTICLE

Profile of the Implantable Medical Devices Registered in Malaysia between the Year 2013 to 2017

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ABSTRACT

Introduction: The Malaysia Medical Device Authority (MDA) has mandated the registration of implantable medical device (IMD) via the MeDC@St online system since 2013. The study aimed to gather information on the IMD registered in Malaysia to understand its economic importance subsequently profile its manufacturers, prior approval by the medical device authorities before the revision of the ISO10993-1 published in 2018. **Methods:** Permission is obtained from the MDA to access the MeDC@St online system to retrieve a five-year (2013 to 2017) registration information, which is manually retrieved using a data collection form and analysed descriptively. **Results:** A total of 11,956 medical devices were registered by the MDA between 2013 to 2017, whereby 16.5% of it is IMDs with the highest and lowest numbers were recorded in 2015 and 2013 with 997 and 39 registrations, respectively. The majority of the registrations consisted of IMD under the MDR technical areas of MD 0200 (20.4%) and MD 0202 (28.2), MD 0204 (9.9%) and MD 0402 (11.1%). The economies associated with the Global Harmonisation Task Force (GHTF) showed apparent influence on the IMD registered in Malaysia whereby 88.5% were manufactured, 98.9% obtained prior approval and 73.6% were assessed for conformity by entities originating from the GHTF economies. **Conclusion:** The IMD has substantial economic importance in Malaysia looking at the continual registration of above 150 new devices annually since 2014. It is believed that the similarity of the medical device laws with the GHTF economies has encouraged the large presence of its IMD in the Malaysia.

Keywords: Medical device, Implantable, Registration, Health and well-being

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INTRODUCTION

The global medical device industry is worth a value of USD 425.5 billion in 2018 and is expected to reach USD 612.7 billion by 2025 (6). The United States of America (USA) expected continues to dominate the global market with the profits crossing of USD 300 billion in the year 2030. This is followed by China and India with USD 40 billion profits, France and Germany are expected to cross USD 50 billion, next with Japan and UK below the USD 50 billion profits (45). A similar scenario can also be reflected in Malaysia that shown that the Malaysian medical device trade industry is worth USD 2.47 billion with the import that worth USD 7250 million in 2018. A report from Malaysian Investment Development Authority (MIDA) showed that Malaysia is becoming a global medical device manufacturing hub, with its medical device industry that comprises of over 200 manufacturers with the implemented investments of RM 14.2 billion (41). A report by the International Trade Administration in 2019 stated that the USA products represented 24.6% of the import market, therefore making the USA the highest exporting country of medical device to Malaysia within the same year. The export is followed by Singapore (17.3%), Germany (10.8%), Japan (9.9%), China (7.9%), Belgium (3.0%) and South Korea (2.6%). In Malaysia, the export sale for the medical device was exceeding RM 20 billion as of November 2018 (30) and expected growing to RM 28.8 billion in 2020 (40).

Jiang and Zhou (25) described that 8% to 10% of the USA population and 5% to 6% of the world industrialised countries populations have experienced having an implantable medical device (IMD) for rebuilding their body functions, expanding longevity and achieving a better quality of life. Examples of implantable device include the cardiac pacemakers, implantable cardiac defibrillators, hip implants, coronary stents, implantable insulin pumps and intraocular lenses (26). The Data Bridge Market Research in 2020 reported that Asia-Pacific orthopaedic implants market alone is expected to reach USD 7.4 billion by 2027 from USD 4.6 billion

in 2020. While the Allied Market Research in 2020 reported that the medical implants market is expected to expand from USD 85.4 million in 2019 to USD 147.5 million in 2027 which is driven by the aging population and increase in prevalence of chronic diseases.

The Malaysian Medical Device Authority of Ministry of Health (MDA) is a statutory body under the Ministry of Health Malaysia and was established under the Medical Device Authority Act 738 (11) to control, regulate medical device, industry and activities as well as to enforce medical device law. The MDA is responsible for assuring the quality, performance, safety and effectiveness of medical device used to treat, prevent, and diagnose diseases (7, 8, 39). Medical device is defined by the Malaysian Act 737 as implements, in vitro reagents, machine, implants, apparatuses, software, material or other analogous products that are meant for the use in the treatment, diagnosis, cure, prevention, the mitigation of disease, the control of conception, life support, sustenance and medical device disinfectant in humans (1, 10). The IMD definition includes medical device that is either totally or partly introduced via surgically or medically method into the human body, and some is intended to remain in the body after the procedure (9).

The Malaysian Medical Device Regulation 2012 under the Malaysian Act 737 (MDR) has prescribed the 4 risk classes (A, B, C & D) which covers 16 rules for general medical device and 7 rules for in vitro diagnostic (IVD) device for basis of mechanism to guide manufacturers in systematically identification of the correct classification. Class A is related to medical device with low individual risk and low public health risk, e.g. surgical retractors and tongue depressors. While for medical device with moderate individual risk and/or low public health risk, e.g. hypodermic needle/suction equipment is assigned under class B. Whereas medical device such as lung ventilator and orthopaedic implant are assigned under class C which is considered having high individual risk and/or moderate public health risk. The highest risk class D is assigned to medical device with high individual risk and high public health risk devices, e.g. heart valves and implantable defibrillator (9, 37).

The IMDs are categorised into class D of those with high risk while those with moderate risks categorised in class B and C based on the description of Rule 8 as described by the MDR; "*All implantable medical devices, and long term surgically invasive medical devices, are in Class C, or unless they are intended to be placed into the teeth, in which case they are in Class B; or unless they are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class D; or unless they are intended to be life-supporting or life-sustaining, in which case they are in Class D; or unless they are intended to be active implantable medical devices, in which case they are Class D; or*
unless they are intended to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class D; or unless they are intended to undergo chemical change in the body (except if the devices are placed in the teeth), in which case they are in Class D; or unless they are breast implants, in which case they are in Class D" (9, 37).

The classification is similar to the system developed by the Global Harmonisation Task Force (GHTF) countries that is documented in the GHTF Principles of Medical Device Classification (9, 12, 13). The GHTF is a voluntary group of delegates consists of regulatory authorities for medical device and members of the medical device industry from five countries namely the United States of America (USA), European Union (EU), Japan, Australia, and Canada, which was founded in 1992 with the aim for international harmonisation of medical device regulation (14). The GHTF role was taken over by the International Medical Device Regulators Forum (IMDRF) in year 2012. The IMDRF members consists of medical device authorities from Australia, Canada, Brazil, Russia, Singapore, EU, USA, Japan, South Korea, and China (5, 20 28). For the harmonization among the member states of the Association of Southeast Asian Nations (ASEAN), the ASEAN Medical Device Directive is accepted on 21 November 2014 to ensure that the medical device marketed in the region conform to a harmonised requirements for safety, quality and the effectiveness of the medical device marketed in ASEAN region (49).

Looking at the substantial social and economic importance of the world medical device market, a five-year retrospective study was conducted aimed to gather information on the IMD registered in Malaysia via the MDA online system known as the "Medical Device Centralised Online Application System" (MeDC@St) to understand its economic importance subsequently to profile its manufacturers, prior approval by medical device authorities and the conformity assessment bodies. It is based on the registration records deposited during its first five years of operation of the online system which began in year 2013 (35).

MATERIALS AND METHODS

Medical Device Centralised Online Application System (MeDC@St)

MDA has developed a web-based online application system, named as MeDC@St (31), a platform for the industry to submit applications for the registration of medical device and establishments license as required by the under MDR, aimed to manage these applications efficiently and effectively. The MeDC@St consists of two main modules, the establishment licensing and medical device registration with the submissions effective since the 1st July 2013. User registration is required before

a private entity or its representative could file the application. (35).

Duration, Retrieval and Collection of Data

The study does not involve direct contact or interaction with the registrants or manufacturers, it only involves retrieval of information deposited in the MeDC@St. The access to the online system was approved by the MDA [Ref: (79) MDA. 500 8/1/35] that gave permission for the retrieval of the data from year 2013 to year 2017. The data retrieval was conducted between August 2019 to February 2020 by using a data collection form that was developed based on the information layout of the window interfaces of the MeDC@St. The data was collected manually by reading each interface window of a particular medical device registration. For each registered medical device, it is uniquely identified by the MeDC@St alphanumerical identification system. However, the details of the registrant identity was not collected as part of the confidentiality rules set by the MDA. The retrieval, inclusion and exclusion criteria of the information collected from the data deposited in the MeDC@St is described at Figure I. The study assumes that all the data in the MeDC@St has been deposited correctly and completed for each registration by the applicant who is either the manufacturer or the authorised representative.

The parameters of the information and the variables of the data collected of each registered IMD using the data collection form are as follows:

Information parameter	Data collection variables
Registration identification	Alphanumerical unique codes
Year of the registration	2013, 2014, 2015, 2016 or 2017
Role of establishment	Authorised representative or Manufacturer
Implant market	Domestic or Export
Implant risk class	Class B, Class C or Class D
Classification rule	Rule 8 only (implantable device)
Implant technical area	MD 0100, MD 0200, MD 0201, MD 0202, MD 0203, MD 0204, MD 0300 MD 0302, MD 0303, MD 0400, MD 0401, MD 0402, MD 0403, MD 1100, MD 1101, AIMD 0100, AIMD 0101, AIMD 0102, AIMD 0103, MDS 7000, MDS 7001 or MDS 7002.
Manufacturer country	Country as stated in the system
Manufacturer GHTF economy	GHTF or Non-GHTF
Pre-market clearance by national regulatory authority	Name of the regulatory authority including notification body
History of prior approval	GHTF approval, Non-GHTF approval or None
Conformity assessment body (CAB)	Name of the conformity assessment body

Statistical analysis

Statistically the collected data covered the entire population of the IMD without sampling which consists of ordinal type frequency and nominal type categories. Thus, the descriptive analysis using the Statistical Package for Social Sciences (SPSS), Version 25.0 was found to be adequate for the aim of the study.

RESULTS

The data collection from the MeDC@St showed a total of 11,956 registrations of medical devices been applied for registration between 2013 to 2017, whereby 1,972 applications (16.5%) were for the IMD with 1,925 applications been successfully registered with MDA (Figure I). The Figure II showed sharp variation of the annual application for registration in year 2013, 2014 , 2015, 2016 and 2017 with 39, 257, 997, 450 and 182 filings with successful registration, respectively.

The MeDC@St requires the applicant during submission for registration to identify their background covering

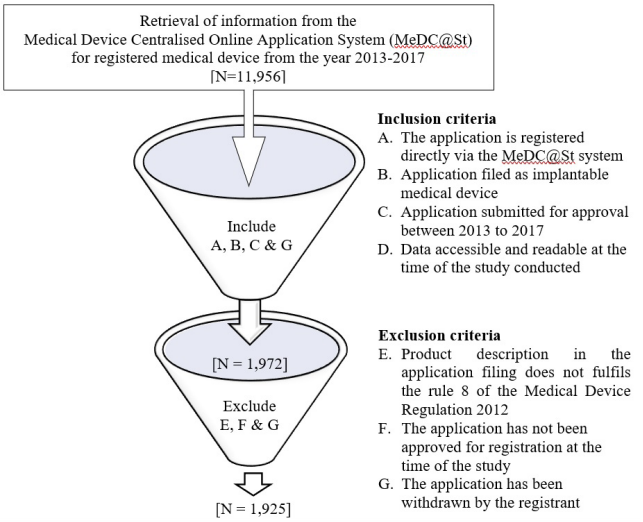

Figure 1: The retrieval, inclusion and exclusion criteria of the information collected from the data deposited in the Medical Device Centralised Online Application System (MeDC@St)

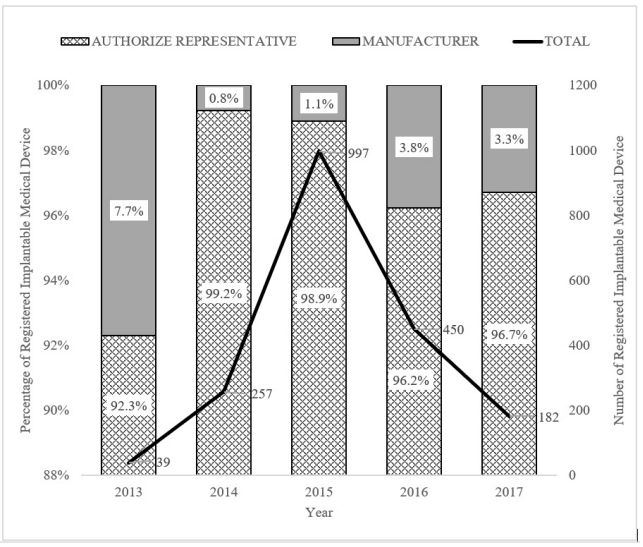

Figure 2: Profile of the 5-year annual registration of the implantable medical devices from 2013 to 2017 by type of registrants (applicant) and number of registration application

the role of establishment (authorised representative or manufacturer), manufacturing entity, the country of manufacturer, and the medical device market (domestic or export). The results at Figure II showed that the majority (> 92%) of the annual application for IMD registration was submitted by an authorised representative on behalf of the manufacturer. The MDR requires foreign manufacturers to appoint their local authorised representatives who shall represent them in registering of their devices and are responsible for the devices in Malaysia.

Further checking into the origin country of the IMD's manufacturer, results at the Table I profiled the manufacturers from the United States of American having the overall highest number of registered IMDs (45.6%) in 5-year with annual registration exceeding 31%. Followed by number of IMDs manufactured in Switzerland, Germany and France were 12.5%, 9.7 % and 5.2%, respectively. Upon consolidating all the 22 countries associated with the GHTF economies, the results showed a strong presence of GHTF economies in Malaysia representing 88.5% of all the registered IMDs. Manufacturer from Malaysia showed similar level of capability with China, India and South Korea that covered 2% to 4% from the total registration.

The MeDC@St information on the IMD's risk class as shown by Figure III described the IMDs with risk class C has the highest number of 970 (50.4%) applications registered by the Malaysian MDA with annual registration above 47% of the filing. Followed by IMDs of risk class D with 708 (36.8%) approved application from 2013 to 2017 with annual registration above 33%. The IMDs with risk class B consistently showed relatively lower overall and annual registration of 244 (12.7%) and below 155

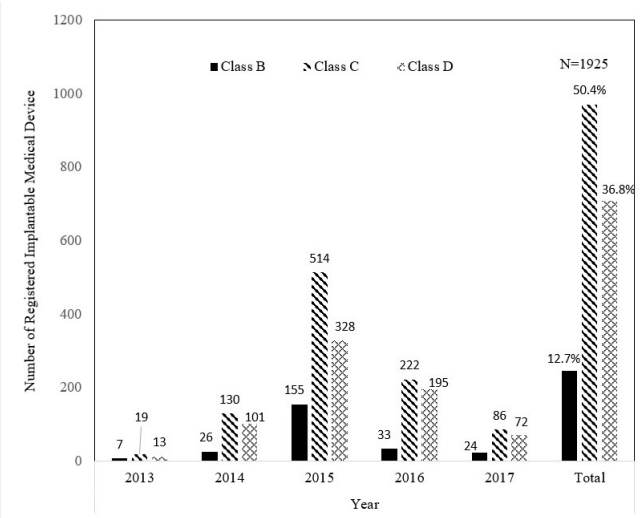

Figure 3: Profile of the of the 5-year annual and overall registered implantable medical devices filed between 2013 to 2017 from the perspective of the implant risk class B, C and D

Table I: Profile of the implantable medical devices registered via Malaysia MedC@ast between 2013 to 2017 from the perspective of the manufacturer country and global harmonisation task force (GHTF)

GHTF Status	Manufacturer Country	% of the registered implantable medical devices in Malaysia					
		Year					5 Years
		2013	2014	2015	2016	2017	
GHTF Economy	Australia	0.0	0.0	0.5	0.2	0.0	0.3
	Austria	0.0	0.0	0.3	0.0	0.0	0.2
	Belgium	0.0	1.6	1.5	0.9	2.7	1.5
	Canada	0.0	0.0	0.4	0.4	0.0	0.3
	Czech Republic	0.0	0.8	0.5	0.0	0.0	0.4
	Denmark	0.0	0.0	0.5	0.0	0.0	0.3
	Finland	0.0	0.0	0.2	0.7	0.0	0.3
	France	7.7	6.6	5.9	3.1	3.8	5.2
	Germany	5.1	11.3	9.9	6.9	13.7	9.7
	Hungary	0.0	0.0	0.2	0.0	0.0	0.1
	Ireland	0.0	0.4	1.7	1.1	3.8	1.6
	Italy	5.1	0.4	1.8	4.9	2.2	2.4
	Japan	0.0	0.8	0.9	0.7	0.5	0.8
	Lithuania	0.0	0.0	0.1	0.0	0.0	0.1
	Netherlands	2.6	0.4	1.2	1.6	2.2	1.3
	Poland	0.0	0.0	0.1	0.2	0.5	0.2
	Portugal	0.0	0.0	0.0	0.0	0.5	0.1
	Spain	5.1	10.1	0.3	0.2	0.0	1.7
	Sweden	0.0	0.8	1.5	1.6	9.9	2.2
	Switzerland	5.1	23.7	14.3	5.3	6.0	12.5
	United Kingdom	0.0	1.2	2.5	3.1	0.5	2.2
	United States	61.5	41.2	45.2	53.1	31.3	45.6
Non GHTF Economy	Brazil	0.0	0.0	0.5	0.0	1.1	0.4
	China	0.0	0.0	1.8	6.7	1.1	2.6
	India	0.0	0.0	1.7	0.9	6.6	1.7
	Liechtenstein	0.0	0.0	0.3	0.2	0.0	0.2
	Malaysia	7.7	0.8	1.1	3.8	3.3	2.0
	Mexico	0.0	0.0	0.2	0.0	0.5	0.2
	North Korea	0.0	0.0	0.0	0.2	0.0	0.1
	Singapore	0.0	0.0	0.4	0.9	0.0	0.4
	South Korea	0.0	0.0	4.0	3.3	9.3	3.7
	Turkey	0.0	0.0	0.2	0.0	0.0	0.1
	Ukraine	0.0	0.0	0.1	0.0	0.0	0.1
Total number of registrations		39	257	997	450	182	1925

(16%) of the IMD's applications, respectively.

The profiling of the IMDs registration from the perspective of the medical device technical area is exhibited at Table II whereby the majority of the registrations consisted of IMD under the MDR technical areas of MD 0200 (non-active implants) and MD 0202 (non-active orthopaedic implants), MD 0204 (non-active soft tissue implants) and MD 0402 (dental materials), representing 20.4%, 28.2%, 9.9% and 11.1%, respectively.

The prior pre-market approval information is required by MDA as part of the registration application in the MeDC@St. The system allows the registrant (applicant) use verification route for the conformity assessment by using the pre-market approval that already been obtained from other market. Table III shows the compilation on the IMD's prior pre-market approval by authorities from GHTF and non-GHTF economies between 2013 and 2017. The findings suggest the IMD registration with history of prior pre-market approval from the GHTF economies make the major portion of the IMDs in Malaysia with 1903 (98.9%) registrations. The larger proposition was contributed by the GHTF economies such as European Union (43.3%), Unites States of America (23.2%), Canada (14.2%) and Australia (14.0%) and Japan (4.0%). While only 5 (0.26%) registrations submitted with prior pre-market approval from the medical device authorities of the non-GHTF economies. There were also 17 (0.88%) registrations without any prior pre-market approval which indicates it is new IMD and MDA is the first authority being applied for registration.

Table II: Profile of the implantable medical devices registered via Malaysia MedC@ast between 2013 to 2017 from the perspective of the medical device technical areas

Medical Device Technical Areas	% of the registered implantable medical devices in Malaysia					
	Year					5 Years
	2013	2014	2015	2016	2017	
MD 0100	0.0	0.8	2.6	3.1	1.6	2.3
MD 0200	23.1	21.8	18.8	25.6	14.3	20.4
MD 0201	12.8	2.7	7.0	7.1	4.4	6.3
MD 0202	20.5	30.0	30.5	26.7	18.7	28.2
MD 0203	2.6	3.5	4.1	5.3	3.3	4.2
MD 0204	17.9	20.6	8.7	4.7	12.1	9.9
MD 0300	0.0	0.0	0.0	0.2	0.0	0.1
MD 0302	5.1	5.8	4.4	4.4	8.8	5.0
MD 0303	0.0	0.8	0.6	0.4	1.1	0.6
MD 0400	0.0	0.0	1.7	2.7	2.2	1.7
MD 0401	0.0	0.8	0.4	0.0	0.0	0.3
MD 0402	17.9	8.9	13.7	4.9	13.2	11.1
MD 0403	0.0	1.2	2.1	3.8	11.5	3.2
MD 1100	0.0	0.0	0.1	0.9	0.0	0.3
MD 1101	0.0	0.0	0.0	0.4	0.0	0.1
AIMD 0100	0.0	0.8	2.1	5.3	3.8	2.8
AIMD 0101	0.0	1.2	1.3	3.1	1.1	1.7
AIMD 0102	0.0	0.0	0.4	0.4	0.5	0.4
AIMD 0103	0.0	0.0	0.6	0.7	2.2	0.7
MDS 7000	0.0	0.0	0.6	0.2	0.0	0.4
MDS 7001	0.0	0.0	0.2	0.0	0.0	0.1
MDS 7002	0.0	1.2	0.0	0.0	1.1	0.3
Total number of registrations	39	257	997	450	182	1925

Note: MD 0100: General Non-Active, Non-Implantable Medical Devices, MD 0200: Non-Active Implants, MD 0201: Non-active cardiovascular implants, MD 0202: Non-active orthopaedic implants, MD 0203: Non-active functional implants, MD 0204: Non-active soft tissue implants, MD 0300: Devices For Wound Care, MD 0302: Suture material and clamps, MD 0303: Other medical devices for wound care, MD 0400: Non-Active Dental Devices and Accessories, MD 0401: Non-active dental equipment and instruments, MD 0402: Dental materials, MD 0403: Dental implants, MD 1100: General Active Medical Devices, MD 1101: Devices for extra-corporal circulation, infusion and haemopheresis, AIMD 0100: General Active Implantable Medical Devices, AIMD 0101: Active implantable medical devices for stimulation / inhibition, AIMD 0102: Active implantable medical devices delivering drugs or other substances, AIMD 0103: Active implantable medical devices substituting or replacing organ functions, MDS 7000: MD / AIMD Specifics, MDS 7001: Medical devices incorporating medicinal substances, according to Directive 2001/83/EC, MDS 7002: Medical devices utilising tissues of animal origin, including Directive 2003/32/EC

Table III: Profile of the implantable medical devices registered via Malaysia MedC@ast between 2013 to 2017 from the perspective of the pre-market approval by the authorities in the global harmonisation task force (GHTF) economies

Year	No Prior Approval	Prior Approval						Total number of registrations
		Non-GHTF Economies	GHTF Economies					
			United States	Australia	Canada	Japan	European Union	
	% of the registered implantable medical devices in Malaysia							
2013	0.0	5.1	21.5	18.8	17.0	4.5	33.1	39
2014	0.4	0.0	24.9	15.3	14.3	3.8	41.3	257
2015	0.1	0.1	24.3	14.0	15.2	2.9	43.4	997
2016	0.9	0.4	20.9	13.8	14.0	6.2	43.8	450
2017	6.0	0.0	21.2	10.6	9.5	6.8	45.9	182
5 Years	0.88	0.26	23.24	14.03	14.22	4.04	43.32	1,925

Part of the registration requirements enforced by the Malaysian MDA is the need for each IMDs to be evaluated by the authorised Conformity Assessment Body (CAB) prior to submission of the registration application. Table IV shows the 16 CABs have been involved in the assessment of the IMDs registered in Malaysia between 2013 and 2017. Majority of the assessments were performed by the MEDCERT (23.2%), SGS (22.2%) and TbV Nord (17%), which are CABs originated from the GHTF economies. Together with another 4 CABs namely TbV SbD, BSI Services, DQS Certification and TbV Rheinland, these CABs were instrumental in the registration of the 1202 (73.6%) IMDs in Malaysia during the 5-year period.

The remaining 723 (26.4%) of the IMDs were assessed by the CAB from non-GHTF origin namely CARE Certification International (11.6%), CI International Certification (6.4 %), KGS Certification (4.1%), SIRIM QAS International (3.0%), Genuine Diamond (1.0%) and Platinum Shauffmantz Veritas (0.3%).

Table IV: Profile of the implantable medical devices registered via Malaysia MedC@ast between 2013 to 2017 from the perspective of the Conformity Assessment Body (CAB) that conduct conformity assessment

GHTF Status	Conformity Assessment Body (CAB)	% of the registered implantable medical devices in Malaysia					
		Year					5 Years
		2013	2014	2015	2016	2017	
GHTF	TÜV SÜD (Malaysia) Sdn. Bhd.	30.8	9.7	4.1	2.0	5	4.8
	MEDCERT Malaysia Sdn. Bhd	2.6	42.8	18.7	22.0	51	23.2
	SGS (Malaysia) Sdn. Bhd.	23.1	28.4	28.8	8.2	21	22.2
	BSI Services Malaysia Sdn. Bhd.	0.0	0.0	4.8	4.2	5	3.7
	DQS Certification (M) Sdn. Bhd.	2.6	0.0	2.5	2.4	1	2.0
	TÜV Rheinland Malaysia Sdn. Bhd.	2.6	0.4	0.7	0.9	0	0.7
	TÜV NORD (Malaysia) Sdn. Bhd.	0.0	4.7	16.8	23.6	43	17.0
	SIRIM QAS International Sdn. Bhd	5.1	0.0	4.5	1.8	3	3.0
	CARE Certification International (M) Sdn. Bhd.	7.7	1.9	9.9	21.6	20	11.6
Non-GHTF	CI International Certification Sdn. Bhd.	17.9	10.9	4.3	5.6	20	6.4
	KGS Certification Sdn. Bhd	2.6	1.2	4.1	6.2	5	4.1
	Platinum Shauffmantz Veritas Sdn. Bhd.	5.1	0.0	0.1	0.4	0	0.3
	Genuine Diamond Sdn. Bhd.	0.0	0.0	0.7	1.1	8	1.0
	Total Number of Registration	39	257	997	450	182	1925

DISCUSSION

The five-year study illustrated the sudden surge of IMDs registration applications in 2015, it was contributed most likely due to the owner and manufacturers of the IMD's in Malaysia market adhered with the enforcement grace period deadline announced by MDA (7). It may have included both existing and new product IMDs to be registered before the enforcement deadline announced by MDA on June 2015 (2). While the second high registration in 2016 is most likely contributed by the extension of the deadline to June 2016 (2, 38). Further, the small percentage (< 8%) of the applications that were filed by manufacture themselves reflects the nature of the IMDs in Malaysia which are mostly imported (30). Hence, the attention to file registration application by the overseas manufactures reflects the economic importance of the IMDs in Malaysia. It could be related to the higher percentage of IMDs under the risk class C (50.4%) which likely to reflect the higher demands for the orthodontics services and orthopaedic surgery including due to the motor vehicle accidents. The IMDs description indicated that most of it falls into the non-active implants, non-active orthopaedic implants, and dental material technical areas (22, 50, 51).

It is believed that the similarity of the medical device laws with the GHTF economies has influenced the large presence of its IMD in the Malaysian market. The similar risk classification allows easy differentiation and adoption of technical documentation to satisfy the Malaysian laws as compared to others (3, 15, 22, 37). Majority of the registered IMDs are imported from United States of America and European Union (31, 48) shows the IMDs in Malaysia adhered to the high degree of standards of quality, efficacy and safety assessment on par with these foreign economies (12, 27, 44, 51) that commands global recognition (21, 24). Moreover the high percentage (98.9%) of registered IMDs already obtained prior pre-market approval from the GHTF economies particularly European Union (29, 42) and the USFDA (44). gave assurance on the comprehensive evaluation in compliance with international standards including ISO 10993. The consideration of the foreign prior pre-market approval by MDA has also encouraged the faster and reliable approval process via the verification (34) process of the IMDs while ensuring reliability. The higher involvement by the CAB originated from the GHTF countries in Malaysian registration could be due to the fact that majority of the implants registered were imported from the GHTF countries (88.6%) as shown at Table I. The results also shows the lacks of involvement by CABs of Malaysian origins. The variation between the CABs could also be contributed by the availability of assessor having the competence in evaluating the IMDs (34).

CONCLUSION

The study results conclude the IMD is economically important in Malaysia based on the continual new application of more than 150 IMDs annually since 2014. The economies associated with the GHTF showed apparent influence on the IMD registered in Malaysia whereby 88.5% are manufactured, 98.9% obtained prior approval and 73.6% are assessed for conformity by entities originating from the GHTF economies. Among the GHTF economy, largest contributor to the registration of IMD in Malaysia for the 5-year duration (2013-2017) is the manufacturer from USA. Therefore

manufacturers, medical device authorities and the conformity assessment bodies of the GHTF origin play instrumental role in the availability of the IMDs in the Malaysian market while assuring high compliance of quality, efficacy and safety to patients equivalent to the those marketed in the respective GHTF economies.

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