A SURVEY ON THE UTILIZATION OF DENTAL DEVICES IN MALAYSIA

A report on a survey on the utilization of dental devices in Malaysia (as part of medical device utilization survey) for the Ministry of Health Malaysia under the Project WP/2006/MAA/BCT/3.2/001 AC.01.01.01.AW sponsored by the World Health Organization

by

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EXECUTIVE SUMMARY

The Ministry of Health Malaysia (the "Ministry") recognized the need to carry out studies to gather pertinent information on the present situation prior to the development and implementation of a regulatory system for the control of medical devices in Malaysia. The studies will put the present situation into a proper perspective and hence assist the Ministry to identify the issues and challenges related to medical devices. It was envisaged that this will help the Ministry to manage and address the issues and challenges by establishing and implementing an effective regulatory system.

Having accurate information on the utilization and the industry of medical device is one of the many important steps in formulating an effective regulatory system and the Ministry took a step to conduct a Survey on Medical Devices Utilization in Malaysia (the "Survey"). However, as an initial step, it only focused on the devices used in dental practice ("dental devices").

This Survey was funded by the WHO under the Project WP/2006/MAA/ BCT/3.2/ 001. The primary objective of this Survey was to address part of the fundamental concern of getting reliable measurement on the magnitude and range of medical devices currently available on the Malaysian market. It also attempted to gather the reactions and concerns of the relevant stakeholders, especially vendors and users of dental devices to assist the Ministry in formulating a feasible and less problematic system.

End-users and suppliers of dental devices were two target groups from where most of the required information was gathered. The end-users were mainly professional dentists, including general and specialist dental practitioners, from various types of end-users' establishments in both the Government and private dental practices. The sample of end-users represented a total of 414 qualified dental practitioners, comprising 220 general dental practitioners and 194 dental specialists from 123 end-users' establishments throughout Peninsular Malaysia. The suppliers included in this Survey were selected from a list of suppliers obtained during the survey on end-users. A total of 30 companies supplying dental devices were included to form the sample for suppliers in this Survey; 16 of them supplied dental devices only, whilst 13 supplied dental and other medical devices. They were mainly from Klang Valley and they varied in their sizes and the range of devices they supplied. The sample of suppliers represents distributors, marketing arm of foreign manufacturers and dental laboratories.

A list of dental devices obtained from this Survey provides an in-sight on the range and volume of dental devices available for use in Malaysia. There were more than 500,000 units from 414 dental device (199 types were equipment and instruments and 214 types were consumables and materials) items included in the list of dental devices, of which more than 95,000 units were equipment and instruments and more than 450,000 units were consumables and materials.

On the Ministry's proposal to introduce medical device regulations, there were mixed reactions amongst the end-users and suppliers of dental devices. The key

positive reaction to the proposed regulations was that it would lead to better quality, safer and more reliable devices. Deep-rooted fears and concerns were held by both end-users and suppliers. Their active participation and cooperation are crucial for a new policy to work, and to achieve this, they need to believe and understand that the Government has the best interests of all parties, including end-users and suppliers, general public as well as the Malaysian healthcare services and industry. Efforts need to be directed to overcome apprehensions and fears of end-users and suppliers to ensure a successful outcome to the introduction and implementation of the new medical devices regulations.

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1 INTRODUCTION

Realizing the many issues and challenges related to medical devices, the Ministry of Health Malaysia (the "Ministry") is keen to develop and implement a regulatory system for the control of medical devices in Malaysia. It is aimed at;

(i) protecting public health and safety;

(ii) allowing patients for earlier access to new technology; and

(iii) facilitating trade and medical device industry.

The proposed regulatory system will be in-line with the recommendations of the World Health Organization (WHO)[1] and Global Harmonization Task Force (GHTF)[2] and the scope covers the entire life span of medical device.

The Ministry has come up with an action plan and identified important milestones in the development and implementation of the regulatory system. Thus far, the Ministry has developed various standards and draft guidance documents on various aspects of medical device regulatory system. In 2005, the Ministry established a dedicated organization called the Medical Devices Bureau entrusted to develop and implement medical device regulatory system in Malaysia. Subsequently, a voluntary registration scheme for establishments dealing with medical devices in Malaysia was launched in 2006. Draft Medical Devices Bill has been prepared to provide a legislative support for the proposed regulatory system.

2 RATIONALES

Due to lack of information related to medical devices, the Ministry recognized the need to carry out studies to gather pertinent information on the present situation in Malaysia. The studies will put the present situation into a proper perspective and hence assist the Ministry to identify the issues and challenges related to medical devices. It was envisaged that this will subsequently help the Ministry to manage and address the issues and challenges by establishing and implementing an effective regulatory system.

The term medical device refers to medical technology, supplies and equipment. It encompasses the very broad range of health care products used in health care for the diagnosis, prevention, monitoring or treatment of illness or handicap but exclude drugs. In contrast with medicinal product the intended primary mode of medical device action to human body is not metabolic, immunological or pharmacological.

GHTF defines medical device as any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article;

a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of;

1 World Health Organization, Medical Device Regulations: Global overview and guiding principles, WHO Geneva Switzerland. ISBN 92 4 1546182, 2003

2 GHTF www.ghtf.org is a voluntary body which was established in 1993 by the governments and industry representatives of Australia, Canada, Japan, the EU and the USA in an effort to harmonize the regulatory practices to ensure safety and effectiveness of medical devices

- diagnosis, prevention, monitoring, treatment or alleviation of diseases;
- diagnosis, monitoring, treatment, alleviation of or compensation for injury;
- investigation, replacement, modification, or support of the anatomy or of a physiological process;
- supporting or sustaining life;
- control of conception;
- disinfection of medical devices;
- providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body;

and

b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means[3].

The variety and volume of medical devices available on the market and use in the health care system is huge ranging from relatively simple devices such as gloves and contact lenses to sophisticated equipment such as CT machines and high risk implanted devices such as heart valves and defibrillator. WHO estimated that in 2000, approximately 1.5 million different medical devices worth over US$145 billion were available on the global market. This figure is expected to exceed US$260 billion in 2006[4]. Capturing and having accurate information on the utilization and the industry of medical device is one of the many important steps in formulating an effective regulatory system.

With that in mind, the Ministry took a step to conduct a Survey on Medical Devices Utilization in Malaysia (the "Survey"). However, considering the huge variety and volume of medical devices, the Ministry took a "step-by-step" approach in conducting the Survey to make it more manageable. This Survey will be undertaken in phases and as an initial step it only focused on the devices used in dental practice ("dental devices"). Besides gathering information about the devices, it was also the intention of this Survey to look into the general reactions towards the introduction of the regulatory system amongst the professionals involved in dental service as well the suppliers of dental devices in Malaysia. Their inputs and feedback would be taken into consideration in formulating the proposed regulatory system.

This Survey was funded by the WHO under the Project WP/2006/MAA/ BCT/3.2/ 001.

3 OBJECTIVES AND SCOPE

The primary objective of this Survey was to address part of the fundamental

3 GHTF SG1, GHTF Information Document Concerning the Definition of the Term "Medical Device" GHTF/SG1/N29, 2005

4 World Health Organization, Medical Device Regulations: Global overview and guiding principles, WHO, Geneva, Switzerland. ISBN 92 4 1546182, 2003

concern of getting reliable measurement on the scope and magnitude of medical devices currently available on the Malaysian market. In addition, it attempted to gather the reactions and concerns of the relevant stakeholders, especially vendors and users of dental devices to assist the Ministry in formulating a feasible and less problematic system.

Specifically, this Survey was aimed at accomplishing the following objectives:

(i) Establishing the range of dental devices (and their intended purposes and intended users) currently available for use in Malaysia;

(ii) Estimating the magnitude of dental devices currently in use, amongst various user groups;

(iii) Developing a framework for a medical device register that will list the range and magnitude of dental devices available for use in Malaysia.

(iv) Developing a list of suppliers of dental devices in Malaysia; and

(v) Soliciting opinions from both users and suppliers of dental devices on the introduction of medical device regulations in Malaysia.

As an initial phase of a bigger medical device utilization survey and consistent with the Ministry's "step-by-step" approach, the scope of this Survey was only confined to dental devices used in dental practices covering general and specialist dental practices in hospitals and non-hospitals (clinics) both in Government and private sectors in Malaysia.

4 METHODOLOGY/APPROACH

Essentially, the approach of the Survey was by making contact and interacting with the target groups of respondents, namely end-users and suppliers of dental devices available for use in various dental practices in Malaysia.

The end-users were representatives, mainly professional dentists, from end-users' establishments in both the Government and private dental practices, which include hospitals, specialist and general dental clinics, throughout Peninsular Malaysia. The end-users' establishments included in this Survey were selected from the database maintained by Oral Health Division of the Ministry. The suppliers included in the Survey were selected from the list derived from the interaction with end-users. They represented local companies supplying dental devices for use in dental practices at various end-users establishments.

The survey on end-users primarily focused on obtaining information regarding the types of dental practices as well as an estimate of the range and magnitude of dental devices used within their establishments. The data collected include particulars of dental practices and data pertaining to the devices including the suppliers of the devices. From the survey on end-users, a list of the suppliers of devices was also obtained.

The suppliers included in this Survey were selected from the list of suppliers obtained during the survey on end-users. Similarly, the data collected from suppliers were basic information about the suppliers and an estimation of the variety and volume of dental devices.

In addition to obtaining information about the establishments and an estimation of the range and magnitude of dental devices, both groups of respondents were

interviewed to obtain their views on various aspects of medical device regulatory control.

The principle means of collecting the data was using 2 sets of questionnaires to be completed by each target group of respondents. The first set of questionnaires was used to obtain the information on the devices. In addition the questionnaires, a booklet was prepared based on the information obtained from Oral Health Division. The booklet contained 2 sets of devices lists; one list for equipment and instruments (where 215 different items were listed) and another for materials and consumables (199 different items). The second set of questionnaires was used to obtain information on the establishments and the views of respondents on various aspects of medical device regulations. Common questions were asked to both suppliers and end-users, where necessary, to facilitate comparisons.

Respondents were left with the first set of questionnaires and the booklet containing the lists of devices earlier prior to the visit. They were requested to complete the questionnaire and the lists of devices. In completing the lists of devices, respondents were also asked to include other devices that were not in included in the lists.

Visits and interviews were conducted to validate and verify the data and to complete the task of getting their views on various aspects of medical device regulatory control. The views on various aspects of the regulatory control were sought usually from a qualified dental practitioner at the end-user's establishment and from senior managerial personnel of the supplier.

Interactions with the Ministry's officials were also made whenever necessary to discuss issues and areas that need clarifications.

5 FINDINGS AND DISCUSSION

5.1 Sample

In order to get a good representation of the population of end-users' establishments, the Survey included a sample of 123 end-users' establishments located throughout Peninsular Malaysia, covering both Government (which includes Ministries of Health (MoH), Education (MoE and Defense (MoD) and private sectors whether in hospitals and non-hospitals (clinics) offering specialist and general dental services. The sample of end-users represented a total of 414 qualified dental practitioners, comprising 220 general dental practitioners and 194 dental specialists, which include oral surgeons, orthodontists, pedodontists, endodontists & prosthodontists and periodontists.

As for the suppliers, a total of 30 companies supplying dental devices were included to form the sample for suppliers in this Survey; 16 of them supplied dental devices only, whilst 13 supplied dental and other medical devices. Most of the suppliers included in this Survey were from Klang Valley as majority of them were based in Klang Valley. In order to get a good representation of suppliers, a variation of different suppliers' companies were included. They varied in their sizes and the range of devices they supplied and comprised of companies who supplied dental devices only as well as companies who supplied both dental and other medical devices. Some companies only focused on specialized niche devices whilst some distribute the whole range of devices covering equipment,

instruments, consumables and disposables. The sample of suppliers represents distributors, marketing arm of foreign manufacturers and dental laboratories.

5.2 End-users

5.2.1 Locations and establishments type

Table 1 shows the geographical locations of the end-users' establishments included in this Survey. It shows that 60 (49%) of the end-users establishments were from Klang Valley while the remaining approximately evenly divided amongst Northern, Southern and East Coast regions. Twenty five (42%) were Government dental practices and 98 (80%) were non-hospitals (clinics). Table 2 shows that the types of establishments include Government and private hospitals and non-hospitals (clinics) whilst the types of practices include general or specialist dental practices. A specialist dental practice has the services of at least one dental specialist whilst a general dental practice has no services of dental specialist. The sample comprised of approximately an equal composition of specialist and non-specialist dental practices. Sixty one (49%) establishments have specialist services, of which 33 (54%) were Government establishments. Clinics have more (30%) specialist services compared to hospitals (19%).

Region	*Type of end-user's establishment*				*Number of establishment*
	Government hospital	*Government clinic*	*Private hospital*	*Private clinic*	
Klang Valley	6	14	5	35	60
Northern	6	8	1	8	23
Southern	3	6	0	13	22
East Coast	4	4	0	10	18
TOTAL	19	32	6	66	123

Table 1: Geographical locations of the participating end-users establishments

Type of establishment and practice	*Number (percentage)*
Government hospital (general)	1 (1)
Government hospital (specialist)	18 (15)
Government clinic (general)	17 (14)
Government clinic (specialist)	15 (12)
Private hospital (specialist)	6 (4)
Private clinic (general)	44 (36)
Private clinic (specialist)	22 (18)

Table 2: Types of end-users establishments and practices

5.2.2 Groups of end-users

Table 3 shows a total of 414 dental practitioners included in the Survey. Of all the practitioners, 220 (53%) were general dental practitioners whilst the remaining 194 (47%) were specialists; of whom 142 (75%) practiced in Government

establishments. Majority of them (48%) were oral surgeons and orthodontists. Periodontists, paedodontists and endodontists/prosthodontists were each almost equally represented.

	Group of specialist									
	General	*Specialist*	*Oral surgeon*	*Ortho-dontist*	*Perio-dontist*	*Paedo-dontist*	*Endo/ prostho*	*Public health*	*Others*	*TOTAL*
MoE/MoD	13	93	16	8	11	8	11	10	29	106
MoH	126	52	18	17	5	11	0	1	0	178
Private	81	49	13	21	3	2	9	1	0	130
TOTAL	220	194	47	46	19	21	20	12	29	414

Table 3: Groups of dental practitioners included in the Survey

5.2.3 Workload

Table 4 shows end-users' workload in terms of the average number of patients per month. The average workload was 214 comprising of 42% new patients and 58% repeat patients. Forty six percent have a workload of between 50 and 200 patients per month and 53% of the establishments have less than 200 patients per month (or less than 10 patients per day; assuming a 5-day week). Sixteen percent of the establishments have an average workload exceeding 400 patients per month (or more than 20 patients per day).

Workload (average number of patients per month)	*Percentage of establishments*
<50	7
51-100	18
101-150	12
151-200	16
201-250	11
251-300	6
301-400	14
401-500	9
501-600	4
>600	3
Overall average	214
Percentage of new patients	42%
Percentage of repeat patients	58%

Table 4: Workload (average number of patients per month)

5.2.4 End-users' preference

End-users were asked the frequency of their purchase from three different categories of suppliers, namely local suppliers, local manufacturers and foreign manufacturers to get an indication of their preferences on suppliers. Table 5 shows that local supplier was the primary (more than 85%) source for the supplies of dental devices.

Frequency	*Local suppliers*	*Local manufacturers*	*Foreign manufacturers*
Never (1)	0 (0%)	75 (61%)	97 (80%)
Seldom (2)	0 (0%)	17 (14%)	10 (8%)
Sometimes (3)	3 (2%)	12 (10%)	6 (5%)
Often (4)	11 (9%)	9 (7%)	2 (1%)
Always (5)	104 (85%)	4 (3%)	2 (1%)
Don't Know	5 (4%)	6 (5%)	6 (5%)
Average rating	4.7	1.6	1.2

Table 5: Frequency of purchase from different suppliers

5.2.5 Implementation of quality assurance program (QAP)

Forty six percent of the establishments indicated that they implement QAP and majority (82%) were Government establishments. Of those who implemented QAP, ISO 9001:2000 was the most common (74%) program. Of the 57 establishments implementing QAP, 48% had more than one standard in use, including the Ministry of Health's QAP, National Accreditation Program and Occupational Health and Safety Act.

5.3 Suppliers

5.3.1 Location of suppliers and devices supplied

A total of 30 companies supplying dental devices were included in the Survey. They comprised of large and smaller companies who import, market and distribute dental devices, companies who act as marketing arms of foreign manufacturers and dental laboratories. Twenty eight (93%) of the suppliers were from Klang Valley, whilst the other 2 were from Northern region (specifically from Penang). Of all the suppliers, 16 (53%) supplied dental devices only, whilst about 43% supplied dental and other medical devices. Of the dental devices, materials and consumables were supplied by 25 (86%) of the suppliers whilst equipments and instruments were distributed by 22 (76%) of them.

5.3.2 Annual turnover

Table 6 shows the annual turnover of dental suppliers' companies. As shown in Table 6, the annual turnover of dental device suppliers varies considerably, ranging from less than RM 1 million to RM 20 million. About 45% of the suppliers have an annual sales turnover of less than RM 3 million and about 14% have an annual turnover of over RM10 million.

Annual turnover (RM)	*Number (percentage) of suppliers*
< 1 million	5 (17)
1-3 million	8 (28)
4-10 million	6 (21)
11-20 million	4 (14)
Not Available	7 (23)

Table 6: Annual turnover of the suppliers

5.3.3 *Registration with Ministry of Finance and business with Government sector*

Most (70%) of the suppliers were registered with the Ministry of Finance. Of those who were not registered with Ministry of Finance, 89% had registered agents to enable them to bid for Government tenders. Almost all (93%) suppliers supplied to both the Government and private sectors as shown in Table 7. Only 2 (7%) suppliers supplied only to private sector. The dependency of the business with Government sector varied of which 33% of the suppliers have over 60% of their business from Government establishments and 37% of the suppliers have less than 40% of their business derived from Government sector.

Percentage of turnover from business with Government sector	*Number (percentage) of establishments*
0%	2 (7%)
1%-20%	4 (13%)
21%-40%	5 (17%)
41%-60%	9 (30%)
61%-80%	6 (20%)
81%-100%	4 (13%)
Don't Know	0 (0%)

Table 7: Contribution from business with Government sector

5.3.4 *Supply and export of Malaysian manufactured products*

Suppliers were asked whether they supplied Malaysian manufactured products direct to Government or private sectors. About 30% acknowledged that they supplied locally manufactured dental devices to end-users establishments. The suppliers were also asked whether they exported Malaysian manufactured dental devices to other countries. Only 3 (10%) suppliers exported Malaysian manufactured products to other countries. The products were mainly exported to ASEAN countries, especially Singapore, Indonesia and Thailand. Taiwan was the only non-ASEAN country mentioned.

6 DENTAL DEVICES

6.1 Expenditure pattern on dental devices

Table 8 shows the average end-users' annual expenditure pattern to get a comparison of the estimated annual expenditure in dental practice. As shown in Table 8, the average annual spending on consumables and materials was about 6% more than that on equipment and instruments. Comparisons with the annual spending on drugs indicated that expenditure on equipment and instruments was 23% more, whilst the expenditure on consumables and materials was 31% more. Majority of the establishments have relatively small budgets (less than RM 30,000) for expenditures on the three items. Fifty percent of the establishments have an annual expenditure of less than RM 10,000 for drugs, compared with 41% for equipment and instruments and 24% for consumables and materials.

Range of annual expenditure (RM)	*Drugs*	*Equipment & instruments*	*Consumables & materials*
Less than 10,000	62 (50%)	50 (41%)	30 (24%)
10,000-30,000	15 (12%)	25 (20%)	35 (29%)
30,001-50,000	14 (11%)	13 (11%)	15 (12%)
50,001-100,000	2 (2%)	12 (10%)	18 (15%)
100,001-500,000	4 (3%)	6 (5%)	9 (7%)
500,001-1,000,000	0 (0%)	0 (0%)	0 (0%)
More than 1,000,000	2 (2%)	3 (2%)	3 (2%)
Don't Know	24 (20%)	14 (11%)	13 (11%)
Average (RM '000)	185	228	242

Table 8: Annual expenditure on drugs, equipment and instruments and consumables and materials

6.2 Contribution of dental devices to suppliers' turnover

Suppliers were asked to indicate the proportion of their annual turnover from the sales of dental devices and the result is tabulated in Table 9. The result shows that the average annual turnover from sales of equipment and instruments was higher (50%) compared to the average annual turnover from the sales of consumables and materials (48%). There was no contribution from the sales of equipment and instruments to the annual turnover of 24% of the suppliers, whilst 14% of the suppliers received no contribution from the sales of consumables and materials. A contribution between 1% and 60% to the annual turnover was received from the sales of equipment and instruments for 64% of the suppliers and from the sales of consumables and materials for 51% of the suppliers. The sales of consumables and materials contributed remarkably (exceeding 80%) to the annual turnover of 28% of the suppliers.

Percentage of annual turnover	*Equipment and instruments*	*Consumables and materials*	*Others*
0%	24%	14%	86%
1%-20%	26%	3%	14%
21%-40%	26%	31%	
41%-60%	12%	17%	
61%-80%	12%	7%	
81%-100%	2%	28%	
Average	50%	48%	2%

Table 9: Contribution from the sales of two categories of dental devices to the annual turnover of the suppliers

6.3 Use of high cost dental devices

For the purpose of this Survey, a high cost device was defined as a device that costs more than RM 50,000. End-users were asked to indicate the number of such devices they had within their establishments, how many were purchased within the past year and how many were expected to be purchase within the next year. The finding is tabulated in Table 10. The average number of high cost devices used within an establishment was 3.5. Thirty three (27%) establishments

had at least 5 high cost devices whilst 12% had no high cost devices. Majority (80%) of the establishments did not purchase any high cost devices during the past year. The pattern for the coming year was similar, with 72% did not expect to make any purchase of high cost devices.

Number of high cost devices	*Number of establishments*	*Number of establishments buying in the past 12 months*	*Number of establishments intend to buy in the next 12 months*
0	15	98	89
1	26	15	15
2	26	4	10
3	16	1	3
4	7	2	3
5	10	0	1
6-7	8	1	0
8-10	8	1	1
>10	7	1	0
Don't Know	0	0	1
Average	3.5	0.53	0.57

Table 10: High cost devices used in dental practices

6.4 Country of origin

Table 11 shows the responds on the countries of origin of the dental devices. Europe and USA were, by far, the two most prominent regions where the devices were originated. Within Europe, Germany was the main country and others were Italy, Switzerland and United Kingdom. Within Asia, Japan was the most prominent followed by China/Taiwan. India/Pakistan was also indicated by both end-users and suppliers. On average, respondents mentioned 3 or 4 different countries where their devices come from.

Country of origin	*Number (percentage) of end-users*	*Number (percentage) of suppliers*
Europe	110 (90)	29 (97)
USA	101 (83)	22 (72)
Japan	66 (54)	10 (34)
China/Taiwan	41 (34)	10 (34)
India/Pakistan	36 (30)	6 (21)
Australia	23 (19)	5 (17)
Korea	11 (9)	4 (14)
Canada	9 (7)	3 (10)
Others	6 (5)	1 (3)

Table 11: Country of origin of dental devices

6.5 *Range and volume of dental devices*

6.5.1 Estimation of range and volume of dental devices

From the survey, a list of dental devices was obtained based on the responses from 119 end-users' establishments. The list is attached as Appendices 1 and 2. This list provides an in-sight on the range (arranged in alphabetical order) and the volume (in terms of the relative percentage) of dental devices available for use in Malaysia. There were 547,448 units (97,291 units equipment and instruments and 450,157 units consumables and materials) from 414 dental device items. These dental device items can be categorized into 5 main categories, namely;

(i) Equipment such as sterilizer, air compressors, mixers, dental chairs, X-ray machines, intra-oral cameras, amalgamators and curing units;

(ii) Instruments used for extraction and restoration procedures such as pliers, excavators, tweezers, probes, forceps and amalgam carvers;

(iii) Consumables are disposables items such as cotton balls, rolls, gauze, cups, gloves and face masks;

(iv) Dental materials such as fillings or dental cements, alloy amalgams and resins;

(v) Reusable instruments are those that are washable, sterilized and reused such as trays, forceps, pliers, mouth mirrors and probes.

All the devices included in the list were generally used by all types of users' establishments. The utilization of sophisticated or state-of-the-art equipment was very much dependent on the location of an establishment and the volume of business, not the type of service. For example, a dental X-ray machine was necessary even for a private clinic. In general, most hospitals (either Government or private) have the full range of equipment to support their roles as the major healthcare providers.

6.5.2 Equipment/instruments

The result of the Survey shows that of all the 215 equipment and instruments listed in the booklet, 213 equipment/instruments were available somewhere within at least one establishment. Table 12 shows the availability of equipment/ instrument within the end-users' establishments, whilst Table 13 shows 10 most available equipment/instruments within end-users' establishments.

Number of equipment/ instrument per establishment	*Number (percentage) of the listed equipment/instrument*
At least 1	87 (40%)
At least 2	57 (27%)
At least 5	30 (14%)
At least 10	17 (8%)
At least 20	10 (5%)

Table 12: Availability of the listed dental equipment/instrument within the end-users' establishment

No	Name of equipment/instrument	Frequency	Average number per establishment
1)	Suction tips	19,623	164
2)	Extraction forceps	6,544	55
3)	Mirror tops	4,378	36
4)	Mirror handles	4,078	34
5)	Impression trays	3,735	31
6)	Elevators	3,054	25
7)	Dental probes	2,982	25
8)	Instrument trays	2,696	22
9)	Tweezers	2,552	21
10)	Plastic filling instruments	2,507	21

Table 13: Ten most available dental equipment/instrument within end-users' establishments

There were 87 (40%) of all the listed equipment/instruments used at least one unit in each establishments; 57 (27%) were used at least two units in each establishment; 30 (14%) were used at least five units in each establishment; 17 (8%) were used at least ten units in each establishment; 10 (5%) were used at least 20 units in each establishment. Amongst the equipment/instruments available within end-users' establishments, suction tip was the most available equipment/instrument; there were almost 20,000 units recorded in the Survey with an average of 164 units per establishment. The second most available was extraction forceps; 6,544 units recorded and average 55 units per establishment. This was followed by mirror top; 4,378 units recorded with an average of 36 units per establishment.

6.5.3 Materials/consumables

Of all the 199 materials/consumables listed in the booklet, 197 materials/ consumables were available somewhere within at least one establishment. Table 14 shows the availability of materials/consumables within the end-users' establishments, whilst Table 15 shows ten most available equipment/instruments within end-users' establishments.

Number of material/consumable per establishment	Number (percentage) of the listed material/consumable
At least 1	115 (58%)
At least 2	93 (47%)
At least 5	63 (32%)
At least 10	40(20%)
At least 20	28 (14%)
At least 50	13 (7%)

Table 14: Availability of the listed dental material/consumable within the end-users' establishment

No	Name of equipment/instrument	Frequency	Average number per establishment
1)	Disposable cups	98,571	821
2)	Disposable sucker tips	60,447	504
3)	Disposable bibs	47,233	394
4)	Dispensing envelopes	45,503	34
5)	Impression trays	3,735	31
6)	Elevators	3,054	25
7)	Dental probes	2,982	25
8)	Instrument trays	2,696	22
9)	Tweezers	2,552	21
10)	Plastic filling instruments	2,507	21

Table 15: Ten most available equipment/instruments within end-users' establishments

There were 115 (58%) of all the listed materials/consumables was available at least one unit in each establishments; 93 (47%) were available at least two units in each establishment; 63 (32%) were available at least five units in each establishment; 40 (20%) were available at least ten units in each establishment; 28 (14%) were available at least 20 units in each establishment and 13 (7%) were available at least 50 units in each establishment. Amongst the materials/consumables available within end-users' establishments, disposable cup was the most available disposable/consumable; there were almost 100,000 units recorded in the Survey with an average of 821 units per establishment. The second most available was disposable sucker tip; 60,447 units recorded and average 504 units per establishment. This was followed by disposable bibs; 47,233 units recorded with an average of 394 units per establishment.

6.5.4 Classification and nomenclature of devices

Even though the devices were classified according to the level of risk, the classification was not in accordance with and not following the classification rules as recommended in the GHTF classification system[5]. A separate exercise would be required to classify the devices in accordance with the GHTF classification system. For the purpose of this Survey, low risk devices (denoted as L in the list in Appendix 1) were mainly consumables such as cotton balls, gauze, tongue depressor, cups, certain instruments and equipments that are not used on patients; medium risk devices (denoted as M) were those devices that were used in contact with patient on a short transient time such as syringes, needles, sutures, pliers, probes, etc; and high risk devices (denoted as H) were devices that were implanted such as fillings, amalgam and resins.

6.5.5 Suppliers

A list of suppliers of dental devices was also obtained from the feedback received from the dental practitioners. A total of 87 suppliers were identified during the Survey. However, the list is not included in this report as a pledge of the Ministry not to reveal the identity of the contributing respondents and participating establishments. As indicated earlier, they were mainly based or have their head offices in Klang Valley.

5 GHTF SG1, Principles of Medical Devices Classification, SG1-N15:2006

7 OPINIONS AND VIEWS ON VARIOUS ASPECTS OF MEDICAL DEVICE REGULATORY CONTROL

In order to gauge their thoughts and feelings on various aspects of medical device regulations, respondents were presented with a series of statements and asked to indicate the extents to which they agreed or disagreed with the statements. The statements were presented to the respondents with the aim of gathering their opinions and views on the following;

(i) The need for regulations to ensure public safety;

(ii) Limitation of the scope to cover high risk devices only;

(iii) The impact of regulations on the price of medical devices;

(iv) The appropriate body to introduce the regulations;

(v) The responsible party for conducting risk assessment.

A 5-point scale was used to assess the level of their agreement on a statement. Scale '1' meant 'strongly disagree' and '5' meant 'strongly agree'. The results obtained from the rating of these statements were indicative of the thoughts and feelings of the respondents.

7.1 The need for regulations to ensure public safety

The statement was presented to get an indication on the level of agreement of respondents on different scope of regulatory control. The statement was presented as follows;

> *There should be a high level of regulatory control introduced on medical (and dental) devices to ensure public safety on;.*
>
> *(i) the **use** of medical (and dental) devices*
>
> *(ii) the **maintenance** of medical (and dental) devices*
>
> *(iii) **suppliers** of medical (and dental) devices*
>
> *(iv) **local manufacturers** of medical (and dental) devices*
>
> *(v) **imported and exported** medical (and dental) devices*

Table 16 summarizes the responds reflecting the views of respondents on the need for regulations specifying the differing scope of control. It shows that the respondents (both end-users and suppliers) generally agreed that there was a need for regulatory control of medical (and dental) devices for ensuring public safety. Overall, there was a high level of agreement with the all the 5 scopes of the regulations whereby all the 5 scopes had more than 70% respondents scoring at least 4 points (slightly agree). However, there was a small percentage (16%) of suppliers who disagreed on the control on suppliers and another 7% chose not to reveal their stands. Amongst the end-users, this trend was lesser, whereby only 9% disagreed over the control on the use of devices and another 6% chose to reserve their comments.

The initial reaction to the introduction of the regulations was generally favorable, as it was perceived to lead to better quality and safer devices being used. Many end-users and suppliers readily commented on the betterment or improved quality of products when thinking about the introduction of regulations. Control was linked

not only to quality but also to safety. The two concepts of 'quality' and 'safety' were often linked together and the link of control and quality of device seemed to be automatic and very strong. Control also meant the exclusion of inferior quality devices being imported into the country, thereby preventing the dumping of out-dated or inferior devices from entering the country. It was also felt the one of the purposes of the control of the users was to limit bogus use of medical devices and to prevent the use of the device by unapproved practitioners. However, the respondents cautioned that the control needs to be done thoroughly because end-users may become less vigilant in their selection of purchases simply because they expect that the devices would have been assessed.

Rating scale	*Percentage of respondents*									
	(i) use		*(ii) maintenance*		*(iii) suppliers*		*(iv) local manufacturer*		*(v) import & export*	
	End-user	*Supp-lier*	*End-user*	*Supp-lier*	*End-user*	*Supp-lier*	*End-user*	*Supp-lier*	*End-user*	*Supp-lier*
Strongly disagree (1)	4	0	2	3	3	3	3	0	2	7
Slightly disagree (2)	5	3	5	7	3	13	0	0	0	0
Neither agree nor disagree (3)	6	3	2	3	3	7	2	10	4	10
Slightly agree (4)	18	21	23	14	25	30	20	23	18	26
Strongly agree (5)	67	73	68	73	66	47	75	67	76	57
Don't know	0	0	0	0	0	0	0	0	0	0
Average of rating	4.4	4.6	4.5	4.5	4.5	4.0	4.6	4.6	4.6	4.3

Table 16: Percentage of respondents rating on the need for regulations to ensure public safety

However, on many occasions, while agreeing to the need for regulations, the respondents also expressed their concerns and fears. Amongst their concerns and fears include;

(i) The thought of regulations lead many respondents to wonder why it would be necessary. They wanted to know the rationales and the objectives, so that all ensuing policy directions of the control can be clearly seen. They expressed that policies need to be beneficial to Malaysian society, applied consistently without prejudice and in accordance with international standards and practice.

(ii) The respondents feared that regulations conjured up visions of rigid policy rules and guidelines. For the regulations to work, it needs the support of the key stakeholders. There were major concerns on the nature of the regulations, that there might be an 'overkill' that may lead to unnecessary restrictions imposed on the development of the industry and limitations in the services provided for the public.

(iii) Most of the suppliers import goods from Europe, USA and Japan which already implemented internal control measures. The concern was on the unnecessary product testing as this is generally seen as duplicity of work, time consuming and adding unnecessary costs.

(iv) It was generally felt that the regulations would reduce and limit the availability of devices on the market. If that was confined to the eradication of inferior devices, then this would be welcomed. However, it was feared that the regulations could lead to restriction of some good devices, especially if the regulations were inflexible and rigid.

(v) With the introduction of the regulations there was a major concern on the timely availability of a device to the patients as there may be excessive delays in getting a device to enter the market. The delays were expected to occur in the registration process and at the Customs entry points, particularly for imported devices.

(vi) There was also fear that the control would unnecessarily limit the choice of devices as well as suppliers and manufacturers. This might lead to the development of some "not so good" practices within the industry and lead away from the positive ethics of enhancing the healthcare industry and the welfare of patients.

7.2 Limiting the scope of medical device regulations

The following statement was put forward to the respondents to get an indication whether or not the scope of regulations should be limited to high risk devices;

Regulations should be limited for high risk devices only

There was a mixed response concerning whether regulations should cover all devices or whether it should be limited to high risk devices only.

Table 17 shows that although 72% of the end-users agreed with the statement, there was a marked difference in the level of agreement as compared to the level of their agreement on the need for regulatory control. At least 22% of the end-users disagreed to the statement, while another 5% did not indicate whether they agreed or disagreed. This trend was also seen amongst the suppliers; amongst the suppliers only 63% agreed with the statement, whilst a remarkable 37% disagreed. The results implicate that the respondents expected that the regulations should cover a wider range of medical (and dental) devices including lower risk devices.

Rating scale	*Percentage of respondents*	
	End-user	*Supplier*
Strongly disagree (1)	14	17
Slightly disagree (2)	8	20
Neither agree nor disagree (3)	5	0
Slightly agree (4)	29	13
Strongly agree (5)	43	50
Don't know	1	0
Average of rating	3.8	3.6

Table 17: Percentage of respondents rating on the limitation of regulations to high risk devices

For those who agreed, it was felt that it would be an administrative nightmare if all devices were to be regulated. The focus should be, at least initially on the higher risk devices. Some dental practitioners gave a more cautious response with an eye to what is considered practical. A minority of dental practitioners and suppliers felt that regulations and registration of dental devices were not necessary, indicating that the real responsibility fell on the users of the device and not the

device itself. Registration would only be appropriate if there were risks on a patient's health.

7.3 Impact of regulations on the price of medical device

The respondents were also asked whether they agree that regulations will cause higher price of medical (and dental) devices. The following statement was posed to them;

Regulations would cause significantly higher-priced products

As shown in Table 18, 63% of the end-users were of the opinion that regulations would lead to higher-priced products. As for the suppliers, 67% agreed that regulations would lead to higher-priced products.

Rating scale	*Percentage of respondents*	
	End-user	*Supplier*
Strongly disagree (1)	15	10
Slightly disagree (2)	9	17
Neither agree nor disagree (3)	11	7
Slightly agree (4)	25	30
Strongly agree (5)	38	37
Don't know	1	0
Average	3.6	3.7

Table 18: Percentage of respondents rating on higher-priced products due to regulations

Cost of regulations was seen as a significant disadvantage, because it will not be borne by the Government. The thinking was that with registration there would be a renewable fee charged for each eligible device that could be extended to cover product line extensions and every minor product variations. Such fees would need to be borne initially by the supplier, which in turn would be passed on to the end-user, the dental professional, who, in turn, would pass this on to the patient, resulting in a higher cost of treatment. There was also fear of abuse of the system, indirectly referring to possible corruption.

Besides registration fee, there will also be impact on administration, such as the consequent needs to hire more staffs to cope with the extra workload to apply for product registration. The perceived extra paperwork and the time taken to satisfy the paper-chase will require extra administrative cost. It was also fear that this may detract the focus from the main business of providing an effective and efficient service to patients.

However, besides the negative comments, it was also felt that the introduction of regulations would assist in the purchase of good acceptable equipments and instruments. Some had felt that there had been some poor decisions making in the past on purchasing policies, resulting in a waste of resources.

7.4 Body to introduce regulations

The following statement was posed to seek the opinions of the respondents on the appropriate body to introduce the regulations

The Government should play the leading role in introducing the regulations

As shown in Table 19, amongst the end-user, 19% disagreed, 71% agreed, including 56% strongly agreed. As for the suppliers 16% disagreed, whilst 63% agreed including 50% who strongly agreed.

Rating scale	*Percentage of respondents*	
	End-user	*Supplier*
Strongly disagree (1)	13	3
Slightly disagree (2)	6	13
Neither agree nor disagree (3)	11	20
Slightly agree (4)	15	13
Strongly agree (5)	56	50
Don't know	0	0
Average	4.0	3.9

Table 19: Percentage of respondents rating on the ideal body for introducing regulations

Even though the Ministry was seen by many as centre to the overall processes of regulations, there were many concerns and fears on those who favor the Ministry's leading role. Of those who disagreed, many suggested an independent statutory body to take up the leading role. The choice of the Ministry as the party to take the leading role was often because of its authority and position in relation to the Government. The attraction of an independent statutory body was its independence. Such a feature would encourage confidence from all participating parties. Some indicated that the appointment of a statutory body was necessary, but it should be appointed by the Ministry and need to be responsible and accountable to the Ministry.

No matter which direction, the respondents wanted to see an open and transparent policy. For any regulations to work for the benefit of all parties involved, they must be seen to be blameless and above reproach with the outworking benefits given impartially and independently and not be subject to any 'hidden' agenda. The creation of an independent watchdog, a sort of 'ombudsman', a body that is acceptable to all parties in case of dispute or claims of unfair practice, would go a long way to alleviate fears and create confidence amongst the profession and trades.

7.5 Risk assessment responsibility

On a more specific issue with regard to risk assessment, the opinions of the respondents were sought on whether they agreed that risk assessment is the responsibility of the manufacturers. The statement was phrased as follows;

Risk assessment is the manufacturer's responsibility

This statement generated a wide range of opinions. As shown in Table 20, amongst the end-users, 55% disagreed with the statement, including 39% who strongly disagreed, compared to 36% who agreed, with 23% who strongly agreed. However in reverse to the trend amongst end-users, substantially more suppliers tend to agree to the statement, whereby 57% agreed and 33% disagreed.

Rating scale	*Percentage of respondents*	
	End-user	*Supplier*
Strongly disagree (1)	39	13
Slightly disagree (2)	16	20
Neither agree nor disagree (3)	8	10
Slightly agree (4)	13	27
Strongly agree (5)	23	30
Don't know	1	0
Average	2.6	3.4

Table 20: Percentage of respondents rating on risk assessment responsibility

Those who agreed often felt that it was the manufacturers who bore the initial responsibility for assessing the risk associated with a device. Amongst those who disagreed, it was generally felt that risk assessment of medical devices was the joint responsibility of both Government and manufacturer, but the initial onus fell on the manufacturer. It was their responsibility to provide the evidence of its purpose of use and the risks involved for users and patients.

Going deeper into the risk assessment issue, many end-users and suppliers did not make any comments at all when asked to make comments on the issue of risk assessment associated with dental and other medical devices. This reflected their relative lack of awareness, though many end-users made some very general comments that risk always present when devices are used. It may be that end-users perceived that the risk associated with dental devices was relatively low compared with other medical devices. Some suppliers linked regulations to the level of classification of risk whilst some linked risk classification with particular types of devices. There were also some suppliers who linked regulations with devices from companies and countries with established regulations.

Some end-users commented at length on this issue, but whenever the comments were made, they always referred to the differing stamps of approval from reputable agencies in developed countries. Some of the suppliers indicated that it was the suppliers' responsibility to verify, usually unofficially, the quality of the devices they supplied. However, they also raised the issue that many times devices were purchased with many features, including safety features, but often such features were not used.

The issue of risk was sometimes linked to the users. Hence, the need for users to be properly trained was raised, particularly on high risk devices, so that they can effectively use the devices in an appropriately safe manner. The suppliers felt that maintenance and training were two main essential ingredients that always need to be in the forefront of the mind of the purchasers and end-users. Risk assessment was seen especially necessary for high risk devices, though many dentists did not feel it was applicable for all devices. The issue of risk assessment and

maintenance was raised obviously because of the nature of the risk associated with a device to some extent depend on the age of the device and how well it has been maintained.

7.6 Other concerns, views and suggestions

7.6.1 Concerns over commercial advertisements in the media

Respondents were asked to indicate any concerns or problems they had regarding commercial advertisements for medical devices presented in various kinds of media which include the professional press, websites, manufacturers' brochures, commercial print media and television/radio.

For end-users, there was considerable concern about advertisements on devices that might be presented in the mass media; 62% of the end-users expressed their concerns over advertisements in television/radio, 68% over advertisement in newspapers/magazines and 41% over advertisements in websites. There were less concerns over advertisements in manufacturers' brochures (31%) and professional medical/dental journals (15%). Unlike the response from end-users, the suppliers have very little concern; 27% expressed concern over advertisements in newspapers/magazines, 23% (television/radio) and about 10% (professional journals, websites and manufacturers' brochures).

Although many acknowledged that there were few examples of devices being presented to the lay person in these types of media, when it occurred, the concerns centered on the nature and correctness of the messages being conveyed and the ability of a lay person to differentiate what was true and what was advertiser's 'hype'. The principal concerns centered on miscommunications being made and the ability of the reader, listener or viewer to assess the correctness of what was being communicated.

7.6.2 Organizations to represent end-users and suppliers

When asked about which organization would be able to represent dental practice on issues related to the introduction and implementation of medical and dental device regulations in Malaysia, most (80%) of the end-users indicated the Malaysian Dental Association (MDA) followed by the Malaysian Private Dental Practitioners Association (MPDPA) (29%). More than half (57%) of the end-users made reference to more than one association or organization would be able to represent them; however 7% felt no organizations could represent their practice. The specialist associations were important to the specialist dental practitioners within the sample.

As for the suppliers, 55% of them indicated that there were no relevant associations available to represent them. Some of them were aware of earlier attempts to set up some form of trade associations, but none had come to fruition. Twenty-one percent believed that the Malaysian Medical Device Association (MMDA), an association representing medical devices industry (but not specifically for dental devices), would be able to represent them. A few suppliers (17%), especially those involve in a particular market niche on devices primarily used by specific types of specialist, felt that the specific professional specialist association would be the ideal intermediary between themselves and the

Government authorities. A similar proportion (17%) of suppliers indicated that the MDA would be the ideal intermediary.

7.6.3 Participation in adverse event reporting programs

End-users were asked to indicate whether they were willing to participate in adverse event reporting program. There was an overwhelming support for such program. Seventy nine percent were willing to support such program in the future as compared to only 21% who were not in favor. However, the support was often qualified by protection from possible litigation and subject to the level of involvement required for such program.

7.6.4 Participation in further consultations

Most respondents (76% of end-users and 90% of suppliers) were willing to take part in further opinion surveys and other forms of consultations with the Government or through independent consultancies on the issues relating to the introduction and implementation of medical device regulations. However, it was often on condition that it should be done professionally and without prejudice, and not too often nor too time-consuming.

7.6.5 Model of the regulations

It was felt that Malaysia should not "re-invent the wheel" and conjure up layers upon layers of regulations. The regulatory systems in other countries with known and acceptable standard, such as those implemented in Europe, USA and Australia, were referred to be the benchmark in developing the system to be implemented in Malaysia. The underlying feeling was Malaysia should incorporate "models" that utilize expertise and experiences of other developed countries and at the same time, provide a system that is flexible to meet current good practices. Such a system should allow for rapid acceptance of technological changes that offer higher quality services to the public.

7.6.6 Scope of the regulations

Control on the quality and safety of the device should not be divorced from its intended use. The level of quality of a device should match its intended use. Many end-users felt that dental devices were considered to be very safe compared to other medical devices. The risk to the patient from possibly a poor quality dental device is small and not life-threatening. As such, dental devices should not be subjected to special rules and regulations. It was felt that problems in dentistry usually come not from the quality of the devices but from the skills and talents of the end-users and their supporting staffs. If anything, it is not the device that needs to be regulated, but the user of the device. Many end-users felt that the use of certain devices should be limited to qualified personnel only. They also suggested the control should ensure that the suppliers themselves should be knowledgeable about their devices and are able to pass on their expertise in the form of training to the users of the device.

7.6.7 Setting and monitoring of standards

All the interested parties should be involved in setting up of the standards to satisfy for local acceptance. The set standards need to be monitored to ensure that devices in use meet the needs of end-users, patients and the industry, keeping pace with technological advances.

7.6.8 Facilities for amendment of regulations

It was felt that regulations on devices will quickly get out of date, so facilities for prompt amendment of regulations were needed without the need for statutory interactions. Regulations need to express the concept and principles, but the detailed references to specific devices need to be outside the immediate scope of the regulations.

7.6.9 Enforcement

It was generally felt that unless there were adequate resources invested in enforcement, the overall exercise would not be worthwhile. The enforcement processes, though seen to be essential, need to be executed fairly, utilizing flexibility in the interpretation of the regulations and allowing freedom of interpretation to embrace the newer technological advances. Openness and transparency were required to dampen the fears of possible abuse that were held by many suppliers. There were many doubts essentially based on previous experiences from the enforcement of other regulations. Hence, a greater transparency in the introduction, implementation and enforcement of the regulations is needed. The organization that is given the responsibility of overseeing the implementation of the regulations must be held responsible and accountable. The introduction of an independent monitoring body, such as an 'ombudsman' would help generate confidence in the system.

7.6.10 Possible delays in product registration

Product registration may cause time delays. Many suppliers raised the issue of devices that had been certified and had undergone a rigorous registration process within their own country should not be subjected to another rigorous procedures before entering the Malaysian market. A common reaction from suppliers was Malaysia should recognize international standards and practices to save time and frustration of the interested parties.

7.6.11 Flexibility in regulations and development of local manufacturing capabilities

Regulations should provide some level of flexibility to be able to stimulate not only the existing good practices within the current importation of medical devices but also the development of Malaysia's own manufactured medical products. In this way, regulations can be readily seen as a positive influence in the development of a soundly-based healthcare industry in addition to providing general public with a safer and higher quality healthcare service. There was also suggestion that the Government should look into developing Malaysia's own manufacturing expertise as an effort to build up Malaysia's own internal capabilities. In addition, regulations need to be regularly reviewed, updated and modified to keep pace especially with product innovations that come with technological advances.

7.6.12 Medical device listing and coordination between Government agencies

The suppliers solicit the support of the Ministry in developing acceptable listings of medical devices to help facilitate smooth dealings with Custom, especially for imported devices. They also called for a greater coordination and collaboration between the various Government agencies to enable them to perform their responsibilities diligently for the betterment of healthcare industry and general public.

7.6.13 Key components of the total device package

A major interest of a number of end-users and suppliers centered not simply on the device itself but on the total package of the service provided to the patients. This included not only the quality of the device, but also the maintenance of the device and the capabilities of the user of the device, including, as appropriate product specific training. Regulations may be product focused, but it needs to incorporate and reflect the principles of the product total package which, in turn, will affect the mind-set of purchasers, end-users and patients. Training seems to be an integral part of the total process to ensure quality devices that are safe for both operator and patient to bring confidence to the user and ultimately to the patient. The issue of maintenance was crucial and the concept of maintenance needs to be considered as part of the overall policy for acquiring new devices.

7.6.14 Laboratory work

The issue of dental laboratories was quite frequently referred to because it is one part of the overall dental support system that tends to be forgotten and neglected. Some suppliers were concerned that there was insufficient attention given by the authorities to the development of dental laboratories within Malaysia, both in terms of the techniques that tend to be used and the abilities of dental technicians employed.

8 SUMMARY AND CONCLUSION

The sample of this Survey, covering 123 end-users' establishments (comprising 220 general dental practitioners and 194 various groups of dental specialists) and 30 companies supplying dental devices, provided a good representation of the practices and industry.

The end-users' establishments were located throughout Peninsular Malaysia, covering both Government and private sectors whether in hospitals and clinics providing specialist and general dental practices. The workload varied from as low as less than 50 patients per month to more than 600 patients per month. Some establishments, especially from Government sector, implemented QAP, especially ISO 9001:2000. Most establishments procured their devices from local suppliers. The annual expenditure pattern shows that end-users' establishments spent more on devices. Compared to the expenditure on drugs, the average expenditure on devices was at least 20% more. The use of high cost devices (more than RM 50,000) amongst end-users' establishments was very low; less than 20% have more than 5 such devices within the establishments. Europe and USA were, by far, the two most prominent regions where the devices were originated.

Majority of suppliers were from Klang Valley and they comprised of large and smaller family owned companies representing distributors, dental laboratories, intermediary and marketing arm of foreign manufacturers. There were also specialist companies focusing on niche devices and some distribute the whole range of dental devices covering equipment, instruments, consumables and disposables. The annual turnover of suppliers varies considerably, ranging from less than RM 1 million to RM 20 million. A small percentage of suppliers acquired their annual turnover from the sales of other than medical (and dental) devices. A total of 87 suppliers were identified from this Survey.

A list of dental devices obtained from this Survey provides an in-sight on the range and volume of dental devices available for use in Malaysia. There were more than 500,000 units from more than 400 dental device items included in the list of dental devices, of which more than 95,000 units were equipment and instruments and more than 450,000 units were consumables and materials. However, there were rooms for improving the presentation of the data on dental devices – for example the devices can be classified and categorized in accordance with the GHTF classification and Global Medical Device Nomenclature (GMDN)[6] system respectively. The list will become a component of a medical device registry that will be developed by the Ministry.

On the Ministry's proposal to introduce medical (and dental) device regulations, there were mixed reactions amongst the end-users and suppliers of dental devices. The key positive reaction to the proposed regulation was that it would lead to better quality devices being made available to both end-users and patients, and hence, as a result, would enhance the overall service being provided to the general public. Better quality devices also meant safer and more reliable products. Regulations would also mean the elimination of inferior products, and safeguarding against the dumping of sub-standard, outdated and possibly hazardous devices. Though the concept of regulations was understood, what was not understood was the likely scope of the regulations. The concerns were what would be covered by the regulations, how would it be enforced and how would it be paid for. Would the scope be principally on the products or would the regulations cover end-users and the suppliers.

The Ministry was generally seen to be the body to take the leading role in introducing and implementing regulations on medical and dental devices, primarily because the Ministry is more knowledgeable on matters of policies and regulations. Both end-users and suppliers, however, were very skeptical about the overall motives, being concerned about possible hidden agendas. Much of their fears were rooted in experiences of existing regulations and to overcome such fears, the Ministry needs to demonstrate an openness and transparency in all the dealings. For any policy to be successful and to benefit the image of the country, it needs the unreserved support on the key participant players and stakeholders. Collaboration and active participation by all key stakeholders within the overall process would be welcome. The suggestion of the formation of an independent 'watch-dog'-type body for this purpose was raised.

Both trade and profession agreed that regulations would be to no avail unless there was the enactment of proper, impartial and without prejudice enforcement. Past experiences have indicated that this may well be a problem and care will need to be taken to ensure that all things are done decently and in order. Again, an independent "watchdog" body may be desirable, if not necessary, to help prevent anomalies, bad practices and possible abuse, and demonstrate the Government's genuine intentions in these matters.

Regulations may indicate a concern for better quality medical and dental devices that are safe and effective but it needs to be on a broader strategies. A strategic plan on the issues of after-sales service, maintenance, education and training on

6 GMDN, http://www.gmdn.org/, is a nomenclature system developed to classify medical devices on the market by the European Standards Body CEN and sponsored by European Commission, with full participation and parallel acceptance by the ISO. It is the only nomenclature in use within European Economic Area and is being endorsed by many legislators. It is endorsed by the GHTF as the global nomenclature system.

the use of the device needs to be undertaken and considered within the overall thinking underpinning the 'life' of the regulations. Another strategy to be considered was the development of the healthcare industry, specifically the development of Malaysia's manufacturing of medical (and dental) devices and the development of the required manpower and other resources.

Deep-rooted fears and concerns are held by both end-users and suppliers. Active participation and cooperation of the key stakeholders are crucial for a new policy to work, and to achieve this, the stakeholders need to believe and understand that the motives behind policy initiatives are genuinely rooted. All stakeholders will need to believe and know that the Government has the best interests of all parties at heart, including end-users and suppliers, general public as well as the Malaysian healthcare services and industry. Efforts need to be directed to overcome natural apprehensions and genuine fears of end-users and suppliers over any new directives to ensure a successful outcome to the introduction and implementation of new regulations on medical (and dental) devices.

Appendix 1: Equipment instruments used in dental practices in Malaysia

No.	Device	Total Quantities	Av. Usage Qty. Per Estab'ment	Risk Level	Class	Intended Use
1	Adam - Spring Forming Plier	96	0.81	M	B	For Orthodontice Treatment
2	Adam - Universal Pliers	170	1.43	M	B	For Orthodontice Treatment
3	Adson forcep	98	0.82	L	A	For Orthodontice Treatment
4	Air polisher	38	0.32	L	A	For Denture polishing
5	Alginate mixer	59	0.50	L	A	For mixing of impression material
6	Amalgam carrier	790	6.64	L	A	Tool for amalgam
7	Amalgam carver ward	775	6.51	L	A	Tool for carving amalgam
8	Amalgam Plugger	1,194	10.03	L	A	Hand tool to plug amalgam
9	Amalgamator	230	1.93	L	A	Amalgam mixing machine
10	Anterior Band Remover	36	0.30	M	B	Tool to remove bands
11	Anvil and riveting hammer	6	0.05	M	B	For prosthetic application
12	Apex locator	43	0.36	L	A	For root canal diagnostic unit
13	Arch bar	95	0.80	L	A	For orthodontic application
14	Arch Wire Holder	53	0.45	L	A	For orthodontic application
15	Artery forceps	631	5.30	L	A	For surgery application
16	Articulator, free plane	298	2.50	L	A	For check on denture high bits
17	Autoclave	221	1.86	H	C	For Sterilisation of Instruments
18	Awty retractor	39	0.33	L	A	For surgery application
19	Band Pusher	66	0.55	L	A	For orthodontic application
20	Band Seater	44	0.37	L	A	For orthodontic application
21	Blade handle	174	1.46	L	A	For surgical blade
22	Blade handle scalpel	449	3.77	L	A	For surgical blade
23	Blade handle for gingivectomy knife	16	0.13	L	A	For surgical blade
24	Bone Awl	39	0.33	M	B	For surgery application
25	Bone chisel	68	0.57	M	B	For surgery application
26	Bone cutter	88	0.74	M	B	For surgery application
27	Bone file	263	2.21	M	B	For surgery application
28	Bone holding forcep	25	0.21	L	A	For surgery application
29	Bone hook	10	0.08	M	B	For surgery application
30	Bowdler Henry rake retractor	68	0.57	L	A	For surgery application
31	Bracket Holder	112	0.94	L	A	For denture application
32	Bracket Removing Plier	60	0.50	M	B	For denture application
33	Bristow's elevator	34	0.29	L	A	For orothodontic application
34	Bur block	385	3.24	L	A	For cutting and polishing
35	Bur Brush metal	276	2.32	L	A	For denture cleaning
36	Burner (prosthetic work)	156	1.31	L	A	For prosthetic application
37	Burnisher	813	6.83	L	A	For denture application
38	Caliper	89	0.75	L	A	For measurement
39	Call-Kit Box stainless steel	30	0.25	L	A	For denture application
40	Caries excavator	1,232	10.35	M	B	For denture application
41	Cartridge syringe	1,716	14.42	M	B	For surgical application
42	Celluloid crown form	849	7.13	L	A	For crowning application
43	Celluloid strip	2,210	18.57	L	A	For contouring of denture
44	Cheatle forceps	231	1.94	L	A	For surgery application
45	Cheatle forceps holding jar	167	1.40	L	A	For holding instruments
46	Chin retractor	44	0.37	M	B	For surgery application
47	Clinical thermometer	56	0.47	L	A	For examination of patient
48	Cotton wool container	235	1.97	L	A	Container for materials
49	Crown contouring pliers	22	0.18	M	B	For crowning application
50	Crown remover	64	0.54	M	B	For crowning application
51	Crown scissors	152	1.28	M	B	For crowning application
52	Currettes (Dental)	405	3.40	M	B	For surgery application
53	Dappen glass	828	6.96	L	A	For proceduring application
54	Dental Digital Camera	22	0.18	L	A	For photographing application

Appendix 1: Equipment instruments used in dental practices in Malaysia

No.	Device	Total Quantities	Av. Usage Qty. Per Estab'ment	Risk Level	Class	Intended Use
55	Dental Laser Unit	12	0.10	H	C	For surgery application
56	Dental loupe	34	0.29	H	C	For filling application
57	Dental Probe	2,982	25.06	L	A	For examination of patient
58	Dental Unit	372	3.13	L	A	For examination of patient
59	Dental Veneer	19	0.16	L	A	For posthetic application
60	Dental X-ray machine	75	0.63	H	D	For X-ray of denture
61	Digital BP set	36	0.30	L	A	For Blood Pressure Reading
62	Digital radiography	11	0.09	L	A	For radiography application
63	Disinfection / sterilising box	346	2.91	L	A	For disinfection of instruments
64	Dissecting forcep non-tooth	76	0.64	L	A	For surgery application
65	Dissecting forcep tooth	280	2.35	M	B	For surgery application
66	Distal End Cutters	103	0.87	M	B	For orthodontic application
67	Drip stand	7	0.06	L	A	For surgery application
68	Drum dressing stainless steel	212	1.78	L	A	For Sterilisation of Instruments
69	Edgewise Ligature Forming Pliers	24	0.20	M	B	For surgery application
70	Elastic dispenser	15	0.13	L	A	For orthodontic application
71	Electric suction pump	81	0.68	L	A	For surgery application
72	Electrosurgery set	22	0.18	H	C	For surgery application
73	Elevators	3,054	25.66	M	B	For surgery application
74	Endodontic set	189	1.59	M	B	For endodontic application
75	Excavators	1,765	14.83	M	B	For endodontic application
76	Explorer (Briaults)	195	1.64	M	B	For examination of patient
77	Extraction Forceps	6,544	54.99	M	B	For surgery application
78	Face mirror	1,128	9.48	L	A	For examination of patient
79	Farebeuf elevator	12	0.10	M	B	For surgery application
80	Forcep for articulation paper	93	0.78	L	A	For surgery application
81	Fork retractor	14	0.12	L	A	For surgery application
82	Gallipot	1,142	9.60	L	A	For examination of patient
83	Gauze jar	295	2.48	L	A	Container for materials
84	Gingivectomy knives	45	0.38	M	B	For surgery application
85	Glass bead steriliser	18	0.15	H	C	For Sterilisation of Instruments
86	Glass box with cover metal	27	0.23	L	A	For mixing of materials
87	Glass slab	446	3.75	L	A	For mixing of materials
88	Hand scalers	926	7.78	M	B	For scaling of denture
89	Handpiece	1,505	12.65	M	B	For scaling of denture
90	Handpiece Steriliser	12	0.10	M	B	For scaling of denture
91	Hayton William's Forcep	1	0.01	L	A	For surgery application
92	Head light with light source	17	0.14	L	A	For examination of patient
93	Heavy Wire Cutter	119	1.00	L	A	For surgery application
94	High speed mixer for dental cement/amalgam	86	0.72	L	A	For mixing of materials
95	High Vacuum Suction unit	106	0.89	L	A	For surgery application
96	Hot air oven	13	0.11	L	A	For Sterilisation of Instruments
97	How's Pliers	48	0.40	M	B	For extraction application
98	Hunts syringe	102	0.86	M	B	For surgery application
99	Impression trays	3,735	31.39	L	A	For mixing of impression material
100	Instrument for bone harvesting	7	0.06	M	B	For surgery application
101	Instrument trays	2,696	22.66	L	A	For placing of instruments
102	Intraoral and craniofacial implant set	30	0.25	M	B	For X-ray application
103	Jar dressing stainless steel	317	2.66	L	A	For placing of instruments
104	Kidney dish	947	7.96	L	A	For placing of instruments
105	Le Cron carver	306	2.57	L	A	Tool for amalgam application
106	Lead apron	100	0.84	L	A	For X-ray application

Appendix 1: Equipment instruments used in dental practices in Malaysia

No.	Device	Total Quantities	Av. Usage Qty. Per Estab'ment	Risk Level	Class	Intended Use
107	Lead screen	47	0.39	L	A	For X-ray application
108	Ligature Cutters	122	1.03	L	A	For surgery application
109	Ligature Tucker	89	0.75	L	A	For surgery application
110	Light cure unit	198	1.66	L	A	For amalgam application
111	Light Wire Plier	86	0.72	L	A	For endodontic application
112	Lingual retractor	18	0.15	M	B	For surgery application
113	Mallet (small & medium)	55	0.46	L	A	For prosthetic application
114	Mandibular molar retractor Killey's third	5	0.04	L	A	For surgery application
115	Mathews	47	0.39	L	A	For surgery application
116	Matrix retainer	481	4.04	L	A	For surgery application
117	Matrix strip	1,859	15.62	L	A	For surgery application
118	Mayo instruments clips	5	0.04	L	A	For surgery application
119	Mayo safety pin	22	0.18	L	A	For surgery application
120	Mcgil sucker	32	0.27	L	A	For surgery application
121	Measuring caliper	56	0.47	L	A	For prosthetic application
122	Medicament bottle	337	2.83	L	A	For medication
123	Mirror handle	4,078	34.27	L	A	For examination of patient
124	Mirror top	4,378	36.79	L	A	For examination of patient
125	Mitchell Trimmer/Osteo Trimmer	199	1.67	L	A	For prosthetic application
126	Mortar and Pestle	144	1.21	L	A	For prosthetic application
127	Mosquito Forcep	353	2.97	L	A	For surgery application
128	Mouth gag	135	1.13	L	A	For examination of patient
129	Mouth prop	563	4.73	L	A	For examination of patient
130	Nance Plier	6	0.05	L	A	For surgery application
131	Nasal respiratory elevator	2	0.02	M	B	For ENT application
132	Nasal Septum Forcep	10	0.08	M	B	For ENT application
133	Needle holder	521	4.38	L	A	For surgery application
134	Nerve canal plugger	84	0.71	M	B	For surgery application
135	Nitrous oxide Quantiflex + Pulse Oximeter	4	0.03	L	A	For surgery application
136	Norm Tray cassettes with inserts	81	0.68	L	A	For Sterilisation of Instruments
137	Orthodontic Grid	3	0.03	L	A	For orthodontic application
138	Osteotome	27	0.23	L	A	For orthodontic application
139	Periosteal elevator	370	3.11	L	A	For surgery application
140	Photograph reflector set	20	0.17	L	A	For examination of patient
141	Pin bending pliers	29	0.24	L	A	For surgery application
142	Plastic filling instruments	2,507	21.07	L	A	For prosthetic application
143	Plating set (implants for rigid internal fixation)	15	0.13	M	B	For implant application
144	Portable dental unit	67	0.56	M	B	For implant application
145	Portable light	88	0.74	L	A	For examination of patient
146	Portable light-cure unit	159	1.34	L	A	For amalgam application
147	Posterior Band Remover	54	0.45	L	A	For prosthetic application
148	Probe Explorer	919	7.72	L	A	For examination of patient
149	Probes periodontal	367	3.08	L	A	For periodontal application
150	Prognathism channel retractor with fibre-optic	0	0.00	L	A	For root canal application
151	Protective goggles	236	1.98	L	A	For examination of patient
152	Pulp Tester	92	0.77	L	A	For denture application
153	Radiograph processing box	27	0.23	L	A	For X-ray application
154	Resuscitator	8	0.07	M	B	For restoration application
155	Retractor soft tissue	55	0.46	L	A	For surgery application
156	Retractors cheek	227	1.91	M	B	For surgery application

Appendix 1: Equipment instruments used in dental practices in Malaysia

No.	Device	Total Quantities	Av. Usage Qty. Per Estab'ment	Risk Level	Class	Intended Use
157	Ribbor Areh Pliers	13	0.11	M	B	For surgery application
158	Root canal excavators	59	0.50	M	B	For root canal application
159	Root canal explorer	87	0.73	M	B	For root canal application
160	Root spreader set	92	0.77	L	A	For root canal application
161	Rowes disimpaction forcep left and right	21	0.18	L	A	For surgery application
162	Rowes Zygomatic elevator	10	0.08	M	B	For surgery application
163	Rubber bowl	429	3.61	L	A	For examination of patient
164	Rubber dam set	150	1.26	L	A	For examination of patient
165	Ruler Orthodontik	49	0.41	L	A	For orthodontic application
166	Sandblaster	11	0.09	L	A	For prosthetic application
167	Saw frame	11	0.09	L	A	For prosthetic application
168	Scissors	538	4.52	M	B	For materials cutting
169	Scissors Dissecting	161	1.35	M	B	For surgery application
170	Scissors Dressing	99	0.83	M	B	For surgery application
171	Scissors gum	183	1.54	M	B	For surgery application
172	Separating Pliers	30	0.25	L	A	For surgery application
173	Sharpening stone	19	0.16	L	A	For polishing application
174	Silver probe	33	0.28	L	A	For examination of patient
175	Sinus forcep	78	0.66	M	B	For surgery application
176	Skin hook	49	0.41	L	A	For surgery application
177	Skin retractor Kilner	24	0.20	L	A	For surgery application
178	Spatula alginate	293	2.46	L	A	For mixing application
179	Spatula stainless steel	376	3.16	L	A	For mixing application
180	Spirit lamp	142	1.19	L	A	For prosthetic application
181	Stainless steel jar for gauze	183	1.54	L	A	For materials storing
182	Steel ruler	152	1.28	L	A	For measurement
183	Stethoscope	26	0.22	L	A	For examination of patient
184	Stillman retractor	0	0.00	L	A	For surgery application
185	Stripping retractor	3	0.03	L	A	For surgery application
186	Suction tips	19,623	164.90	L	A	For examination of patient
187	Surgical burs	1,170	9.83	M	B	For surgery application
188	Tension Gauge	8	0.07	L	A	For orthodontic application
189	Thermafil oven	16	0.13	L	A	For Sterilisation of Instruments
190	Tissue forceps	297	2.50	M	B	For surgery application
191	Tongue depressor	128	1.08	L	A	For examination of patient
192	Tongue flap retractor	13	0.11	L	A	For surgery application
193	Tongue retractor	32	0.27	L	A	For surgery application
194	Torch for waxing	33	0.28	L	A	For mixing application
195	Towel forceps	60	0.50	L	A	For examination of patient
196	Tumbler	2,005	16.85	L	A	For cleaning application
197	Turret	8	0.07	L	A	For cleaning application
198	Tweed Pliers	27	0.23	L	A	For surgery application
199	Tweezer	2,552	21.45	L	A	For surgery application
200	Ultrasonic cleaner	66	0.55	L	A	For cleaning application
201	Ultrasonic scaler	153	1.29	L	A	For denture cleaning
202	Vaculyser	88	0.74	L	A	For surgery application
203	Visors (face shield)	317	2.66	L	A	For examination of patient
204	Walsham septum forcep	7	0.06	M	B	For surgery application
205	Water distiller	67	0.56	L	A	For clean water
206	Water pump (For Ultra Sonic Scaler)	30	0.25	L	A	For cleaning application
207	Wax knife	361	3.03	L	A	For prosthetic application
208	Weingart	70	0.59	L	A	For surgery application

Appendix 1: Equipment instruments used in dental practices in Malaysia

No.	Device	Total Quantities	Av. Usage Qty. Per Estab'ment	Risk Level	Class	Intended Use
209	Welder	13	0.11	L	A	For prosthetic application
210	Wheel chair	19	0.16	L	A	For patient usage
211	Wires soft	198	1.66	L	A	For orthodontic application
212	X-ray duplicator	4	0.03	L	A	For X-ray application
213	X-ray guide	18	0.15	L	A	For X-ray application
214	X-ray Viewer	138	1.16	L	A	For X-ray application
215	Younker sucker	45	0.38	L	A	For surgery application
	Total	**97,291**				

Appendix 2: Consumables and materials used in dental practices in Malaysia

No.	Device	Total Quantities	Av. Usage Qty. Per Estab'ment	Risk Level	Class	Intended Use
1	Absorbant Cotton Wool	4,545	38.19	L	A	For Cleaning & Absorbing Fluid
2	Absorbant Gauze	1,908	16.03	L	A	For Cleaning & Absorbing Fluid
3	Advantage Strip	1,722	14.47	L	A	For Impression application
4	Alginate	1,341	11.27	L	A	For Impression application
5	Alloy	1,068	8.97	L	A	For denture application
6	Aluminium Oxide Powder	19	0.16	L	A	For denture application
7	Alvogyl Paste	171	1.44	H	C	Medicament application
8	Amalgam Remover	43	0.36	M	B	For surgery application
9	Aquasil Intraoral Tips	167	1.40	L	A	For patient examination
10	Aquasil Mixing Tips	548	4.61	L	A	For mixing of materials
11	Articulating Paper	1,808	15.19	L	A	For Impression application
12	Aspirator Tips	6,906	58.03	L	A	For patient examination
13	Assorted Strip Crowns	1,035	8.70	L	A	For crowning application
14	Autoclave Tape	682	5.73	L	A	For sterilising application
15	Ball Retainer Clasp	368	3.09	L	A	Instruments for amalgam application
16	Band Lower Molar	2,985	25.08	L	A	For orthodontic application
17	Band Matrix Squiveland	461	3.87	M	B	For orthodontic application
18	Band Pusher	56	0.47	L	A	For orthodontic application
19	Band Upper Molar	3,796	31.90	L	A	For orthodontic application
20	Barbed Broaches	491	4.13	M	B	For root canal application
21	Bleaching Kit	65	0.55	L	A	For cosmetic application
22	Bondable SWA Buccal Tube	350	2.94	L	A	For orthodontic application
23	Bonding Agent	3,837	32.24	L	A	For orthodontic application
24	Bracket Holder	109	0.92	L	A	For denture application
25	Braided Silk	370	3.11	M	B	For surgery application
26	Brush Nylon Polishing Cup	2,991	25.13	L	A	For denture application
27	Bur Brush	268	2.25	L	A	For surgery application
28	Calcium Hydroxide	228	1.92	L	A	For denture application
29	Carbide Burs	859	7.22	M	B	For surgery application
30	Cavity Varnish	92	0.77	L	A	For denture application
31	Ceramcore Silver Powder	0	0.00	L	A	Dental materials
32	Ceramic Tip	0	0.00	L	A	For surgery application
33	Cerclage Wirre Soft Do. Coil	15	0.13	L	A	For orthodontic application
34	Cloroform/Xylol	16	0.13	L	A	For antiseptic application
35	Coiled Spring Open	108	0.91	L	A	For orthodontic application
36	Cold Curing Powder + Liquid	693	5.82	L	A	For prosthetic application
37	Collagen Matrix	16	0.13	M	B	For surgery application
38	Coloured Tapes	18	0.15	L	A	For sterilising application
39	Composite Self Cure / Chemical Cure	400	3.36	L	A	For denture application
40	Copper Niti 0.018 Round (U)	159	1.34	L	A	Dental materials
41	Cord Rings	38	0.32	L	A	For orthodontic application
42	Cotton Rolls	8,379	70.41	L	A	For Cleaning & Absorbing Fluid
43	Creosote	551	4.63	L	A	For root canal application
44	Crown & Bridge Impression Material	165	1.39	L	A	For crowning application
45	Cylindrical Tungsten Carbide Burs	499	4.19	L	A	For surgery application
46	Dental Floss	1,356	11.39	L	A	For denture application
47	Dentine Pin 20's	490	4.12	L	A	For orthodontic application
48	Dentosept (Perio)	22	0.18	L	A	Medicament application
49	Desensitising Paste	554	4.66	L	A	For denture application
50	Diamond Burs	5,818	48.89	L	A	For surgery application
51	Dispensing Bottle	5,840	49.08	L	A	For medication
52	Dispensing Envelopes	45,503	382.38	L	A	For medication

Appendix 2: Consumables and materials used in dental practices in Malaysia

No.	Device	Total Quantities	Av. Usage Qty. Per Estab'ment	Risk Level	Class	Intended Use
53	Disposable Bibs	47,233	396.92	L	A	For patient examination
54	Disposable Cups	98,571	828.33	L	A	For patient examination
55	Disposable Probes	1,717	14.43	L	A	For patient examination
56	Disposable Sucker Tips	60,447	507.96	L	A	For patient examination
57	Disposable-Shield For Multipurpose	31	0.26	L	A	For patient examination
58	Duran	2	0.02	L	A	For surgery application
59	Edta Paste (RC Prep)	45	0.38	L	A	For root canal application
60	Elastic In. Oral	635	5.34	L	A	For orthodontic application
61	Endo Files	2,607	21.91	M	B	For endodontic application
62	Endodontic Finger Spreader	267	2.24	L	A	For endodontic application
63	Endodontic Stopper	1,593	13.39	L	A	For endodontic application
64	Endo-Z Non-End Cutting Burs	100	0.84	L	A	For endodontic application
65	Enlight Cure Adhesive	25	0.21	L	A	For denture application
66	Etching Gel	290	2.44	L	A	For denture application
67	Eugenol - Free Temporary Luting Cement	97	0.82	M	B	For denture application
68	Expansion Screws	129	1.08	L	A	For orthodontic application
69	Ext. Spring	42	0.35	L	A	For orthodontic application
70	Extra Hard Wax	86	0.72	L	A	For prosthetic application
71	Face Bow	144	1.21	L	A	For patient examination
72	Face Mask	14,615	122.82	L	A	For patient examination
73	Fibre-Reinforced Post	122	1.03	M	B	For implant application
74	Finger Spreader - RCT	291	2.45	L	A	For implant application
75	Finishing Bur	753	6.33	L	A	For denture polishing
76	Finishing Strips	1,069	8.98	L	A	For denture polishing
77	Fissure Sealant	200	1.68	L	A	For denture application
78	Fluoride Varnish	59	0.50	L	A	For filling application
79	Front Surface Mirror Tops	1,153	9.69	L	A	For patient examination
80	Gates Glidden Burs	351	2.95	L	A	For denture polishing
81	Glass Ionomer Cement	761	6.39	L	A	For filling application
82	Glove Dental	17,072	143.46	L	A	For patient examination
83	Glove Surgical Latex	6,235	52.39	L	A	For patient examination
84	Glune Desensitizer	24	0.20	L	A	For cleaning application
85	Gold Chain	20	0.17	L	A	For implant application
86	Gold/Amalgam Polishing Kit	88	0.74	L	A	For polishing application
87	Goose Neck/Pulp Chambers Burs	71	0.60	L	A	For polishing application
88	Grafton Demineralized Bone Matrix	7	0.06	L	A	For prosthetic application
89	Green Stone Bur	653	5.49	L	A	For restoration application
90	Gutta Percha Points	5,788	48.64	L	A	For restoration application
91	Haemostatic Agents	795	6.68	L	A	For bleeching application
92	Headstrom Files	1,709	14.36	M	B	For root canal application
93	Heat Carrier Plugger	97	0.82	L	A	For surgery application
94	Heavy Wire Cutter	113	0.95	L	A	For orthodontic application
95	High Pull Strap	51	0.43	L	A	For extraction application
96	Hygiene Protection Cover	629	5.29	L	A	For patient examination
97	Impression Compound	92	0.77	L	A	For Impression application
98	Impression Paste - Zinc Oxide	352	2.96	L	A	For Impression application
99	Irrigating Needle, Blunt End	247	2.08	L	A	For surgery application
100	Jota Diamond Disc	28	0.24	L	A	For polishing application
101	Ketac-Silver Intro-Pack	71	0.60	L	A	For patient examination
102	Kobayashi Hooks 0.014	1,551	13.03	L	A	For orthodontic application
103	Lancet	39	0.33	M	B	For surgery application
104	Light Cure Shield	169	1.42	L	A	For denture application
105	Lightning Strips	1	0.01	L	A	For surgery application

Appendix 2: Consumables and materials used in dental practices in Malaysia

No.	Device	Total Quantities	Av. Usage Qty. Per Estab'ment	Risk Level	Class	Intended Use
106	Lingual Cleats Short	379	3.18	L	A	For surgery application
107	Lint Absorbant White	114	0.96	L	A	For surgery application
108	Liquid - Heat Cure (Acrylic Material)	215	1.81	L	A	For posthetic application
109	Low Pull Strap	58	0.49	L	A	For surgery application
110	Low Shringkage Acrylic Resin	11	0.09	L	A	For prosthetic application
111	Luting Cements - Relyx Arc Refills	29	0.24	L	A	For prosthetic application
112	Luting Cements - Resin Cement	52	0.44	L	A	For prosthetic application
113	Luting Cements - Zinc Phosphate	53	0.45	L	A	For prosthetic application
114	Mandrell For Sandpaper Lab	360	3.03	L	A	For prosthetic application
115	Mask Surgical Disposable	6,409	53.86	L	A	For patient examination
116	Master SWA Brackets	360	3.03	L	A	For surgery application
117	Mineral Trioxide Aggregate	3	0.03	M	B	For polishing application
118	Mini 2000 Diamond Bkt.	125	1.05	L	A	For posthetic application
119	Mini Ligature Cutter	46	0.39	L	A	For surgery application
120	Mixing Cup 500 mg	591	4.97	L	A	For patient examination
121	Modelling Wax	708	5.95	L	A	For prosthetic application
122	Molar Band Trial Kit For Upper	954	8.02	L	A	For orthodontic application
123	Neckpads Padded	57	0.48	L	A	For patient examination
124	Needle Hypodermic	5,625	47.27	M	B	For surgery application
125	Needle Suture	1,504	12.64	M	B	For surgery application
126	Nitional 0.014	1,892	15.90	L	A	For orthodontic application
127	Non-Setting Calcium Hydroxide	43	0.36	L	A	For denture cleaning
128	Occlusal Foil	9	0.08	L	A	For prosthetic application
129	Occlusal Marking Tape Two-Sided	214	1.80	L	A	For prosthetic application
130	Optiband (Band Cement)	10	0.08	L	A	For prosthetic application
131	Ortho Cast Bondable Tube	113	0.95	L	A	For orthodontic application
132	Orthoresin (Powder & Liquid)	26	0.22	L	A	For orthodontic application
133	Paper Points	7,088	59.56	L	A	For root canal application
134	Parapost Xp Post System For	14	0.12	L	A	For casting application
135	Paste Carriers	92	0.77	L	A	For prosthetic application
136	Periocare Kit	9	0.08	L	A	For periodontic application
137	Plastic Syringe 2s & 1 Brush	95	0.80	L	A	For surgery application
138	Ploydentia - Fiber Splint Multiplayer	3	0.03	L	A	For crowning application
139	Polycarbonate Crown	559	4.70	L	A	For crowning application
140	Polyvinylsiloxane Impression Materials	65	0.55	L	A	For crowning application
141	Porcelain Etch & Silane Coupling Agent	26	0.22	L	A	For prosthetic application
142	Porcelain Polishing Kit	40	0.34	L	A	For polishing application
143	Post Space Bur	34	0.29	L	A	For polishing application
144	Power Chain	184	1.55	L	A	For surgery application
145	PQI Single Resin Bonding Refill	22	0.18	L	A	For restoration application
146	Prefabricated Parapost	81	0.68	L	A	For casting application
147	Profile Assorted	79	0.66	L	A	For restoration application
148	Prophylaxis Brush	3,806	31.98	L	A	For restoration application
149	Prophylaxis Paste	142	1.19	L	A	For restoration application
150	Protaper Starter Kit	51	0.43	L	A	For restoration application
151	Pulp Canal Sealer	91	0.76	L	A	For root canal application
152	Pumice Powder	149	1.25	L	A	For restoration application
153	Relyx Family Kit	16	0.13	L	A	For restoration application
154	Replacement Pads	53	0.45	L	A	For patient examination
155	Retraction Cords	90	0.76	L	A	For extraction application
156	Root Canal Sealer	122	1.03	L	A	For root canal application
157	Root Canal Solution	2,565	21.55	L	A	For root canal application

App ndix 2: Consumables and materials used in dental practices in Malaysia

No.	Device	Total Quantities	Av. Usage Qty. Per Estab'ment	Risk Level	Class	Intended Use
158	Round 0.014(U)	1,040	8.74	L	A	For orthodontic application
159	Rubber Dam	121	1.02	L	A	For orthodontic application
160	Rubber Polishing Cups	783	6.58	L	A	For restoration application
161	Scaler Insert	242	2.03	L	A	For scaling and restoration
162	Scaler Tips	545	4.58	L	A	For scaling and restoration
163	Self Cure Denture Material - Clear	108	0.91	L	A	For restoration application
164	Self Sealing Pouches	682	5.73	L	A	For medication
165	Sep Strip	11	0.09	L	A	For restoration application
166	Separator	2,436	20.47	L	A	For orthodontic application
167	Shade Guide	144	1.21	L	A	For restoration application
168	Silicone Fit Checker	13	0.11	L	A	For orthodontic application
169	Silicone Polisher For Acrylic	188	1.58	L	A	For restoration application
170	Sodium Perborate	52	0.44	L	A	For restoration application
171	Spot Metal Tip (Interdental)	275	2.31	L	A	For restoration application
172	Stainless Steel Ligature Wire	2,549	21.42	M	A	For orthodontic application
173	Stancing Gauze	56	0.47	L	A	For patient examination
174	Steel Bur	6,795	57.10	L	A	For polishing application
175	Steinr's Wedge Short	17	0.14	L	A	For surgery application
176	Sterilization Wrapping Paper	2,351	19.76	L	A	For sterilising application
177	Surgitip	560	4.71	L	A	For endodontic application
178	Surgitip - Micro For Endo Use	52	0.44	L	A	For endodontic application
179	SWA Bracket MBT	237	1.99	L	A	For orthodontic application
180	Syringe Disposable	6,293	52.88	M	B	For surgery application
181	Temporary C&B Material - Acrylic Resin	52	0.44	L	A	For crowning application
182	Teru Plug	1	0.01	L	A	For root canal application
183	Thermacut	1	0.01	L	A	For prosthetic application
184	Thermafil Obturators Refills - Posterior Kit	109	0.92	L	A	For prosthetic application
185	Thermafil Verifier	56	0.47	L	A	For surgery application
186	Tungsten Carbide Bur	1,036	8.71	L	A	For polishing application
187	Tungsten Carbide Surgical Bur	911	7.66	M	B	For polishing application
188	Ul 1st Molar B.Tube Comb. Peerless	73	0.61	L	A	For root canal application
189	Ultrasonic Scaling Tip	392	3.29	M	B	For scaling and restoration
190	W9506t Vicryl 4/0 45cm P-Needle Cc 16mm	1,107	9.30	L	A	For surgery application
191	Water Syringe Sleeves	1,047	8.80	L	A	For syringe application
192	Wax Tracing Stick	218	1.83	L	A	For prosthetic application
193	White Head Varnish	9	0.08	L	A	For restoration application
194	White Stone Bur	890	7.48	L	A	For polishing application
195	Whiting Powder	30	0.25	L	A	For restoration application
196	Wilcock Wire	51	0.43	L	A	For orthodontic application
197	Wire Stainless Steel	390	3.28	L	A	For orthodontic application
198	X-Ray Film	3,289	27.64	L	A	For X-ray application
199	Zinc Oxide Eugenol	243	2.04	L	A	For restoration application
	Total	**450,157**				