

Advanced Structured Materials

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Biomaterials and Medical Devices

A Perspective from an Emerging
Country

 Springer

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Contents

Structure and Properties of Biomaterials	1
Sulistioso Giat Sukaryo, Agung Purnama and Hendra Hermawan	
Naturally Derived Biomaterials and Its Processing	23
Raden Dadan Ramdan, Bambang Sunendar and Hendra Hermawan	
Biocompatibility Issues of Biomaterials	41
Widowati Siswomihardjo	
Animal Study and Pre-clinical Trials of Biomaterials	67
Deni Noviana, Sri Estuningsih and Mokhammad Fakhru Ulum	
Bioadhesion of Biomaterials	103
Siti Sunarintyas	
Degradable Biomaterials for Temporary Medical Implants	127
Ahmad Kafrawi Nasution and Hendra Hermawan	
Biomaterials in Orthopaedics	161
Ferdiansyah Mahyudin, Lukas Widhiyanto and Hendra Hermawan	
Biomaterials in Dentistry	183
Margareta Rinastiti	
Tissue Bank and Tissue Engineering	207
Ferdiansyah Mahyudin and Heri Suroto	
Indonesian Perspective on Biomaterials and Medical Devices	235
Ferdiansyah Mahyudin, Sulistioso Giat Sukaryo, Widowati Siswomihardjo and Hendra Hermawan	

Indonesian Perspective on Biomaterials and Medical Devices

Ferdiansyah Mahyudin, Sulistioso Giat Sukaryo,
Widowati Siswomihardjo and Hendra Hermawan

Abstract Indonesia is an emerging country with population about 255 million in 2015 and 40 % of this population is in their productive age. The country's nominal GDP for 2015 is about 900 billion USD with 5 % annual growth and general government debt stays at 26 % of GDP. The government has put healthcare service as one of the strategic program in the 2015–2019 National Development Plan along with a new effective national healthcare financing scheme. Indonesia is a big market for medical products with a market value about 800 million USD in 2015 and estimated to reach 1.2 billion USD in 2019. The government has set policies and a clear roadmap for assuring the availability and distribution of medical devices by fostering local production, improving the quality of local products and tightening the surveillance to the pre- and post-market devices. The challenge lies on unifying the country's experts to mutually collaborate under a strong leadership on the same interest toward the national independency in producing effective yet low cost medical devices.

Keywords Biomaterials · Indonesian government · Market · Medical devices · Policy · Regulation

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1 Indonesia, Facts and Figures

Indonesia is the largest archipelagic country with 17,508 islands spreading over a 5,271 km distance from East to West and 2,210 km from North to South with five biggest islands namely Sumatra, Java, Kalimantan, Sulawesi and Papua. It is located over the equator line between Asia and Australia with total land area of 1,904,569 km² or about 5 million km² total territorial claim including the sea. The country declared its independence on 17 August 1945 after three centuries-long tireless fight against the Dutch colonialization and started their nation building 5 years later after winning the heroic post-independence war against the Dutch military aggression attempting to recolonialize Indonesia (Reid 1974).

Indonesian nominal GDP for 2015 is estimated at 895.677 billion USD with 5 % annual growth or by considering the purchasing power parity the total GDP stands at 2.840 trillion USD or 11,135 USD per capita (IMF 2015). Its economic activity remains significant thanks to a contribution of commodities sector even though the value of production and exports has been affected by global recession in recent years. The declining public debt in Indonesia since the late 1990s has strengthened the economy's resilience, maintaining favorable fiscal and debt positions compared with its peers. Indonesian general government debt stays at 26 % of GDP at end 2014 and current gross funding needs of around 4 % of GDP a year are much lower than the median of other emerging market economies such as Brazil, Malaysia and Turkey (IMF 2015).

The 2011 census reported Indonesian population was 237,424,363 and estimated to be 255,461,700 in 2015, making Indonesia the 4th country with the largest population in the world (Statistics Indonesia 2015). About 40 % of this population is in their productive age. Indonesian ethnic composition varies very widely as the country has hundreds of ethnic and cultural diversity. However, more than half of the population are dominated by two largest ethnics, the Javanese (41 % total population) and the Sundanese (15 % total population). Both of them are the native of Java, the most populated island in Indonesia, home for approximately 60 % of the total population of Indonesia. In general the population consists of 50.3 % male and 49.7 % female with the current life expectancy stands at 72 years old (Ministry of Health et al. 2013).

In 2013, Indonesia has 11 cities with population over 1 million, with Bogor City is quickly approaching the 12th. Jakarta, the national capitol, is not just the most populated city in Indonesia, it is also the most populated city in Southeast Asia and the 13th most populated city on earth. The official metropolitan area, known as "Jabodetabek", is the second largest in the world, and the metropolis suburbs extend even further. The entire area has a population surpassing 28 million, which makes it one of the largest conurbations on earth. It is also one of the fastest growing cities on earth, growing faster than Beijing and Bangkok, with population density in the city reaches 15,342 people per square kilometer (Ministry of Health et al. 2013).

All of the above facts, in turn, affect the population health and healthcare service in Indonesia which at some points touch the aspects in biomaterials and medical devices as shown in previous chapters. In recent years, the Indonesian authorities have embarked on an initiative towards universal social insurance, including for health insurance and old-age security. The initiative began in 2004 with enactment of the Law on the National Social Security System, followed in 2011 by a law establishing a single social insurance administrator for health care, or BPJS Health (*Badan Penyelenggara Jaminan Sosial Kesehatan*). Under this framework, the government began implementing a universal health insurance system in January 2014, consolidating several public health insurance schemes, and is financed through contribution payments and aims at covering the entire population by 2019 (IMF 2015).

2 Challenge and Opportunity

It has been shown in previous chapters that the large population creates some challenges in providing basic healthcare services, notably dental care (Chap. "Biomaterials in Dentistry"). In addition, the concentrated population in main Indonesian cities has created chronic crowd traffics dominated by motorcycles that in turn contributes to high traffic accidents causing a high incidence of traumatic bone fractures (Chap. "Biomaterials in Orthopaedics"). These examples show a challenge related to providing adequate quantity of medical products in dentistry and orthopaedics which can be turn into opportunities of producing local, effective and low-cost biomaterials and medical devices. At some points, this opportunity can be also related to utilization of abundant Indonesian natural resources for even producing innovative biomaterials with strong local "taste" and self-sustainability (Chaps. "Naturally Derived Biomaterials and Its Processing", "Biocompatibility Issues of Biomaterials", "Biomaterials in Dentistry", and "Tissue Bank and Tissue Engineering").

Currently, Indonesia is merely a big market for imported medical products with a market value about 800 million USD in 2015 and estimated to 1.2 trillion USD in 2019. This market is dominated by diagnostic imaging, medical consumable products and implants. The Indonesian medical device market remains one of the fastest growing, with a compound annual growth rate of 14.6 % to 2019 (BMI Research 2015). The expansion of the health insurance programme, increased government spending on healthcare and infrastructure development projects will further spearhead growth.

The Government realizes that medical devices are important component in the healthcare service where their production relies strongly with the technology and economic strength of the country. They are considered as one of most valuable trading commodities with big social impact, therefore with the opening of ASEAN free-trade zone in 2015, the capability of producing medical devices locally becomes a strategic issue in Indonesia. According to a survey by the Ministry of

Health, it is revealed that only 6 % of medical devices are produced locally and the rest of 94 % are imported. This number is far below compared to the percentage of local products in the neighboring countries such as Malaysia (10 %), Vietnam (13 %), India (18 %) and Thailand (33 %), indicating a high dependence of Indonesia toward import (Hariyanti 2015).

Locally-owned domestic production mainly consists of the manufacture of basic items, such as surgical gloves, bandages, orthopaedic aids and hospital furniture, but a few local manufacturer produces orthopaedic implants competing some medium grade imported products (Chap. "Biomaterials in Orthopaedics"). One of the main challenge to local manufacturing of medical devices is the Government regulation itself that incurs 15 % taxes to imported raw materials while applies tax holiday to imported ready to use medical products. However, the actual market price for imported implants is always more expensive compared to similar products produced locally. This could be related to high overhead fee, shipping fee and promotional fee that at the end must be included in the selling price in Indonesia. Therefore, local products can be more competitive up to 60 % when those three factors are excluded. However, the next challenge is acquiring the technology of medical devices manufacturing and setting up manufacturing plants whereas the investment cost is high and increases as the level of technological content (added value) of the devices increases.

Indonesia is not lack of experts in medical devices and its manufacturing. They spread in many universities, research institutes and governmental institutions, such as those who contributed to the writing of this book. The country is not lack of potential investors either as there is always a number of rich Indonesians listed in yearly Forbes billionaires list. The total wealth of the 2015 Forbes list of 50 Indonesian richest business persons reaches 89.84 billion USD (Forbes 2015). The challenge is to unify those experts to mutually collaborate on the same interest toward the national autonomy (independency) in producing medical devices under an effective leadership. The Government should trigger the investment during the early research and development phase and when the potential become evidence, private investors will naturally be attracted.

3 Government Policy

3.1 Regulation

Indonesian Government have put healthcare service as one of the strategic program in the 2015–2019 National Development Plan. Along with creating strategic missions such as increasing access to healthcare service for all 255 million population, the authorities developed an effective national healthcare financing scheme that ensures, among all, the availability of drugs and medical devices (Table 1). The Ministry of Health has set a policy for assuring the availability and distribution of medical devices by fostering local production, improving quality of local medical

Table 1 Classification of medical devices according to the Indonesian Ministry of Health

Class	Consequence of failure or misuse	Requirement for approval	Example
I	Will not cause significant medical problem	Assessment is focused on product and its quality	Toothbrush, mask, dental flos, bandage, icebag, sunglasses (without ordonance), etc.
Ia	Can cause significant medical problem to patient but not serious (life threatening)	Requires complete assessment but clinical test is unnecessary	AC powered dinamometer, reflex-hammer, wheelchair, etc.
Iib	Can cause very significant medical problem to patient but not serious	Requires complete assessment, including risk analysis and safety proof but without clinical test	Contact lenses, ophthalmic laser, etc.
III	Can cause serious medical problem to patient or operator	Requires complete assessment, including risk analysis and safety proof and clinical test	Ventricular bypass device, orthopaedic implants, silicon gel filled breast, etc.

products and surveillance to the pre- and post-market medical devices. Another policy was enacted to strengthen national independency in fulfilling the need for pharmaceutical products and medical devices. One of the policy is the 2009 Law on Health that sets a strict standard on safety, efficacy and quality of pharmaceutical products and medical devices, pointing out on their affordability (Law 36 2009). A monetary fine up to 100,000 USD can be charged to individual who produces medical devices that don't meet the standard or illegally distributes any kind of medical product.

3.2 Roadmap for Medical Devices Development

The Government has a strong vision toward national independency on high quality medical devices produced based on a rigorous research and development program. Since 2014, serious efforts have been made to fulfill the demand of medical devices by local industry by facilitating investment in this sector, increasing the variety and quality of local medical devices, giving incentive to local industries and reducing import. The authorities enforce a regulation in prioritizing the use of local products while redefine stringent regulation for import such as the prohibition of using the state budget to subsidize import. The Indonesian Ministry of Research, Technology and Higher Education, have launched a multi-years grant scheme to Indonesian researchers for conducting research and development on biomaterials and medical devices utilizing optimum local content, and encourage collaboration with local industries.

Table 2 Indonesian roadmap for medical devices development (2014–2022)

Stage	Period	Aim
I	2014–2016	Optimizing current medium-low technology of local medical devices industry
		Increasing number of production facilities for medical devices
		Increasing use of local medical devices
		Setting up research and development in medical devices technology
		Initiating collaboration among industry, university and the Government
II	2017–2019	Developing research-based medium-high technology for medical devices
		Increasing number of production facilities with standardization from ISO 13485:2003 and good manufacturing practice of medical devices
		Increasing research and development activities in medical devices technology
		Increasing availability of local raw materials
		Decreasing number of imported medical devices distribution yet maximize the use of local products
		Increasing export of medical devices
III	2020–2022	Achieving national independency on research-based high technology medical devices
		Increasing number of production facilities with standardization from ISO 13485:2003 and good manufacturing practice of medical devices
		Increasing investment in medical devices industry
		Decreasing number of imported medical devices distribution
		Optimizing export of medical devices

Finally, the Indonesian Ministry of Health has launched a medium-term (8 years) roadmap for realizing the above vision. This roadmap is divided into three stages as described in Table 2 (Permenkes 86 2013).

One of actual example of national projects conducted under this roadmap is the research and development of coronary stents, a small implant used to open coronary artery occlusion. About 10 % of Indonesian population is elderies having potential cardiovascular problem and the prevalence of cardiovascular patients in Indonesia was around 530,000 in year 2013 (Ministry of Health Information Center 2013). All coronary stents used to treat Indonesian patients are imported, soaring the cost of stent implantation to exceed most of health insurance coverage limit (Tontowi et al. 2013). The Indonesian Ministry of Research, Technology and Higher Education has appointed Gadjah Mada University to lead a research and development on coronary stent which was started in 2013 under a “Triple Helix” model of university-government-industry interaction. The team have been conducting an interdisciplinary research covering materials and engineering aspect of stents till in vitro study and planned in vivo and clinical trials (Taufiq et al. 2015; Tontowi et al. 2015).

Apart of this roadmap, examples of other research and development resulting into commercially produced biomaterials and medical devices have been briefly exposed

in previous chapters. These include the GAMA-CHA human bone apatite composite for bone substitution developed at Gadjah Mada University (Chap. "Biocompatibility Issues of Biomaterials"), Bio-hydrox bovine hydroxyapatite scaffolds and various type of stainless steel bone plates developed at Airlangga University in collaboration with the Indonesian Agency for the Assessment and Application of Technology (Chap. "Biomaterials in Orthopaedics").

Finally, we would like to conclude that all favorable factors permitting the achievement of the national vision toward independency on medical devices evidently present. The high demand for medical devices has become the Government's concern reflected in the new policy of universal public healthcare insurance. The enthusiastic Indonesian biomaterials scientists find a place in the roadmap of medical devices development, where their creativity will continue to transform the actual challenge and opportunity into innovating effective and low-cost medical devices.

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