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Global trade and health: an Indonesian perspective on the ASEAN medical device directive policy

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Abstract

Purpose: Health care equipment international trade could serve a new strategic revenue for Indonesia. Since its implementation in 2015, AFTA has been a very strategic issue in creating export opportunities for its member countries. One of the sectors that becomes a priority for ASEAN integration is in the field of medical devices which is regulated in the ASEAN Medical Device Directive (AMDD) policy. Indonesia itself has officially ratified AMDD policy since 2018, but Indonesia will have been facing the problem of quality, innovation and diversification of medical devices. This study examines the competitiveness opportunities for domestic medical devices in ASEAN Free Trade Area. **Method:** This study used a qualitative method where information was obtained from in-depth interviews and document review. The informants came from policy makers, implementing officers, and stakeholders. **Results:** Indonesia has harmonized 26 out of 31 standards mandated by AMDD. Conformity assessment bodies in Indonesia that have been certified by the National Accreditation Committee have received international recognition. Indonesia has many potential exporting innovative medical devices to ASEAN countries. Fulfillment of medical devices is carried out through compulsory licensing and parallel import mechanism. **Conclusion:** Indonesia has a considerable opportunity in facing the ASEAN free market in the field of medical devices. AFTA is estimated to be able to meet the need for national medical devices in order to achieve a good degree of public health.

Keywords: ASEAN medical device directives; medical device; quality; export

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INTRODUCTION

Since its implementation in 2015, the *ASEAN Free Trade Area* (AFTA) is a very strategic issue in creating export opportunities for domestic products. One of the sectors that is the priority for ASEAN integration is medical devices which are regulated in *the ASEAN Medical Device Directive* (AMDD) policy. This AMDD regulates standards, technical rules and conformity assessments in order to create a world trade system that is increasingly open, free and competitive (ASEAN, 2015). The better the quality of medical devices, the better the competitiveness of medical devices in the global market [1,2].

For Indonesia, the AMDD policy is quite an open opportunity for various export activities of medical devices that have been produced and at the same time a challenge to produce competitive medical devices in the ASEAN regional market. Efforts in this direction seem to require more serious action from the government, industry and the *stakeholders* involved. This is because in general Indonesian medical devices will continue to be faced with problems of low quality, innovation and diversification of medical devices [3,4]. Whereas the aspect of fulfilling quality and innovation

in medical device technologies is an important point in international trade [5].

Trade liberalization is expected to be able to improve regional public health status by increasing accessibility to medical devices. However, trade liberalization cannot be completely free because there are limitations related to the protection of intellectual property rights [6–8].

Protection of intellectual property has been regulated internationally through *Trade Related Aspects of Intellectual Property Rights* (TRIPs) [7,9,10]. In its development, there is considerable concern that the use of intellectual property rights by inventors can cause economic justice problems and conflicts of interest which lead to global health problems [6,9]. On the one hand, intellectual property rights must be able to provide incentives for the invention of medical devices. The basic principles of the *World Trade Organization* (WTO) stipulate that in international trade there should not be discrimination, especially regarding access to affordable medical devices [6]. Therefore, in facing trade liberalization in ASEAN, Indonesia must have a policy to provide accessibility to medical devices for ASEAN countries while still ensuring the sustainable development of the health system that has been built.

One study showed that Indonesia's membership in AFTA did not have a significant impact on Indonesia's agricultural exports, so it is necessary to formulate policies related to implementing economic globalization to produce agricultural commodities that are competitive internationally. Other studies also reveal that the use of *preferential tariffs is* only concentrated on natural resource products, which causes a lack of export diversification. There is no evidence that the reduction *in preferential tariffs is* able to reduce the growth of imports from non-member countries [14].

While studies on free trade and its impact on the export position of Indonesian products have increased [11–13], there has been no research that discusses ASEAN free trade in medical devices which focuses on non-tariff matters. This study wants to examine the opportunities for competitiveness of Indonesian medical devices in ASEAN free trade and whether AFTA is able to meet the needs of national medical devices.

METHODS

This qualitative study collected data through in-depth interviews and document review. The informants were selected by *purposive sampling* using structured interviews, from August-September 2020 in several institutions implementing the AMDD: the Ministry of Health, the National Standardization Agency for Indonesia, the Ministry of Trade, the National Accreditation Committee for the Indonesian Medical Device Manufacturers Association (ASPAKI), Medical Device Manufacturers and the Conformity Assessment Institute.

RESULTS

Table 1 shows that of the 392 medical devices that can be produced in Indonesia, the government has formulated 318 Indonesian National Standards (SNI) and 16 SNIs in the opinion poll stage. Based on the results of interviews with informants, in the last two years the Technical Committee for Standard Development has focused on reviewing existing standards.

Table 1. Number of reference standards

	Number
SNIs That Have Been Issued	318 SNIs
SNI in the Polling Stage	16 SNI
Types of medical devices that alreadySNI	105 products
Types of medical devices capable of being produced in Indonesia	392 products

Source: List of SNI (National, 2020) (Penalkes, 2020)

Table 2 shows that Indonesia has harmonized 26 of the 31 standards mandated by AMDD.

Table 2. List of medical device standards to be harmonized in ASEAN countries

Harmonization	Detailed equipments
Standards that must be harmonized by ASEAN countries	IEC 60601-1, ISO/IEC 17011, ISO 13485, ISO 14971, ISO 15223-1, ISO 11135, ISO 11137-1, ISO 15190, ISO 11607-2, ISO 14155, ISO 10993 series (17 part), ISO 14729, ISO 14730, ISO 81060-1, IEC 60601-2
Standards that have not been harmonized by Indonesia	IEC 60601-1, ISO 13485,, ISO 15223-1, ISO 11135 , ISO 11607-2, ISO 10993 series (17 part), ISO 14729, ISO 14730, ISO 81060-1, IEC 60601-2
Standards not yet harmonized by Indonesia	ISO/IEC 17011, ISO 14971, ISO 11137-1, ISO 15190, ISO 14155

Source: Data on harmonized standards in ASEAN and a list of published SNIs (The ASEAN Secretariat, 2015) (National, 2020)

Table 3 presents the composition of domestic medical devices based on risk class is: class A (3114 products), class B (3564 products), class C (926 products and class D (21 products).

Table 3. Number of medical devices by class risk

Class Risk	Number of products
A	3114
B	3564
C	926
D	21

Source: List of Medical Device Info (Health, 2020)

Table 4 informs the availability of a conformity assessment agency (LPK) for 28 test laboratories, 2 equipment management system certification bodies, 29 calibration laboratories and 3 certification bodies in Indonesia that have received accreditation from the National Accreditation Committee (KAN). The majority belong to the government. Medical Device Management System Certification Bodies (LSSMA) still involve auditors from abroad.

Table 4. Number of conformity assessment bodies

	Number
Test Laboratories	28 institutes
Medical Device Management System Certification Bodies	2 institutes
Calibration Laboratories	29 institutes
Product Certification Bodies	3 institutes

Source: Accredited Client Directory (National Accreditation Committee, 2020)

Table 5 provides information that there are various types of medical devices that have great export opportunities to ASEAN countries because these products are innovative products of downstream research.

Table 5.Potential medical devices for export to ASEAN countries

No	**Type of Medical Devices**
1	Respiratory viral panel multiplex nucleic acid and assay
2	Hepatitis A Virus (HAV) serological Assays
3	Ultrasound and Muscle Stimulator
5	Covid detection device through breath (in the test phase clinical)
6	Water Powered Purifying Respirator
7	Pedicle Screw
8	Orthopedic implant
9	Nasopharyngeal Cancer Early Detection Tool
10	Machines anesthesia
11	Picture archiving and communication systems
14	Rapid test dengue testing
15	Semilunar flushing valve system
18	Electrocardiograph
21	Absorbable hemostatic agent and dressing
22	Impedance phlebograph
23	Perinatal Monitoring System and Accessories
24	Resorbable calcium salt bone void filler device
25	Aqueous shunt
26	Obstetric Gynecologic camera
29	Resin tooth bonding agent
30	Impression material

Information was obtained that KAN has obtained international recognition for the laboratory accreditation system: Asia Pacific Laboratory Agreement Cooperation (APLAC), International Laboratory Accreditation Cooperation (ILAC), Mutual Recognition Agreement (MRA), inspection bodies within the APLAC and MRA and accreditation of institutions. quality and environmental management system certification in the PAC/IAF MLA (Multilateral Recognition Agreement).

Table 6 shows changes in the average export of medical devices per year before implementing the AMDD (2015-2018) are: Singapore (0.91%), Thailand (9.40%), Philippines (7.23%), Malaysia (6.36%), Vietnam (8.40%), Myanmar (107.29) Cambodia (88.27%), Brunei Darussalam (14.81%), Laos (0.98%) and the change of overall ASEAN countries (5.23%). From 2015-2019, the trend of medical devices export increased. Meanwhile, the value of changes in exports of medical devices to ASEAN countries since the implementation of the AMDD (2018-2019) respectively as follows: Singapore (-4.66%), Thailand (11.51%), Philippines (6.32%), Malaysia (4,704%), Vietnam (-18,259%), Myanmar (-34.26%), Cambodia (15%), Brunei Darussalam (4.8%), Laos (195.92%) and the change of the whole ASEAN countries (-1.51 %).

Table 6. Changes in exports of Indonesian medical devices to ASEAN

Countries	% change in average exports per year before AMDD (2015-2018)	% change in exports per year after AMDD (2018-2019)
Singapore	0.91	-4.66
Thailand	9.40	11.51
Philippines	7.23	6.32
Malaysia	6.36	4.70
Vietnam	8.40	-18.26
Myanmar	88.27	-34.26
Cambodia	107.29	15.00
Brunei Darussalam	14.81	4.86
Laos	9.98	195.92
ASEAN	5.23	-1.51

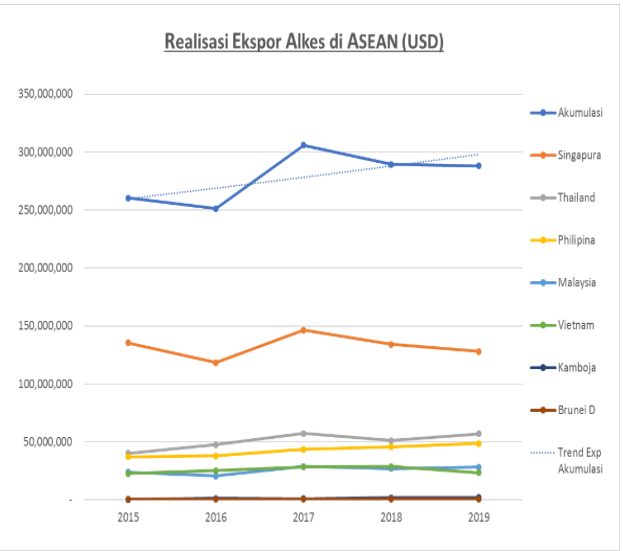

Figure 1. Medical device export trends 2015-2019 (in USD)

DISCUSSIONS

The results show that the standard Indonesia's reference is still lacking. The number of SNIs has not been able to keep up with the development of domestic types of medical devices. This means that so far the industry is still using a combination of SNI and international standards as a reference in manufacturing products. Reference standards play a role in efforts to comply with regulations and as a reference for the industry to ensure the safety, quality and performance of medical devices [15,16]. The shortage of existing standards is partly due to the fact that the Technical Committee for the formulation of standards in the last two years has focused on reviewing irrelevant standards stipulated in Regulation of the National Standardization Agency for Indonesia No. 6 of 2018 concerning SNI Review Guidelines [17]. Therefore, the improvement of the medical device standardization system is to improve quality control and encourage the development of the medical device industry [18].

Judging from the standards mandated by the AMDD to be harmonized by member countries, Indonesia has harmonized most of these standards into SNI. Standards that have not been harmonized into SNI are standards related to risk class D medical devices. This means that Indonesia has been able to penetrate the ASEAN market for low and medium risk medical devices. This is because standards have a role as a reference for shaping trade equality so as to minimize global trade imbalances [5]. Even though it has only harmonized 26 of the 31standards AMDD, Indonesia actually has quite a big opportunity to export medical devices. This can be seen from the composition of risk class A, B and C medical devices more than 99% [19]. If this opportunity is utilized properly, it is very possible that market share ASEAN'scan be owned by Indonesia.

LPK or what is often referred to as a notified body, is an institution that is very important in ensuring the quality of medical device products. This LPK has a function to check the compliance of medical devices to predetermined standards through testing, certification and inspection [20,21]. Just like in other countries, LPK in Indonesia are appointed and supervised by an agency authorized by the government, namely KAN [22]. KAN is appointed by the President and is responsible to the President through the Head of BSN [23]. With the international recognition that has been obtained by KAN, it means that the test certificate issued by the LPK can be used as a condition for exporting medical devices abroad. So that when entering ASEAN countries, these medical devices no longer need to be retested.

Based on the research results, the number of LPK is still very low. One of the reasons for this lack of LPK is the lack of private sector involvement in the provision of LPK. The lack of private sector involvement in LPK provision makes conformity assessment less competitive in terms of both time and service costs. The lack of availability of LPK, especially test laboratories, can cause the industry to conduct product testing abroad which requires greater costs. Test costs can affect the cost of production of medical devices which can cause the price of medical devices to be high [22]. Furthermore, it can affect the competitiveness of domestic medical devices.

In addition, the most important thing in the competitiveness of this medical device is the fulfillment of ISO 13485 which is certified by LSSMA. ISO 13485 certification is very important to ensure that the medical device industry management system meets the standards [24]. In Indonesia currently there are only two institutions LSSMA and involve auditors from abroad. This means, so far the industry has also involved LSSMA from abroad to carry out testing, certification and inspection of medical device management systems.

Through the innovation of medical devices it can be seen that there is a serious effort to provide better medical devices in terms of diversity, safety and effectiveness [25]. In order to protect Intellectual Property Rights (HKI) in the field of medical devices, the government provides that it has ratified the TRIPS (*The Agreement on Trade-Related Aspects of Intellectual Property Rights*) into Law Number 13 of 2016 concerning Patents and Law Number 28 of 2014 concerning copy rights [26]. Particularly in the health sector, Indonesia has issued several policies related to the regulation of Intellectual Property Rights (IPR) as

outlined in the Health Minister's Decree Number 1179A/Menkes/SK/X/1999 concerning the National Policy for Research and Development of IPR, Balitbangkes Strategic Plan 2010-2014 which stated that one of the main indicators in research and development of medical devices is the acquisition of IPR [26]. This IPR policy regulates incentives for medical device innovators.

In facing the challenges of global public health problems as a form of IPR protection, the fulfillment of medical devices is carried out through several mechanisms, namely compulsory licensing and parallel imports [27]. The compulsory license allows Indonesia as a developing country to import licensed medical devices from patented medical devices. Meanwhile, parallel imports can be done by importing from other countries that have been licensed by the inventor [27]. However, this policy has not been described in detail in the IPR policy in Indonesia.

Export data shows that since 2015, 9 ASEAN countries have annually imported medical devices from Indonesia, especially from Singapore and Thailand. This shows that Indonesian medical devices meet the quality requirements for entry into ASEAN countries. When viewed from the change in the average export per year, before the implementation of AMDD in 2015-2018, it increased by 5.23%. Meanwhile, after the implementation of AMDD in 2018-2019, there was a decrease of 1.51%. Based on these data, it cannot be concluded whether thepolicy AMDD has a positive or negative impact on the export of medical devices. This is because the AMDD has only lasted 2 years, and data collection has only been carried out until 2019. Based on the results of research conducted by previous researchers, the AFTA arrangement has a positive impact on manufacturing trade [28].

The increase in exports of medical devices is not only influenced by the implementation of AMDD, but also by *supply* and *demand factors*. An increase or decrease in ASEAN free trade can also occur due to the large number of product choices for importing countries, so that the *market share* of exporting countries *existing* decreases [11]. When viewed from the available data, the potential for medical device exports is expected to continue to grow, given that Indonesia is geographically closer to ASEAN countries than Europe and America, which are known as the *leader* of medical devices in the world. This geographic location is often a barrier to trade because of the high distribution costs that can affect product prices [11,29]. If this potential is utilized properly, Indonesia can achieve medical device independence and gain an economic impact in the trade sector [30,31].

CONCLUSION

Indonesia has a considerable opportunity in facing the ASEAN free market in the field of medical devices. AFTA is estimated to be able to meet the need for national medical devices in order to achieve a good degree of public health.

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