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## **Solution to the Problem of Costs of Medicines and Medical Devices (Alkes) Judging from Law no. 17 of 2023 concerning Health**

**Eko C. Burnama<sup>1</sup>, Najib Albana Daulay<sup>2</sup>, Mira Husna Nasution<sup>3</sup>, Desy Radhiyah<sup>4</sup>, Yusuf Sitinjak<sup>5</sup>**

<sup>1,2,3,4,5</sup>Master of Health Law, Panca Budi Development University

[ekoboer74@gmail.com](mailto:ekoboer74@gmail.com), [jipeenajibalbanadaulay@gmail.com](mailto:jipeenajibalbanadaulay@gmail.com),

[miamout84@gmail.com](mailto:miamout84@gmail.com), [desyradhiy12@gmail.com](mailto:desyradhiy12@gmail.com), [yusuf.sitinjakkep19@gmail.com](mailto:yusuf.sitinjakkep19@gmail.com)

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### **Abstract**

It is hoped that the Omnibus Law Law No. 17 of 2023 concerning Health will provide solutions to various problems in the health sector. Such as health services which are still dominated by curative approaches, availability and distribution of Health Resources (HR), readiness to face health crises, aspects of pharmaceutical independence and Medical Devices. One of the most important issues in the transformation of the health resilience system is the high cost of health services in Indonesia, one of the causes of which is the high price of pharmaceutical preparations and medical devices in Indonesia. Through this law, the government is implementing solutions to prioritize raw materials at the Domestic Component Level, providing fiscal and non-fiscal incentives, marketing certainty and incentives in research development. It's just that the ethical approach is not listed. Derivative regulations that discuss follow-up solutions to the high prices of pharmaceutical preparations and health equipment are still urgently needed.

**Keywords:** Medicines, pharmaceutical preparations, pharmaceuticals, medical devices

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### **INTRODUCTION**

The President of the Republic of Indonesia finally signed Law no. 17 of 2023 concerning Health on 8 August 2023, which was ratified at the DPR Plenary Session on 11 July 2023. For derivative regulations from Law no. 17 of 2023 concerning Health, namely in the form of a Government Regulation, which will be completed by the end of 2023. With the enactment of the Omnibus Law, Law No. 17 of 2023 concerning Health, it is hoped that it will provide solutions to various problems in the Health sector. Such as health services which are still dominated by a curative approach, availability and distribution of Health Resources (HR), readiness to face health crises, aspects of pharmaceutical independence and medical equipment.

However, of course, this aspect of the independence of pharmaceuticals and medical devices is hampered by the high cost of medicine which is a result of the high prices of medicines and medical devices in Indonesia because the condition of the pharmaceutical and medical equipment sector is still dependent on imports. Until now, 90% of medicinal raw materials for local pharmaceutical production are still imported, 88% of medical device transactions in 2019-2020 in the e-catalog are still imported products. Indonesia is one of the countries with the highest drug spending in the world, around 40% of its total health spending. Compare this with Japan, which spends only 15% of its drug spending and Germany only 19% of its total health spending.

Before the issuance of Law no. 17 of 2023, the government has made real efforts to rationalize the prices of generic drugs and drugs that are procured by the government. In 2006, Minister of Health Decree No. 336/Menkes/SK/V/2006 concerning the price of generic medicines where the net pharmacy price (HNA) has decreased by up to  $\pm 70\%$ . Likewise, the next Minister of Health Decree, namely number 521/Menkes/SK/IV/2007 and 302/Menkes/SK/III/2008 concerning the price of generic medicines, contains the same thing and there have been no principal changes. Furthermore, Minister of Health Decree Number HK.03.01/Menkes/146/I/2010 was issued which regulates the prices of generic drugs as follows; Of the 453 generic medicine items listed, the government reduced the prices of 63 types of generic medicines consisting of 106 generic medicine preparation items and increased 22 types of generic medicines consisting of 33 generic medicine preparation items, while the remaining 335 items had fixed prices. Through the Decree of the Minister of Health Number 094/Menkes/SK/II/2012, it was stated that there was an increase in prices for 170 medicines, but prices for 327 types of medicines fell.

The next step, the government issued Minister of Health Regulation no. 63 of 2014 which started implementing a system for ordering/purchasing medicines and medical devices through e-catalogs and e-purchasing payment systems.

This system is electronic information that contains lists, types, technical specifications and prices of certain goods from various providers of government goods/services. With this system, the government is trying to make the prices of medicines and medical devices more transparent and accountable.

A research conducted at the Jakarta Cempaka Putih Islamic Hospital to see the effectiveness of the implementation of the e-catalog on drug prices, found a significant downward trend in drug prices, both based on the type of drug and therapeutic class in the period after the implementation of the e-catalog with a reduction reaching more than 80%.

There are no strict sanctions yet for those who violate the selling price above the Highest Retail Price (HET) for medicines and medical devices in Law 17 of 2023. Consumers are not aware that their right to obtain correct, clear and honest information regarding the condition and guarantee of the goods and/or services they receive is protected in Law Number 8 of 1999 article 4 letter C concerning Consumer Protection. Meanwhile, in article 8 letter f, business actors are also prohibited from producing or trading goods and services that do not comply with the promises stated in labels, labels, information, advertisements or sales promotions for said goods and services.

According to Niken Ariati (2017), a researcher from the Corruption Eradication Commission, stated that the cause of high drug prices in Indonesia is that the drugs sold on the market are brand-name drugs and not generic drugs made by the government, there are no regulations regarding the Highest Retail Price (HET). for branded drugs, high promotional costs (marketing fees), imposition of Value Added Tax (VAT) on drugs for outpatients is 10% and this rate will increase to 11% from 1 April 2022 and to 12% on 1 January 2025 in accordance with article 5 of Law of the Republic of Indonesia Number 7 of 2021 concerning Harmonization of Tax Regulations, and the imposition of Luxury Goods Tax on Medical Devices.

*The USAID Medicines, Technologies, and Pharmaceutical Systems (MTaPS)* program conducted research comparing the policies of 11 Asian countries in determining drug prices in those countries. The results state that only India and Vietnam publish prices for all drugs registered in the country (generic or patented drugs) and only two countries, namely Indonesia and the Philippines, provide open tenders for the procurement of drugs and medical devices and ensure that the results of these tenders can be accessed. by all parties.

For this reason, the Indonesian Ministry of Health is working to improve government regulations and policies in Omnibuslaw Law No. 17 of 2023. And based on the information above, this research will conduct a review of Law No. 17 of 2023 concerning Health by focusing on the government's efforts to suppress high prices of medicines (pharmaceutical preparations) and medical devices in Indonesia.

## METHOD

This research is normative legal research with an analysis approach to government policy before and after the issuance of Law No. 17 of 2023 (statute approach) which is used to see the suitability and consistency of a statutory regulation with the government's targets. Research data is secondary data with data collection through literature study. Data analysis uses descriptive analysis which is used to discuss legal provisions regarding pharmaceutical services and the use or provision of medical devices in statutory regulations.

## RESULTS AND DISCUSSION

The concept of omnibus law is characterized by the ability to amend and repeal several laws in one law that covers all aspects. The presence of Omnibuslaw Law no. 17 of 2023 concerning health, which revokes 11 other laws, is the government's step in making adjustments to various policies to strengthen the health system in an integrative and holistic manner.

The fact that more than 90% of medicinal raw materials are still imported is one of the causes of the still high price of medicines in Indonesia so that the independence of domestic pharmaceutical products and medical devices has not been achieved. The value of imported medicinal raw materials reaches 30-35% of the total value of the national pharmaceutical business. The domestic medical equipment industry has been able to meet 50.82% of the minimum equipment standards for class A hospitals and 69.44% of the minimum equipment standards for class D hospitals. Currently produced domestically, it is dominated by low to medium technology products. Indonesia is still unable to make high-tech medical devices.

In Law no. 17 of 2023, the government opens up the widest possible opportunities for the public and industrial players to research, develop, produce, distribute, improve and use pharmaceutical preparations and medical devices whose benefits and safety can be accounted for and must meet the standards and requirements in accordance with legislation. . Article 326 states that independence in Pharmaceutical Preparations and Medical Devices is carried out through developing and strengthening supply chain governance from upstream to downstream in an integrated manner by prioritizing the use and fulfillment of domestically produced Pharmaceutical Preparations and Medical Devices.

To reduce the cost of importing medical devices, the government must strengthen supply chain governance, therefore the government issued regulations implementing freezing and unfreezing mechanisms. The freezing mechanism is carried out if the medical device product that is suitable for health service needs has been produced domestically and has a distribution permit and/or the production capacity of the medical device has met the planned medical device needs with product specifications that are suitable for health service needs. However, if these criteria are not met, an unfreezing mechanism will be implemented, which will reopen imports of medical devices if national needs have not been met by

the production capacity of the domestic medical device industry, and/or product specifications that cannot be produced in Indonesia.

The medical device industry throughout the world is a relatively small type of industry but requires special material specifications. If we look at the raw materials for certain medical devices, especially electromedical devices, they meet the TKDN (Domestic Component Level) requirements set by the government through Minister of Industry Regulation No. 31 of 2022, which states that domestic medical device products that will be a priority for procurement in state-owned facilities are medical devices that have been TKDN certified with a minimum local content value of 25 percent. In addition, medical device users are required to use domestic products if there are domestic products that have a combined TKDN value and Company Benefit Weight value of at least 40 percent.

The first problem arises, the demand for medical equipment in Indonesia is still small, so fulfilling the TKDN raw material target of reaching 25% is very difficult to obtain, especially electromedical equipment. If industry players meet the minimum TKDN standard target, the government must also guarantee that the downstream side must be prepared to accommodate the production results. This means that the government must ensure that the product will be absorbed by the market, at least the domestic market. If not, then fulfilling TKDN will be in vain because entrepreneurs will definitely prefer to just import.

The second problem is the priority of purchasing by the government. Currently, the first purchasing priority by government institutions is given to TKDN and BMP certified products of at least 40 percent. Second priority is given to TKDN certified products of at least 25 percent to below 40 percent. The third priority is given to Domestic Medical Device (AKD) products that have not been TKDN certified or have a TKDN certificate with a value of less than 25 percent. And the final priority is given to imported medical devices (AKL products). As a result, medical device business actors are competing to catch TKDN and BMP of at least 40 percent or even more. This means that the weight of security, quality, performance, is no longer the center of attention. Strengthening the implementation of TKDN is interpreted as a signal to choose products with the highest TKDN value, whatever the conditions.

The third problem, it turns out that government support in preparing medical devices with TKDN standards is not accompanied by the availability of an adequate certification assessment surveyor body. Currently there are only 2, namely Surveyor Indonesia and Sucofindo. The large number of requests for equipment certification assessments makes it difficult for the surveyor team to meet the time target, making it difficult to achieve the time target quickly and of course the costs are neither cheap nor easy.

The final issue concerns the minimum production quantity, because this minimum quantity will determine the continued production of these medical devices. If the minimum target for product manufacturing/marketing is not achieved, it will be difficult for business actors to continue the product's sustainability.

For pharmaceutical preparations, the government through the Ministry of Health prioritizes the use of domestically produced raw materials listed in electronic catalogs with a domestic component level (TKDN) value of at least 52% (fifty two percent) for medicines and traditional medicines, and at least 70% (seventy percent) for vaccines and serums according to the determination of the ministry that handles government affairs in the industrial sector. Fulfilling TKDN standards for pharmaceutical preparations is certainly not as difficult as for medical devices, what is important for the government is market availability, ease of licensing and implementation of incentives.

In article 326, other support by the government comes by providing fiscal and non-fiscal incentives for the pharmaceutical and health equipment industry. In terms of providing fiscal incentives, the government provides tax reductions and elimination of import duties. When Covid-19 hit, the government poured it outfiscal incentives in the form of eliminating import taxes, import duties and others for medical equipment (Alkes) amounting to IDR 799 billion from the value of imported goods of IDR 4 trillion for medical equipment needed to handle Covid-19. However, providing fiscal incentives also has a negative effect, lest the tax discounts given do not return to the state in the form of tax revenues. That will make the government spend more money rather than getting future revenues due to increased industrial performance.

The non-fiscal incentives provided include ease in business licensing, prioritization of the use of domestic products for government procurement of goods/services, and ease in trade governance. Regulations regarding this drug are one of the biggest obstacles in the drug production process because the rules are very strict. This regulatory process in Indonesia is handled by the Food and Drug Monitoring Agency (BPOM). The discovery of a substance for pharmaceutical preparation must start from testing on animals, after which it will go through 3 phases of testing on humans, before finally a recommendation is issued. You can imagine how complicated and difficult it is to be in these phases and of course the costs are also very large. During the last Covid-19 pandemic, we heard about the existence of an Indonesian vaccine, even though it was an urgent situation, BPOM did not provide a recommendation to proceed to phase II testing because the phase I test found problems. Ethically, this deserves a thumbs up because BPOM really respects and protects every life if it turns out the results are not appropriate. However, from an economic perspective, of course this is very detrimental to business actors who make the vaccine.

According to Articles 318-319, the Central Government has the authority to regulate and control the prices of Health Supplies, especially Medicines and Medical Devices. However, until now the majority of drugs sold on the market are branded drugs and not generic drugs made by the government and until now there are no regulations regarding the Highest Retail Price (HET) for branded drugs. Another obstacle to increasing drug prices is the existence of patent rights granted by the government for the discovery of new drugs. With monopoly patent rights, there is freedom for factories to set

prices as high as possible to get the highest profits<sup>1</sup>. So there is also a need for strict regulations regarding the regulation of patent rights.

Norway, England and Sweden are the 5 countries with the cheapest drug prices in Europe implementing regulations that suppress profit margins taken by pharmacies/pharmacies<sup>2</sup>. Policies to regulate profit margins from the downstream side such as pharmacies or drug stores also need to be made in one regulation, just as the government sets a profit margin limit for government procurement of goods and services of 10% -15%.

Burton et al (2001) stated that in controlling drug costs, apart from the economic side, there must also be normative values in the form of ethics held by the health sector. These values will be present if awareness arises regarding limited resources for procuring medicines, the patient's right to get the best, a sense of humanity for the sick and miserable, shared trust, and awareness regarding the choice of medicine as a joint decision.<sup>3</sup> Law 17 of 2023 does not include this ethical approach with the aim of reducing the high prices of medicines and health devices.

In terms of implementing a law, of course there are rules that regulate sanctions for business actors. Criminal provisions for business actors or distributors in the pharmaceutical and medical device sector are contained in Law no. 17 of 2023 will increase, both in terms of length of detention and monetary fines. Previously in Law No. 36 of 2009 concerning health it was stated that, Every person who deliberately produces or distributes pharmaceutical preparations and/or medical devices that do not meet the standards and/or requirements for safety, efficacy or usefulness, and quality as intended in Article 98 paragraphs (2) and paragraphs (3) are punishable by a maximum imprisonment of 10 (ten) years and a maximum fine of Rp. 1,000,000,000.00 (one billion rupiah). In Law no. 17 of 2023 shall be punished with a maximum imprisonment of 12 (twelve) years and a maximum fine of 5,000,000,000.00 (five billion Rupiah).

## CONCLUSION

The high cost of health services in Indonesia is an important factor that must be resolved immediately. Because this could disrupt the Transformation of the National Health Security System. One of the reasons for the high cost of health services is due to the high cost of medicines and medical equipment in Indonesia. For this reason, the government is simplifying legislation and making everything easy to reduce the production costs of pharmaceutical preparations and medical devices. However, the government should also not ignore the obstacles that occur, especially in the field, because this could become an obstacle to the implementation of future government programs.

However, behind all that, there are still other important questions that might influence the prices of medicines and medical devices and open up opportunities for further research, namely an ethical approach to answering the question, Are there still moral considerations and ethical rules in the pharmaceutical industry sector?

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