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**THE CURRENT SITUATION OF USING DOMESTICALLY
PRODUCED WESTERN MEDICINES WITHIN THE
PAYMENT SCOPE OF HEALTH INSURANCE IN PUBLIC
HOSPITALS AND IMPACTS OF POLICY INTERVENTIONS,
2017-2019**

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RATIONALE

According to statistics from the Ministry of Health, the average ratio of domestically produced medicines used in 2012 at medical facilities at the district level was 61.5%, but this ratio at the provincial level was only 33.9% and at the central level was only 11.9%. Although the global medical community has been increasingly supporting for domestic production of medicines, the psychology of most people and even medical staff still prefer prescribing and using expensive imported medicines for the healthcare and medical treatment demands. To address such situation, the Ministry of Health issued Circular No.10/2016/TT-BYT on the list of domestically produced medicines that meet the requirements of treatment, prices and supply capacity (Circular 10). After a period of time implementating of Circular 10, some questions are raised, including How does Circular 10 affect the use of medicines domestically and Who is affected by the Circular? And how is the current status of using domestically produced medicines that are covered by the health insurance (HI) fund in public hospitals in Vietnam? We have conducted a study on the topic: **"The current situation of using domestically produced western medicines within the payment scope of health insurance in public hospitals and impact of policy interventions, 2017-2019"** with the following objectives:

- 1. Describe the current situation of using domestically produced western medicines within the payment scope of the Health Insurance Fund in public hospitals in Vietnam in 2017.*
- 2. Analyse the impact of Circular No.10/2016/TT-BYT on the use of domestically produced western medicines within the payment scope of the Health Insurance Fund in public hospitals in Vietnam in the period 2017 - 2019 and a number of subjects affected by the policy.*

NEW CONTRIBUTIONS OF THE THESIS

This is a research project which conducted for the first time to comprehensively and completely evaluate actual situation of using domestically produced western medicines within the payment scope of HI as well as to analyze the impact of the Circular 10 on the use of domestically produced medicines in the entire public hospital system in Vietnam and on a number of target groups affected by this policy. The scientific information from the topic will be the premise to suggest further studies in the field of domestical medicines, health insurance, medicine prices, and using medicines rationally.

By describing the current situation of using western medicines within the scope of payment of the HI fund, the research project has provided an overview of the structure of domestic and foreign drug use, as well as reflecting the change of drug use structure during the implementation of Circular 10. The analysis of the impact of Circular 10 on a number of subjects affected by the policy is a crucial and core basis for proposing recommendations to state management agencies and pharmaceutical enterprises to ensure the timely and sufficient supply of high quality and affordable prices for the citizens.

STRUCTURE OF THE THESIS

The main part of the thesis is 149 pages long, including the following parts: Rationale: 2 pages; Chapter 1 - Overview: 30 pages; Chapter 2 - Subjects and research methods: 21 pages; Chapter 3 - Results: 53 pages; Chapter 4 - Discussion: 40 pages; Conclusion and recommendations: 3 pages. The thesis has 138 references, including 90 documents in Vietnamese and 48 documents in English. The thesis has 26 tables, 12 figures and 26 boxes. The appendix contains 13 appendices and 67 pages.

Chapter 1: OVERVIEW

1.1. Some concepts

❖ *The concept of medicine*

Medicine means a preparation containing a pharmaceutical ingredient or medicinal materials for the purpose of prevention, diagnosis, cure, treatment or mitigation of human diseases or modification of physiological functions of the human body. Medicines include chemical medicinal products, herbal medicinal products, traditional drugs, vaccines and biological medicinal products.

❖ *The concept of western medicine*

In the field HI payment, the term "western medicine" is used in this study to refer to chemical medicinal products and biological medicinal products.

❖ *Domestically produced medicine, imported medicine*

Based on the source and origin of medicines, medicines are divided into two categories: domestically produced medicines (also called Vietnamese drug, domestic drug, “inner drug”) and imported medicines (also called foreign drug, “outer drug”, oversea imported drug).

1.2. The situation of using domestically produced western medicines within the scope of payment of the HI fund in hospitals

According to statistics from Vietnam Social Security, over the recent years, the medicine bills have accounted for a relatively large proportion of the cost of health examinations and treatment covered by HI. From 2009 to 2012, the medicine costs accounted for more than 60% of health examination and treatment costs covered by HI.

According to a survey on HI medicine’s assurance activities conducted by Ho Canh Hau at the 105 Military Hospital between 2015 and 2018, the number of items (NOI) of purchased domestic drugs (DD) accounted for

about 45.83% - 49.77%, slightly lower than the foreign drugs (FD), however, the amount spent on FD is always much higher than on DD, accounting for 70-83% of the total annual drug value.

According to the findings from Nguyen Thanh Thao's analysis of the list of medicines covered by health insurance classified by origin in public hospitals in Da Nang City in 2016, the number of items of DD is higher than that of FD, but in terms of drug value, DD are lower than FD at the central and provincial levels.

1.3. Impact of Circular 10 on the use of domestically produced western medicines that are covered by the HI fund in hospitals

❖ The basis for promulgating Circular 10

In order to guide Article 50 of Law on Bidding No. 43/2013/QH13 of November 26th, 2013 (“For domestically produced drugs which were announced by the Ministry of Health and meet the requirements of treatment, drug price and supply capacity, the bidding documents are required to stipulate that the contractor is not allowed to offer imported drugs”), on May 5th, 2016, the Ministry of Health issued a list of domestically produced drugs that meet the requirements of treatment, drug price, and supply capacity.

❖ The main content of Circular 10

Circular 10 consists of 4 articles and takes effect from July 1st, 2016, promulgating a list of 146 western medicines which have technical criteria meeting WHO-GMP principles and standards. Accordingly, for medicines which is on the List of this Circular, if they belong to the technical criteria of any medicine group, the bidding documents of public medical examination and treatment facilities must impose that the contractors are not allowed to offer imported medicines in that medicine group as well.

Chapter 2: SUBJECTS AND RESEARCH METHODS

2.1. Subject, location, time of research

2.1.1. Research subjects

2.1.1.1. Subjects of quantitative research

- Database on the current situation of using domestically produced western medicines at public medical examination and treatment facilities in 03 years 2017, 2018 and 2019.

- *Selection criteria:* subjects must meet all of the following criteria:
Available in Vietnam Social Security database from 2017-2019.

Under the type of public hospitals or medical centers with hospital beds (hereinafter referred to as "hospitals").

Under one of the following classes: special, first, second or third class.

- *Exclusion criteria:* Traditional medicine hospitals.

2.1.1.2. Subject of qualitative research

❖ Targeted groups who were affected by the policy in 2020

- Patient group includes those who have visited public medical examination and treatment facilities and have completed medical examination and treatment procedures.

- Hospital group: Doctors who have been treating at hospitals and have at least 05 years of working experience at hospitals; Pharmacists in the department of pharmacy who obtained university degrees in pharmacy and have been working at the pharmacy department of the hospital and has one of the following duties: drug bidding or pharmacy profession, and have at least 05 years of working experience at hospitals.

- Business group: Representatives of DD production or enterprises obtaining university degrees or higher, having at least 03 years of working experience at the enterprises; Representatives of FD trading enterprises

who had university degrees or higher, having at least 03 years of working experience at the enterprises.

❖ Targeted groups who implement the policy:

- State management agency in charge of pharmaceuticals: Representatives of Drug Administration of Vietnam (Ministry of Health) who are leaders at the departmental level or higher, having university degrees in pharmacy, and being in charge of one of the following areas: Drug Price Management or Drug Quality Management.

- Vietnam Social Security: The representatives of Vietnam Social Security by 2020 who have at least 05 years of working experience and having duties related to Drug Price Management.

❖ General exclusion criteria for qualitative research subjects:

- Inability to answer research questions.

2.1.2. Research location:

- Drug Price Management Department - Committee of Health Insurance Policy Implementation in Vietnam Social Security.

- From the website of the Drug Administration of Vietnam - Ministry of Health.

- 108 Military Central Hospital; Lung Central Hospital; Friendship Hospital and Thanh Nhan Hospital.

2.1.3. Study time: from December 2016 to December 2020.

2.2. Research methods

2.2.1. Study design: Cross-sectional design, collecting both quantitative and qualitative data, which composes 03 phases: Phase 1 – A retrospective cross-sectional descriptive study; Phase 2 – Policy analysis research; Phase 3 – Qualitative Research

2.2.2. Study sample size

❖ **Quantitative study:** Selected all database on the current situation of using domestically produced western medicines at public medical examination and treatment facilities in 03 years 2017, 2018 and 2019 of 1,010 public hospitals from the central level to the district level that met the selection criteria.

❖ **Qualitative research:**

(1) Targeted group who were affected by the policy (22 people):

- Group of patients: purposive selection of 06 people.
- Hospital group: purposive selection of 06 doctors and 02 pharmacists working in pharmacy department.
- Business group: purposive selection of 04 representatives of DD manufacturing and trading enterprises; purposive selection of 04 representatives of FD trading enterprises.

(2) Target group who implement the policy (04 people):

- State management agency in charge of pharmacy: purposive selection of 02 officials (Ministry of Health)
- Vietnam Social Security: purposive selection of 02 officials.

2.2.3. Variables and indicators of the study

(1) Description of the current situation of using domestically produced western medicines in Vietnam in 2017:

- Ratio of using western medicines by the number of drug items between DD and FD.
- Ratio of use of western medicines by the monetary value used between DD and FD.
- Ratio of using western medicines by the drug value of using DD in hospitals.
- Ratio of using the number of items of DD and FD by the bidding package/contracting group.

(2) Analysis the impact of Circular 10

- Impact of Circular 10 in the use of domestically produced western medicines

+ Ratio of the number of domestic drug items under Circular 10 that were used to the total number of items used in 2017, 2018, and 2019 at different hospital levels.

+ Ratio of the monetary value of DD in Circular 10 to the total amount of drugs used in 2017, 2018, and 2019 at different hospital levels.

+ Ratio between the number of items of FD under Circular 10 that were used compared to the total number of drug items used in 2017, 2018, and 2019 at different hospital levels.

- Impact of Circular 10 on some groups affected by the policy

+ Topic: Effects of Circular 10 on patients, doctors, pharmacists working in pharmacy department, payment of HI fund and state management of pharmaceuticals.

2.3. Data collection tools and methods

(1) Collecting information for quantitative research

- Collecting data from the secondary databases: Using Microsoft Excel to extract information related to the current situation of using western medicines according to TT10 of 1,010 hospitals.

- Using a Microsoft Excel file in which a pre-designed data table is created to necessary additional information where the data from the Vietnam Social Security is not available, unclear or incomplete.

(2) Collecting information for qualitative research

Methods of information collection: In-depth interviews with relevant subjects (patients; doctor; pharmacist at department of pharmacy; enterprises producing and trading in DD; enterprises trading FD; staff of Drug Administration of Vietnam - Ministry of Health; staff of Vietnam Social Security).

2.4. Data analysis:

Quantitative data are aggregated using Power Query in Microsoft Excel (Professional Plus version 2019), and then brought into Power Pivot in Microsoft Excel version 2019 for management and analysis.

Policy effectiveness assessment: Stata software (version 15) was used to perform statistical tests. Statistical test Chi-square is used to compare the difference in the ratio of the number of drug items, the number of active ingredient items for DD or FD over time during the implementation of Circular 10 (compare the ratio in 2018 and 2019 to those in 2017). The Fisher Exact test value is used to replace the value of the Chi-square value in the case that at least 20% of the cell values have the expected value < 5 . The ratio was used to compare the difference between the monetary value used for domestic and FD over time during the implementation of Circular 10 (compare the ratios in 2018 and 2019 to those in the year of 2017).

Qualitative data were recorded, transcribed, noted additionally and analyzed according to interview content, data analysis by topics.

2.5. Research ethics

This research was conducted with the approval of the Doctoral Dissertation Proposal Council of Hai Phong University of Medicine and Pharmacy. The implementation of the study by the doctoral research student was approved by the Drug Administration of Vietnam (Ministry of Health). Information is collected only with the consent of Vietnam Social Security and the research subjects. The personal information of research participants is protected by encryption. Research is conducted on the basis of ensuring the integrity and objectivity of the research implementers. The figures and data published on this topic are for research purposes only and will not be used for any other purpose.

Chapter 3: RESULTS

3.1. The situation of using domestically produced western medicines under the payment scope of HI in public hospitals in Vietnam in 2017

The study was conducted on 1,010 public hospitals in Vietnam to describe the current situation of using domestically produced western medicines within the payment scope of the HI fund in 2017. It showed that DD accounted for a higher proportion of drug items (60.13%).

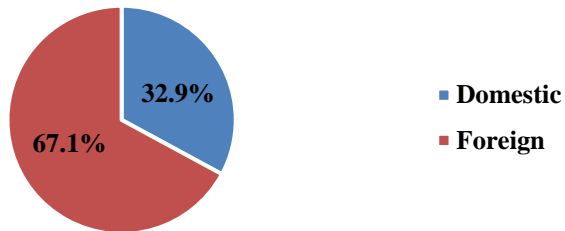


Figure 3.2. Distribution of domestic and foreign drug structure by value of drugs used in 2017

Comment: The value of FD use is higher than that of DD (67.10% compared to 32.90 %).

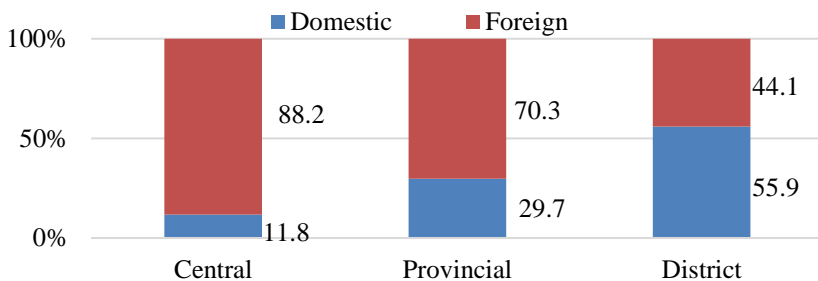


Figure 3.5. Distribution of domestic and foreign drugs by value of drugs used in hospital lines in 2017

Comment: The value of DD use is highest at the district level (accounting for 55.9%); and lowest at the central level (accounting for 11.8%).

**Table 3.4. Structure of western medicine use by bidding package/
bidding group and origins and sources in 2017**

(*Unit: Billion VND)

Bidding Package/ Bidding group		Drug item number Quantity (%)			Monetary value of drug use* Value (%)		
		DD	FD	Total	DD	FD	Total
Brand name		248 (20.26)	976 (79.74)	1,224 (12.4)	893.57 (9.27)	8,749.87 (90.73)	9,643.44 (38.8)
Generic	Group 1	800 (33.39)	1,596 (66.61)	2,396 (24.3)	2,397.22 (29.66)	5,685.56 (70.34)	8,082.78 (32.6)
	Group 2	548 (35.26)	1,006 (64.74)	1,554 (15.7)	1,352.83 (41.20)	1,930.52 (58.80)	3,283.35 (13.2)
	Group 3	4,172 (100.00)	0 (0.00)	4,172 (42.3)	3,302.49 (100.00)	0.00 (0.00)	3,302.49 (1.3)
	Group 4	128 (94.12)	8 (5.88)	136 (1.4)	221.74 (94.33)	13.34 (5.67)	235.08 (0.9)
	Group 5	41 (10.46)	351 (89.54)	392 (4.0)	2.02 (0.71)	281.53 (99.29)	283.55 (1.1)
Overall		5,937 (60.13)	3,937 (39.87)	9,874 (100)	8,169.87 (32.90)	16,660.82 (67.10)	24,830.69 (100)

Comment: In the brand name package and groups 1, 2, 5 generic FD have a higher number of drug items and a higher value of usage amount than DD. Groups 3 and 4 generics have a much higher number of items and monetary value of DD than FD, with group 3 generics having 100% of DD.

3.2. Impact of Circular 10 on the use of domestically produced western medicines within the payment scope of the HI fund in public hospitals in Vietnam in the period 2017 - 2019 and some groups affected by the policy.

3.2.1. Impact of Circular 10 on the use of domestically produced western medicines

Table 3.8. Comparison of the ratio of domestic drug use in Circular 10 during the periods of 2018 and 2019 to that of 2017 by number of drug items

Number of drug items		2017 (1)		2018 (2)		2019 (3)		χ^2 P^{*}_{21}	χ^2 P^{*}_{31}
		NOI	%	NOI	%	NOI	%		
Total 3 levels	DD-Circular 10	809	8.19	858	8.15	821	7.66	0.01 0.90	2.03 0.15
	Total drug	9,874		10,534		10,723			
Central	DD-Circular 10	371	6.14	369	5.91	349	5.60	0.29 0.58	1.63 0.20
	Total drug	6,040		6,246		6,233			
Provincial	DD-Circular 10	680	7.86	706	7.77	664	7.26	0.05 0.81	2.34 0.12
	Total drug	8,650		9,091		9,152			
District	DD-Circular 10	737	9.09	787	9.05	750	8.50	0.00 0.92	1.83 0.17
	Total drug	8,108		8,697		8,823			

(p_{21} : 2018 compared to 2017; p_{31} : 2019 compared to 2017)

*: Using test Chi-square)

Comment: The numbers of DD items under Circular 10 in 2018 and 2019 are higher than in 2017 across hospital levels. The number of DD items under Circular 10 as a percentage of the total number of drugs in 2018 and 2019 is lower than in 2017 at all levels and at each hospital level. This difference was not statistically significant ($p > 0.05$).

Table 3.9. Comparison of the ratio of domestic drug use in Circular 10 during the periods of 2018 and 2019 to that of 2017 based on the value of drugs used

(*Unit: billion)

Variable		2017 (1)		2018 (2)		2019 (3)		Ratio (2-1)	Ratio (3-1)
		Value*	%	Value*	%	Value*	%		
Total 3 levels	DD-Circular 10	810.23	3.26	902.28	3.05	1,247.58	3.47	0.93	1.06
	Total drug	24,830.69		29,620.82		35,977.52			
Central	DD-Circular 10	39.14	0.64	39.23	0.47	52.63	0.52	0.72	0.80
	Total drug	6,069.54		8,427.79		10,142.73			
Provincial	DD-Circular 10	281.09	2.43	320.70	2.44	432.57	2.75	1.00	1.13
	Total drug	11,555.73		13,157.26		15,707.02			
District	DD-Circular 10	490.00	6.80	542.34	6.75	762.38	7.53	0.99	1.11
	Total drug	7,205.42		8,035.77		10,127.77			

Comment: The monetary value of DD under Circular 10 during the years of 2018 and 2019 is higher than that of 2017 at all hospital levels as well as at each hospital level. Ratio of monetary value of DD under Circular 10 in total 3 levels compared to the total value of drugs used in 2019 is higher than in 2017.

Table 3.10. Foreign drug use ratio under Circular 10 for the years of 2018-2019 compared to 2017 by number of items

Number of drug item		2017 (1)		2018 (2)		2019 (3)		χ^2 P* ₂₁	χ^2 P* ₃₁
		NOI	%	NOI	%	NOI	%		
Total 3 levels	FD-Circular 10	316	3.20	310	2.94	290	2.70	1.13 0.28	4.42 0.03
	Total drug	9,874		10,534		10,723			
Central	FD-Circular 10	193	3.20	193	3.09	171	2.74	0.11 0.73	2.17 0.14
	Total drug	6,040		6,246		6,233			
Provincial	FD-Circular 10	268	3.10	261	2.87	248	2.71	0.79 0.37	2.38 0.12
	Total drug	8,650		9,091		9,152			
District	FD-Circular 10	260	3.21	262	3.01	248	2.81	0.52 0.46	2.27 0.13
	Total drug	8,108		8,697		8,823			

(p_{21} : 2018 compared to 2017; p_{31} : 2019 compared to 2017)

*: Using test Chi-square test)

Comment: The number of FD items under Circular 10 in 2018 and 2019 is higher than in 2017 for all hospital levels. The percentage of FD items in Circular 10 calculated by all hospital levels in 2019 (2.70%) is lower than in 2017 (3.20%), and the difference is statistically significant ($p < 0.05$).

3.2.2. The impact of Circular 10 on some groups affected by the policy

Box 3.16. Effects of Circular 10 on doctors

"...The doctors tend to prescribe medicines which are available in the hospitals. If imported drugs from countries that are not well known in the drug market are eliminated from the bidding process, I would feel more confident to prescribe medicines because the quality of imported drugs are not always stable."

(Doctor-02)

"The specific condition of my patients is very severe and requires surgery. The use of post-surgery medication must be considered very carefully. Therefore, I often prescribe high-quality foreign drugs to help my patients recover more quickly."

(Doctor-03)

"...Except the patients suffering serious and critical illnesses, I usually prescribe domestic drugs to ensure recovery from the illness and to reduce the cost of the patient's medications...Circular 10 allows prescribing domestic drugs more convenient."

(Doctor-04)

Receive review: Some other doctors said that Circular 10 empowered doctors conveniently to prescribe DD drugs to ensure effectiveness and suitability with the patient's economic conditions. In addition, there are also some doctors who often prescribe FD for patients to recover quickly after the surgery.

Box 3.17. Effects of Circular 10 on pharmacists

"...Circular 10 provides a list of domestically produced drugs that meet the criteria of both meeting the treatment requirements and at affordable prices, so it is very convenient for building a drug list at the hospital. Moreover, hospitals are currently in the autonomous stage, so they have to balance how to still buy drugs to meet the treatment requirements at optimal cost to ensure hospital revenues and expenditures...."

(Pharmacist-02)

Comment: Circular 10 has created a legal basis and favorable condition for healthcare facilities in building a drug list, selecting and purchasing drugs that ensure high-quality, effective treatment at affordable price.

Box 3.21. Effects of Circular 10 on the state management of pharmaceuticals

“Circular 10 aims to institutionalize policies that promote the development of domestic pharmaceutical production, contribute to the improvement of health security by promoting the development of the domestic pharmaceutical industry and thereby limiting dependence on imported drugs. It minimizes the risk of supply chain disruption when the source of imported drugs is interrupted, and the price of imported drugs is high.”

“Drugs of Circular 10 are those that have at least three registration numbers of three domestic manufacturers according to the group of technical criteria, so it will help avoid price increases due to not offering foreign drugs ...”.

(DAV-01)

“...The issuance of Circular 10 by the Ministry of Health will create a driving force to promote the development of Vietnam's pharmaceutical industry...”

(DAV-02)

Comments: Circular 10 aims to institutionalize policies that promote the development of Vietnam’s pharmaceutical industry, thereby helping to improve health security by limiting dependence on imported pharmaceuticals. It also minimizes the risk of supply chain disruption in case of FD supply source disruption and increased FD price, while at the same time help avoid price increases due to not offering the FD.

Chapter 4: DISCUSSION

4.1. The situation of using domestically produced western medicines within the payment scope of the HI fund in public hospitals in Vietnam in 2017

A study of 1,010 public hospitals in Vietnam on the current use of domestically produced western medicines under the payment of the HI fund showed that in 2017, the number of DD items was higher than that of FD 60.13. % vs. 39.87%. The results of this study are nearly three times higher than those of Le Thi Tuyet Mai's study (2016) at Bach Mai Hospital, where the number of items of DD accounted for 22.1% of the total. This result could be attributed to the fact that Le Thi Tuyet Mai's study conducted at the Central Hospital, meanwhile our study was conducted at all three levels (central, provincial, and district).

Although the number of DD items comprised a higher proportion than that of FD items, the total value of DD accounted for only 32.90% of the total cost of drugs used in 2017 (Figure 3.2). This result is consistent with a study by Nguyen Thanh Thao (2018), which analyzed a list of western medicines covered by HI in 21 public hospitals in Da Nang city in 2016, in which, the number of DD items was higher than that of FD, but the value of DD was much lower than that of FD.

Regarding the total drug monetary value, DD value is highest at the district level (accounting for 55.9%) and lowest at the central level (accounting for 11.8%) (Figure 3.5). This result is similar to a study by Ha Van Thuy in 2013 on the analysis of structure of HI drugs in Hai Phong city, which found a larger share of FD used in city hospitals than at the district level (81.7% and 45.2%).

Structure by bidding package/bidding group: The innovator medicine package and Generic groups 1, 2, and 5 have higher numbers of items and

monetary values of FD than that of DD, while Generics groups 3 and 4 have the number of items and monetary value of DD much higher than that of FD, with Generic group 3 accounting for 100% for DD (Table 3.4). For the innovator medicine package in our study, the results showed that the use of FD in Generic Group 1, and the use of DD in Generic Group 3 are consistent with Nguyen Thi Xuan Phuc's study, which analyzed the results of bidding drugs in Nghe An Provincial Health Department in 2016. In that study, the monetary values of FD in the innovator medicine package and Generic Group 1 were 100% and 99.70% respectively, while the monetary value of DD in Generic group 3 is 100%.

4.2. The impact of Circular 10 on the use of domestically produced western medicines within the payment scope of the HI fund in public hospitals in Vietnam from 2017 to 2019 and some groups affected by the policy

4.2.1. Impact of Circular 10 on the use of domestically produced western medicines

To assess the impact of Circular 10 on the use of domestically produced western medicines, this study compared the structure of the number of items and monetary values of DD and FD in Circular 10 in different time periods in 2018, 2019 compared to 2017 in 1,010 public hospitals across the country. When we compared to the use of DD under the Circular 10 in periods of 2018 and 2019 to the year of 2017, the numbers of drug items in 2018 and 2019 were higher than in 2017 for the total number of hospital levels. However, when we calculated by total number of hospital levels and by each hospital level, the total number of drug items used in 2018 and 2019 was higher than in 2017, leading to a ratio between the number of DD items under Circular 10 and the total number of pharmaceutical items in 2018 and 2019 was lower than in 2017 in all hospitals at different levels and at each hospital level, and this difference was not statistically significant ($p > 0.05$)

(Table 3.8). Thus, while there is an improvement in the number of DD drug items under Circular 10 during the implementation of Circular 10 when we calculated across hospital levels, however, this improvement is not significant.

Comparing the DD use under Circular 10 in the years of 2018 and 2019 to the year of 2017 regarding the total amount of drug used shows that: the total amount of drugs under Circular 10 in 2018 and 2019 was higher than in 2017, not only in the hospital levels but also in each hospital level as well. The percentage of the value of DD use for Circular 10 to the total value of drugs used in 2018 and 2019 was higher than in 2017 at the provincial level, but decreased at the central level compared to 2017 (Table 3.9).

According to the results of our research on comparing the ratio of use of DD in Circular 10 between 2018 and 2019 compared to 2017 by the number of drug items, it shows that: Number of FD items in Circular 10 in 2018, 2019 is higher than 2017 in terms of total hospital levels. The proportion of FD in Circular 10 by total hospital levels in 2019 (2.70%) was lower than 2017 (3.20%), the difference was statistically significant ($p < 0.05$) ($p < 0.05$) Table 3.10). Thus, Circular 10 has made an impact in reducing the number of FD items when we calculated by the total hospital levels. By each hospital level, the number of FD under Circular 10 was reduced during the implementation of Circular 10, but the reduction is not significant.

4.2.2. Impact of Circular 10 to some groups affected by the policy

For the impact of Circular 10 on physicians: According to the interview results, some physicians believed that the drug list mentioned in Circular 10 made them feel more confident to prescribe medicines for patients. It also helped to reduce the cost of drugs for their patients and made them more convenient to prescribe DD. The opinion of physicians that the quality of FD "is not always stable" (Doctor-02) is consistent with the

results of a study by Vo Thi Bich Lien and Nguyen Thi Mai Dieu, who assessed the situation of quality drug violations in Vietnam in 2019. Of these, the quality violation ratio for FD was 62.22%, higher than the quality violation ratio for DD. In addition, some authors also argue that physicians often prescribe FDs to help patients recover faster after surgery (Doctor-03). This is the opinion of a physician in the Department of Hepatobiliary and Pancreatic Surgery at the 108 Central Military Hospital, where he has been an attending physician since 2015. Surgery of the liver, bile, and pancreas is considered major surgery. Patients after major surgery often need to use drugs to help to recover quickly after surgery.

Regarding the impact of Circular 10 on pharmacists in Department of Pharmacy: the opinions of the 02 interviewed pharmacists indicate that Circular 10 has created a legal basis and facilitated the favorable conditions and opportunities for medical institutions to develop the drug list and purchase high-quality, effective drugs at reasonable prices (Box 3.17). The evidence that drug costs can be saved when replacing FD in Circular 10 with DD has been shown in some previous studies. According to a study in 2016 by Le Thi Tuyet Mai in Bach Mai Hospital, 22 FD having active ingredients, content, and route of use which are identical to those in Circular 10 were replaced by DD with guaranteed quality and reasonable price, and this replacement saved approximately 7,559 billion dongs per year.

For the impact of Circular 10 on state management of pharmaceuticals: Circular 10 aims to institutionalize policies that promote the development of Vietnam's pharmaceutical industry, thereby contributing to improved health security by reducing the dependence on pharmaceuticals from the imported sources. It also help avoid the price increases due to no bidding offer of FD (Box 3.21). Currently, the state has issued a number of policies and regulations to increase the production and use of DD. The development of DD production can help reduce prices, improve quality, and increase

access to medicines. In addition, officials of the Drug Administration also gave opinion that the development of the domestic pharmaceutical industry will help improve health security, which is also consistent with the practical context in many countries where health security received a lot of attention.

4.3. Limitations of the thesis

Regarding the current situation of using western medicines under the payment scoper of HI fund, the author discussed many other influential factors apart from Circular 10 that indirectly affect and support the increase in the ratio of using DD. In order to further and evaluate these factors in detail, other studies are needed to prove it.

For quantitative research, the thesis conducts research and analyzes secondary data, so there are difficulties due to not directly observing and investigating. Furthermore, this study only analyzes the impact of Circular 10 on the use of domestic western medicines within the payment scope of HI fund and does not evaluate the impact of this Circular on the use of western medicines which were not covered by the HI fund.

For qualitative research, on the basis of the database of 1,010 public hospitals from central to district level selected to be included in the study, the study only assessed 22 people in the affected group. policy is still low. In addition, from the policy maker's perspective, we can see how the policies affect some targeted groups. Other information from patients and prescribing physicians can also be used and analyzed. However, this information does not allow for the further analysis and evaluation of drug effectiveness. Therefore, additional studies related to this content are needed.

CONCLUSION

1. The situation of using domestically produced western medicines within the payment scope of the HI fund in public hospitals in Vietnam in 2017

- DD account for a higher proportion of the number of drug items (60.13%) but a lower proportion of the value of drug use (39.87%) compared to FD. At all three levels (central, provincial, and county), the number of DD items is higher than that of FD. Drug expenditures for DD are highest at the district level (55.9%) and lowest at the central level (11.8%).

- Generic drugs in Groups 3 and 4 have a higher number of items and a higher value for DD compared to FD. The innovator medicine package and Generics Group 1, 2, and 5 have more drug items and higher monetary value of drug use among FD than among DD.

- Among the 10 groups of pharmacological effects with the highest drug monetary value, there are 03 groups with higher monetary value for DD than FD. The rest of the groups have higher monetary value for FD than DD, in which the highest group is Cancer treatment and immunomodulatory drugs (92.31%).

- The number of drug items under Circular 10 represents 11.4% of the total number of drugs in use. At the hospital level, the total value of drugs under Circular 10 only comprised of 6.7% of the total value of all drugs. The district level has the highest use of DD under Circular 10 (63.9%), and the highest percentage of value in FD use under Circular 10 is at the central level (84.9%).

2. The impact of Circular 10 on the use of domestically produced western medicines within the payment scope of the HI fund in public hospitals in Vietnam from 2017 to 2019 and some groups affected by the policy

Circular 10 had certain impacts on promoting the alternative use of some FD with some DD under the payment of the HI fund in Vietnamese

public hospitals in 2018 and 2019 compared to 2017, more specifically as below:

- The number of generic drugs and the amount of drugs used for DD in Circular 10 and Groups 2, 3, and 4 were higher than in 2017 for each total hospital level when we calculated on a combined basis for 2018 and 2019.

- The ratio of the number of FD items in Circular 10 to the total number of drug items calculated by total hospital levels in 2018 and 2019 was lower than that in 2017, and the difference between 2019 and 2017 is statistically significant ($p < 0.05$).

- The ratio of the monetary value of FD in Circular 10 to total drug expenditures in 2018 and 2019 is lower than in 2017 when we calculated by total hospital levels, at the provincial level, and at central levels.

Circular 10 has positive effects on patients, physicians, pharmacists, enterprises and distributors of FD, HI fund payments, and state management.

- Circular 10 increases patient trust and makes drug prices become affordable for patients who do not have adequate economic conditions.

- Circular 10 will make it more convenient for physicians when prescribing DD, ensuring that they are both effective in treatment and appropriate for the patient's financial situation.

- Circular 10 creates a legal basis and facilitates the favorable condition for selection and purchase of drugs for which medical institutions can compile a list and ensure high quality, effective treatment at a affordable price.

- Circular 10 creates a competitive advantage for companies that produce and trade DD by allowing them to participate in the bidding process.

- Circular 10 reduces the risk of overspending by HI funds.

- Circular 10 helps improve health security by limiting dependence on foreign drug sources.

RECOMMENDATION

1. Enterprises need to focus on investing in the production of specialty drugs, specialized drugs, the drugs with high technical standards, such as reaching EU-GMP or equivalent standards. Bioequivalence and therapeutic equivalence with brand name or reference medicines should be confirmed; facilitating the provision of information to convince physicians that DD are of good quality.

2. The Ministry of Health should consider expanding the list of drug in Circular 10 in the direction of adding medicines with high technical standards, such as compliance with EU-GMP or equivalent standards, and medicines of high value, such as specialty drugs or specialized drugs; adding more criteria to confirm the effectiveness of the DD; strengthen inspection of the quality of DD.

3. Further evaluation studies with larger sample sizes are needed to determine stakeholders' negative reactions to the MOH's issuance of Circular 10.

**LIST OF SCIENTIFIC PAPERS PUBLISHED
RELATED TO THE THESIS**

1. **Ngo Thi Huong Minh**, Do Xuan Thang, Nguyen Thi Thuy Linh, Hoang Thi Thuan, Pham Minh Khue (2022), “The situation of using domestically produced western medicines within the payment scope of health insurance fund in public hospitals in Vietnam in 2017 ”, *Journal of Preventive Medicine*, Volume 32, No. 8, 2022, pp. 161-169.
2. **Ngo Thi Huong Minh**, Do Xuan Thang, Nguyen Thi Thuy Linh, Hoang Thi Thuan, Pham Minh Khue (2023), “Effectiveness of promoting the use of domestically produced western medicines within the payment scope of health insurance in public hospitals”, *Journal of Community Health*, Volume 1, Issue 64, 2023, pp: 145-151.
3. **Ngo Thi Huong Minh**, Do Xuan Thang, Nguyen Thi Thuy Linh, Hoang Thi Thuan, Vu Duc Canh, Pham Minh Khue (2023), “Comparison of the structure of using domestically produced western medicines within the payment scope of health insurance at public hospitals as per implementation of Circular No. 10/2016/TT-BYT for the period 2017 - 2019”, *Journal of Community Health*, Volume 3, No. 64, 2023, pp: 198-204.