Paper#1569319551 (Use the ID number provided to you in your letter of acceptance)

Resolution of drug-lag problem using point program

Yosuke Nakajima[1)], Toshiyuki Yasui[2)]

1) The SDM Institute, Keio University Graduate School of System Design and Management, Kyoseikan, 6F - 4-1-1 Hiyoshi, Kohoku-ku, Yokohama-shi, Kanagawa 223-8526 Japan
y.nakajima.mobile@gmail.com
2) Keio University Graduate School of Systems Design and Management
Kyoseikan, 6F - 4-1-1 Hiyoshi, Kohoku-ku, Yokohama-shi, Kanagawa 223-8526 Japan
t.yasui@z2.keio.jp

Abstract

This paper to analyze the problem of medical treatments supported by the drug development and to propose its resolution. In Japan, there are not-yet-approved drugs that have already used in foreign countries but that have not been approved in Japan due to financial or institutional deficiencies, so-called the drug-lag problem. Thus, it is necessary for us to constantly improve the quality and reliability of the drug development system. In this research, a wide-ranging examination of these complex drug development systems and designing some scenarios will be proposed to perform using the system engineering and other useful methods.

This paper is to propose the solution for promoting to produce new drugs in Japan which are medically valuable but that have not approved due to financial or institutional reasons by using the point program system instead of the governmental finances. The result for the assessment of the proposed point program system is very positive. It is thus concluded that the solution with the point program for not-yet-approved drugs in Japan is one of the new social systems to be designed for next decades.

1. Introduction

1.1 Definition of the not-yet-approved drugs.

The medicine that cannot be used in our country yet exists though it has already been used in foreign countries. It is called the not-yet-approved drugs (*mishonin-yaku*) problem or the drug lag problem. Especially, the lack of the new medicine for the intractable disease and the scarce disease patient is serious. In this paper, I propose the solution of the not-yet-approved drugs and verify it.

1.2 Features of the problem

Previous studies about the drug lag are many. However, the balanced grasp of the current state and opinions in previous studies related to this topic have not yet done. In particular, a systematic problem of which the not-yet-approved drugs happen is concerned has to be developed. Next, setting up the hypothesis for the solution is indispensable of the study. Necessary elements in the system are extracted from a social system on that based on this hypothesis, and the validity is examined. At the final part, the whole picture of the solution proposes by this paper is shown and verified.

2. Previous research and analyze the present status

2.1 Analysis of problem of medicine development system

The drug lag is mainly caused according to the research on the drug lag (medicine industrial Institute for Policy studies 2008.6) for three reasons. They say that those are difference between US/EU and Japanese:

・Clinical trial start time
・Clinical development (clinical trial) period
・Examination period.

Therefore, it is said that the cancellation of the drug lag would be brought form overall improvement of strengthening a further corporation among medicine manufacture

enterprises, medical institutions and regulatory agency. And a plan of continuing and development for pharma industry by the government exists. The Ministry of Health, Labour and Welfare shows 'Medicine industrial vision' (Ministry of Health, Labour and Welfare 2002). They showed a posture of the industry policy.

Thus some groups have already discussed the solutions on this problem. However, the resolutions which are told by those previous researches are always related to resource issues. For example, some groups suggest that the people who run approval processes of new drug should be increased. Actually the size of the organization in Japan is smaller than the one in US, it is FDA. And they always say that those resources should be provided from Japanese government. But, Japanese government finance is not good as everyone knows.

In this paper, I re-research the actual current condition of Medical system of Japan using a system engineering tools and will suggest a new resolution model which would not depend on government resources.

2.2 Analysis by the CVCA

To show specific of the related stake-holder and each role in the medicine development system of our country in this paper clearly, I used the Customer Value Chain Analysis is called CVCA and analyzed the system. The CVCA is understood and it is effective to arrange it though CVCA is a technique used by the system engineering with characters in a certain system.

Here, I made a CVCA concerning fiscal resources of a current medical treatment and the flow and it confirmed the stake-holder of the current capital related to Medical in Japan (Figure 1).

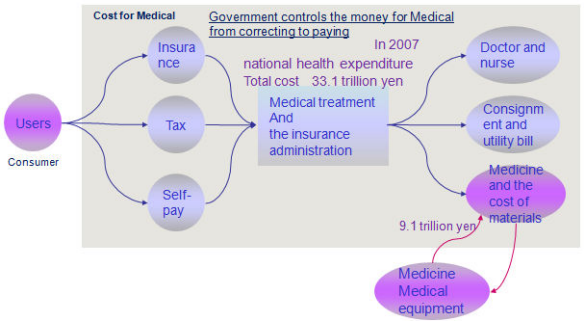

Figure 1. CVCA: Current medical costs follow

And, all almost the management that hangs to those medical treatments by the capital that government collects from the people and the enterprise is covered under the existing system.

Fiscal resources of the national medical treatment system of our country depend on:

1) Insurance
2) Tax
3) Self-pay

Those are the three charges for the medical treatment.

2.3 Specified causes.

The discussion concerning a present system has already been done as being also in the previous studies which are mentioned above. However, the problem of the cost that always hangs to the system change of the discussion exists. In the problem of the drug lag, it is frequently discussed that the speed of the new medicine examination of our country is slow. Therefore, the solution like the education and the staff increase of the examiner of PMDA that is the new medicine examination organization is proposed. In this solution, after all, it becomes a discussion about an increase in the cost for the education and the staff increase.

Thus, securing fiscal resources that become those original capitals is always a bottleneck of the discussion though everyone is thinking that the current system should be improved.

3. Hypothesis of the not-yet-approved drugs

development cost and its solution

3.1 The development cost of not-yet-approved drugs

I investigated how much was necessary for the solution of the not-yet-approved drugs handled by this paper. I researched some materials concerning the development cost of not-yet-approved drugs. The cysteamine and the betaine according to the trial calculation of the development cost to some not-yet-approved drugs of Ministry of Health, Labour and Welfare Central Social Insurance Medical Council (Ministry of Health, Labour and Welfare Central Social Insurance Medical Council Special Committee on Drug Prices and 2009.11). It is estimated that about 1.3 billion JPY per one not-yet-approved drug is necessary though there is a change depending on the cost that lies introduced of the license of those compounds. In this paper, I assumed that this was adopted as a standard of the development cost of the not-yet-approved drugs. Therefore, about 1.3 billion JPY is made a standard as cost that hangs to the development for each not-yet-approved drug for an intractable disease or a rare disease.

3.2 Recognizing the systems engineering

First of all, the note of the mechanism making that improves the medicine development system must be thought. It makes years considerably with the national medical treatment system that exists in the place what is more putting it and a present medicine development system is the one that was crowded, and is keeping a slight balance. Therefore, the good policy is neither the destruction of broken system nor restructuring.

Then, a dramatic increase of healthcare resources from the people and the enterprise cannot expect it from the grasp of the situation of previous fiscal resources in the future. Therefore, it aims at the mechanism making to which the medical treatment system of our country is supported by it not only relies on fiscal resources from government but also having effectively used private power.

3.3 Selection of elements from the social system

It has been described up to now that securing fiscal resources in which it doesn't rely on government is necessary and discussed what choices exist here. I select a necessary element from a social system.

The usual ways of the funding that doesn't rely on government is as follows:

1) Funding by financial institution
2) Funding by personal asset
3) Funding by the stocks
4) Funding by contribution
5) Funding using prepaid card
6) Funding using point program

And it is also possible to combine these some. However, the number only of stake-holders like the contribution increases simply with the financial institution to aim at the simplification of the system as much as possible in this paper and the combination that doesn't obtain the synergy effect easily is excluded.

The method of the funding by the best private organization for the improvement of the national medical treatment system is examined by using Pugh concept selection that is one of the techniques of the system engineering by the above-mentioned choices. Pugh concept selection is a technique that can be done by comparing two or more choices and making the process settled to finally one concept visible when a promising concept is examined and developed. Evaluation figure uses the above-mentioned note. As a result, the funding using the point program seems to be the best (Table 1).

Table 1: Pugh Concept Selection of better option for funding

Pugh Concept Selection Process Summary Chart
PROJECT: Select better option for fundraising

		Options					
		1	2	3	4	5	6
	Criteria	Funding by financial institution	Funding by personal asset	Funding by the stocks	Funding by contribution	Funding using prepaid card	Funding using point program
1	Amount of money of procurement	−	−	DATUM	−	−	S
2	Clearness of procurement purpose	+	+		+	S	S
3	User understanding of funding purposes	−	−		S	+	+
4	Sympathy with funding purpose	−	+		+	+	+
5	Easiness of participation	−	−		S	+	+
	Score	−3	−1		1	2	3

Compare with DATUM
- : Worse Alternative
S : Same Alternative
+ : Better Alternative

3.4 Feasibility of funding by the point program

The amount of the point issue of our country of fiscal year 2006 is about 660 billion JPY a year. The growth of 20 billion JPY scale is expected as for the future every year, and it expands up to about 780 billion JPY in 2012. A theoretical point issue amount upper bound is thought to be about 19 trillion JPY of a present enterprise of six trillion JPY of sales promotion expense 13 trillion JPY plus advertising expenses.

There might be a possibility to be able to fund the cost for not-yet-approved drugs development by using the point program if this scale exists.

3.5 The point program

The point program that this paper proposes is the one like following. The user who makes it to the target by the point programming is a medical treatment and a consumer healthily interested in the commodity. The amount of money that corresponds to about 1% of the value of sales of each commodity when the manufacturer that manufactures the commodity related to the medical treatment and health participates in this point program and a pertinent commodity is shipped is shifted to the fund of the point program. In this case, when shipping it, each enterprise sums up the point issue according to International Financial Reporting Standards (IFRS) to mortgage the continuance of this point program. The realization rate from the point to the currency is assumed to be 1 JPY a point. In the back, the point that shifts to this fund becomes the original capital for the not-yet-approved drugs development cost. Then, it participates in this point program in the retail store where those commodities are treated. When a pertinent commodity is sold, about 0.5-1% of the value of sales is reduced to the user who is the consumer. A mark to describe the mind of participation of this point program is used.

4. Possibility and verification of funding

4.1 Examination of the amount that can be procured for the problem-solving

The amount of funding of the capital is examined based on the above-mentioned assumption. The breakdown continues with 160.8 billion JPY and the cellular phone 108.5 billion JPY of the credit card with 201.7 billion JPY of the household appliance store at the top though the point issue amount of our country of fiscal year 2006 is about 665.4 billion JPY.

The point of the drugstore where a medical treatment and a healthy related product are treated is about 4.3 billion JPY a year by the rate of reduction of 1% of the sales commodity. In this case, about 4.3 billion JPY as points will be issued from both the manufacturer and the retail store during year respectively by the fund and the user in this point program. Similarly, an integrated supermarket and the convenience store are included.

It comes to be able to sell two kinds and three kinds of the non-prescription pharmaceutical recently by introducing the registration salesman system in the supermarket and the convenience store and it is used as a window of the medicine purchase. Moreover, foods which the ingredient assumed to be good for the body and are called "TOKUHO" are sold in the supermarket. Then there is a base that agrees to the purport of this point program. The point issue amount from

the convenience store is five billion JPY a year. A supermarket is 21.4 billion JPY a year. Therefore, if these three genres are totaled, the funding would be about 52.1 billion JPY.

However, all commodities sold in drugstores, convenience stores and supermarkets are neither a medical treatments nor healthy relations. Therefore, it is assumed that the commodity that corresponds to about 1/3 of the value of sales participates in this point program and expects the funding of about 17.4 billion JPY/year in the maximum.

4.2 Use of IT to the point program

It is indispensable to use IT for the point program for such a mechanism making. IT that takes the electronic tag and POS systems is used, and the mechanism making to which the user can efficiently acquire the point is necessary. And I think that it is easy to handle for the users that the point program allows to use a seal for reorganization of its ID Number for each user. The system which relates the not-yet-approved drugs development should be reflected the user's opinion to the mechanism for the point program.

5. Validation

5.1 The Methodology for validation.

The feasibility of the point program proposes by this paper is verified actually in consideration of consumer's behavior pattern and the consumer's sentiment. Here, the hearing survey that was one of the marketing techniques was executed.

5.2 The Survey table

In the hearing survey table, the person of fictitious that assumed an actual user was made to appear. The action during a day was described by the story form though it knew the point program that the person proposed by this paper, and it did not know what reaction you showed afterwards. The impression to this point program following afterwards was caught and investigated.

5.3 Result of hearing survey

The hearing survey was done by using a survey table which contains features of this solution for not-yet-approved drugs development using point program. It cooperated in 26 people in total in this hearing survey. The breakdown was man 69 %(18 people), and the female 31 %(8 people).

The age was 15-24 years old 19 %(5 people), 25-34 years old 31 %(8 people), 35-44 years old 27 %(7 people), 45-54 years old 11 %(3 people), and 55-64 years old 4 %(1 person).

In the occupation, the company employee was 38 %(10 people), and it was student 35 %(9 people), 23 other %(6 people), and unanswered 4 %(1 person) besides.

The answer to the question concerning the point program was as follows. The respondent who selected "It was very good" or "It is good" as an impression to the point program proposed by this paper was 77 %(20 people), and it was 19 %(5 people) that answered, "Not bad". Moreover, there was no respondent who selected a negative impression.

The respondent who selected "I wanted to participate" and "I want to participate by all means" was 61 %(16 people) for the question that it wanted to participate in the point program. 35% of the remainder (9 people) selected "Examined it", and there was no negative answer for this question.

In the question of feeling the advantage for participation of this point program, there were a lot of "It was possible to cooperate in the problem of the intractable disease and the not-yet-approved drugs" with 85 %(22 people).

In the comment description column expecting it of the proposed point program, there were affirmative opinions "I wanted you to tie to good medicine development", "It is thought that consideration to the disease", and "New mechanism that the social infrastructure is supported".

And, "Is it really used to solve the problem purposing?" and "Is there the one that it is possible to exchange it besides goods for the disaster?", "The seal can be taken. The exchange when it is dirty?" Those comments

were drawn.

5.4 Validity of result of hearing survey

The range from the composition of the respondent of the hearing survey (sex, age, and occupation) from which it was able to allow it as a user image in which it participated when this paper was actually operated though some ratios of the woman were fewer than the man.

5.5 Calculation of amount of procurement expectation

It previously described, and it is assumed that the commodity that corresponds to 1/3 of the amount of sales during year in a drugstore, a convenience store, and an integrated supermarket participates in this point program, and the funding of 17.4 billion JPY/year becomes possible. It is employed to this that it is a participation user as for about 60 percent with the participation intention from the hearing survey result as the expectation. Therefore, it became a result that about 10.4 billion JPY/year was able to be expected as amount of the funding by 17.4 billion JPY × 0.6 (60%).

In addition, an increase in further amount of the funding can expect earnings of the medicine that obtains the manufacturing sales approval by supporting this point program in the future by making the mechanism that a part of profits come back to this fund again.

Therefore, it was clarified that the amount of the expectation fund for not-yet-approved drugs development by the point program proposed by this paper was about 10.4 billion JPY a year/year.

5.6 Whole picture of the solution

An existing national medical treatment system is made with decades and is an attempt of optimization by the crowded one. Therefore, forcibly changing only part that is the element of the system is high the possibility of dropping the performance of the system.

Then, it secures a fund by the point program in this paper, and I propose the mechanism that an existing national medical treatment system is supported.

This is a new national medical treatment system which was presented by using the flow chart of healthcare resources (Figure 2).

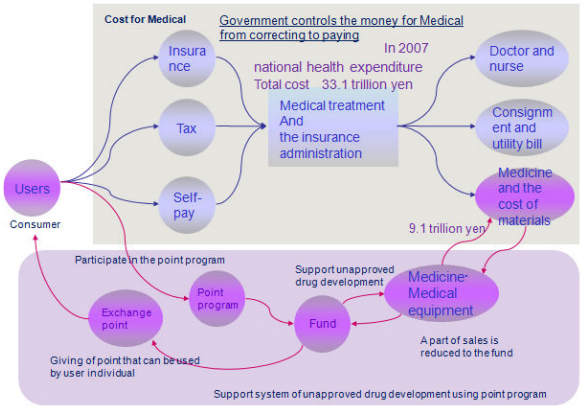

Figure 2. CVCA: New drug development system supporting current medical treatment system

6. Future Study

It is necessary to deepen the more discussion about the method of clearly telling the use of point program from the hearing survey result. Not only a necessary research and the development cost but also the promotions of the research for the maintenance of the clinical environment of the new medicine development and the drug development and the applied studies to promotion will be needed as a development support for the intractable disease and the not-yet-approved drugs for the purpose of spending money of this capital. It wants to do the investigation, practice and the verification repeatedly for this part and to keep more concrete.

The whole image is an especially cramped system in the people who do not have the medicine because of the chance to be deeply involved in this field. Moreover, it is necessary to try turning plainly by making good use of the technique of the system engineering in the research in the future. It is possible to be involved deeply because different possibilities of those who look are in a multi view by various standpoints, too.

7. Conclusion

In this paper, at first, I analyzed the current status of the medical treatment system related to drug development system and specified its problem. Next, I selected a factor of being a part of the solution from current social system related to finance. Because the not-yet approved drug problem was based on financial issues deeply. In a present national medical treatment system, it is because that fiscal resource in the country that supports the medical treatment of our country was drying up. The element for new fiscal resources acquisition of point program was brought as a part of solution. And I proposed the solution to solve the problem which is support current medical treatment system especially from fiscal resources side and I evaluated it using hearing survey. Thus, the system flow of fiscal resources from the people who supported the development of the rare diseases and the not-yet-approved drugs and not depend on government was suggested in this paper. A new system that used the point program was able to expect the fiscal resources securing for the not-yet-approved drugs development of about 10.4 billion JPY a year.

A new system using point program that consists of the cooperation mind of the citizens whom supports an important part of the social security with high publicity like drug development system is one of the important systems that lead a new society.

References

Keita Ishibashi *Investigation concerning drug lag in Japan - current situations and issues based on medicine manufacture enterprise questionnaire -,* Medicine industrial policy laboratory research paper series, 2008.6

The Ministry of Health, Labour and Welfare Political and Economic Affairs Division *New pharma industry vision - It aims at industry that has global competitiveness that bears the innovation-,* 2007.8.

Nomura Research Institute of Technology Economics corporate Currency project team, *Corporate currency marketing*, Toyo Keizai Shinposha, 2008.3

Medicine industrial Institute for Policy studies *Image of the future of medicine manufacture industry - Mission and problem of industry for 2015* - , 2007.5

Akira Goto and Hiroyuki Odagiri *Industrial system 3 of Japan Scientific industry* NTT Publishing Ltd., 2003.03

Monthly mix *Kasumigaseki REPORT Cancellation and fear of stall as for the not-yet-approved drugs* Elsevierjapan, 2009.11

The Ministry of Health, Labour and Welfare Central Social Insurance Medical Council Special Committee on Drug Prices *Drug price system reform, domestic not-yet-approved and add-on drug problem of Nichiyakuren proposal*, 2009.12

Biography

Yosuke Nakajima

Fellow, the SDM Research Institute, Graduate School of SDM, Keio University

Upon graduating from the Seikei University (Bachelor of Arts in Economics) in 1996, Yosuke Nakajima is working for an international healthcare research company as a research manager. He has over 9 years of experience of R&D for new drugs in the pharmaceutical industry before the current company. He earned Master's degree (MS in System Design and Management) at the Keio University Graduate School of System Design and Management (2008-2009).

Toshiyuki Yasui

Special Research Professor, Graduate School of SDM, Keio University

Upon graduating from the University of Tokyo (BA in International Relations) in 1985, Toshiyuki Yasui joined the Japanese Ministry of Finance. He spent 25 years in various government posts including Councilor for the Financial Services Agency (2008-2009), Director for the FILP Research & Planning Office of the Ministry of Finance (2000-2001), and First Secretary in the Embassy of Japan for India (1992-1995). He also worked as Senior Fellow of the Institute of JBIC (2001-2005) and Trainee-Consultant for the OECD (1987-1989). He is a former Visiting Professor of Chuo University (2007-2008).