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Factors affecting the decision to purchase innovative pharmaceutical products by the thai pharmaceutical industry

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Article History:	Abstract							
Received on: 13.03.2019 Revised on: 24.06.2019 Accepted on: 28.06.2019 <i>Keywords:</i>	The purpose of this paper is to investigate the relationship between factors affecting the decision to purchase and the need for innovative pharmaceuti- cal products by the Thai pharmaceutical industry. An orally disintegrating tablet (ODT) is an example of an incremental pharmaceutical innovative prod- uct which is still a new concept in Thailand. The results show that financial fac-							
purchasing decision, pharmaceutical excipients, orally disintegrating tablet (ODT), innovative product, Thai pharmaceutical industry	tors, as well as governm on the purchasing decis pharmaceutical industr	ment policy and drug regulations, have a positive effective of pharmaceutical excipients for ODT from the That ry.						
*Corresponding Author		Administration (Thai FDA). The Thai pharmaceu-						
Name: Narueporn Sutanthavibul Phone: +66-83-455-9393 Email: Narueporns@chula.ac.th ISSN: 0975-7538 DOI: https://doi.org/10.26452/ijrps.v10i3.1395 Production and Hosted by IJRPS https://ijrps.com		tical industry is confronted with a decrease in the value of the country's domestic pharmaceuti- cal products compared to imports. Moreover, there are many threats from the cooperation of South						
		 east Asian countries, resulting in ASEAN harmonization in many areas, such as with the Pharmaceutical Inspection Cooperation Scheme in Good Manufacturing Practice (PIC/s GMP) and the proliferation 						
					the Free Trade Agreement (FTA) between Thailand			

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INTRODUCTION

The Thai pharmaceutical industry is currently being hampered from importing pharmaceutical products because of social expectations, consumer responsibility, encouragement, cost of research and development, quality assurance, and the regulatory and registration procedures of Thailand's Food and Drug and the United States of America for business benefit. This phenomenon has led to the closure of many domestic businesses.

Nonetheless, technological changes in the pharmaceutical industry have a significant influence on innovation (Malerba, 2002). Advancement in pharmaceutical innovation involves two components: active pharmaceutical ingredients (API) and pharmaceutical excipients. API are chemicals used for curing and alleviating diseases. The development of API takes time, with at least 16 years being necessary for the completion of all phases (Nolan *et al.*, 1980). In Thailand, there has never been complete API development due to the high cost and time required. Thus, in Thailand, the development of an innovative pharmaceutical product should emphasize pharmaceutical excipients since they have a greater potential for success than API.

However, there is no evidence to suggest that the Thai pharmaceutical industry will adopt such an innovative product. Thus, the purpose of this paper is to investigate which factors affect the decision to purchase innovative pharmaceutical excipients from the Thai pharmaceutical industry by using pharmaceutical excipients for ODT as the case study. The factors affecting the decision to purchase an innovative product from the Thai pharmaceutical industry are investigated and discussed. Thus, this research can be used as a guideline for assessing the purchasing decision of the Thai pharmaceutical industry toward other pharmaceutical innovative products.

This research is divided into six sections, the first of which provides an introduction. Secondly, an explanation of the background to ODT and the factors influencing the purchasing decision are reviewed. The third section outlines the methodology used to develop and validate the conceptual framework. The fourth section provides the results of the purchase intention and the factors affecting the decision to purchase an innovative product from the Thai pharmaceutical industry. The fifth section provides the results and discusses the factors affecting the decision to purchase, focusing on five components. Finally, the last section concludes the research findings and proposes ideas for future research.

Literature Review

Innovative products are unlikely to be successful in the marketplace due to a lack of customers demand. Thus, whether or not the pharmaceutical industry in Thailand should adopt innovative products is an interesting topic. In this section, the background to ODT, and factors affecting the decision to purchase an innovative product are reviewed.

Orally disintegrating tablet (ODT)

The ODT is in oral dosage form, immediately dissolving or disintegrating in the mouth without water or other liquids (Watanabe *et al.*, 1995). According to the United States Pharmacopeia 41 (USP41) and the National Formulary 36 (NF36), the ODT tablet must take no longer than one minute to dissolve, depending on the design and composition of the formula. The ODT is suitable for bed-ridden patients, children, the elderly, or psychotic patients (Nagar *et al.*, 2011). It also elevates the patient's compliance since it can be taken without water. The ODT formula comprises only active pharmaceutical ingredients (API) and suitable pharmaceutical excipients.

Active pharmaceutical ingredient (API)

API is a specific chemical for the purpose, with no special ODT requirement. In general, researchers use several drugs to produce ODT, such as anticonvulsants, antibiotics, analgesics, diuretics, neuroleptics, as well as antidiarrheal, anticancer, and heart disease medication.

Pharmaceutical excipients for ODT

The development of ODT by direct compression involves specially designed pharmaceutical excipients to reduce disintegration time. Therefore, finding alternative pharmaceutical excipients for ODT is very important.

Factors affecting the decision to purchase an innovative produc \boldsymbol{t}

A review of the available literature reveals various factors affecting the decision to purchase an innovative product, as summarised in Table 1.

The literature review highlighted a lack of research on the identifying factors affecting the decision to purchase innovative products in the Thai pharmaceutical industry. Therefore, this study proposes a conceptual framework for investigating this aspect, consisting of five components: 1) financial factors, 2) marketing factors, 3) production factors, 4) innovation factors, and 5) government policy and drug regulation factors, with the following hypotheses.

H1: Financial factors are affecting the decision to purchase an innovative product in the Thai pharmaceutical industry

H2: Marketing factors are affecting the decision to purchase an innovative product in the Thai pharmaceutical industry

H3: Production factors are affecting the decision to purchase an innovative product in the Thai pharmaceutical industry

H4: Innovation factors are affecting the decision to purchase an innovative product in the Thai pharmaceutical industry

H5: Government policy and drug regulation factors are affecting the decision to purchase an innovative product in the Thai pharmaceutical industry

Components	Indicators	References
Financial	Reduced production cost	(Novak and Popesko, 2014)
Factors	Pharmaceutical excipients for ODT help to reduce	
	the cost of production	
	Reduced expenditure	(Hsien and Sloan, 2008)
	expenditure	
	Economies of scale	(DiMasi <i>et al.</i> 2003)
	Pharmaceutical excipients for ODT have	
	economies of scale	
	No additional investment	(DiMasi <i>et al.</i> , 2003)
	Pharmaceutical excipients for ODT can be used	
	alone without additional investment	
	Return on investment	
	Pharmaceutical excipients for ODT enhance	
	Investment returns	(Elvolund and Dorsson
	Pharmaceutical excinients for ODT are profitable	2003 DiMasi <i>et al</i> (1991)
Marketing	Need for the product	(Nolan <i>et al.</i> , 1980: DiMasi <i>et al.</i> ,
Factors	The market needs pharmaceutical excipients for	1995; Abbott, 1995)
	ODT	
	Patient compliance	(Chauhan and Mason, 2008)
	Pharmaceutical excipients for ODT enhance	
	patient compliance	$(N_{\rm class} \ a \ a) \ 1000)$
	Dearmacoutical ovcinionts for ODT have a clear	(Notali <i>et ul.</i> , 1980)
	customer target	
	Size of the target market	(Manchanda and Honka, 2005)
	Pharmaceutical excipients for ODT have a large	
	target market	
	Advertising costs	(Manchanda and Honka, 2005;
	Pharmaceutical excipients for ODT can reduce	Liu and Gupta, 2012)
	advertising costs	(Livered County 2012) Melanha
	Distribution channels Dearmacoutical excipients for ODT have many	(Liu and Gupta, 2012; Maierba,
	distribution channels	2002)
Production	Capable of use with general tableting machines	(Al-khattawi and Mohammed,
Factors	Pharmaceutical excipients for ODT can be used	2013; Nagar <i>et al.</i> , 2011)
	with general tableting machines	
	Capable of use with other production lines	(Al-khattawi and Mohammed,
	Pharmaceutical excipients for ODT can be used	2013; Nagar <i>et al.</i> , 2011; Zucker
	with other production lines in the pharmaceuti-	and Darby, 2001; Lawrence,
	cal industry	2008) (All Inhetterri and Mahammad
	company with Aris and other pharmaceutical excinients	(AI-KIIAUAWI ANU MONAMMEO, 2013: Nagar <i>et al</i> 2011.
	Pharmaceutical excipients for ODT are compat-	Lawrence 2008)
	ible with APIs and other pharmaceutical excipi-	2000
	ents	
	Increase productivity	DiMasi <i>et al.</i> (2003)
	Pharmaceutical excipients for ODT can increase	
	productivity	

Table 1: Factors affecting the decision to purchase an innovative product according to the literature review

Continued on next page

Table 1 continued				
	Reduce production errors	(Cur	rieux-Belfond <i>et al.</i> , 2009;	
	Pharmaceutical excipients for ODT help to reduce Gilm		ore and Smith, 1996;	
	errors in production	Lawr	ence, 2008)	
	Save time in production	(Cur	rieux-Belfond <i>et al.</i> , 2009;	
	Pharmaceutical excipients for ODT help to reduce	Gilmo	ore and Smith, 1996;	
	production time	Lawr	ence, 2008)	
Innovation	New knowledge acquisition	(DiM	lasi <i>et al.</i> , 2003, 1995; Car-	
Factors	knowledge through the use of pharmaceutical	dinal, 2001)		
	excipients for ODT			
	Capable of representing other products in the	(Mal	erba, 2002)	
	industry			
	Pharmaceutical excipients for ODT have the capa-			
	bility to represent other products in the industry			
	Capable of developing their own patent	(Nol	an <i>et al.</i> , 1980; Grabowski	
	Pharmaceutical excipients for ODT have the abil-	et al.,	2002)	
	ity to develop their own patent for the pharma-			
	ceutical industry			
	Reduce research and development costs	(Grabowski, 1989; DiMasi <i>et</i> 2003; Grabowski <i>et al.</i> , 2002)		
	Pharmaceutical excipients for ODT help to reduce			
	Reduce failure in new product development	(Malerba, 2002; Alkhateeb <i>e</i>		
	Reduce failure in new product development			
	failure in new product development	2009)		
	Value-added to the product (Hsie		tieh and Sloan 2008)	
	Pharmaceutical excipients for ODT help to add	(mon	2000)	
	value to new products			
Government	FDA approval in drug registration		(Kola and Landis, 2004;	
policy and drug	Pharmaceutical excipients for ODT ensure drug re	egis-	Danzon and Chao, 2000)	
regulation	tration approval by the FDA		-	
factors	Financial support policy		(Maynard and Bloor,	
	The government has set a financial support pe	a financial support policy		
	regarding pharmaceutical excipients for ODT			
	Tax reduction policy	(Kyle, 2007)		
	The government has set a tax reduction policy regar	ding		
	pharmaceutical excipients for ODT			
	Technological transfers	(Maynard and Bloor,		
	Agreement between the government and pharma	2003)		
	ODT			
	Agreement between the government and pharmace cal industry			
	Agreement between the government and pharma	iceu-		
	tical industry regarding pharmaceutical excipients	s for		
	ODT			
	Pharmaceutical standards and safety		(Grabowski <i>et al.</i> , 1978)	
	Pharmaceutical standards and safety ensure to use			
	pharmaceutical excipients for ODT			

The conceptual framework for investigating five hypotheis is shown in Figure 1.

MATERIALS AND METHODS

Data collection

A survey questionnaire involving pharmacists currently working in the Thai pharmaceutical industry was used as the method for collecting data by purposive sampling. The quantitative method was applied to reduce bias. The questionnaires were distributed to respondent pharmacists from a list issued by the Thai FDA. The questionnaires were in the Thai language and consisted of four parts,

1) demographics and basic data on the respondents,

2) corporate data consisting of general information on companies and sales and products,

3) a five-point Likert scale rating of five factors, each consisting of six indicators, with a total of 30 questions, and

4) open-ended remarks and suggestions. The questionnaire was validated by three experts in the pharmaceutical field using the index of item-objective congruence (IOC).

The data from the questionnaire was collected and analysed using a five-point Likert scale. The questionnaire was sent directly to participants in paper and online format. The factors were calculated using multiple regression SPSS version 22. The raw data was examined via factor analysis, correlation analysis, reliability analysis, and regression analysis.

Variables and measurements

Independent variables: the independent variables consist of five factors: financial, marketing, production, innovation, as well as government policy and drug regulation. The independent variables were measured using a five-point Likert scale.

Dependent variable

The decision to purchase is the dependent variable. The dependent variables were measured using a five-point Likert scale.

Validity and reliability analysis

In this research, the collected data was measured for reliability and validity. Validity is the degree to which the test measures what it is supposed to measure. Reliability refers to the stability and consistency of the measurement. Factor analysis was used to assess the validity and produce a set of observable variables.

The research was validated by sending the questionnaire to three experts in the pharmaceutical field. All experts gave their comments, which led to the modification and improvement of the questionnaire.

The consistency method was applied to measure the reliability of this research. Cronbach's alpha coefficient was used to test reliability, with a value of 0.6 considered acceptable, and 0.8 and above indicating a high level of reliability.

Correlation and regression analysis

Respondents were requested to consider each factor in the questionnaire, consisting of six indicators. The average score for each indicator was then calculated. Pearson correlation was performed to identify the relationship between the financial, marketing, production, innovation as well as government policy and drug regulation factors. Multiple regression analysis was also performed to test the five hypotheses concerning the decision to purchase an innovative product.

RESULTS AND DISCUSSION

Demographics of respondents

The demographic characteristics of the respondents include education, job position, duration of business, type of business, type of firm, business income, and a number of employees. The results are shown in Table 2.

Validity and reliability analysis

The purpose of validity and reliability analysis is to ensure the results are free from random errors. In this study, the IOC is performed by specialists. All questions have an IOC of between 0.6–1.0, implying that the variables are valid. Consistency testing is examined by Cronbach's alpha coefficient, ranging from 0 to 1. The higher the Cronbach's alpha coefficient, the greater the reliability. The analysis is shown in Table 3, indicating that the questionnaire is a reliable instrument for measuring the variables.

Correlation analysis of variables

Pearson correlation is used to identify the correlation between financial, marketing, production, innovation, as well as government policy and drug regulation factors. A correlation coefficient ranging from 0.10 to 0.29 is considered weak, 0.30 to 0.49 medium, and 0.50 to 1.0 strong. However, to avoid multicollinearity, the correlation coefficient should not go above 0.8 (Wang and Benbasat, 2007). Positive correlation represents that one variable increases or decreases in line with another. Conversely, a negative correlation means that one variable does not increase or decrease in line with another. The results of this study show that there is no multicollinearity. There is a correlation between



Figure 1: Conceptual Framework for the decisionto purchase an innovative product

innovation and marketing factors, indicating a positive effect (0.273). Innovation and production factors have a negative relationship (-0.285). The correlation matrix is shown in Table 4.

Multiple regression analysis

Multiple regression analysis is conducted on the model with data manipulation used to remove outliers. From the original 192 respondents, 185 remained in the sample after removal of the outliers. Correlation analysis is employed to test the interaction between variables, whereas regression analysis is conducted to test hypotheses H_1 , H_2 , H_3 , H_4 , and H_5 . The correlations are shown in Table 5. The enter method is used for multiple regression analysis. The model shows a good fit with a p-value of 0.000 (which is not greater than 0.05). The collinearity adjustment R^2 is 30.90%.

Hypothesis testing

Hypothesis 1

H1 posits that a relationship exists between financial factors and the decision to purchase (p = 0.000). Its p-value is under 0.05, positing that H1 is strongly supported. The results of the tests reveal (Beta = 0.458, t = 7.106) that the decision to purchase an innovative product is a major determinant.

Hypothesis 2

H2 shows that marketing factors are not related to the decision to purchase (p = 0.482). The data in Table 5 (Beta = -0.046 and t = -0.704) indicates that marketing factors have an insignificant effect on the decision to purchase an innovative product.

Hypothesis 3

H3 exhibits that production factors do not have a significant relationship with the decision to purchase (p = 0.615). The data in Table 5 (Beta = 0.034, t = 0.504) indicates that production factors do not affect the decision to purchase an innovative product.

Hypothesis 4

H4 reveals that the relationship between innovation factors and the decision to purchase is insignificant (p = 0.073). Variables in the equation (Beta = 0.058, t = 0.854) indicate that the decision to purchase does not substantiate the results of other studies on innovation factors.

Hypothesis 5

H5 displays that government policy and drug regulation factors have a relationship with the decision

Characteristics		Frequency	Percentage
Education	Bachelor's degree	70	36.46
	Master's degree	117	61.57
	Doctor of Philosophy	5	1.97
Job position	Managing director	6	3.10
	Manager	36	18.80
	Supervisor	54	28.10
	Other	96	50.00
Duration of business	Under 10 years	90	46.90
	10–20 years	12	6.30
	20–30 years	6	3.10
	Over 30 years	84	43.80
Type of business	Distributor	24	11.76
	Pharmaceutical manufacturer	64	47.05
	Supplementary manufacturer	18	8.82
	Exporter	24	11.76
	Other	42	20.58
Type of firm	Single owner	18	9.40
	Limited partnership	6	3.10
	Limited company	142	84.40
	Public company	6	3.10
Income of business	Under 50 million baht	42	22.30
	50–200 million baht	60	33.30
	Over 200 million baht	78	43.30
Number of employees	Less than 50	30	15.60
	50-200	75	46.90
	More than 200	72	37.50

Table 2: Demographic characteristics of respondents and firms (n=192)

Table 3: Reliability analysis

Variables	Cronbach's Alpha
Financial factors	0.790
Marketing factors	0.740
Production factors	0.780
Innovation factors	0.770
Government policy and drug regulation factors	0.760
Decision to purchase an innovative product	0.730

Table 4: Correlation matrix

	Financial	Marketing	Production		
Financial factors	1.000				
Marketing factors	112	1.000			
Production factors	062	161	1.000		
Innovation factors	037	.273*	285*	1.000	
Government policy and drug regulation factors	137	170	.099	.007	1.000

Statistically significant at: p < 0.05 (2-tailed)

Multiple R	.575					
R2	.331					
Adjust R2	.309					
Standard Error	.73965					
F	14.754					
Sig. F	0.000					
		Variables in the equation				
Variables	В	Std. Error	Beta	t	Sig.	
Financial factors	1.173	.165	.458	7.106	.000*	
Marketing factors	090	.128	046	704	.482	
Production factors	.058	.116	.034	.504	.615	
Innovation factors	.103	.121	.058	.854	.394	
Government policy and drug reg- ulation factors	.235	.085	.180	2.757	.006*	

Table 5: Multiple regression analysis

to purchase (p = 0.006). Its p-value is under 0.05, from which it can be concluded that H5 is supported. In addition, from the findings Beta = 0.180 and t = 2.757, it can be concluded that the decision to purchase is less likely when the effect of government policy and drug regulation factors increases.

From the findings, it can be concluded that the factors affecting the decision to purchase are financial and also relate to government policy and drug regulation. Financial and government policy and drug regulation factors are shown to have a positive effect on the decision to purchase with a standardised coefficient of 0.458 and 0.180, respectively.

Factors affecting the decision to purchase an innovative product in the Thai pharmaceutical industry were based on multiple regression and assessed using SPSS software version 22, where the established model was found to be acceptable. Details of the factors are described below:

Financial factors

Financial factors were found to be the most important, and have a positive effect on the decision to purchase an innovative product from the Thai pharmaceutical industry. This is no surprise since it confirms the experts' opinion that most pharmaceutical companies would prefer a reduction in the cost of pharmaceutical excipients. It also concurs with the suggestion by Wiggins (1991) that the cost of capital affects product validity. This is also similar to other industries in that the cheaper the raw materials, the greater the profit.

Marketing factors

Marketing factors were found to be insignificant. (Nolan *et al.*, 1980) state that a decrease in marketing may result in increased costs for developing new drugs, leading to more safety regulations, which may prolong the time interval between patenting and marketing. However, according to the interviews with experts, marketing may impact on the consumer but was not shown to be important to the manufacturer since drug sales in Thailand are not influenced by users but by law and regulation or governance.

Production factors

Production factors were not found to be significant. Pharmaceutical production of tablets involves milling, mixing, granulating, drying, and tableting (Lawrence, 2008). Lawrence also states that critical raw material attributes, process parameters, and design space lead to product development. If there are fewer production steps, the production time is also reduced. However, some respondents reported that there are various problems affecting production time as well as production steps, such as out of service machinery or human error.

Innovation factors

Innovation factors were found to be insignificant. (Hsieh and Sloan, 2008) investigated the adoption of pharmaceutical innovation and the growth of drug expenditure in Taiwan, finding that overall, the adoption of pharmaceutical product innovation is worth the increased cost of new drugs. The respondents commented that Thai patients paid little attention or were unaware of innovation since they did not feel it was important to them or had no usefulness. However, the government should encourage and emphasise the advantages of innovation by providing more knowledge to the public.

Government policy and drug regulation factors

Government policy and drug regulation factors were

ranked second in affecting the decision to purchase an innovative product from the Thai pharmaceutical industry. (Danzon and Chao, 2000) reported that generic drug competition has a significantly negative effect on free price regulation in the United States, United Kingdom, Germany, and Canada, whereas, in countries with strict price regulation such as France, Italy, and Japan, the number of generic competitors has either no effect or a positive effect on prices. In Thailand, price competition and drug registration are controlled, specifically in relation to pharmaceutical products regulated by the Thai FDA. These regulations influence the registration of pharmaceutical products. Hospitals are the biggest buyers of pharmaceutical products and must follow the regulations of the FDA. Hence, government policy and drug regulation factors affect the decision to buy ODT products from the pharmaceutical industry, as also confirmed by experts.

The results from respondents show that they decided to purchase pharmaceutical excipients for ODT, with an average score of 4.56 from 5.00 (S.D.= 1.82). This suggests that the price of an innovative product is extremely relevant to Thai people because their importance has not been emphasized. They suggest that good technological exploitation should incorporate the government, private sector, and small, medium-sized enterprises. However, there are many barriers to technological exploitation, such as the amount of supporting data needed to convince authorities concerning the laws and regulations of the FDA and ensure confidence in the quality of drugs in Thailand.

CONCLUSION

Pharmaceutical excipients for ODT still represent a new concept in Thailand. However, there is no research identifying factors affecting the purchasing decision regarding pharmaceutical excipients for ODT. This study investigates the relationship between five factors: financial, marketing, production, innovation as well as government policy and drug regulation, and the decision to purchase from the Thai pharmaceutical industry. The results are ranked in order of importance, with financial factors (beta = 0.458) and government policy and drug regulation factors (beta = 0.180), being first and second, respectively. The prototype of pharmaceutical excipients for ODT is considered in relation to costs, profits, and meeting the registration criteria of the Thai FDA. Respondents are interested in pharmaceutical excipients for ODT, which has the potential to adopt this innovation into the market.

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