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A Study on Drug Innovation Lag in Taiwan

CHIA-JUNG CHUNG AND WENG-FOUNG HUANG*

Institute of Health and Welfare Policy, National Yang Ming University, 155 Li-Nong St., Sec. 2, Beitou District, Taipei City 112, Taiwan, R.O.C.

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ABSTRACT

Drug lag, also known as drug innovation lag, can be categorized into marketing lag and reimbursement lag. This study investigates the trend and factors influencing drug innovation lag in Taiwan, and makes a comparison with major countries like USA, Canada, Japan, and Europe on marketing lag. The reimbursement lag in the National Health Insurance (NHI) of Taiwan is also explored. This is a retrospective study covering a total of 347 new drugs that were reimbursed by the Bureau of National Health Insurance (BNHI) from 1996 to 2002. Data collection includes time of regulatory approval, type of innovation, country of origin, and time and price of reimbursement by BNHI. The time of new drug approvals in study countries was obtained from relevant websites for comparison. The drug lag index between Taiwan and study countries was also analyzed. Data were analyzed by SPSS software for frequency distribution and multiple regressions. We found that new drugs are predominantly imported, and predominantly imported, and the average marketing lag was up to 30.5 months in Taiwan. Most of the new drugs were of me-too nature; only very few could be classified as breakthrough new drugs. In terms of marketing lag, USA was the shortest (5.6 months), followed by European countries (8.2 months), Canada (18.0 months), and Taiwan (30.5 months). The reimbursement lag was 11.7 months on average after product license granted by DOH, yet it was not affected by the NHI reimbursement price. The drug lag index from smallest to largest was: the USA (0.14), Europe (0.21), Canada (0.45), and Taiwan (0.76). Drug marketing lag is a serious issue in Taiwan. The average marketing lag of 30.5 months could be attributed to the fact that nearly all new drugs were of foreign origins. The average time after DOH's regulatory approval to NHI reimbursement was as long as 11.7 months. The government should re-examine the current function of the regulatory and reimbursement systems. More specifically, the health authorities should focus on faster regulatory process for breakthrough medicines instead of approving only "me-too new drugs".

Key words: drug lag, marketing lag, reimbursement lag, Taiwan

INTRODUCTION

The regulatory approval time for new drugs is a recurring focus for healthcare policy analysts in many countries. New drug applications have been evolved into a complicated and time-consuming regulatory process since the thalidomide event in the early 1960s. It was intended to ensure drug safety and efficacy, but may compromise public accessibility to pharmaceutical innovation in time. The delicate balance between drug safety and drug accessibility has become an important policy issue.

Drug innovation lag is mostly related to the regulatory process of new drug approvals. It refers to the phenomenon whereby the introduction of new drugs into a country is delayed, and the inefficiency of the regulatory system was regarded as the cause of the delay[1]. In countries that have national health insurance systems, drug reimbursement lag or social drug lag is caused by the delayed listing of new drugs into benefit coverage. In the United States, Medicaid patients may not have access to newly approved drugs because of formulary restriction by state governments. In countries like Australia, Canada and France, the third party payment system requires cost-benefit evaluation before a new drug can be reimbursed[2-5]. Schweitzer developed the drug lag index, or the Drug Availability Index (DAI), as the measuring stick of drug lag. DAI measures the time taken for the new drug to be approved in a certain country within four years of its approval in the first country. DAI ranges from 0 (no drug lag) to 1 (serious drug lag), a larger value indicating a more serious drug lag[2]. Andersson, however, further classified drug delay into relative drug lag (the relatively early introduction of new drugs in some countries compared to other countries) and absolute drug lag (i.e., some drugs are never introduced into a country)[6].

Studies on drug lag mostly focused on industrialized countries, especially the United States and European countries. Wardell compared the introduction of new drugs in the UK and the USA during 1962-1971 with focus on nine types of therapy. Each country had an average of 2.4 years and 2.8 years of drug lags against the other country respectively. In terms of relative drug lag, 82 new drugs were introduced in the UK 0.7 years earlier than in the USA while the absolute drug lag indicated that 77 new drugs introduced in the UK were never introduced in the USA and 21 new drugs were introduced only into the USA during the study period[7].

Since Wardell's publication in 1973, numerous researches involving international comparative studies were published and focusing on relative drug lag and absolute drug lag. There were substantial differences between the numbers of new chemical entities (NCEs) introduced to studied countries. In addition, most new drugs were also the first introduced into their country of origin[8-12]. Rawson examined the new drug approval time between 1999~2001

* Author for correspondence. Tel: +886-2-2826-7175; Fax: +886-2-2820-5892; E-mail: huang@ym.edu.tw

in USA, UK, Sweden, Australia and Canada, and found that USA had the shortest process time of 371 working days, followed by Sweden, UK and Australia, while Canada had the longest process time[13-14].

The only one study on new drug approval process in Taiwan in 1992 involved 182 new drugs introduced between 1989 and 1991[15]. It took an average of 34.2 months for a new drug to be approved in Taiwan from the date it was marketed in its originating country, while it took drug manufacturers an average of 13 months from submitting an NDA to obtaining drug approval by the Department of Health (DOH).

This study explored the factors affecting drug innovational lag in Taiwan, and compared such trend with that of major countries (USA, Canada, European Union and Japan). The reimbursement lag by the Bureau of National Health Insurance (BNHI) after license approval was also explored.

METHODS

I. *Measurement*

The drug lag in this study was based on medicines introduced to Taiwan, USA, the EU and Canada during 1996~2002. It was defined by the difference between the time a drug received its first license in the study countries and the time it was approved for marketing in Taiwan. The reimbursement lag is the time lag between drug approval by the DOH and its reimbursement by the BNHI.

The therapeutic groups are based on the Anatomical Therapeutic Chemical (ATC) classification system of the WHO Collaborating Centre for Drug Statistics Methodology. By ATC, drugs are classified into 13 groups including those pertaining to the alimentary tract and metabolism (A), the blood and blood-forming organs (B), the cardiovascular system (C), and rare diseases (X), etc.

The classification of new drug innovation is based on three categories proposed by the the Canadian Patented Medicine Prices Review Board (PMPRB): category 1 (line extension) comprises new drugs with a similar chemical composition to existing drugs but differing in method of administration; category 2 (breakthrough) describes new drugs which provide the first effective treatment of a particular disease; and category 3 (me too) comprises new drugs or new dosage forms of existing drugs that have similar therapeutic effect to existing drugs (http://www.pmprb-cepmb.gc.ca).

II. *Data Collection and Analysis*

This study reviewed 347 new drugs listed for reimbursement by the NHI between 1996 and 2002. The approval time of new drugs in various countries were obtained from the websites of the following entities: CDER in FDA (USA), Health Products and Food Branch, Department of Health (Canada), the European Agency for the Evaluation of Medicinal Products (EMEA); Japan Pharmaceutical Manufacturers Association (Japan), and the Bureau of Pharmaceutical Affairs, DOH (Taiwan). In addition, the drug innovation level was based mainly on the Canadian PMPRB, while the data on the country of origin were obtained from Taiwan's DOH. The reimbursement time and the approved price were obtained from the BNHI website.

Data were analyzed using the SPSS software for frequency distribution and multi-regression.

RESULTS

15.3% of the 347 new drugs covered in this study were from Taiwan and the remaining 84.7% were from foreign countries. Taiwan ranked the number one country of origin (15.3%), followed by UK, USA, Germany and France in descending orders. In terms of ATC grouping, the leading five categories are drugs for nervous system (N) 15.3%, drugs for systemic anti-infective use (J) 14.7%, anti-neoplastic/immunomodulating agents (L) 13.8%, agents for respiratory system (R) 10.1%, and agents for cardiovascular system (C) 8.4%. Drugs for rare diseases (1.2%), systemic hormonal preparations (1.4%), and genito urinary system and sex hormones (4.0%) are a minority.

Since the data on new drug innovation attributes are based on the Canadian PMPRB classification, only 124 new drugs (36%) were available for analysis. Category 1 (me too new drug) accounts for the largest proportion (70.2%) while drugs of significant breakthrough make up only 11.3% (Table 1). Regarding reimbursement price in NHI, we observed a negative skew distribution whereby 62.0% were priced below NT$ 200. Nevertheless, distribution became normal when corrected with natural logistic transformation (Ln).

For the 80 new drugs that were all approved for marketing in the study countries, the average drug lag in Taiwan was 30.5 months when compared to the first approval in other countries. Bivariate analysis indicated that there was no difference in terms of domestic/foreign origins ($P = 0.355$), yet there were statistically significant differences in terms of country of origin ($P = 0.024$), ATC therapeutic group ($P = 0.004$), and new drug innovation attribute ($P = 0.018$).

The average lag between DOH's approval and the listing of NHI reimbursement was 11.7 months. Only the ATC therapeutic group ($P = 0.001$) showed a significant difference in the bivariate analysis. The other factors, such as domestic/foreign origin, country of origin, innovational attributes of new drugs, and ln (drug prices expressed in log value) all showed no significant difference.

I. *Multiple Regression Analysis*

While predicting the regression model of marketing lag, the variable of drug innovation attributes was excluded

due to limited data availability. There was also a problem of co-linearity in the analysis when domestic/foreign origin was taken into account. Therefore, only two variables (country of origin and ATC category) were included in the multiple regression analysis. Since most variables were categorical, virtual variables were created for further analysis and grouped to facilitate the application of the multiple regression model. Genito-urinary system and sex hormones (G) and rare disease drugs (X) were excluded from the model as the frequency of these categories was zero. The remaining categories with less than 5% frequency were combined as a single group. In total, only 8 groups and 7 virtual variables were analyzed. Country of origin was grouped into five categories: (1) Taiwan, (2) USA and Canada, (3) European countries (UK, Germany, France, Belgium, Sweden and Switzerland), (4) Asian countries (Japan and Australia), and (5) other countries (Italy, Puerto Rico, Spain, Denmark and Finland).

Table 1. Description of NHI reimbursed new drugs in Taiwan (1996~2002)

Characteristics	Number of new drugs listed (%)
Country of origin (n = 347)	
Taiwan	53 (15.3)
UK	44 (12.7)
USA	33 (9.5)
Germany	29 (8.4)
France	28 (8.1)
Others (Japan, Switzerland, Puerto Rico, Australia, Sweden, etc)	160 (46.1)
ATC therapeutic group (n = 347)	
Agents for nervous system (N)	53 (15.3)
Anti-infective for systemic use (J)	51 (14.7)
Anti-neoplastic and immunomodulating agents (L)	48 (13.8)
Agents for respiratory system (R)	35 (10.1)
Agents for cardiovascular system (C)	29 (8.4)
Others	131 (37.8)
New drug attribute (n = 124)	
Line extension new drug (category 1)	23 (18.5)
Breakthrough new drug (category 2)	14 (11.3)
Me too new drug (category 3)	87 (70.2)

Table 2. Multiple linear regression analysis of drug lag (n = 80)

Variables	Regression coefficient	T value	P value
ATC therapeutic group			
Nervous system (N)	Reference		
Anti-neoplastic and immunomodulating agents (L)	-14.471	-2.511	0.014[a]
Musculo-skeletal system (M)	-4.332	-0.688	0.494
Respiratory system (R)	-6.781	-1.032	0.306
Cardiovascular system (C)	-2.816	-0.420	0.676
Anti-infective for systemic use (J)	-21.198	-2.695	0.009[b]
Sensory organs (S)	-7.183	-0.909	0.367
Others (A, B, D, H)[c]	-16.152	-2.629	0.011[a]
Country of origin			
Taiwan	Reference		
USA, Canada	-42.936	-4.012	0.000[b]
UK, Germany, France, Belgium, Sweden, Switzerland	-35.747	-3.597	0.001[b]
Japan, Australia	-37.651	-3.015	0.004[b]
Others	-32.865	-3.260	0.002[b]
Constant	73.168		
$AdjR^2 = 0.237$; $F = 3.232$[b]			

[a] $p < 0.05$.
[b] $p < 0.01$.
[c] Alimentary tract and metabolism (A); blood and blood forming organs (B); dermatologicals (D); systemic hormonal preparations (H).

Table 3. Multiple linear regression analysis of reimbursement lag (n = 280)

Variables	Regression coefficient	T value	P value
ATC therapeutic group			
Anti-neoplastic and immunomodulating agents (L)	Reference		
Nervous system (N)	2.214	1.045	0.297
Anti-infective for systemic use (J)	5.808	2.888	0.004[a]
Respiratory system (R)	1.368	0.632	0.528
Cardiovascular system (C)	0.731	0.294	0.769
Sensory organs (S)	6.606	2.740	0.007[a]
Blood and blood-forming organs (B)	0.658	0.270	0.787
Musculo-skeletal system (M)	-3.521	-1.293	0.197
Dermatologicals (D)	1.858	0.694	0.488
Alimentary tract and metabolism (A)	0.994	0.355	0.723
Others (G, H, X)[c]	2.106	0.848	0.397
Country of origin			
Taiwan	Reference		
USA, Canada	3.747	1.709	0.089
UK, Germany, France, Belgium, Sweden, Swiss	1.479	0.866	0.387
Japan, Australia	0.437	0.200	0.841
Others	1.759	0.973	0.332
Ln[d] (drug price)	0.106	0.348	0.728
Constant	7.751		
$AdjR^2 = 0.098$; $F = 1.902$[a]			

[a] $p < 0.05$.
[b] $p < 0.01$.
[c] Genito-urinary system and sex hormones (G); systemic hormonal preparations (H); rare diseases (X).
[d] Log value.

In Table 2, the regression model shows a significant difference in the marketing lag (F = 3.232, P = 0.001) with an explainable proportion coefficient, $R^2 = 0.237$. For individual ATC group and country of origin, the *p* values of anti-neoplastic and immunomodulating agents (L), anti-infective for systemic use (J), and others (including A, B, D, H) and source of origin (categories 2, 3, 4, and 5) showed a statistically significant difference to the control group.

When calculating the reimbursement lag, a drug Fluarix was excluded as if it is distributed without a value. The variables of drug innovation type and country of origin were also excluded with the former excluded due to limited data availability and the latter due to the problem of co-linearity. All the remaining variables (ATC category, country of origin, and NHI reimbursement price) were taken into the multiple regression model analysis. In the ATC category, the categories with less than 5% representation were grouped together, including genitor-urinary system and sex hormones (G), systemic hormonal preparations (H), rare diseases (X). There were a total of 10 groups of which 9 virtual variables were set for the regression analysis together with source of origin and NHI reimbursement price.

As shown in Table 3, the result of the regression model presented a statistically significant difference (F = 1.902, P = 0.023) with the regression coefficient value of $R^2 = 0.046$, whereas only the individual coefficients of anti-infective for systemic use (J) and sensory organs (S) showed a statistical difference.

II. *Comparison between Countries*

Only 4 drugs were available simultaneously in Taiwan, Japan, USA, the EU, and Canada. However, excluding Japan from analysis, 80 new drugs were available simultaneously in the remaining four countries. Among 80 new drugs, USA has the shortest marketing lag of 5.6 months, followed by the EU (8.2 months), Canada (18.0 months), and Taiwan (30.5 months). The indexes of drug lag were 0.14 for the USA, 0.45 for Canada, 0.21 for EU, and 0.76 for Taiwan, indicating that the drug lag in Taiwan was the most serious.

DISCUSSION

The introduction of innovational new drugs in Taiwan has been heavily dependent upon the importing sources, especially UK, USA, Germany, France, and Japan. This phenomenon is expected since these countries belong to pharmaceutically developed countries. 5.7% of new drugs were imported from Puerto Rico, attributable to the tax incentives that attract American pharmaceutical companies to invest. Although 53 new drugs were of domestic origin, 25 (47.2%) were actually produced by member companies

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of the International Research-Based Pharmaceutical Manufacturers Association (IRPMA) and 28 (52.8%) by non-members. Non-member companies TTY Biopharm, Yung Shin Pharm and Ko Chin Pharm accounted for 13 new drugs.

Leading ATC categories of new drugs are for treatment of the nervous system, systemic anti-infective, tumors, respiratory system, and cardiovascular system. This closely mirrors the current emphasis on drug research and development.

Regarding the attribute of innovation that was based on Canadian PMPRB criteria, 70.2% (72/124) of new drugs introduced to Taiwan are of me-too nature, 11.3% are breakthrough new drugs. Contrary to the findings of the OECD report[16]. The 'me too' new drugs are favored by pharmaceutical companies as they offer similar therapeutic effects as innovative drugs but are relatively risk free from the regulatory perspective. It, however, may significantly increase overall medical expenditure. It is worth noting that the criteria of Canada's PMPRB on new drugs categorization take both financial perspective in health insurance and their therapeutic value into consideration. Therefore, PMPRB has stricter definition of innovative drugs. In addition, new drugs not available in both Canada and Taiwan are not included for this analysis, therefore, the interpretation of this result should be taken conservatively.

The marketing lag in Taiwan is 30.5 months in this study, 3.7 months shorter than the 34.2 months reported by Cheng in 1992[15]. Although the definition of these two studies are not the same, Cheng defined the time lag based on the approval time of the originating country while this study adopted the first approval time among the study countries. It can still project a trend that the marketing lag in Taiwan has not been improved. It could also be caused by delay in an NDA submission by the pharmaceutical company. In order to promote the development of pharmaceuticals industry in recent years, it is important for the government to create a more favorable regulatory environment to expedite the approval time for new drugs.

In the regression analysis after controlling the ATC groups, USA and Canada have a negative coefficient of 42.936, indicating that these countries have a decreasing effect on the marketing lag in Taiwan. In other words, marketing approvals in both USA and Canada are much sooner than that of Taiwan. The European and Asian countries come next with coefficient of -35.747 and -37.651, respectively, both moving toward a decrease in marketing lag. These findings are consistent with the observation that a country enjoying a more substantial market would be more aggressive to launch their products in Taiwan, which in turn narrow the marketing lag in Taiwan.

When the country of origin is used as a control, the ATC groups of anti-tumor and immune system regulation (L), systemic anti-infective (J) and others all show significant negative coefficients. This means new drugs in these therapeutic groups are introduced into the Taiwanese market earlier than new drugs for nervous system of the control group. As a result, patients suffering from cancers have better access to these new drugs.

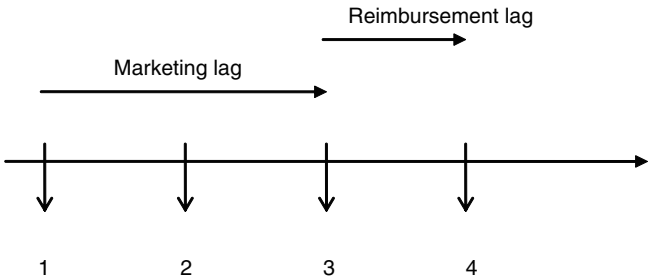

Figure 1. Drug innovational lag (marketing lag and reimbursement lag). 1. The new drug approved in the first country; 2. NDA submission for license approval in Taiwan; 3. NDA approved by Taiwan; 4. New drug listed in NHI for reimbursement.

The main purpose of comparing drug lag index is to gradually decrease drug lag as regulatory experiences among various countries were accumulated. USA has the smallest drug lag index (0.14), followed by the EU (0.21), Canada (0.45) and Taiwan (0.76). This figure indicates drug lag index in Taiwan is 5.43 folds, 3.62 folds and 1.69 folds of USA, EU and Canada, respectively. Since USA is the leading country in the world for new drug research and development, it makes sense that USA has the smallest drug lag index. Great drug lag index in Taiwan is understandable since nearly all new drugs are of foreign origins.

In fact, marketing lag may happen as a result of two time periods: an NDA submission time by a pharmaceutical company and license approval time by the health authority. Delayed NDA submission will automatically create marketing lag, while inefficient regulatory process will also contribute to the marketing lag. Our study did not differentiate the marketing lag based on the above two time factors because the submission time for an NDA was not available for analysis.

When country of origin and the NHI reimbursement price are maintained as control, the ATC groups of systemic anti-infective (J) and drugs for sensory system (S) show significant difference but only with small positive values, meaning NHI reimbursement is more difficult for these therapeutic groups than for the control group (anti-tumor and immune system regulation (L). Although drugs for systemic anti-infective (J) have a negative correlation coefficient in marketing lag, the regression coefficient of its reimbursement lag is positive. It could be interpreted that there may be a reimbursement lag without presence of the marketing lag.

When other variables are held constant, NHI reimbursement price does not have a notable effect on the reimbursement lag in Taiwan. This is a good sign. This research started with the hypothesis that drug pricing affects reimbursement lag, as this lag might be prolonged considerably for expensive new drugs which in term will affects public access to new drugs. However, our findings showed that such consideration does not exist in Taiwan.

This study also found that for the new drugs approved prior to 1996 yet were reimbursed only after NHI implementation, the average reimbursement lag was 13.3 months, not much different from those new drugs approved after 1996. Therefore, no further analysis was performed.

Due to the co-linearity on domestic/foreign source with country of origin and data availability on innovation attributes, the reimbursement lag was not significant after controlling other variables. It is good to see that there is no effect of new drug price on reimbursement lag. It was hypothesized that reimbursement lag may exist for more expensive new drugs which in turn will affect public access to pharmaceutical innovations. This study provides an evidence-based result to dissolve such concern. The BNHI may not be responsible for the average reimbursement lag of 11.7 months because that the new drug license holders are not required by law to apply for NHI listing and pricing after license approvals. It may take the license holder several months after license approval to submit NHI reimbursement application.

Since countries vary on the regulatory process of NDAs, data were collected primarily based on drug brands and supplemented by manufacturers in order to maximize sample size. Moreover, this study based on the new drugs listed for NHI reimbursement during 1996~2002 which may not be 100% consistent with the new drugs approved by the DOH during this study period.

CONCLUSIONS

Drug lag, especially marketing lag, is a serious issue in Taiwan. The average marketing lag in Taiwan is 30.5 months since its first approval in other country. The drug lag index of 0.76 also far exceeds corresponding figures of USA (0.14), EU (0.21), and Canada (0.45). We found no reimbursement lag for NHI listed new drugs during 1996~2002 due to NHI reimbursement prices. However, the average time lag after regulatory approval to NHI reimbursement is as long as 11.7 months. We recommend the government to examine the current regulatory and reimbursement process for new drugs. Focus should be on encouraging faster market access to breakthrough medicines instead of devoting substantial efforts to approve “me-too new drugs”.

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