

Original Research

The impact of South Korea's new drug-pricing policy on market competition among off-patent drugs

Hye-Young Kwon^{1,2}, Hyungmin Kim³, *Brian Godman^{4,5}, Michael R. Reich¹

¹Department of Global Health and Population, Harvard School of Public Health, Boston MA 02115, USA. Email: reich@hsph.harvard.edu

²Institute of Health and Environment, Graduate School of Public Health, Seoul National University, Seoul South Korea. Email: haeyoungkwon0111@gmail.com

³National Health Insurance Service, Seoul, South Korea. Email: yanki@hanmail.net

⁴Department of Laboratory Medicine, Division of Clinical Pharmacology, Karolinska Institutet, Karolinska University Hospital Huddinge, SE-141 86 Stockholm, Sweden; ⁵Strathclyde Institute for Pharmacy & Biomedical Sciences, University of Strathclyde, Glasgow, UK

*Author for correspondence: Strathclyde Institute of Pharmacy and Biomedical Sciences, University of Strathclyde, Glasgow G4 0RE, United Kingdom. Email: Brian.godman@strath.ac.uk. Telephone: 0141 548 3825. Fax: 0141 552 2562 and Division of Clinical Pharmacology, Karolinska Institute, Karolinska University Hospital Huddinge, SE-141 86, Stockholm, Sweden. Email: Brian.Godman@ki.se. Telephone + 46 8 58581068. Fax + 46 8 59581070

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Abstract

Introduction: A new pricing policy was introduced in Korea in April 2012 with the aim of strengthening competition among off-patent drugs by eliminating price gaps between originators and generics. **Objective:** Examine the effect of newly implemented pricing policy. **Methods:** Retrospectively examining the effects through extracting from the National Health Insurance claims data a 30-month panel dataset (January 2011 - June 2013) containing consumption data in four major therapeutic classes (antihypertensives, lipid-lowering drugs, antiulcerants and antidepressants). Proxies for market competition were examined before and after the policy. **Results:** The new pricing policy didn't enhance competition among off-patent drugs. In fact, price dispersion significantly decreased as opposed to the expected change. Originator-to-generic utilization increased to 6.12 times ($p=0.000$) after the new policy. **Conclusions:** The new pricing policy made no impact on competition among off-patent drugs. Competition in the off-patent market cannot be enhanced unless both supply and demand-side measures are coordinated.

Introduction

Generics are therapeutically equivalent to originator medicines but less costly at appropriate doses [1-2]. Once a generic is available, the monopolistic market for an originator medicine becomes more competitive. But just how competitive the market actually becomes varies considerably across countries depending on implemented policies [3-8]. The price decrease in high generic market share countries was more substantial (-43.18%) than in those with low generic market share countries (-21.56%) [8].

Increasing the prescribing and dispensing of generics can free up considerable resources to fund new medicines and increased volumes without increasing health insurance costs [9-14]. Accordingly, insurers, governments and the World Health Organization encourage the use of generics to realize considerable savings and enhance efficient resource allocation [13-18]. This can be achieved by policies such as reference pricing with patients covering the additional costs themselves, substitution targets in pharmacies, compulsory generic substitution, encouraging International Nonproprietary Names (INN) prescribing, prescribing targets, as well as financial remuneration for physicians to enhance the prescribing of generic medicines [14-19].

In April 2012, the Korean government implemented a new drug-pricing policy in order to make its off-patent market more competitive [20]. The core of this new policy was to set the same maximum reimbursement price (ceiling price) between originators and generics. It was envisaged that this would make the market competitive, as generic manufacturers would freely compete with lower prices. Others though have argued that this policy would still favor originator pharmaceutical products, given the general belief that an originator medicines, often from an international pharmaceutical company, assures better quality. However, to date, no study has examined the effects of this new policy. We evaluated the impact of South Korea's new pricing policy on market competition among off-patent medicines using the national health insurance claims data 15 months prior to policy implementation and 15 months post implementation.

Context of new drug pricing policy

- National Health insurance coverage for medicines in Korea

Korea is one of countries that quickly achieved universal health coverage, achieved within 25 years. The Korean National Health Insurance (NHI) has been providing universal coverage in all populations and health services. Approximately 97% of the entire population in Korea is now covered by the NHI, and the remainder are protected by the medical aid from the government [21].

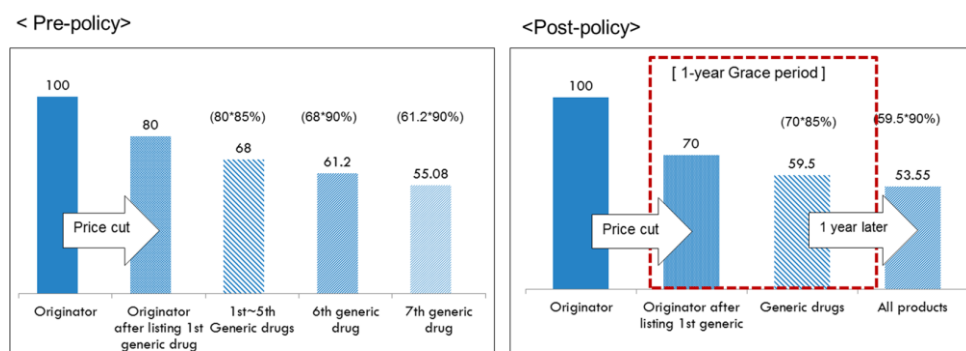
Spending on pharmaceuticals has appreciably increased in recent years, and its portion over total health expenditure including reimbursed and non-reimbursed technologies accounted for 21.3% of total expenditure in 2011, which is higher than the OECD average of 16.0% [22]. Based on national health expenditure statistics which just includes reimbursed expenditure, spending on pharmaceuticals accounted for 27.1% of total health expenditure in 2012 [23]. In view of this high spend, the government has been trying in recent years to reduce the growth rate and the overall portion of expenditure on pharmaceuticals through different measures as it looks to contain costs.

The cost-sharing for pharmaceuticals is currently 30% of total medicine costs per each visit in ambulatory care. For inpatient services, only 20% of the total costs is charged to patients [24]. Given that 74.9% of pharmaceutical expenditure occurred in pharmacies in 2012 [23], the majority of patient copayments have costed 30% of the total cost per prescription. This includes drug costs based on the reimbursement prices that are equal to the pharmacy retail prices, pharmacist fees for dispensing and for counseling for drug administrations. Since prices of pharmaceuticals that are reimbursed by the NHI are regulated by the Ministry of Health and Welfare (MOHW), there is no doubt that cheaper medicines translate into lower costs for patients. How much cheaper medicines are is important for patients, especially those with chronic diseases, to improve aspects such as compliance if costs are a concern [25, 26].

Previously, prices of generic drugs in Korea have been determined by the order of their entry into the market, so called "stepwise pricing scheme". When the patent of a particular molecule has expired, immediately thereafter, the price of originator medicine was cut by 20%. The first to fifth generic drugs entering the market were priced at 85% of the brand name (originator) medicine price. Subsequent generics were priced at 90% of the lowest price of previous generic versions [27]. Therefore, the prices of off-patent drugs used to be set in a step wise fashion (see Figure 1). Theoretically after 24 months post-patent loss, the lowest generic medicines could be priced at 9% of the initial price of the originator. Thus, price dispersion among competitors was introduced by regulation, not by competition.

However, the weighted average prices (WAP) of the generic medicines were 72.5% of the originator' prices despite the fact that minimum prices of generic medicines were the lowest followed by Sweden, US, Germany [28], which implies high-cost generic medicines are widely used even though lower priced generics are available.

Fig. 1. Pricing scheme for off-patent drugs at a glance



This may be because there are currently no demand-side measures to encourage the prescribing of cheaper generics in Korea. Only financial incentives for pharmacists to substitute with cheaper drugs have been in place. However, the effect was very minor and has become almost obsolete. Annual cost savings from pharmacist's substitutions to low cost medicines incurred KRW 161 million (USD 152,183) and incentives provided to pharmacies were only KRW 99 million (USD 93,174) in 2009 [29]. This is because whilst pharmacies receive 30% of price difference between the prescribed medicine and the cheaper substitute [30,31] and they should report by law any substitution to the prescribers, who are not usually satisfied with pharmacist's substitutions [32], they receive compensation based on fee-for-services in proportion to the number of prescriptions they dispense and do not want to upset prescribers because their revenues mainly depend on prescriptions [33]. Consequently it's hard to expect pharmacists to substitute more expensive medicines for cheaper molecules unless the incentive system is changed.

For consumers, the price gaps between different brands of the same molecule were not large and 30% of this for patient copayment was not sufficient to change their behavior towards requesting cheaper generics, especially if they had concerns with their quality. Consequently, there is a need for additional measures for the Korean NHI to fully gain from the increasing availability of standard medicines as generics. This resulted in the new pricing policy for off-patent medicines.

- New pricing scheme for off-patent medicines

The newly implemented pricing policy aims to both lower the prices of off-patent drugs and introduce market competition in the off-patent market to take advantage of potentially low cost generics. According to the new pricing policy, once the patent for a substance expires, the prices for both generics and originators are set at the same maximum reimbursement price (ceiling price), which is 53.55% of the previous price of originators. However, the government gave a 1-year transition period in order to mitigate the impact of the new policy before its full-fledged implementation. During the transition period, the price of originators was reduced by 30% with all generic medicines priced at 85% of the originator's price (box in figure 1). The price gaps between originators and generic drugs have narrowed down to 10.5%p (70% minus 59.5%) from more than 12%p (80% minus 68% for the first to fifth generics), also the price of originator medicines has lowered by 10%p (80% to 70%) more than before. Accordingly, as of 1 April 2012, approximately 40.1% (6,505 over 13,814) of products listed on the formulary were re-priced [20]. Figure 1 shows the outlines of newly implemented pricing mechanism compared to the previous stepwise pricing scheme.

The government's intention is to regulate the maximum reimbursement prices at the same level for both originator and generic medicines, and for generic companies to freely compete on lower prices, making the market more competitive. Therefore, the key to making this new policy effective is whether generic manufacturers would willingly reduce their prices, and if so, by how much lower compared with the originator's prices. Otherwise, patients would be less likely to choose generics after the new policy because the price gap between originators and generic medicines would become even closer

during the transition period and eventually be the same.

Materials and methods

The data used for this study were extracted from the National Health Insurance (NHI) data warehouse (NHI DW) where NHI claims data were reposit without patient information. Monthly cost and quantity for each pharmaceutical were included in the NHI DW. The data were approved to use for this study through the NHIS internal review process.

We selected oral forms of medicines among four major therapeutic classes including antihypertensives, lipid-lowering drugs, antidepressants and antiulcerants. These therapeutic classes composed 23.4% of the total spending of oral medicines in 2012 [34].

We established a monthly panel dataset containing pharmaceutical consumption between January 2011 and June 2013 (30 months). The data included aggregated costs and quantities prescribed for each medicine on a monthly basis. Monthly volumes are presented as standard units (i.e. tablet or capsule).

Proxies of market competition were considered as dependent variables. Previous studies addressing market competition among off-patent medicines have employed (i) market share of either originators or generic drugs [4,35-37], (ii) the prices of generics or brand name drugs [35,38,39] and (iii) price ratios of originators and generic medicines [1,37,40] as a proxy of market competition. In this study, we considered price dispersion (D^P), originators' market share in value (MS^O) and relative ratio of consumptions of originators versus generic drugs ($R^{O/G}$) as proxies of market competition. Price dispersion was calculated as log scale of the variance of prices. Based on the government expectation, if generic manufacturers took a price differentiation strategy in order to penetrate the market, then prices would be widely dispersed. We measured the price dispersion in order to directly show how the government expectation works in the market place in practice.

The simple panel data model [35] was presented below:

$$Y_{it} = \alpha_i + \beta X_{it} + \varepsilon_{it}$$

Y_{it} represents, for example, the market share of originator in i substance at time t . X_{it} is the vector of explanatory variables for i substance at the t th time period including the new pricing policy effect (time dummy), number of products for substances (log), ages of the first generic drugs (log), month whether or not having a new generic entry and market value (log). α_i denotes unobserved substance specific effects. The ε_{it} is the stochastic disturbance for the i th case at the t th time period. We also included therapeutic classes as time-invariant characteristics of substance i . This is captured by the substance fixed effect, α_i .

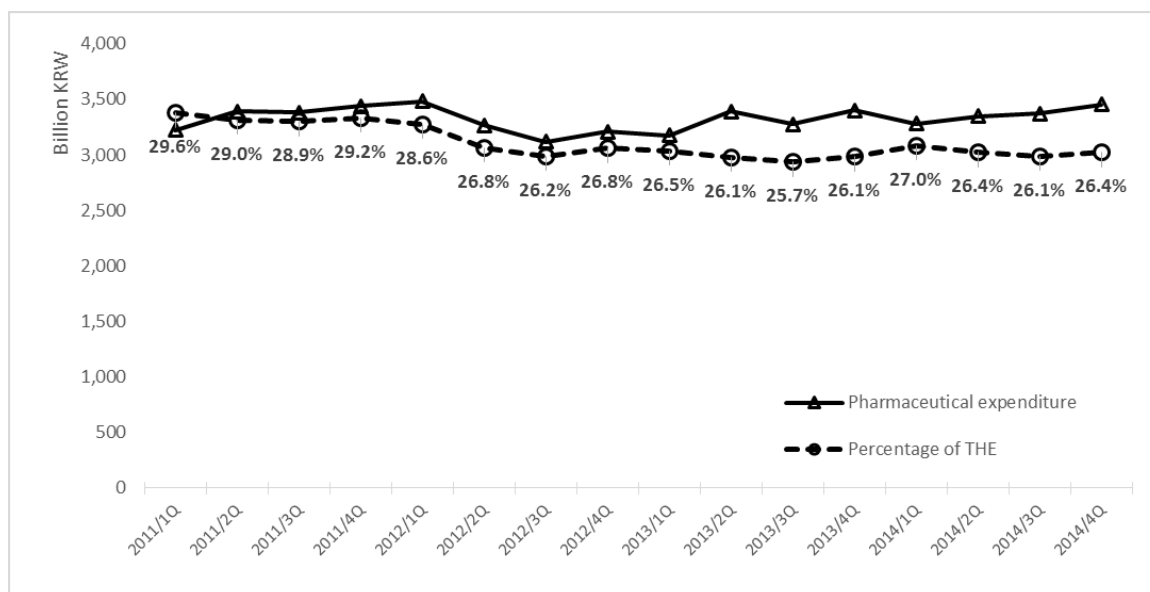
The assumption behind the relationship between X_{it} and α_i makes the fixed effects and random effects model different. The fixed effects model assumes that α_i is treated as non-random and there is the correlation between the observed explanatory variables (X_{it}) and α_i while the random effects approach assumes that α_i is random and not correlated with X_{it} and puts it into the error term [35]. Therefore, Hausman's specification test was conducted to assess whether to apply a fixed effect or random effect model [41,42]. Stata/SE 11 (StataCorp, 2009) was used for analysis.

Results

- Overall trend of total pharmaceutical expenditure

Overall trend of total drug spending was depicted in Figure 2. After the new policy, total drug spending has decreased in 2Q/2012 but rebounded in 1Q/2013. However, the portion of total pharmaceutical expenditure has dropped to around 26% since after.

Fig.2. Overall trend of drug spending and its portion of total health expenditure

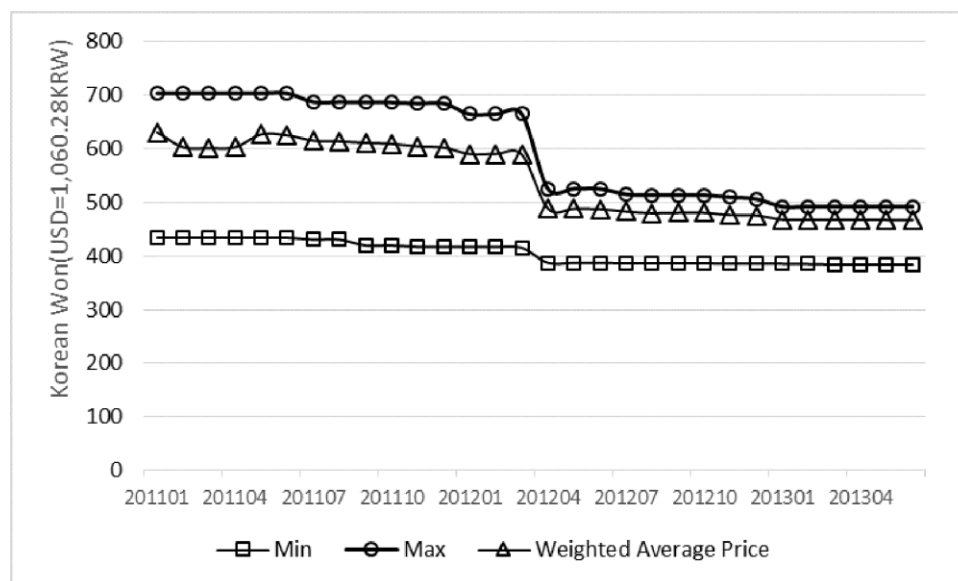


Source : Statistical indicators of medical expenses, Health Insurance Review & Assessment Service

- *Policy effect on Market competition*

As shown in Figure 3, the price trends overtime narrowed after the new policy. The price for each substance was calculated by dividing total cost by the total quantities prescribed. The maximum of the prices of substances of approximately 700 KRW (1US\$=1,060.28 KRW as of October 2014) decreased to approximately 500 KRW. In contrast, minimum prices marginally decreased after the new policy. The average price declined after the new policy. However, it came closer to the maximum price for the chosen classes (Figure 3). This implies that medicines with a closer price to the maximum prices have been more prescribed than before. Prices conversed rather than dispersed. Thus, there were no price differentiation strategies undertaken by generic manufacturers after the new policy, which was in direct contrast to government expectations.

Fig. 3. Price dispersion of all medicines after the new pricing policy.



The results of the panel analysis are presented in Table 1. According to Hausman's test, the fixed effect estimation was suitable for all models. Thus, the therapeutic class variable was omitted due to correlation with other explanatory variables.

Table 1. Fixed effect of panel analysis

	<i>Price dispersion (log)</i>		<i>Share of originators(log)</i>		<i>originator-to-generic utilization ratio</i>	
	β	S.E	β	S.E	β	S.E
Constant	2.23*	0.83	3.06**	0.23	-221.08**	11.82
Policy effect_dummy	-0.92**	0.04	-0.01	0.01	6.12**	0.41
Ages of the first generic drugs(log)	-0.48**	0.06	-0.13**	0.02	-11.41**	0.69
Number of competitors (log)	-0.52**	0.13	-0.09*	0.04	-3.79*	1.48
Entry of new generic drugs_dummy	-0.01	0.05	0.02	0.01	0.13	0.50
Market value(log)	0.25**	0.04	0.07**	0.01	14.03**	0.58
R ²	0.028		0.132		0.042	
Hausman's Test	51.01**		33.54**		510.67**	

*p<0.05, **p<0.001

The policy impact on price dispersion has showed, as appeared by Figure 3, a significant decrease of 0.92 (p<0.001). Each additional length of post period and competitors induced nearly 48% (p<0.001) and 52% (p<0.001) monthly decreases in the price dispersion, respectively. This result is somewhat inconsistent with the economic reasoning that the degree of competition is positively related to the number of competitors in the market. However, the price dispersion has increased by 25% with 1% increase of the market value.

The market share of originators (log) has marginally but not significantly decreased with the new policy. However, all other significant factors can explain well the dynamics of the market share of originators. The share of originators has significantly decreased by 13% ($p=0.000$) and 9% ($p=0.013$) respectively with longer periods of the first generic drugs available and with increased number of competitors. However, the market value showed a significantly positive association with the market share of originators.

The results showed that the originator-to-generic utilization ratio ($R^{O/G}$) significantly increased by 6.12 ($p=0.000$) after the new policy. So, originator medicines were prescribed 6.12 times more than generic drugs after the new policy. However, with a longer period of post-patent expiry and more competitors in the market, the relative ratio significantly decreased. Therefore, generics medicines could be more likely prescribed soon after patent loss or where there are more competitors in the market place. In contrast, the market value showed a positive association with the originator-to-generic utilization ratio. Therefore, originators are more likely to be prescribed than generics where market value is high.

Discussion

In April 2012, the Korean government implemented new price regulation schemes for off-patent medicines by setting the maximum reimbursement prices at the same level for both originator and generic drugs. This new policy was supposed to promote market competition among off-patent medicines on the assumption that generic manufacturers might implement price differentiation strategies to penetrate the market if their maximum reimbursement prices are same as the originators. In this study, we've examined this assumption by analyzing data over 30 months (January 2011-June 2013) from pharmaceutical claims data from the NHIS. The extent of market competition was expressed as price dispersion, market share of the originators and originator-to-generic utilization ratios.

Although total pharmaceutical spending decreased after the new pricing policy, this trend rebounded one year later (Figure 2). In terms of market competition, the results showed the belief of strengthened market competition among off-patent drugs following the implementation of the new pricing policy was not seen in practice. In fact, price dispersion narrowed rather than being broader as expected (Figure 3), which implies generic manufacturers have not lowered their prices as a marketing strategy. Market share of originator medicines has not significantly changed. However, the originators have been prescribed 6.12 times more often than generic drugs after the new policy implementation (Table 2). Consequently, the new pricing policy has not contributed to promoting market competition. In fact the reverse was seen with the originators taking advantage of this policy even after the patent has expired.

Consequently, although competition among off-patent drugs should lead to price reductions and potentially create savings to healthcare system based on previous experiences [13-17, 43-49], this was not achieved in the Korean market place. As a result, it seems difficult to believe that market competition among off-patent medicines will be achieved in Korea even with the recent changes in the pricing policy. The level of prices for off-patent medicines can easily be regulated but promoting the prescribing of low priced medicines is hard to address in Korea given current limited demand-side measures among physicians and the current incentives for pharmacists. Stimulating price competition to lead to an increase prescribing of low cost generics cannot be achieved solely with price regulation policies as this study revealed. Demand-side measures to promote increased prescribing and dispensing of the lowest priced product include reference pricing with patients covering the additional costs themselves for a more expensive molecule, compulsory substitution with the lowest cost product, providing pharmacists with substitution targets as well as compulsory or high voluntary INN prescribing [14,16,17,47-51]. Overall, price competition can be achieved when coordinated demand and supply-side policies are considered [8]. Care is not compromised with demonstrated bioequivalence between generics and originators [1,2, 52-54]. Supply-side measures such as price cutting are relatively easy to implement in Korea but the lack of demand-side measures appears insufficient to create a competitive market. Demand-side measures such as reference pricing based

on the lowest cost molecule or compulsory substitution with the cheapest medicine applied in Sweden can be considered for Korea [14-19]. Otherwise, the Korean NHI will fail to achieve the potential savings from the availability of low cost medicines.

We acknowledge this study has limitations. The follow-up of the new pricing policy included mostly its transition period. Consequently, we did not fully capture the effect of the full-fledged pricing policy. During the transition period, the price gaps between originators and generic medicines have not fully eliminated but reduced than before. However, it is not expected that competition would be stronger with a longer follow-up period. Originator medicines would be prescribed much more than generics after eliminating price gaps between originators and generics. We also acknowledge we need additional studies with longer follow-up in order to thoroughly evaluate the effect of the new pricing policy. However, we believe the findings are relevant, providing direction to the authorities in Korea.

Key issues

- In April 2012, a new pricing policy was implemented in South Korea in order to strengthen market competition among off-patent drugs by eliminating the price gaps between originators and generic medicines.
- This new pricing policy was supposed to promote market competition among off-patent drugs on the assumption that generic manufacturers might implement price differentiation strategies to penetrate the market if their maximum reimbursement prices were the same as the originators.
- We retrospectively evaluated the effect of the new pricing policy analyzing panel data over 30 months (Jan. 2011~Jun. 2013) from the National Health Insurance Claims data. The extent of market competition was expressed as price dispersion, market share of the originators and originator-to-generic utilization ratios.
- The results demonstrated that the assumption of strengthened market competition among off-patent drugs following the new pricing policy enactment was not seen in practice. In fact, price dispersion narrowed rather than being broader as expected, which implies generic manufacturers have not lowered their prices as a marketing strategy. The originators have been prescribed 6.12 times more often than generic drugs after the new policy implementation.
- The new pricing policy has not contributed to promoting market competition. In fact, the reverse has been seen with the originators taking advantage through this policy even after the patent has expired.
- Price competition cannot be achieved solely with price regulation policies as this study revealed. Supply-side measures such as price cutting are relatively easy to implement in Korea. However, the lack of demand-side measures failed to create a competitive market. Demand-side measures such as reference pricing should be considered for Korea to take advantage of low cost generics.

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