(GE_COMPETITION) has weak positive effects on demand (0.033 for "All Sample"). "LARGE_PACKAGE" do not promote demand. "HIGH_STRENGTH" ,"COPROMOTION", and "HIGH_PRICED_PRODUCT" do not affect demand. These individual characteristics are either unimportant determinant for demand. We need to be cautious about the interpretation since the individual characteristics must be captured by the price ratio itself. So the effects of individual characteristics in this specification is those for unexplained by the price ratio. Also policy makers should be cautious when they implement the price regulation. The government seems to apply the same universal method to all products without accounting for individual characteristics. But in reality, the effects of the prices ratio differ significantly across dose forms.

We also find that demand fluctuates significantly over time periods. The QUARTER3 (October-December) dummy variable has a large positive effect (0.355) while fourth quarter (January-March) has negative effect (-0.259). Similar results are found for "Capsule & Tablet" and "Injection". This may reflect actual transactions between hospitals/pharmacies and wholesalers. We can conclude that demand will surge in the third quarter and decrease in the fourth quarter. This result, however, does not allow a straight interpretation since Japanese wholesalers negotiate the sales price long after they supplied products to hospitals/pharmacies. It takes sometime several months after delivery. We need more information to analyze the reasons behind the demand fluctuation over quarters.

Period time period dummy variables are assigned to the period for price revision in 1992, 1994, 1996, 1997, and 1998 and 2000. We exclude 1990 and 2002 official price revisions due to small number of observation. In the period of the official price revision, we find large increase in demand (all periods except for Q_199204 and Q_199704 for "All Sample", and all periods for "Capsule & Tablet". These effects are fairly short and do not persist more than two quarters. We conclude that when the government reduces the official prices, it would decrease demand through the shrinking price ratio, but would increase demand in the period. This implication is very important in price regulation. When the government revises the official price, it does not account for the change in demand caused by the revision. In fact, the price revision could increase demand for product significantly.

Next we use equation (8) to assess year effects and quarterly effects for the official price revision.

$$\frac{\Delta q_{hit}}{q_{hit}} = \delta \left(\frac{\Delta(\overline{P}_{hit}/P_{hit})}{\overline{P}_{hit}/P_{hit}} \right) + \sum_{m=1}^{M} \phi_m M_{hi} + \sum_{d=1}^{4} \eta^d QUARTER_d + \sum_{y=1990}^{2001} \psi_y T_{ht}^y + \sum_{s=1}^{3}\sum_{d=0}^{3} \eta_{-d}^s \ Subperiod\_REVISION_{ht}^d + \varepsilon_{hit}$$

(9)

Time effects include "quarter effects". The effects of the price revision are estimated by the "year time variables" for each year, and the product of quarterly dummy variables and sub-sample period dummy variables. In order to

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evaluate lingering effects of the price revision we use one to three quarters lag for the variables. This specification assumes that effects of the official price revision may continue in the same fiscal year and that quarterly effects are different in the periods with or without the official price revision. Table 7 reports the results.

— Table 7—

Coefficients of year dummy variables are all positive. Years with the official prices revision (1990, 1992, 1994, 1996, 1997, 1998), they all increase demand significantly, while years without the official price revision, their positive effects are limited. This result does not hold for year 2000 as show by small coefficient of YR_2000. We conclude that official price reduction has long increased demand up to 1998. Because we do not have many observations after 2000, we cannot conclude whether these effects become smaller latterly.

When compared estimation of equation (8) with that of (7), quarterly effects have the same effects which indicates there are decline in demand in the QUARTER1, QUARTER2, and QUARTER4. We find that coefficients for quarterly dummy variables for the first period and second periods are all significant ($Subperiod\_Q\_\mathrm{Re}v_{-d}$). When we do not include these sub period quarterly dummy variables for the official price revision, explanatory power of the model declines significantly. Figure 3 depicts the constructed sum of the effects of year dummy variables, quarterly dummy variables, and quarterly dummy variables for price revision in three periods. For example, the effects in year 1992, quarter 1 , and the price revision effects are constructed as follows.

$$\frac{\Delta q_{hit}^{E}}{q_{hit}^{E}} = +1.230\,(YR\_1992) - 0.363\,(QUARTER\ 1) - 0.780\,(FP\_\mathrm{Re}\,vision\_D) = 0.088$$

Figure 3 is the constructed estimates of effects of year and quarter. The official price revision previously increases demand significantly, while years without revision have negative effects on demand. These negative effects, however, almost disappear after the late 1990s.

—Figure 3—

6. Conclusion

This study investigates price regulation and competition in Japanese pharmaceutical market. The price regulation has established a long-term downward trend of pharmaceutical prices in Japan. The price difference

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between the official price and the wholesale price has played a key role in pharmaceutical market. This study investigates two empirical questions. One is how the price difference ratio (divided by the official price) is determined. The other is how demand for each product is determined. We focus on various product profiles including "age", "corporation " , "ingredient", "form", "strength", "package volume transaction", "generic competition", "co-promotion/co-marketing". We also focus on "quarterly effects" on the price difference and demand. This study uses detailed transaction data on popular anti-infective and cardio-vascular products in 1990-2002 when the government had conducted aggressive price reduction.

This study finds that the price difference ratio is explained by individual characteristics in the framework of "hedonic price model". The ratio is higher for "co-promoted products", "higher strength products", "larger package volume product", "INJECTION" form, and "HIGH_PRICED_PRODUCT". However, the ratio is found to be lower for products facing with generic competition (GE_COMPETITION). There is no difference between "OLD_PRODUCT" and "NEW_PRODUCT". The structural change is found to exist between the early 1990s (1990-1994) and the rest of the period. Although OLD_PRODUCT enjoyed higher price ratio in the early 1990s, its effects disappeared in the late 1990s.

This study also finds that demand for product is well explained by our model. The price ratio is an important determinant of demand. Individual characteristics do not capture demand. It might be due to the fact they are already reflected in the differences in the price ratio as shown in our hedonic price model. Significant differences in dose forms are found. Our model explains demand for "Capsule & Tablet" while it fails to explain demand for "Injection".

This study concludes that Japanese pharmaceutical price regulation has significantly affected pharmaceutical prices as well as demand. Because the government applies the same pricing formula to all products, it does not reflect product-specific characteristics. In particular, it fails to capture the differences between "Capsule & Tablet" and "Injection". The government should take the unexpected response of the regulation into account. In particular, the official price reduction could increase demand. These results have policy implications for countries like Taiwan, Korea, and others who have newly establish a nation-wide health insurance and are committed to tight price regulation.

This study evaluates Japanese pharmaceutical price regulation by using anti-infective products. This study finds

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that the "price difference ratio (Dif)" had declined to 10 percent in 1998. The trend, however, was reversed after 1998. There is a structural change of the effects of price regulation between the first period (1990 1Q-1998 2Q) and the second period (1998 2Q-2002 2Q). In the first period, "old product", "high strength", "large package" increase the price difference ratio. "Capsule & tablet" and "old product" contribute to higher demand. In the second period, "large package" increase the price difference ratio. Suppliers can increase demand for "capsule & tablet" by the combination of "old product" and "medium strength" for smaller package, or by "high strength" for larger package. The effects of the price difference ratio are high for the "large package" in the second period.

Although the government seems to have achieved the goals as intended, our interpretation is not that straightforward. The effects of the "price difference ratio" on demand have become even larger, in particular for large package. The role of the price difference has not yet disappeared. To promote demand, suppliers can target hospitals and pharmacies that purchase products with high volume and discount. The upward trend of the price difference ratio after 1998 can be explained by this behavior. Regulators should be cautious about the differences in product profiles when they implement pharmaceutical price regulation. In particular, when they apply the uniform price formula, suppliers and consumers could react to it by utilizing differences in product profiles, which might cause unintended results.

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Table 1. Pharmaceutical Transactions and Prices

Pharmaceutical Firms

$\downarrow$ ··············Manufacturer's Sales Price P^M (listed price)

Wholesalers

$\downarrow$ ··············Wholesale Price P^W

Hospitals/Pharmacies

$\downarrow$ ··············Official Price $\overline{P}$ for the National Health Insurance Purpose

Patients

Table 2. Sample of Anti-infective Products

	Brand Name	Ingredient Name
#1	Cefspan	cefixime
#2	Cefmetazon	cefmetazole sodium
#3	Dalacin	clindamycin
#4	Tarivid	ofloxacin
#5	Tienam	impenem/cilastatin
#6	Doyle	aspoxillin
#7	Tosuxacin	tosufloxacin
#8	Tomiron	cefteram pivoxil
#9	Tomiron	cefteram pivoxil
#10	Baccidal	norfloxacin
#11	Pasetocin	amoxicillin
#12	Pasetocin	amoxicillin
#13	Banan	cefpodoximine proxecil
#14	Panimycin	dibekacin sulfate
#15	Halospor	cefotiam hydorochloride
#16	Pansporin	cefotiam hydorochloride
#17	Biklin	amikacin
#18	Firstcin	cefozopran hydrochloride
#19	Farom	faropenem sodium
#20	Flumark	Enoxacin
#21	Flomox	cefacpene pivoxil hydrochloride
#22	Bestcall	cefmenoxime hemihydrochloride
#23	Penglobe	bacampicillin hydrochloride
#24	Pentcillin	piperacillin sodium
#25	Fosmicin	Fosfomycin
#26	Miocamycin	midecamycin acetate
#27	Minostacin	minocycline hydrochloride
#28	Minomycin	minocycline hydrochloride
#29	Meiact	cefditoren pivoxil
#30	Megalocin	fleroxacin
#31	Meropen	meropenem trihydrate
#32	Modacin	ceftazidime
#33	Unacin	sultamicillin
#34	Rasenazolin	cefazolin sodium
#35	Ricamycin	rokitamycin
#36	Rulid	roxithromycin

Table 3 Price Difference Ratio

	observation	10-%ile	Median	90-%ile
199004	93	1.24	1.41	1.80
199104	105	1.24	1.41	1.75
199204	116	1.17	1.30	1.57
199304	121	1.20	1.33	1.66
199404	128	1.19	1.27	1.43
199504	133	1.18	1.27	1.43
199604	139	1.14	1.21	1.35
199704	139	1.11	1.19	1.27
199804	146	1.07	1.13	1.19
199904	149	1.09	1.14	1.22
200004	147	1.08	1.12	1.19
200104	146	1.09	1.13	1.20
200204	138	1.11	1.15	1.22

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Table 4. Price Determination I. (Dependent Variable is the Official Price to Wholesale Price Ratio)

	All Period (with a constant term)			All Period (without a constant term)		
	Coefficient		Std Error	Coefficient		Std Error
1. Constant	1.607	***	0.105			
2. OLD_PRODUCT	0.011		0.008	0.011		0.008
3. GE_COMPETITION	−0.048	***	0.011	−0.048	***	0.011
4. HIGH_STENGTH	0.062	***	0.009	0.062	***	0.009
5. MEDIUM_PACKAGE	0.029	***	0.011	0.029	***	0.011
6. LARGE_PACKAGE	0.183	***	0.010	0.183	***	0.010
7. INJECTION	0.042	***	0.013	0.042	***	0.013
8. CAPSULE & TABLET	0.007		0.010	0.007		0.010
9. COPROMOTION	0.104	***	0.008	0.104	***	0.008
10. HIGH_PRICED_PRODUCT	0.089	***	0.009	0.089	***	0.009
11. YR_1990				1.607	***	0.105
12. YR_1991	−0.259	**	0.105	1.348	***	0.018
13. YR_1992	−0.115	***	0.025	1.492	***	0.102
14. YR_1993	−0.363	***	0.105	1.244	***	0.017
15. YR_1994	−0.163	***	0.025	1.444	***	0.103
16. YR_1995	−0.434	***	0.105	1.173	***	0.017
17. YR_1996	−0.595	***	0.142	1.012	***	0.096
18. YR_1997	−0.621	***	0.141	0.986	***	0.095
19. YR_1998	−0.687	***	0.142	0.920	***	0.096
20 YR_1999	−0.566	***	0.105	1.041	***	0.016
21. YR 2000	−0.574	***	0.107	1.033	***	0.025
22. YR 2001	−0.565	***	0.105	1.042	***	0.016
23. YR 2002	−0.543	***	0.111	1.064	***	0.040
24. FP REVISION D	−0.277	***	0.103	−0.277	***	0.103
25. FP REVISION D[1]	−0.266	***	0.103	−0.266	***	0.103
26. FP REVISION D[2]	−0.275	***	0.103	−0.275	***	0.103
27. FP REVISION D[3]	−0.272	***	0.103	−0.272	***	0.103
28. SP REVISION D	0.096		0.096	0.096		0.096
29. SP REVISION D[1]	0.102		0.096	0.102		0.096
30. SP REVISION D[2]	0.102		0.096	0.102		0.096
31. SP REVISION D[3]	0.108		0.096	0.108		0.096
32. TP REVISION D	−0.012		0.031	−0.012		0.031
33. TP REVISION D[1]	−0.007		0.031	−0.007		0.031
34. TP REVISION D[2]	−0.003		0.031	−0.003		0.031
35. TP REVISION D[3]						
Observation	6.152			6.152		
R-squared	0.227			NA		
R-bar Squared	0.223			NA		
D.W.Ratio	0.136			0.136		

Notes: Estimation by OLS with dummy variables.

D.W. ratio indicates sutocorrelation due to omitting explanatory variables.

*** significant at 1 percent level

** significant at 5 percent level.

FP is first period, SP is second period, TP is third preiod.

REVISION is REV.

Table 5. Price Determination II. (Dependent Variable is the Official to Wholesale Price Ratio)

	First Period 1990–1994			Second Period 1995–1998			Third Period 1999–2002		
	Coefficients		Std.Error	Coefficients		Std.Error	Coefficients		Std.Error
1. Constant									
2. OLD_PRODUCT	0.090	***	0.016	−0.009		0.012	−0.041	***	0.012
3. GE_COMPETITION	−0.037	*	0.022	−0.064	***	0.017	−0.035	**	0.017
4. HIGH_STRENGTH	0.086	***	0.018	0.052	***	0.013	0.045	***	0.013
5. MEDIUM_PACKAGE	0.040	*	0.023	0.025		0.016	0.032	**	0.016
6. LARGE_PACKAGE	0.258	***	0.022	0.172	***	0.016	0.123	***	0.016
7. INJECTION	0.026		0.030	0.073	***	0.020	0.042	**	0.020
8. CAPSULE & TABLET	−0.062	***	0.021	0.031	**	0.015	0.061	***	0.015
9. COPROMOTION	0.159	***	0.017	0.099	***	0.012	0.062	***	0.012
10. HIGH_PRICED_PRODUCT	0.068	***	0.019	0.079	***	0.014	0.124	***	0.016
11. YR_1990	1.635	***	0.127						
12. YR_1991	1.305	***	0.031						
13. YR_1992	1.519	***	0.123						
14. YR_1993	1.206	***	0.030						
15. YR_1994	1.475	***	0.125						
16. YR_1995				1.177	***	0.021			
17. YR_1996				1.011	***	0.088			
18. YR_1997				0.986	***	0.087			
19. YR_1998				0.918	***	0.088			
20 YR_1999							1.054	***	0.019
21. YR_2000							1.049	***	0.025
22. YR_2001							1.061	***	0.019
23. YR_2002							1.086	***	0.037
24. FP_REVISION_D	−0.346	***	0.123						
25. FP_REVISION_D[1]	−0.335	***	0.123						
26. FP_REVISION_D[2]	−0.343	***	0.122						
27. FP_REVISION_D[3]	−0.340	***	0.122						
28. SP_REVISION_D				0.100		0.088			
29. SP_REVISION_D[1]				0.106		0.088			
30. SP_REVISION_D[2]				0.106		0.088			
31. SP_REVISION_D[3]				0.112		0.088			
32. TP_REVISION_D							−0.015		0.026
33. TP_REVISION_D[1]							−0.009		0.026
34. TP_REVISION_D[2]							−0.003		0.026
35. TP_REVISION_D[3]									
Observation	2028			2231			1893		
R−squared	NA			NA			NA		
D.W.Ratio	0.143			0.107			0.404		

Notes: Estimation is OLS with dummy variables.
D.W. ratio indicates sutocorrelation due to omitting explanatory variables.
*** significant at 1 percent level
** significant at 5 percent level
FP is first period, SP is second period, TP is third preiod.
REVISION is REV.

Table6. Estimation for Demand I.

Variable Name	All Sample Coeff		Std Error	Capsule & Tablet Coeff		Std Error	Injection Coeff		Std Error
1. Change in Price Ratio	0.410	***	0.107	3.557	***	0.211	−0.346	**	0.149
2. OLD_PRODUCT	0.005		0.011	0.001		0.013	0.007	***	0.023
3. HIGH_STENGTH	−0.024	*	0.012	−0.015		0.015	−0.061	*	0.023
4. MEDIUM_PACKAGE	−0.029	**	0.014	−0.006		0.015	−0.064	*	0.072
5. LARGE_PACKAGE	−0.041	***	0.014	−0.020		0.013	−0.078		0.072
6. GE_COMPETITON	0.033	**	0.015	0.036	*	0.019	0.069	*	0.031
7. COPROMOTION	0.002		0.011	−0.004		0.013	0.000	***	0.025
8. HIGH_PRICED_PRODUCT	−0.010		0.011	−0.034	***	0.012	−0.015	**	0.071
9. QUARTER1	0.003		0.019	−0.086	***	0.019	0.162	*	0.080
10. QUARTER2	−0.016		0.020	−0.044	**	0.021	0.047	*	0.082
11. QUARTER3	0.355	***	0.020	0.362	***	0.021	0.222	***	0.082
12. QUARTER4	−0.259	***	0.035	−0.220	***	0.036	−0.265	**	0.102
13. Q_199007	−0.091	**	0.044	−0.104	**	0.046	−0.069	*	0.087
14. Q_199010	0.097	**	0.043	0.181	***	0.044	0.108		0.086
15. Q_199101	0.116	**	0.051	0.111	**	0.052	0.072	*	0.107
16. Q_199201	0.163	***	0.049	0.128	**	0.052	0.133		0.107
17. Q_199204	0.034		0.041	0.362	***	0.047	0.028	**	0.086
18. Q_199207	0.066	*	0.039	0.101	**	0.041	−0.006	***	0.083
19. Q_199210	0.112	***	0.039	0.035		0.041	0.295		0.081
20. Q_199301	0.178	***	0.048	0.194	***	0.050	0.093	*	0.102
21. Q_199401	0.145	***	0.048	0.104	**	0.050	0.138		0.102
22. Q_199404	0.162	***	0.038	0.261	***	0.040	0.266		0.079
23. Q_199407	−0.014		0.038	−0.016		0.039	−0.035	*	0.080
24. Q_199410	0.011		0.037	0.015		0.039	0.060	*	0.080
25. Q_199501	0.315	***	0.047	0.351	***	0.049	0.286		0.101
26. Q_199601	0.088	*	0.047	0.026		0.049	0.113		0.100
27. Q_199604	0.278	***	0.036	0.488	***	0.040	0.168		0.075
28. Q_199607	−0.043		0.036	−0.011		0.038	−0.106		0.076
29. Q_199610	0.035		0.036	0.012		0.038	0.088		0.076
30. Q_199701	0.152	***	0.046	0.129	***	0.049	0.186		0.098
31. Q_199704	−0.009		0.036	0.131	***	0.039	−0.081		0.075
32. Q_199707	−0.044		0.036	−0.042		0.038	−0.037		0.076
33. Q_199710	−0.002		0.036	−0.044		0.038	−0.012		0.076
34. Q_199801	0.206	***	0.045	0.193	***	0.047	0.146		0.098
35. Q_199804	0.133	***	0.035	0.277	***	0.038	0.133		0.076
36. Q_199807	0.045		0.035	0.035		0.037	0.090	*	0.076
37. Q_199810	0.019		0.035	0.020		0.037	−0.021	**	0.076
38. Q_199901	0.271	***	0.045	0.277	***	0.047	0.308		0.098
39. Q_200001	0.108	**	0.045	0.072		0.047	0.115		0.098
40. Q_200004	0.381	***	0.035	0.396	***	0.037	0.482		0.075
41. Q_200007	−0.029		0.035	−0.028		0.037	−0.094	*	0.077
42. Q_200010	0.062	*	0.035	0.062	*	0.037	−0.001	***	0.077
43. Q_200101	0.036		0.045	0.010		0.048	0.068	*	0.099
Observations	6272			2968			2140		
Durbin-Watson Statistic	2.330			2.380			2.270		

Note: *** 1% significance
** 5 % significance
* 10% significance
FP is first period, SP is second period, TP is third preiod.
REVISION is REV.

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<u>Table 7. Estimation for Demand II.</u>

Variable	All Sample Coeff		Std Error	Capsule & Tablet Coeff		Std Error	Injection Coeff		Std Error
1. Change in Price Ratio	0.385	***	0.108	3.380	***	0.213	−0.360	**	0.149
2. OLD_PRODUCT	0.004		0.011	0.001		0.013	0.007		0.024
3. HIGH_STENGTH	−0.021		0.012	−0.009		0.015	−0.058	**	0.023
4. MEDIUM_PACKAGE	−0.026	*	0.014	−0.006		0.015	−0.059		0.073
5. LARGE_PACKAGE	−0.037	***	0.014	−0.018		0.014	−0.076		0.073
6. GE_COMPETITON	0.028	*	0.016	0.034	*	0.019	0.057	*	0.032
7. COPROMOTION	0.005		0.011	−0.001		0.013	0.004		0.025
8. HIGH_PRICED_PRODUCT	−0.008		0.012	−0.027	**	0.012	−0.013		0.072
9. QUARTER1	−0.363	***	0.061	−0.451	***	0.064	−0.352	**	0.150
10. QUARTER2	−0.358	***	0.061	−0.384	***	0.065	−0.462	***	0.150
11. QUARTER3	0.011		0.061	0.017		0.065	−0.285	*	0.150
12. QUARTER4	−0.503	***	0.057	−0.496	***	0.061	−0.673	***	0.143
13. YR_1990	1.197	***	0.232	1.253	***	0.210	1.079	**	0.502
14. YR_1991	0.382	***	0.060	0.372	***	0.064	0.562	***	0.131
15. YR_1992	1.230	***	0.230	1.255	***	0.207	1.147	**	0.500
16. YR_1993	0.336	***	0.060	0.313	***	0.063	0.541	***	0.130
17. YR_1994	1.256	***	0.230	1.251	***	0.208	1.185	**	0.497
18. YR_1995	0.305	***	0.060	0.305	***	0.063	0.445	***	0.130
19. YR_1996	1.277	***	0.279	0.817	***	0.288	0.630	***	0.131
20. YR_1997	1.206	***	0.278	0.720	**	0.287	0.548	***	0.131
21. YR_1998	1.289	***	0.279	0.816	***	0.288	0.669	***	0.131
22. YR_1999	0.332	***	0.059	0.331	***	0.063	0.485	***	0.130
23. YR_2000	0.277	***	0.046	0.283	***	0.049	0.474	***	0.099
24. YR_2001	0.345	***	0.060	0.357	***	0.063	0.501	***	0.130
25. FP_REVISION_D	−0.780	***	0.225	−0.594	***	0.203	−0.500		0.487
26. FP_REVISION_D{1}	−0.883	***	0.225	−0.881	***	0.202	−0.681		0.487
27. FP_REVISION_D{2}	−0.823	***	0.225	−0.848	***	0.202	−0.485		0.487
28. FP_REVISION_D{3}	−0.787	***	0.224	−0.763	***	0.200	−0.584		0.485
29. SP_REVISION_D	−0.764	***	0.274	−0.136		0.282	−0.029		0.073
30. SP_REVISION_D{1}	−0.932	***	0.274	−0.455		0.282	−0.127	*	0.073
31. SP_REVISION_D{2}	−0.900	***	0.274	−0.449		0.282	−0.093		0.073
32. SP_REVISION_D{3}	−0.814	***	0.274	−0.315		0.281	0.000	***	0.000
33. TP_REVISION_D	0.466	***	0.050	0.470	***	0.053	0.520	***	0.109
34. TP_REVISION_D{1}	0.034		0.050	0.025		0.053	−0.061		0.109
35. TP_REVISION_D{2}	0.126	**	0.050	0.120	**	0.053	0.029		0.109
Observations	6136			2905			2093		
Durbin=Watson Ratio	2.345			2.397			2.291		

Note: *** 1% significance
** 5 % significance
* 10% significance
FP is first period, SP is second period, TP is third preiod.
REVISION is REV.

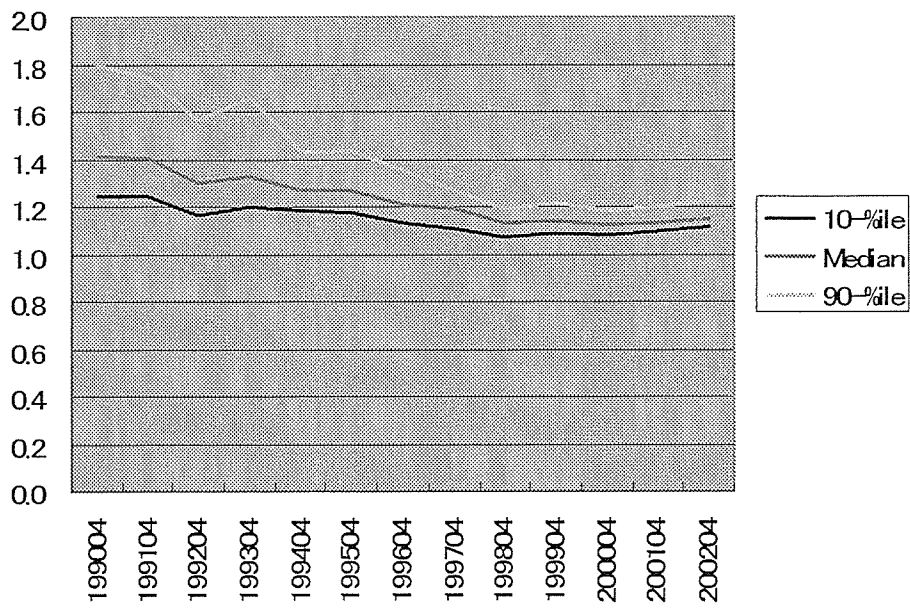Figure 1.Price Ratio
Official Price to Wholesale Price

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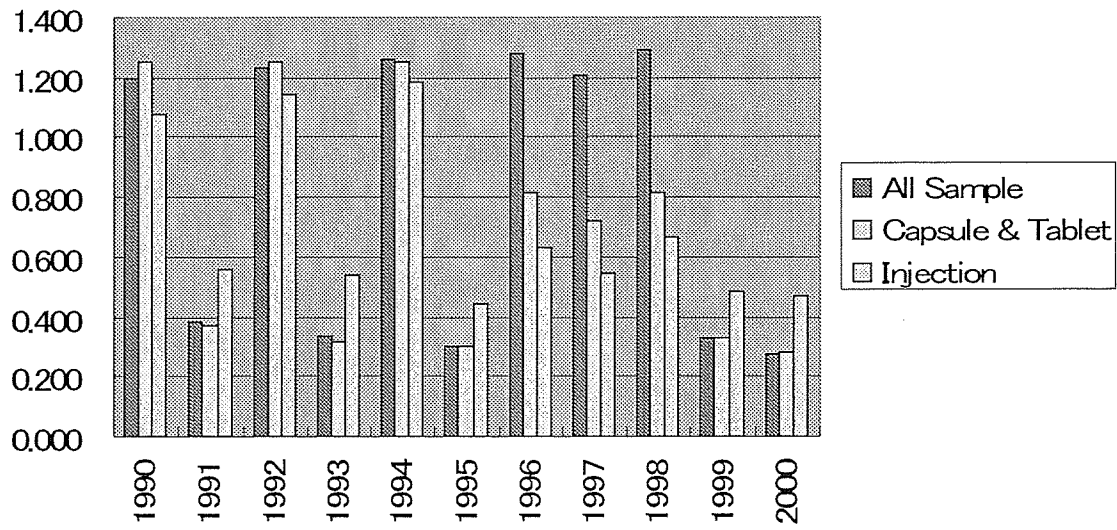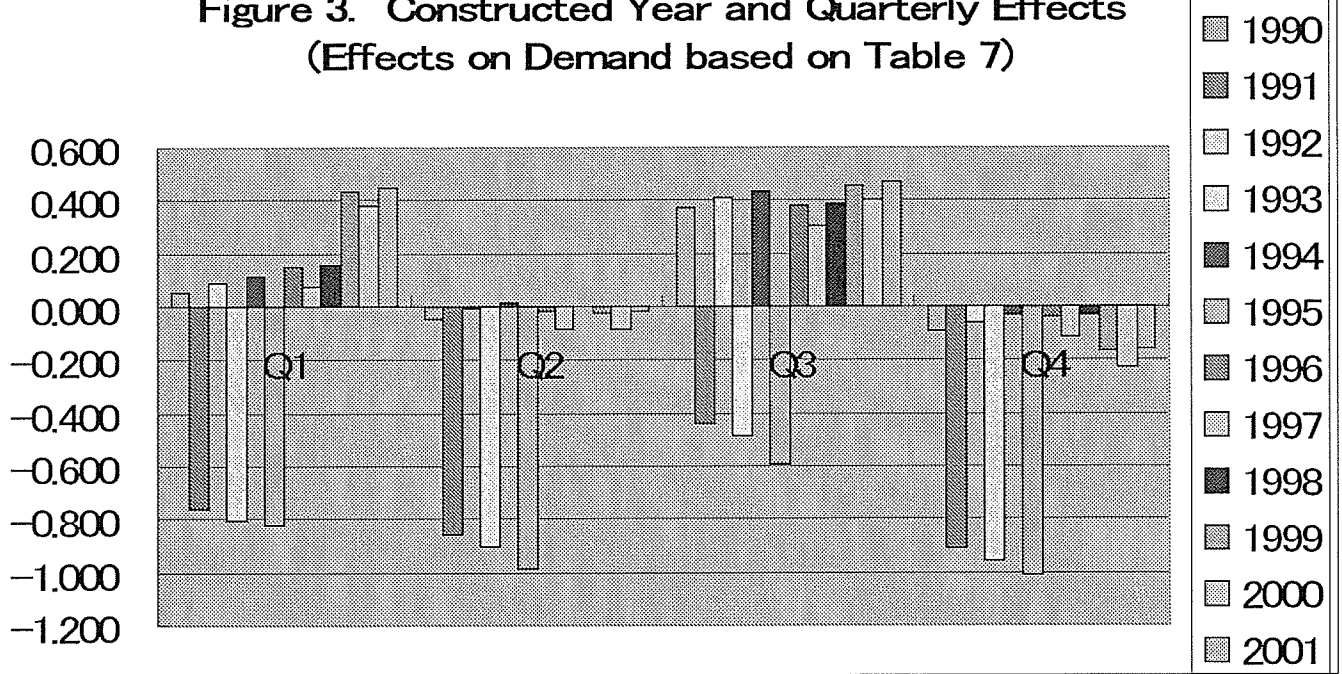Figure 2. Coefficients of Year Dummy Variables, (Effects on Demand, Table 6)

Figure 3. Constructed Year and Quarterly Effects (Effects on Demand based on Table 7)

II. 研究成果の刊行に関する一覧表

現在刊行準備中である。

書籍

著者氏名	論文タイトル名	書籍全体の編集者名	書 籍 名	出版社名	出版地	出版年	ページ

雑誌

発表者氏名	論文タイトル名	発表誌名	巻号	ページ	出版年

II. 研究成果の刊行物・別刷

現在刊行準備中である。

なお，平成 17 年度の研究成果を修正したものを平成 18 年度に刊行した。

姉川知史「第 6 章，日本の医薬品産業」吉森賢『世界の医薬品産業』東京大学出版会，平成 19 年.pp.221-282.

6章 日本の医薬品産業

姉川知史

序

　過去60年間の日本医薬品産業には成功と失敗の2つの側面がある．その成功は次のとおりである．日本の医薬品産業は公共政策の保護育成のもと，積極的な外国技術導入，旺盛な設備投資，飛躍的な医薬品需要の伸びによって世界に例のない高度成長を遂げた．その医薬品生産額は1965年以来アメリカ合衆国に次いで世界2位の規模を維持している．日本の医薬品産業はアメリカ合衆国を除く他のどの国よりも多数の医薬品を開発し，その一部は多数の外国市場において販売される国際的医薬品として世界の医療に貢献した．医薬品産業は他産業と比較して高い利益率を実現し，高所得の雇用を供給してきた．患者は医療保険制度によって多様な医薬品を安価に利用することができた．

　他方，その失敗は次のとおりである．第2次世界大戦直後，日本の医薬品技術は欧米にはるかに遅れていたため，日本の医薬品企業は欧米で承認された医薬品の技術導入を行い，製造技術の向上を重視した．日本の医薬品企業が研究開発志向型に転換するのは1980年代まで遅れた．また，医薬品の副作用等による深刻な薬害も発生した．1980年代に入っても医療機関・薬局に納入する納入価格低下競争が激しく，薬価と納入価格の間に大きな薬価差が存在した．そのため薬価差の大きな医薬品の処方が量的に拡大し，医薬品の適切な使用が歪められた．医薬品企業は薬価差の大きな医薬品開発を目指し，既存の医薬品と類似した医薬品が多数開発された．その結果，日本の医薬品産業による画期的医薬品の開発は少なく，そのような医薬品を国際的に販売する医薬品企業も限定された．

　これらの成功と失敗は日本の医薬品産業の現在を形成している．1990年代以降，世界全体では急速に市場規模が拡大するなかで，日本市場の規模は薬価低下政策によって停滞し，その世界市場における占有率は急速に低下している．そのような状況で，ゲノム科学やIT，分析機器等，医薬品の技術革新が急速に進んでいる．また，医薬品の研究開発，製造，販売，流通の機能が分化し，それぞれにおいて専門の供給主体が成立し，社会分業が進展し，従来の医薬品企業の概念が変化している．また，公共政策の転換によって，医薬品は国内のみならず，国際的に販売されるようになり，寡占企業による国際競争が激化している．日本の医薬品企業はこのような医薬品産業の基本条件の変化について対応を迫られているが，少数の規模の大きな例外的企業を除いて対応能力を失っている．

　本章では日本の医薬品産業を展望する．そこでは歴史，公共政策，企業の関係に注目して，次の問題に答える．第一は，日本の医薬品産業がどのように成長してきたかである．第二は，公共政策が医薬品産業にどのような影響を与えたかということである．第三は，日本の医薬品産業の国際的な特徴とその競争力を評価することである．第四は，医薬品企業と政府とが現在直面する課題を示し，その解決方法について検討することである．

1　研究方法と定義

　本章は医薬品産業を対象とした「産業分析（industry analysis）」を行う．ここで産業分析とは，特定産業を対象にして，その歴史，公共政策，技術，市場，企業等について文章と統計データによる包括的記述を行い，その産業の現状，課題，将来展望を明らかにするものと定義する．

　また，医薬品を「生物由来，医薬化合物等で，人間の病気を治療し，症状を軽減し，予防し，診断する物質」とする．この医薬品を消費者である患者に供給する供給過程を「研究開発」，「製造」，「販売」「流通」として区別する．このうち研究開発は基礎研究，応用研究，開発研究が含まれる．ここで基礎研究は医薬品となるべき薬効のある物質を「探索（explore）」，「発見（discover）」する過程と定義する．これには疾患をもたらす「遺伝子の探索」，その遺伝子

に作用する「分子の特定」, 医薬品となるべき「物質の発見」, その「物質の最適化」, 物質の「薬効の評価」等含まれる. 次に応用研究とは医薬品となる物質の「体内吸収, 排泄, 代謝」, さらに各種の毒性試験を含む「安全性試験」, 「製法の研究」, 「品質管理」等を含む. 開発試験はヒトを対象とした「臨床試験」あるいは「治験」と呼ばれる研究であり, 医薬品の薬効と安全性を確認する. また, 「市販後調査研究」もこれに含まれる. 製造は販売目的の医薬品の大量生産である. 医薬品の販売・流通は医薬品企業による卸企業に対する販売と, 卸企業による医療機関・薬局に対する卸取引, 医師による処方, 薬剤師による調剤, 医療保険による医薬品給付によって構成される. 医薬品企業の販売・流通にはマーケティング・販売, MR 活動が含まれる. MR 活動とは MR (Medical Representative, 医薬品情報担当者) による医師に対する医薬品情報提供を指す. 消費は患者による医薬品の摂取である.

　医薬品の研究開発, 製造, 販売, 流通には多様な主体が関与する. 研究開発については大学, 研究機関, 医療機関, 開発業務受託機関 (CRO : Contract Research Organization), 治験支援機関 (SMO : Site Management Organization), 特定技術の研究を行うバイオテクノロジー企業その他のベンチャー企業等がある. 製造については製造受託企業 (CMO : Contract Manufacturing Organization) がある. マーケティング・販売・MR 活動については販売受託企業 (CSO : Contract Sales Organization) が関係する. さらに流通には卸企業, 薬局, 医療機関等がかかわる. 医師は医薬品を処方し, 薬剤師は調剤を行う. さらに医療保険制度は医薬品供給の対価を負担することで医薬品供給に関与する (付属資料1). ここで本章の対象とする医薬品企業とは医薬品の研究開発, 製造, 販売を統合して行う企業を想定し, その集まりを医薬品産業とする. 医薬品の研究開発の一部のみを担うバイオテクノロジー等の企業は本章では医薬品企業としては扱わない. さらに本章では日本の医薬品企業を国内企業と外国企業とに区別する. 前者は日本で設立され, 成長してきた医薬品企業であり, 後者は外国で設立され, 本社機能が外国にあるものを指す.

　日本の医薬品取引ではその取引段階に応じて3種類の価格が区別される. 第一は, 医薬品企業が卸企業に対して医薬品を供給するときの価格で, ここでは「医薬品企業販売価格」と呼ぶ. 第二は, 卸企業が医療機関・薬局に医薬品を