An Empirical Study on the Impact of drug licensing on sales

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Abstract: To study the impact of drug licensing on its sales, and to provide a reference for drug development and corporation between pharma. METHODS: Based on the variables “license station”, “co-development or co-marketing”, “licensor in accord with key marketing company or not” and “time for drug licensing” which reflected drug licensing and sales, with SPSS statistical software, T-test and Q-test of drug licensing and the sales of drugs were carried out on the 151 sample drugs collected in IMS Health. RESULTS & CONCLUSIONS: Drugs with licensing activities have higher sales than those without licensing. There is no significant difference between co-development and co-marketing for the drugs, Licensor hold the key marketing right helps improve sales of drugs. The optimum time for drug licensing is phase III.

1. Purpose of research

Drug licensing is a common way used by pharmaceutical enterprises, including the transfer of molecular entities, technology, patent development transference, production and marketing rights [1]. Facing the dilemma of innovation and marketing, an increasing number of pharmaceutical companies try to reduce risks and gain more profits through the method of co-development and co-marketing. Over the recent decade, frequent licensing activities between chemical pharmaceutical manufacturers, biotechnology companies, contract research organizations and commercial companies have formed the concept of big pharma [2]. In this system, co-development can enhance development benefits by utilizing the innovation advantages of all parties [3]. Enterprises with co-marketing expand the sales force through the complementarity of product lines and the sharing of channel resources [4]. This paper aims to study the influence of drug licensing on sales，four problems will be discussed: (1) whether the drug a licensing can affect sales; (2) Which licensing mode is more beneficial for sales to choose co-development or co-marketing; (3) whether the original research enterprise should master the marketing right; (4) the influence of licensing development time on sales.

2. Data and Methods

From the World Review of IMS Health database, this paper selected the top 150 patented drugs and the top 50 biopharmaceuticals in world sales from 2005 to 2009, excluding duplicated drugs and drugs without R&D information. A total of 151 drugs were collected as research samples.

Extract marketing time, authority-holders, transferees, R&D history and sales data from 2005 to 2009 from each drug's R&D profile. According to the information of R&D profiles and the intention of this paper, four variables are selected: “licensing station”, “co-development or co-marketing”, “licensor in accord with key marketing company or not” and “time for licensing”

The average marketing time of sample drugs was 1998. Generally, they had reached the mature stage of sales in 5-10 years, so the samples had become mature between 2005 to 2009. Thus this paper takes the average of these five years' sales as the drug sales target.

Firstly, in order to determine whether there is a significant correlation between variables (the significant level is $P<0.05$), independent-sample T test for the average sales of samples

corresponding to the three indicators of “licensing station”, “co-development or co-marketing”, “licensor in accord with key marketing company or not” is conducted by SPSS22.00.Then, one-way ANOVA is conducted for the average sales corresponding to the classification variable of “licensing time” to determine the significance of the difference between groups, If P<0.05, LSD method is used to compare the average number of samples in pairs, i.e., Q test, to determine whether the impact of different intervention time on sales was significant.

3. Empirical results and analysis

3.1 Whether license station can affect drug sales

Table 1 Group Statistics (Unit: million dollars, same as below)

	License station	N	Mean	Std. Deviation	Std. Error Mean
Sales	yes	122	1903.46	1699.073	153.827
	no	29	1227.10	994.047	184.590

As can be seen from table 1, there were 122 authorized activities in the process of drug development, with an average sales 1.903 billion dollars. There are 29 unlicensed drugs with average sales of 1.23 billion dollars.

Table 2 Independent Samples Test

		Variance consistency test		Equality of means test						
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval Lower	Upper
Sales	homogeneity test	4.270	.041	2.058	149	.041	676.353	328.605	27.026	1325.680
	Heterogeneity test			2.815	72.322	.006	676.353	240.283	197.393	1155.313

Following information can be found from table 2, F value 4.27, significance P=0.041<0.05, and variance heterogeneity. The second row of data was selected as the result of the analysis, t value 2.815, significance P=0.006<0.05, indicating that at the significance level of 0.05, the two groups’ average sales was significantly different, and the sales of drugs with licensing activities have higher sales than those without licensing.

3.2 Influence of co-marketing/co-development on sales

From table 3, we can find that there are 43 drugs had only signed co-marketing agreements, whose average sale is $1.63 billion. And 79 drugs had signed co-development agreements, whose average sale is $2.05 billion.

Table 3 Group Statistics

	Station	N	Mean	Std. Deviation	Std. Error Mean
Sales	o-marketing	43	1630.18	1359.900	207.383
	co-development	79	2052.20	1849.040	208.033

3.3 The licensor in accord with key marketing company or not influent the sales

According to table 4, the F value is 0.758, the significance P=0.386>0.05, the homogeneity of variance. The first row of data was selected to analysis. T value is -1.315, significance P=0.191>0.05, which indicate that there was no significant difference in average sales between the two groups at significance level of 0.05. Drug sales under co-development agreements are slightly higher than those under co-marketing, but the results of two models are not significant.

Table 4 Independent Samples Test

		Variance consistency test		Equality of means test						
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval Lower	Upper
sales	homogeneity test	.758	.386	-1.315	120	.191	-422.023	321.027	-1057.634	213.587
	Heterogeneity test			-1.437	109.404	.154	-422.023	293.744	-1004.190	160.143

Based on table 5, there are 72 drugs that are mainly marketed by the licensor in the sample, with an average sale of $2.22 billion. The situations are different about another 50 drugs, with an average sale of $1.45 billion.

Table 5 Group Statistics

	licensor / key marketing company	N	Mean	Std. Deviation	Std. Error Mean
sales	same	72	2219.28	1971.420	232.334
	different	50	1448.68	1067.565	150.976

3.4 Influence of time for drug licensing on sales

As can be seen from table 6, F value 2.81, significance P=0.096>0.05, homogeneity of variance. The first row of data was selected to analysis, T value 2.517, significance P=0.013<0.05, which indicate the average sales of the two groups of samples was significantly different at the significance level of 0.05. For the original researchers, the sales of drugs with the main marketing right is obviously higher than those without the marketing right.

Table 6 Independent Samples Test

		Variance consistency test		Equality of means test						
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval Lower	Upper
sales	homogeneity test	2.810	.096	2.517	120	.013	770.597	306.103	164.535	1376.659
	Heterogeneity test			2.781	114.134	.006	770.597	277.079	221.712	1319.482

As can be seen from table 7, there are 79 co-development samples, we research five licensing time points: pre-clinical, ClinicalI, ClinicalII, Clinical III, pre-registration. Following numbers are the corresponding sample number and average sales: 29, $ 1.607 billion; 9, $1.53 billion; 16, $1.92 billion; 18, $3.36 billion; 7, $1.504 billion.

Table 7 Descriptive

licensing time	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
					Lower Bound	Upper Bound		
pre-clinical	29	1607.06	943.401	175.185	1248.21	1965.91	448	3785
clinicalI	9	1530.18	824.450	274.817	896.45	2163.91	711	2985
clinicalII	16	1916.06	1208.481	302.120	1272.10	2560.01	294	4215
clinical III	18	3364.48	3142.812	740.768	1801.59	4927.36	744	13338
pre-registration	7	1504.31	904.254	341.776	668.02	2340.61	489	2696
total	79	2052.20	1849.040	208.033	1638.04	2466.36	294	13338

By ANOVA, F value 3.419, P=0.013<0.05 which indicate the mean number of samples between groups is not completely equal at the significance level of 0.05. So we compare the mean number of

samples in pairs by LSD.

Table 8 ANOVA

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	4.159E7	4	1.040E7	3.419	.013
Within Groups	2.251E8	74	3041674.754		
Total	2.667E8	78			

As shown in table 9, the significant degree P between the fourth groups and other groups is always less than 0.05, indicating that at the significant level of 0.05, the differences between the fourth groups and the other groups were significant. The sales licensed in the stage III stage were significantly higher than those of the other stages (see Fig. 1).

Table 9 Multiple Comparisons

		Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
pre-clinical	2	76.881	665.469	.908	-1249.10	1402.86
	3	-308.998	543.130	.571	-1391.21	773.21
	4	-1757.419*	523.323	.001	-2800.16	-714.67
	5	102.744	734.446	.889	-1360.67	1566.16
clinicalI	1	-76.881	665.469	.908	-1402.86	1249.10
	3	-385.878	726.683	.597	-1833.83	1062.07
	4	-1834.300*	712.001	.012	-3252.99	-415.61
	5	25.863	878.913	.977	-1725.41	1777.14
clinicalII	1	308.998	543.130	.571	-773.21	1391.21
	2	385.878	726.683	.597	-1062.07	1833.83
	4	-1448.422*	599.238	.018	-2642.43	-254.41
	5	411.742	790.335	.604	-1163.04	1986.52
clinical III	1	1757.419*	523.323	.001	714.67	2800.16
	2	1834.300*	712.001	.012	415.61	3252.99
	3	1448.422*	599.238	.018	254.41	2642.43
	5	1860.163*	776.857	.019	312.24	3408.08
pre-registration	1	-102.744	734.446	.889	-1566.16	1360.67
	2	-25.863	878.913	.977	-1777.14	1725.41
	3	-411.742	790.335	.604	-1986.52	1163.04
	4	-1860.163*	776.857	.019	-3408.08	-312.24

*. The mean difference is significant at the 0.05 level.

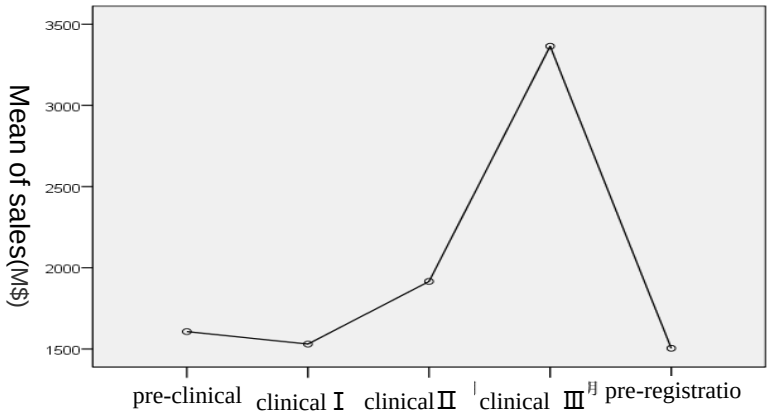

Figure 1 Means Plots

4. Discussion and conclusions

Licensing is a common cooperative activity in the modern pharmaceutical industry, especially in today's emerging environment of biotechnology companies and CROs. Large pharmaceutical groups introduce (License-in) biotechnology companies to cooperate in the development of certain products, and authorize (license-out) compound patents to CRO companies for clinical trials, new dosage forms, new indications development, or grant production rights to generic drug manufacturers, and marketing rights to pharmaceutical Trading companies [2]. This paper discusses the influence of licensing on sales from the perspectives of the authorized person/transferee, R&D/marketing, original researcher/marketer, and licensing time. The following conclusions are drawn:

(1) By authorizing and integrating external resources, the balance of cost, risk and benefit can be achieved, and the sales volume of drugs can be effectively increased. This is in line with the new idea of openly innovation of modern medicine, that is, enterprises use the ideas and knowledge of external innovators to gain innovation in the process of innovation [5]. At the same time, it also accord with the new strategy of modern enterprise market development, that is, enterprises use local enterprises to achieve market share in the process of development.

(2) There is no obvious difference between the two licensing modes of co-development or co-marketing on sales, thus pharmaceutical companies should make decisions to choose the mode according to their actual conditions. Licensing at the development stage can reduce the risk of R&D, as well as improve the performance of drugs in terms of safety/efficacy and quality control. Co-marketing, on the other hand, can rapidly expand marketing channels, improve market penetration and build brand image.

(3) Original researchers need master the main marketing rights. Technology, commerce and law are the three major factors influencing drug sales: high technology content, mature commercial development and the market monopoly right brought by patent protection, which are the key conditions of the big-selling medicines [6]. The original researchers have both core technologies and corresponding patents, if they can also grasp the right to commercial development or play a leading role in co-marketing, it will certainly promote the sales performance of drugs.

(4) Licensing at the stage of clinical III will benefit enterprises more. Most development licensing agreement occurred early, namely between pre-clinical trials and clinical II[2].The reason is most pharmaceutical companies sign agreement in lower prices for higher uncertainty in early time [7]. But in this paper, the results show that the drugs in the clinical III issue authorization eventually achieve maximum output. The reason is that the drug technology at this stage is relatively mature, the uncertainty and risks are reduced, and the best game point can be found in the cooperation between the two sides, which is of more positive significance to promote drug sales.

For the first time, continuous sales data mean is adopted in this paper, corresponding to different licensing variables, and empirical analysis is carried out to verify the influence of licensing on sales. In fact, there are many factors influencing sales, and licensing is only one of them. This paper is not intended to explain the clear causal and quantitative relationship between licensing mode and sales, nor does it expect to predict sales through licensing data. This analysis is based on the single data of IMS Health, and there are some shortcomings :(1) The sample size is relatively small due to the need to take into account both the R&D information and the five-years sales data, and most of them are top-ranking drugs;

The rising R&D cost and the decreasing innovation yield year by year make pharmaceutical development enterprises to adopt new strategies and business models [8]. Enterprises can get a better market performance through technology transfer, market cooperation, and M&A activities. Thus, reasonable licensing is undoubtedly an effective strategy.

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