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APPROPRIATE TECHNOLOGY FOR THE MANUFACTURE OF DRUGS AND PHARMACEUTICALS

THE PHARMACEUTICAL INDUSTRY OF THE REPUBLIC OF KOREA
Background Paper

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THE PHARMACEUTICAL INDUSTRY OF THE REPUBLIC OF KOREA

by

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PREFACE

This study has been organized in seven chapters to cover the topics which seem essential for examining the Korean historical experiences in an effort to determine what factors aided and/or hindered the pharmaceutical industrial development.

To delineate the pattern of the development illustrated with case-experiences, and to retrospect what was an appropriate technology under the ever changing market environment of the past Korea, the history had to be analyzed and arranged in the chronological order.

The rationale was that the appropriate technology embodied throughout the Korean history could be elucidated only in the whole economic process that extended from factors supplies on the one hand to the marketing outlets on the other, and should be illusrated with the behind-story or highlights of each era implying the interrelatedness not only within the firms but also between firms and even between industries.

Also, the rationale of the inclusion of the topics in the pre-war era lies in their applicability to the main issues of the present day, particularly to the current efforts to decide the appropriate technology such as how to develope the traditional medicines, how to maximize the role of the small-business etc.

It is believed that the matters of consequences which had happened, should not have happened, have been successfully handled or have been making trouble, etc., are included in the pertinent chapter where their significance must be most stressed.

The statistics, data or informations required to understand the past & present status are collected side by side, by the form of the primary and secondary figures in the tables. The tables are distributed in each pertinent chapter, so that many idea may be said only by the table.

It is hoped many suggestive line of thoughts shall be yielded by making perusal on the study how Korea has been experiencing the same issues as are faced by some countries today.

SUMMARY

1. How Korea has been experiencing the same issues as are faced by today's many countries was studied in the chronological order of the Korean Pharmaceutical Developmental history.

2. The pattern of the development, characterized in that two discreet cycles have been repeated during the period of 1900 through 1977, was illustrated with the topics and highlights of each age, and the key factors that aided and/or hindered the development was determined.

3. The appropriateness of the technology attempted, developed, transferred and diffused was evaluated in the light of the ever changing market-environments. And the best policy to invest for the appropriate facility and to select the appropriate product was elucidated with the case stories of success and failure, with the importance of the appropriateness of such.

4. The impact of the transnational corporation was analyzed with the view how Korea could gain from such foreign firms. The matter of technology-transfer and the issue of foreign trademarks were particulary studied to suggest how to make the best of such opportunities by the licensees. Accordingly the market-powers of the foreign brands were analyzed.

5. The impact of the foreign state administrative policy was studied and it was described how wisely drug-manufacturers should face the policy such as G.M.P., drug efficacy reevaluation, etc.

6. The derangement of the market distribution order, the frequent bankruptcy of the small-enterprises, the drug-quality deteriorations, self-destructive competition, etc., such social disorders were described with the view how they were related with the other problem such as the technology development, the interest of the firms, and the interest of the industry. And how they were controlled & stabilized by the cooperation of the industry & the governments, was illustriated.

7. The semi-state run cooperative buying programme which has been well performed since 1965 by the Korean Pharmaceutical Manufacturers Cooperative Association was introduced with the buying principles and with other activity.

8. Most of the important issues inevitably faced by the pharmaceutical society during the developmental process from the import-substitution through import-ban to the raw material production were illustrated. In connection with such, particularly the matter of product-licensing policy & patent was studied how they were interrelated and/or reactive with each other, and how they were helpful for the technology-diffusion, together with how those issues could be solved by the governmental control measures.

9. The developmental aspect of the Korean traditional medicines was studied with the definition, the matter of disregard & the mistakes of methodology, and how to develop them was suggested.

10. The role of the minority group was emphasized as a driving force or a crystal seed for the technological development as well as for the transfer & diffusion of the technology.

And it was suggested that a few elite groups should be encouraged to try everything, regardless of the nominally classified technological level of their country, by the few qualified entrepreneurs, who was trained with specially well-organized package-programme.

11. What could be best performed for the pharmaceutical development during the time of hopeless adversity like wartime was exemplified.

12. The far sighted educational policy, the building-up of the good environment for the information-diffusion, the government's public information service, the full understanding by the enterpreneurs of the government's economic plan, the formation, maintenance & upgrading of the competitive environment and the ever reinforced control & inspection system, etc, these were all illustratively emphasized as essential developmental factors through which the pharmaceutical society could create the appropriate environment for the progress of the total system.

And it was accentuated that the more important was the enterpreneur's voluntary action of the good & strong-will sublimated out of the interreaction of those factors.

It seems that appropriateness is the very thing that can be created not by the maximization or the minimization of a certain isolated factor such as price, drug, know-how etc., but by the optimization of all the elements of the environment of each age.

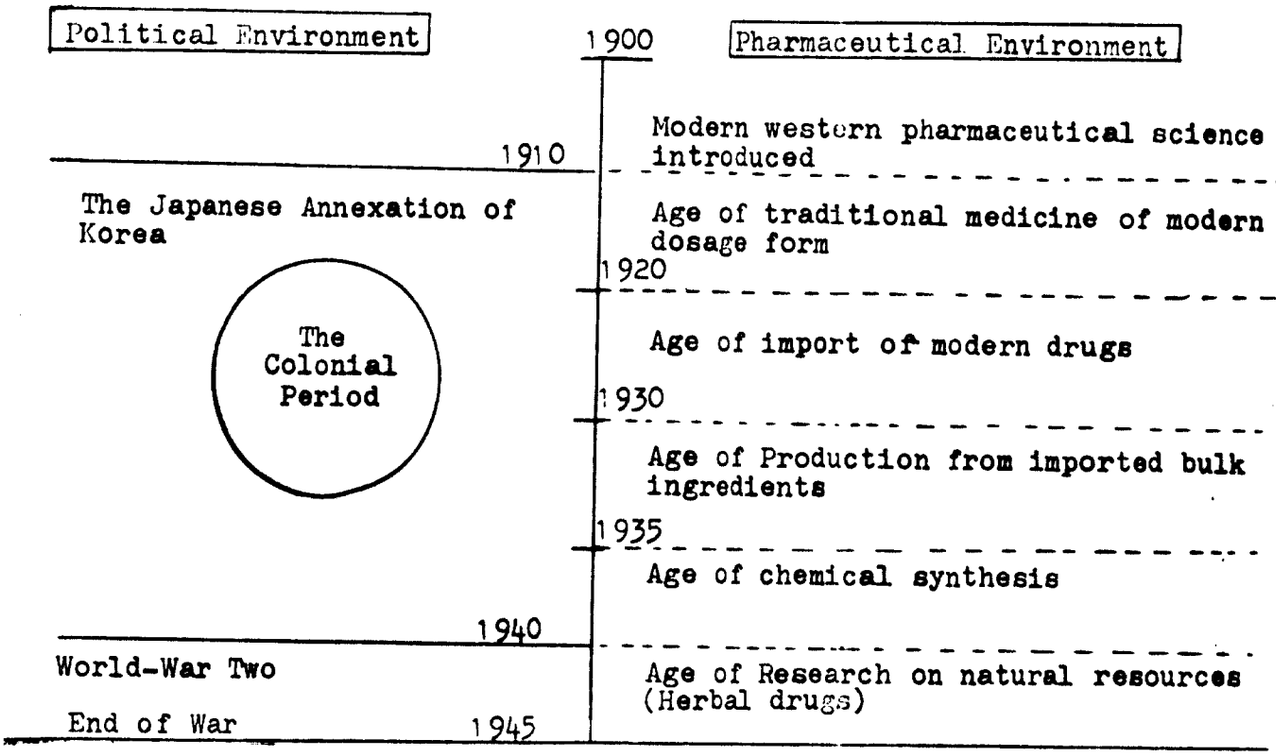
Part One: CHRONOLOGY Chapter 1

The Development Steps of Korean Drug and Pharmaceutical Industry

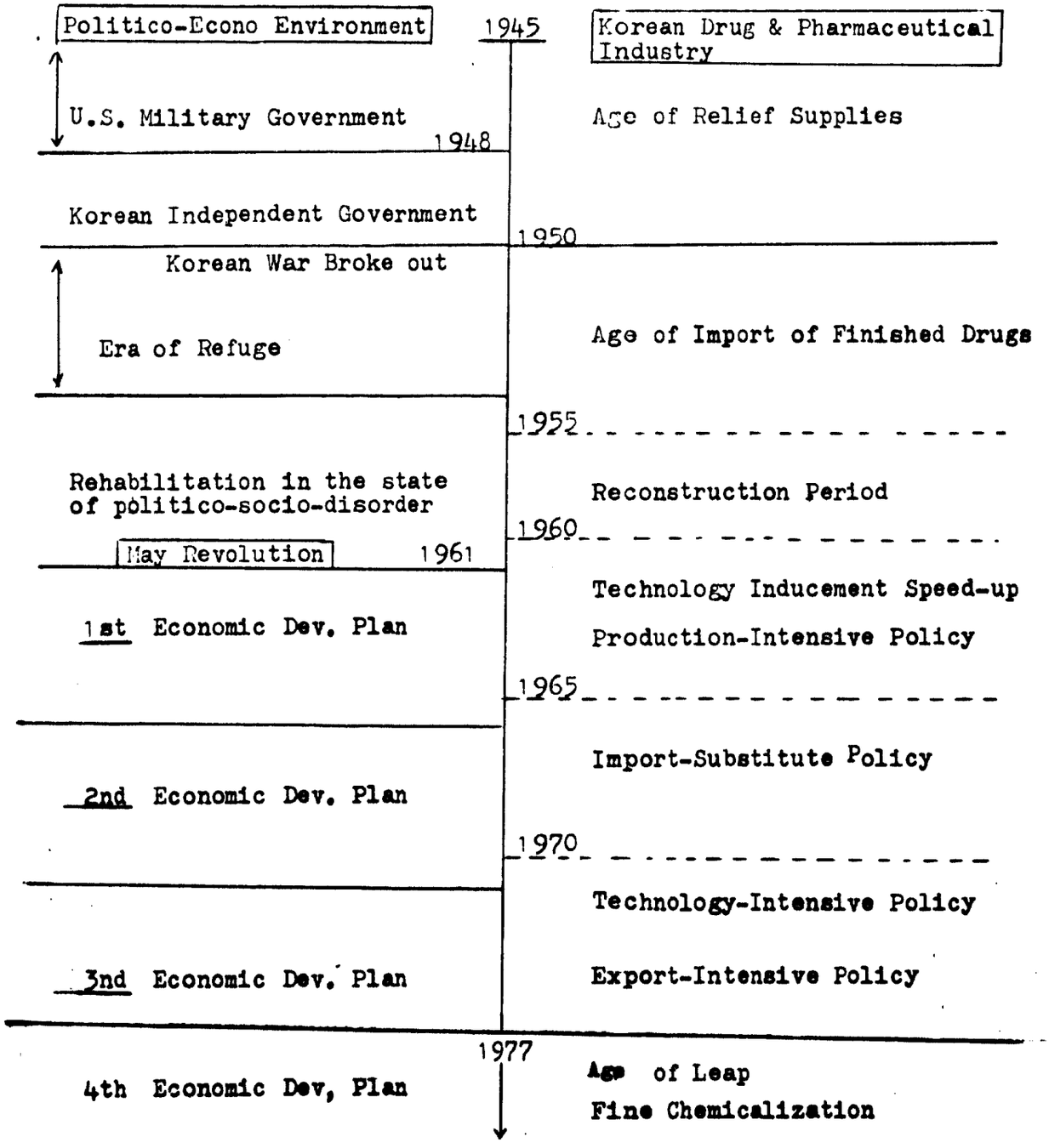
1. Four score of years have passed since modern western pharmaceutical science was introduced to Korea from the beginning of 1900. As many other countries, the history of the past pharmaceutical development of Korea may be divided into two eras, Pre-War and Post-War for the purpose of study.

2. In case of Korea the learning curve that had been marked with accumulative effect throughout the years of Pre-War era was extrapolated to the Post-War developmental steps;
therefor it is worthy making some description on the former.

3. The following diagram shows the chronological contrast of the pharmaceutical development with the political environment during the years 1900 thru 1945;



4. The Korean pharmaceutical development steps of the Post-War era started from 1945 to continue through 1977 in response to the politico-economic environmental challenge as diagrammed below:



5. Two Discreet Cycle

The Korean Drug & Pharmaceutical Industry has been developing for the past eighty years on the waves of the two discreet cycles one for the Pre-War era and other for the Post-War era.'
The former cycle composed of three steps in the consecutive progress -formula like "Import of finished drugs ----→ Dosage fabrication ----→ Bulk drug production", mostly with the official drugs developed during that period. And so did the latter cycle, only with the new drugs discovered after 1945. The existence of such two cycles can be explained in that almost 10years of hibernation continued between those two cycles due to the war and the Post-War situation, where no information flowed in.

6. However, it may seem necessary to make a chronological examination first on the Pre-War cycle and then with the Post-War period in order to determine what factors aided and/or hindered the pharmaceutical technology-transfer and diffusion in Korea.

Part Two: PRE-WAR ERA Chapter 2

The Korean Drug & Pharmaceutical Industrial Development Until 1945 (Pre-War Era)

A. Introductory Stage of The Modern Pharmaceutical Science

7. 1900 - 1920 : Herbal medicines were the only drugs that had been used in the traditional medicines of Korea until 1900. Entering 20 centries, the modern western pharmaceutical science was introduced by Japanese pharmacists, who opened the pharmacies in Korea. And following the Japanese Annexation of Korea in 1910, the modern pharmaceutical law was enacted to be effective until 1945. It was in 1915 that the first school of modern pharmacy was established. The first Korean pharmacist was licensed in 1920 after the state examination.

8. During the years of 1910 through 1920, a number of Korean drug houses appeared and began to produce many drugs in a variety of modern dosage forms such as powder, pills, extract, tincture. These drugs, however, were mostly from the combination type in that the traditionally prescribed herbal medicines were mixed with some of the modern drugs. Of such drugs developed at that time, there are still marketed a considerable number. For example, a liquid herbal drug developed in 1910, having digestive & gastropain relieving action was sold in 1977 by the number of 100 million bottles (50cc) and one year sales of us $8million.

B. The Golden Age of Drug Trade (1920 - 1930)

9. The number of drug houses continued to increase, and particularly the combination drugs of the herbal medicine with modern chemical ingredients were in the height of prosperity with their sales.

10.. On the other hand, most of the Japanese pharmacopeic official drug were imported as finished goods and European firms like Roche, Bayer etc., opened their branches, displaying the promotional activity. The way of such promotion was so interesting that Korean firms positively followed the western style of marketing.

11. Approximately 1,500 kinds of medicines were on the transaction during the period. It was the natural phenomena that the increase in the number of drugs and the appearance of me-too drugs was followed by the bombastic advertisement, the price-competition, the marvelous bonus-sales & discount, and then by the deluge of inferior medicines. Eventually the then Korean pharmaceutical society suffered from the disbelief by the public.

C. Formative Period of Modern Pharmaceutical Manufacturing Industry (1930 - 1935)

12. Entering 1930's pharmaceutical manufacturing firms were formed with the modern facilities, began to operate business in the modern western way and moved toward internationalization with trade, production and marketing.

13. It is much interesting to find that Korean drug houses rather than Japanese obtained the exclusive right of distributorship from many of the U. S. drug companies and deployed the exporting activities throughout the south-east Asia during the Japanese colonial period. A new drug, prontosil was imported in 1935 as first-Asia and one Korean firm established information sources in 20 cities scattered throughout the world to find new drugs.
It is noteworthy that rare drugs such as antimeingococcus, Whooping-Cough vaccine, serum preparation, insulin etc. were imported not for profit but for therapeutic purpose, what is hardly expected today.

14. For the technology-development, German Chemists & Engineers were employed. The Korean pharmaceutical technological level of that time may be said to be between group 2 and Group 3 according to the classification method of UNIDO, since most of official drugs were produced in the dosage forms including I.V. infusion, ampule etc. Particularly the R & D was strong in the area of parenteral preparations.

D. Production of Active ingredients of Drugs (1935 - 1940)

15. Many enterpreneurs who earned much from drug-business started to organize research teams and encouraged them to find synthetic m methods of the new drugs which were thought to be profitable or promising. The usual team financially supported was two or three elites of pharmacist. The R & D facility was nothing .
But their design for research was seemingly reckless and too great, because the attempt was always to start with basic chemicals rather than late intermediate.
In spite of such, SALVARSAN was successfully manufactured from phenol and many new drugs such as merchurochrome, sulfonamides, were produced by their own methods.
And the enterpreneurs were said to be very much happy to see the good return on investment within so short period.

16. The success story was fast communicated and the technology also fast diffused among the concerned personnels. Through such simple phenomenon, Korean pharmaceutical technology could be leveled up by one step further.
It was of prime invaluableness that the other colleagues could be motivated.

E. During the War (1940 - 1945)

17. When the pacific war broke out, all supply sources of raw materials & finished drug were completely blocked. Morever, Korean owned manufacturing firms were consolidated under the war time mobilization decree, without operation.

18. On the other hand, research activities were allowed to continue. So started the quadruple collaboration for research by school of pharmacy, university hospital, herbal medicine research institute and pharmaceutical firms. Under the war-circumstances chemicals were least available. Therefore natural resources were the primary targets for research and in addition the nutritional field, hygiene and pollution problems.
During this adverse time, three hundreds kinds of herbs were studied to identify chemical components, and establish some assay methods.

Chapter 3

Experience & Learning (The Pre-War Era)

A. The Developmental Aspect of Traditional Medicines

19. The Korean traditional medicine handled by the pharmacetical manufacturing firms are the combination-drugs in that a multiple kind of herbs or a single herb is processed with or without modern drug-components in the convenient dosage forms such as tablet, pill, capsule, granule, ointment or liquid etc. The prescription formula of such herbs are originated from the traditionally systemized oriental medicine and limited to those accepted by the authoritative school.

20. The Production value of Korean traditional medicine during the year 1977 amounted to us $45 million, 10% total drug production. And the number of products was 426 items, 8% of total number of Korean drugs.
And surprisingly the top 50 brands includes 7 items of traditional medicines, among which one item had the yearly sales of us $8million.

21. Many of such traditional medicines date back to the time of 1920 when they were firstly developed as today's dosage forms. Such long life-cycle may be a sort of indirect evidence to demonstrate the superiority in the effectiveness and safety of those traditional medicines.
However, from the view point of the modern drug evaluation they are least acceptable drugs because neither clinico-pharmacological data nor quality control methods are available.
Such being the case, the Korean advisory committee who have been implementing the drug reevaluation since 1975, are very much unwilling to take up the existing traditional medicines as scheduled items.

Market Power of Traditional Medicine

(As of 1977, Korea)

	Total Drug (A)	Traditional (B)	B/A %
Number of Producers	272	91	33%
Number of Drug	5,296	426	8%
Production Value	$445,635,000	$44,960,000	10.1%

22. The stalemate of the traditional medicine may be ascribed to the matter of disregard(a) and the mistake of methodology(b).

(a) Matter of disregard;

Since the introduction of modern medicine, the traditional medicine has been graded just as an extra.
Even those manufacturers of traditional medicines wouldn't allocate sufficient time and effort for the scientification of such drugs.
So to calculate, the total time and sofar invested efforts by Korean all concerned for obtaining clinical pharmacological data are nearly negligible.

(b) Mistake of Methodology;

23. In Korea several research Laboratories have been said to study the traditional medicines. But in fact they have been handling not traditional medicines but herbal pharmacognosy.
The most concerned by these researchers has been the phytochemistry and modern pharmacology of any chemical component discovered in the herbal extract. Therefore their target was not toward the combined drug composed of multiple herbal plants but always toward a single herbal plant.

24. With a single plant, they tried to isolate any active component, to ascertain any pharmacological action therefrom and establish production method with assaymethods from the plant.
But such methodology is a big mistaken one from the viewpoint of the development of the traditional medicines.

25. It is simply because the synergistic effectiveness displayed by the multiply combined herbal preparation cannot be expected from the total addition of the information obtained from each individual plant.

And it is simply because most of the effort to single out any active component and to produce it on mussive scale ends without realistic gain.
Many researchers enthusiatic with such unrealistic approach would be likely fascinated at any substance, when it is singled out and shows some similar pharmacologic action, compared with any well-known active ingredient.
It is therefore easily failed to notice that even in such case the chemical synthetic way is still more economic than the extraction process from the plant.

B. How to Develope the Traditional Medicines

26. A product list shall be made seperated from the national total drug information list, and then some of them shall be selected as priority items.
The priority shall be given on the basis of a certain chosen criteria such as; Longer life-cycle (How long it has been increasingly used), consumption scale (How much it has been produced & consumed), raw material indigenousness (How much it is produced with indigenous raw materials), etc.
The criteria shall be set from the pragmatic view.

27. Of the priority products, a few shall be chosen as first target. Relevant protocols shall be made up for these chosen items & entrusted to a certain institute or voluntary team for R & D.

28. The protocol shall be conditioned like the following:

(a) Do not try to identify any active substance.

(b) Do not try to ascertain any pharmacological action of each individual herbal component.

(c) Do not try to set up any assay method for each individual herbal component only.

(d) Do establish physico-chemical constants of the target-item as homogenous liquid or solid in the range of possibly occurence.

(e) Do obtain pharmacological data through animal test with the target-item.

(f) Do obtain clinical data with the target item.

(g) Do obtain clinico-pharmaco comparative data of the target item with any contrast item chosen from the modern drugs.

29. Any new application for manufacturing license of a traditional medicine shall be submitted with the above-mentioned investigational data.

30. An international congress shall be created for periodic exchange of such information.

31. The conventional methodology in that most of the effort hasbeen poured in identification, isolation and mass-production of any active substance from a single herb shall be continuously applied not by the field or traditional medicine but by the field of modern medicinal chemistry or by the name of phytochemisrty.

C. Minority group and Synthetic Technology

32. During the period of 1920 through 1945, the number of Korean pharmacist increased from 2 to 20, and 250 drug houses produced most of the official drugs from bulk and some drugs were totally synthesized from basic chemicals.
It was by very few elite-pharmacists that not only the formulation technology but also the total synthetic production were developed.

33. If it were today, the synthetic production should have been tried with late intermediatee at first, and it would have been stepping backward from later one to basic chemicals.
..nd other preparations should have been manufactured before attempting to make I. V. infusions.
To Korean past experience, it is not always true that the technological development plan of step by step is better way.
Moreover, most of the pharmaceutical technology has been successfully developed by the cooperation of individual enterpreneur and innovator.
Many of the chemical process are small scale of batch type. There are few that go beyond the reach of the individual ingenious chemist.

34. To say that a country is in a statge of Group 1 or Group 2 (UNIDO's Classification), it should mean a general status reached finally after a certain period of developmental process.

35. ...erefore it is very much needed that a few elite group should be encouraged to try everything regardless of the nominally classified technological level of the nation.
If one country is said to belong to Group 1 or Group 2, any technology available from Group 2 to Group 4 may be attempted by the elites at their convenince. But it is the best way to choose the technology on the basis of economic benefit and time required to achieve rather than on the basis of health requirement.
It is sure that such minority group can be discovered among the existing pharmacists of any country.

36. But one thing remains to be solved. It is to find a few qualified enterpreneurs and train them with a package programme.
Such programme shall include total management information and operating methods for running a standard drug manufacturing firm.
To organize and systemize this programme seems not so difficult.

Part Three: POST-WAR ERA Chapter 4

Korean Drug & Pharmaceutical Industrial Development (Post-War Era)

A. Age of Aid (1945 - 1950)

37. From the end of the World War Two until 1948 the independent year of Korean Government, Korea was controlled under the U.S. military administration. But since then, Korean pharmaceutical industry continued to undergo various influences of the United States of America.

38. During the period some figure shows increase as follow;

Number of	1945		1950
Pharmacists	122	⟶	1,000
Manufacturer	255	⟶	362
Product	2,263	⟶	4,057

But the pharmaceutical industry was stand-still without significant activities.

39. The reason of such inactivities:

(a) No procurement of drug due to lack of foreign capital

(b) Immense volume of medical AID supplied for free distribution

(c) Overwhelmed and discouraged by so many new drugs such as Penicillins, Streptomycin, PAS etc.

41. The finished drugs supplied as U.S. AID were distributed as free, but were not able to meet the public demand, however much they were provided, for satisfaction with medical care does not lie in drug itself. What's worse, at that time the health delivery system was not well-organized, and necessary statistics were not available. On the other hand the AID suppressed the desire of the enterpreneurs to restart the manufacturing business.'

42. But in 1949, bulk medicine of us $300,000 was imported from U.S. The production value of that year was US$2 million; Official drugs 14%, parenteral 20% and others including traditional medicines 66%.
And in 1950 Korean war broke out, while the pharmaceutical industry was groping in the dark.

B. Challenge & Response (1950 - 1954)

42. The sudden outbreak of the Korean war in 1950 delivered a crushing blow on the industry, which was attempting to grow. Almost 80% of the drug-Houses were destroyed. Most of the people led refugee life at a port city called Pusan, only one unconquered area (0.3% of total territory).

43. During the period of such adversity there happened many remarkable affairs:

(a) The number of college of pharmacy established;

	College of Pharmacy	
until 1952	1	11
1953	6	
1954	4	
1956	2	
1965	1	
	14	

(To produce 1,000 pharmacists per year)

(b) The activity of pharmaceutical manufacturers were like:

	1950	1954
Number of Makers	362	411
Import of finished drug	$720,000	$3,740,000
Production	$9,300,000	$56,500,000

14%	——	Official drug ———	10%
20%	——	Parenteral ———	30%
66%	——	Others ———	20%
		Antibiotics ———	40%

(c) The law of Korean pharmaceutical affairs was enacted in 1953

44. Adbersity, A Training for Development

The fact that so many colleges of pharmacy appeared at the time of hopeless adversity, was a kind of good response to challenge. In 1960's it was critisized that such many colleges caused cut-throat competition, but in 1970's pharmaceutical industry is faced with the difficulty in recruiting necessary number of pharmacists due to the industrial expansion. And it is said that todays pharmaceutical industry is owing to the establishment of so many colleges.

45. During the time of refuge all pharmaceutical personnel, enterpreneurs, officicals, researchers, professors would frequently come together to discuss the matter of interest, exchange the information of the new drugs and seek advice how they could start pharmaceutical manufacturing firms if the war ended.
Particularly the enterpreneurs were busy in absorbing knowledge about antibiotics, to start the business with it when permitted, since it was antibiotics that made them most surprised at that time.

46. It was noteworthy that some pharmacists submitted to the government in refuge the application for manufacturing antibiotics in 1953. But the application was rejected because the government herself was planning to establish state-run antibiotics manufacturing factory. And when it was confirmed that the governmental plan to build the plant could not be materialized due to the rejection by the congress, the first manufacturing license of antibiotics was authorized to a private enterpreneur in 1954.

47. Today's commentators agree that it was a fortunate thing that the state-run antibiotic manufacturing corporation could not be formed and that today's antibiotic technology of Korea should have never been achieved if it had been formed.

C. Age of Reconstruction (1955 - 1960)

48. Following the Korean War (1950 - 1953) the rehabilitation of Korean economy was actively started largely with the aid of the International Cooperation Administration (ICA) and the United Nations Korean Reconstruction Agency (UNKRA).

49. This external aid was like a life-line for pharmaceutical industry, to which most of today's large pharmaceutical firms are owing, and by which most of the then enterpreneurs were spurred to start again.

50. At that time when allocating the fund, the Korean Pharmaceutical Manufacturers Association (KPMA) took an important role by advising good policy to the authority, by recommending proper beneficiary and by requesting the raise of fund. The ICA fund was mostly to appropriate for facility-construction, and approximately 30% of the fund was allocated to the antibiotic area as the ratio of 30 to 70, which had been requested through KPMA by manufacturers.

5. To look into the allocation;

	$470,000	in 1955
	$263,000	in 1956
	$420,000	in 1957
	$ 50,000	in 1958
Sum	$1,203,000	For equipments & Facilities
	$ 330,000	For bulk import
	$ 670,000	For finished drug import
Grand Sum	$2,203,000	From ICA Fund

And local fund corresponding to a tenth of the allocated ICA.

52. The manufacturers started production immediately after proper facilities were provided, and realized a rapid growth as shown below:

	1955	1960
Number of Maker	296	427
Number of Product	4,700	6,575
Production value	($) 4,172,000	$19,476,000
Import of bulk	($) 326,000	$ 2,479,000
Import of Finished Drug	$ 3,875,000	$ 2,784,000

Now that the manufacturers were well-equipped to be able to perform local production by importing bulk active ingrefients, the import-ban was imposed by the government.
So it was from 1958 that import of bulk was on the increase.

53. The foreign aid began to decline from the peak in 1957, but the chronic deficit in the international balance of payments remained problematic as ever. Therefore the government's policy was to make it easier to obtain dollar for bulk-import and to make it more difficult to obtain dollar for import of finished goods.
Under such situation turned many importers to manufacturers.

54. Furthermore such categorical conversion was strongly motivated by observing the pharmaceutical market-environment of that time where the market started booming and everybody seemed making money only by having one simple tabletting machine set up in a small space.
In fact, it was the good old days, when any sort of drug produced made good sales; That's to say the market was too far from being saturated.

55. On the other hand, among the well-equipped and early operated manufacturers, appeared the fast growing firms, who already entered the local production of bulk ingredient such as diastase, yeast, ephedrine, carbarsone etc. from basic materials. And the process patents related to pharmaceuticals were registered by twenty inventors during the period.

56. Lights are usually followed by shadows.
While manufacturers were increasing by the number, inferior drugs emerged to become an issue.
And just at last the ad hoc committee organized in 1954 finished to compile the pharmacopaeia and the national formulary, which were promulgated as the first edition in 1958.

4. Appropriate Facilities

(Learning from the Age of Reconstruction)

57. The external fund allocated for industrial facilities worked as essential growth-factor to some of the early manufacturers, while on the contrary it caused other incipient manufacturers to go bankrupt. Such diametrically reversed phenomena may be explained with the point of appropriateness of their facilities.

58. (a) The successful beneficiary;

They did not imitate the same design of the modern plant.
They had the facilities equipped on the minimum requirement basis.
Manual type was chosen rather than semi-automatic one, and production capacity was operated by two-shift or by full month.
Feeling was that production capasity was always in need of expansion.
And they managed skillfully to utilize a part of the fund as working capital. They had sufficient knowledge of production process so that any change could be made by eliminating, supplement or modifying a part of the facility within the limit of the budget.

59. (b) Ill-fated beneficiary

Automatic or semi-automatic mass production system was established.
The excessive production capacity without full month operation was causing additional burden cost. They were always in need of working capital. The devaluation of the Korean currency was repeated and the U.S. Dollar exchange rate rose so high within a short period of time that their debt was fast increased.
Finally in the middle of 1960's when hard times came, they went into bankruptcy.

60. Most of the manufacturers who have successfully grown up, chose the antibiotics as the main profi -making products at their beginning stage. Such product-policy may well be said to be well-done in various aspects.
Antibiotics were fast-moving and most consumed products as now. And the production technology of antibiotics covers all area of pharmaceutical preparations. Therefore once a firm acquired the production technology of the antibiotics, other area of technology should be easily self-learnt.

61. Not only from the economic & Technological viewpoint, but also the therapeutical point, antibiotics shall be the appropriate products with which to develope the drug & pharmaceutical technology for any developing country.

Chapter 5

The Korean Drug & Pharmaceutical Industrial Development (The Era of Economic Development Plan)

A. Production Intensive & Dark side (196' - 1965)

62. The first five-year economic development plan (1962 - 66) was formulated with the determined objective of accelerating industrialization and achieving self-sustained growth.
The structure of the manufacturing industry at that time was extremely weak. Therefore, the aggregate power was primarily concentrated in the key industries.

To look into the situations of now and then with some index:

	GNP per capita	Drug Consumption per capita	Total manufacturing per GNP	Drug Production per manufacturing
1961	$83	$0.60	13.4%	5.04%
1965	$106	$0.93	17.9%	5.96%
1970	$242	$3.38	25.6%	7.3%
1977	$864	$12.30	30.9%	7.6%

63. For the time being the small & Medium-sized enterprises including the pharmaceutical industry were left to themselves without any direct support from the government. However, the new ambitious government never forgot to voice her conviction, and made them clearly understand her principal policy toward import-substitution and export-intensification. Accordingly the authority concened began to strengthen the strategy to induce rapid technological development through voluntary action of the pharmaceutical manufacturers.

64. On the other hand the then pharmaceutical market was being overflowed with so many me-too drugs produced by small-scale manufacturers mushroomed, and cut-throat competition developed among whole-sales and retailers:

	Number of			
	Pharmacist	Makers	Pharmacy	Products
1961	5,025	321	3,139	5,462
1965	10,854	468	6,563	10,747

As a result, the tendency toward distrusting local drugs became strong and the passionate love for foreign goods rose on the high tide.

65. During this fierce competition period, there began to appear the enterpreneurs who switched their marketing policy from price competition to the promotion by quality.
Those wise groups went out to seek the chances of tie-up with transnational corporation having good brands already well-known to the public during those days of finished drug importation.
During this period four transnational companies entered the market by allowing their Korean partners to produce and sell their products by their trademarks.

66. The pharmacists used to refuse to cut prices and tried to offset their decline in sales volume by working 15 hours a day and keeping stores open 7 days a week. They formed buying clubs and retail cooperatives.
On the other hand the wholesalers went to lose their business foundation and completely demoralized. On this occassion emerged so-called big-scale pharmacies where they perfomed wholesale as well as retail. Such bi-functional tactics though illegal were very much profitable, because manufacturers approached them with the best

most favorable conditions, and even retail pharmacy procured from them. What's worse, there appeared a number of brokers, who rode about on a bicyle to seek cheapest drugs, make sales to or barter with, retail pharmacy.

67. Such disruption of normal trade channel caused many of whole salers to go bank-rupt and as a chain-reaction, many of manufacturers went into bank-ruptcy, too.

68. The 1965 was a very unlucky year for the pharmaceutical industry. A narcotic trafficking case was exposed to the public.
It was with methadone.
For a long time, intermediate chemicals were legally imported but nobody had doubt about the usage of the chemicals because these were controlled by the ministry of commerce & industry who had no sufficient knowledge of nartotic synthesis. These materils moved to secrete place where methadone was synthesized.
The methadone synthesized like this was secretly sold to several pharmaceutical firms where it was formulated with well-known proprietary drugs such as with sulfa drug injectable, with sulpyrin injectable, etc. which the firms had been marketing. Therefore it was very difficult to discover the case.

69. Also in 1965 was the inferiority of many antibiotics exposed to the public. It was with chloramphenolol and Tetracycline.
Some capsule was found to contain less than 30% of the standard, others found to contain nothing but lactose.
In those days as today all antibiotics were marketed after total inspection was executed and certificate stamp was attached on every package. Those swindlers subtly managed to collect the once used stamps, which were then reused for such illegal trade.
As such, the professional prestige of the pharmaceutical society was gone.

70. It was during the period that the Korean government reinforced the control method and expanded the necessary system.

7. Some Guiding Principle (Lesson from the Past)

71. Forming a link in a chain of import-substitute policy, an encouragement plan was prepared by the collaborative effort of the academic world, and the manufacturer's association, and submitted to the government. The plan was like the following:

13 important items were selected such as Chloramphenicol, Tetracycline, Sulfadimethoxine, PAS, INH, Sulpyrine, Nicotinamide, Phenacetine etc; each manufacturer was decided per each item; detailed supporting factors were proposed, to the government, which read;

(a) To arrange a favorable financing for necessary facility & equipment (Long term loan with lower interest)

(b) Tax-exemption for capital goods importation

(c) To lower the custom tariff on the intermediates

(d) Reduction in corporate tax

(e) Immediate import-ban when the raw materials are produced

72. Such proposals were in principle understood by the government but the first two (a), (b) remained unsolved, for the then government was also in need of foreign capital.
However, all projected items were successfully produced by the planned manufacturers within a few years, without any financial support from the government. Today's commentators all agree that such inspiring achievements were attributed to the earnest effort of communication to the industry from the government. It was because the industry understood fully the sincere plan of the government, and it was because the industry came to believe in the future.
Such case is a good example proving that public information activity is one of the essential factors for economic development, as has been reiterated by many economists.

73. During the period, there were marketed a considerable number of unnecessary drugs such as a drink type containing many vitamines but as bit as a drop in a bucket. The new government imposed an excise tax on such pretended drugs.
Despite of the fact, such things have been growing up to be in top brand list, since the manufacturers have made much more investment in advertising.

74. Therefore, the government should have deleted those products from the licensing register if they had been proved unnecessary as drug, but the excise tax should have never been imposed on, if they had been enough worthy to be called drug.

3. Age of Control and Stabilization (1966 - 1970)

75. Through the 1966 new year's message the president of the Republic of Korea raised the issue of the business order, indicating the derangement of the distribution order, the frequent bankruptcy of small-scale enterprises, and the drug quality deterioration etc., and urging to normalize such disorders by all means.

76. The message paved the way for pharmaceutical concerned to be able to take the practical measure. Immediately the pharmaceutical business stabilization committee and distribution order normalization committee were organized. The problematic bifunctional dealing was prohibited. The price-cutting competition was put under the continuous observation. The price tag system was promoted. And minimum allowance price was applied.

77. Through the amendment in the working rules for the implementation of the pharmaceutical affairs law the scope of the public advertisement was shrunken: The prohibited area were antibiotics, anti-tuberculosis agents, anti-cancer drug, all sort of parenteral preparations, sex-hormones and anti-leprosy agents.

78. To enhance better quality control administration, the inspection system was rein-forced.
During the period, yearly 6,000 cases of the inspection on all pharmaceutical products in the market by random sampling were obligated to National Institute of Health and municipal and/or provincial hygienic laboratories.

7). The inspection case during the period totaled 712,248. The rate of violation including all areas such as drug quality examination, advertising control etc. was gradually decreased from 11.7% of 1966 to 4.1% of 1970, but average rate of the period was 7.5% as illustrated below.

	Inspection case	Rate of Violation	Drug Quality rejected	Penalty		
				Product Cancelled	License Suspended	Manufacturer License Cancelled
1966	98,212	11.7%	17.6%	1,869	1,062	85
1967	126,501	6.5%	10.3%	1,437	696	169
1968	173,220	10%	6.2%	1,822	1,588	54
1969	167,685	6.8%	5.4%	3,420	907	33
1970	146,630	4.1%	4.4%	397	913	29
	712,248	53,441 (7.5%)				

To Compare Two Periods:

	Rate of Violation	Inspected Case
1966 - 1970	7.5%	712,248
1971 - 1975	2.2%	919,799

It was confirmed that the more the inspection system was strengtend, the better the pharmaceutical environment was improved.

31. It is noteworthy that a kind of drug reevaluation was performed during the period, even though it was quite different from today's well-known drug reevaluation originated from U. S. A.
The first attempt was to choose 2,000 items among total licensed products (6,365). The purpose of the reevaluation was to find out any inconsistency in the contents of the product license, for there have been licensed so many products on the basis of ever changing principle and there have been found contradiction between two principles applied each at different time for the same subject. Then the findings were explained to each licensee to apply for amendment.

32. The habit-forming drugs control law was reinforced by the congress and pulled in the benzodiazepins under its control power. The benzodiazepins that had been making big sales declined suddenly to be very slow-moving products.
The control law prohibited to sell benzodiazepin without registering the buyer's personal status and the pharmacists avoided on purpose to handle such drugs. In those days as today very few people visited pharmacy by meanse of doctor's prescription. Most of the drugs would be substituted by pharmacist's recommendation.

33. To assist the small-size enterprises it was permitted to form the Korean pharmaceutical manufacturers cooperative association. Most of the manufacturer participated in the membership by opening their account.
This association has been a good performer for the member makers particularly with two main activities; cooperative buying and mediation of economic technology.

. As cooperative buying, 2,562 items were imported for 10 years
d allocated to the members at the rate of their account:

1965	$200,000	1971	$525,000
1966	$273,000	1972	$269,000
1967	$345,000	1973	$501,000
1969	$397,000	1974	$823,000
1970	$542,000	1975	$1,072,000
	$2,030,000		$3,190,000

uch buying activity has been in many repects contributing to the
omestic economy as well as the international traders.

ost of the drug ingredients are required very small in quantity
nd in value.
are drugs and a certain drugs in the first introductory phase are
equired in very small quantity. If each individual manufactrer
ad attempted to purchase his own requirement from oversea, the
price should have been multiple.

he cooperative buying strategy has never been involved in compul-
sory reduction of the selling price, has never asked to reduce the
price much lower than the international normal price, but the stra-
tegy lay in the maximization of the quantity and the promise of the
re-order schedule.

4. On the other hand this association has assisted the member
to have connection with many useful sources of the technology
(soft & hard) such as I. E. S. C. etc.

5. During the period 40 or more manufacturers started to make
the products by the foreign brand names and perform marketing with
new methods in the ralationship of the technology-inducement agreement
or joint-venture.

A flood of foreign technology, this was the symbol phrase of those days. Technology was fast diffused throughout the country. Once a firm started production of any special formula, many followers did the same or better. During the period most of the formulation technology including quality control, technical administration, marketing, general management etc. were absorbed from the foreign partners and digested to be able to modify into Korean appropriate methods

2. Learning From Experience

86. Optimization

It was attributed to the reinforced inspection system and strengthened administrative control but performed in total optimization concept that those social issues so long accumulated trouble could be cleared during the period.

In retrospect, it has been confirmed that the problems of quality, the matter of price, distribution, promotional behavior, the advertising ethics, and the interst of industry, technology, public interest etc., any of them could not be isolated to tackle with.
The more deeply one element was handled, the more broadly other elements had to be handled together.

87. Take the matter of the price for example.
As easily understood, the reduction of the price is just for the sake of the public lay people. But whatever lower price of materials are purchased, the public may not be benefited, if the reduced price remained gain only for the manufacturers. In this regard the best policy for the public might be the price-reduction naturally induced by the severe market-competition among distributors.
This theory, however, was found wrong. The price-reduction caused too many social troubles eventually bringing loss to the public, to the industry, and to the society as a whole.
Such loss was proved too severe to clear quickly.

88. It was one of the lessons from the past Korea that price must not have been the first thing even to lighten the economic burden of the public.
Moreover, what made the public unhappy was not the real matter ofthe price of drugs but the dissatisfaction brought by comparing psychology and the indignation caused by buying the inferior.

To extract out the ultimate concern of the public, it was the total concept (cured or not cured) of the health services but not the individual concept among the services that is to say price of drug, price of treatment etc.

89. From the view point of such totality concept and of the Korean experience, all elements cannot be maximized nor minimized, but oly optimized. But the individual optimization should be closely related to the degree of the optimization of the other elements.

Part Four: PRESENT DAY Chapter 6

The Age of Technology-Intensive (1971 -)

A. Product Licensing & Patent

90. Since 1960's, the product licensing policy has been mainly focussed on : (a) upbringing the raw material production, (b) expediting the export and (c) preventing the self-destructive competitions. Such criteria were all economy-concerned rather than public health-interest.
Therefore the working rule & regulations for the implementation of that policy had to be frequently changed, sometime including even the copernician conversion, whenever the market environment changed.

91. The import-substitute policy followed by import-ban and the exclusive right or the monopoly right given to the raw material producer were the most concerned bonus to the manufacturers.
So tried all enterpreneurs competitively to develope the synthetic technology and submitted the application for the production license. Whenever such application was filed, there soon appeared several followers. The most competitive case was Amoxycillin synthetic license in 1975. Within the interval of 2 days there were filed 9 manufacturers, who insisted to each other that his own was better and more economic than other's. Remarkably it was the time when neither finished product was imported nor Amoxycillin bulk was imported. Surprisingly the first Amoxycillin products introduceed to and prescribed by the Korean doctors were the antibiotics synthesized by Korean manufacturers.

92. Such technological competitions as Amoxycillin case have been giving the government officials many troubles.
That was the reason why the product licensing policy has been dancing with the patent problems.
Whatever many manufacturers competed with a rush of application, the government officials always relied on the patent situation to solve the trouble.

Until 1965, any patentee was authorized with the priority to get the manufacturing license, and even to eliminate the granting of the same license to others who had the know-how developed but not patented. In those days as today Korean patent system was process patent one. Therefore there has been always latent the possible explosion of the new type of competition among the patentees.

93. Such worry came true in 1966. The matter was brought to the professional reserch to study whether the product licensing should be handled in connection with patent situation or not. Finally it was concluded to seperate them. Since 1966, the product license was given to the earlier applicant, If the patentee had been a late comer and rejected to get the license on the ground that the existing licensee were already so many, he would have had no alternative course but the appeal to the law outside. the pharmaceutical world.

94. Entering 1970, the policy was again changed. It was because the philosophy of the new officials was different and accordingly the way of understanding the law was different. Since 1970, not only the patentee was protected by the pharmaceutical administration but also the patent-applicant whose application-file was announced as opening patent, was authorized to get the product manufacturing license in the exclusive way.

95. Again it was amended in 1974. Since 1974, only the registered patentee was protected but the applicant having opening patent was handled just like non-patentee.

96. In 1975 when Amoxycillin case exploded, as explained in the above paragraph 92, the patent was seperated from product licensing. And this policy is still effective.

97. Through the years while the relationship between the product licensing and the patent has been playing a flip-flap movement, many manufacturers acquired the deep knowledge about matter of process patent. Many enterpreneurs started to have patent department organized in their systems, participate in the membership of Korean science and technology information center (Korstic) and collect every patent copies from the global sources.
Korstic supplied the computerized information of the medical products in the form of periodical catalogue; particularly the catalogue was edited according to each interested category such as Cephalosporins, Cimetidines or Anti-tuberculosis agents etc. on the other hand, the Korean Pharmaceutical Manufacturers Association started to circulate the letter of patent to all members which carried such directions "here attached is the copy of the patent application filed by xx. Please prepare a formal objection and submit it until xx, if anybody finds a different opinion."
And futhermore the Korean patent office provided instruction course to the industry. The course was once a month-long intensified one, including a week of study tour to Japan.

98. Such environment was very much influential to the extent that some of the transnational corporations lost the chance to market t their original products in Korea.

E. The Matter of Number, Product & Manufacturers

99. As shown in the Table 1, the number of the licensed products have undulated with four periodical cycles during the post 30 years from 1945 to 1977.
The spontaneously ever increased numbers was reduced by the governmental control measureres. During the recent years about 6,000 has been the steadily remained number.
To reduce the number, the control measures and criteria have been always revised and reinforced. Under the present rules such items belonging to the following categories are not generally licensed:

Table 1

Number of Manufacturers & Products (R. O. K.)

Year	Makers	Number of Products	
1945	255	2,363	End of World War Two
47	334	3,280	
49	344	3,861	
51	383	4,209	
54	411	4,756	
			Government Control
1956	248	1,190	
57	271	2,815	
58	382	4,105	
59	327	5,317	
60	427	6,575	
			Social Effect
1961	321	5,462	
62	373	6,365	
63	392	7,676	
64	482	10,447	
65	468	10,747	Intensified Administrative Control (Nation-wide inspection)
1966	349	7,039	
67	305	6,856	
68	294	6,259	
69	295	6,023	
70	286	6,068	Number of Makers and Products Remain in Controlled Steady State.
71	284	6,020	
72	291	6,249	
73	286	6,279	
74	293	7,161	
75	300	8,841	Drug Reevaluation
76	271	5,485	
77	272	6,059	

T. F 2

Market Share of Top Brand- (%)
(R. O. A.)

Total market size by Production Value	1975	1976	1977	Remark
	$265M	$358	$446	($ Million)
Number of Top Brands				
1 - 5	4.9	4.9	5.6	
1 - 10	7.1	7.0	7.8	
1 - 20	10.6	10.2	10.7	
1 - 30	12.6	12.3	12.7	
1 - 50	16.3	16.0	15.6	
1 - 100	21.8	21.9	20.7	

TABLE 3

Concentration by Production Value (%)

(R. O. K.)

	Number of Manufacturers				
Year	TOP 10	TOP 20	TOP 30	TOP 40	TOP 50
1972	64%	79	86	91	93
1973	62	78	86	90	92
1974	57	77	86	90	93
1975	56	77	86	91	94
1976	54	74	83	87	91
1977	54	73	82	87	91

The concentration pattern of Korean pharmaceutical manufacturers seems to be corresponding to those of U. S. A. and U. K.

(a) Combined or liquid preparations of such agents; antipyretic-analgesics, tonics, digestant, antiacid, antidiarrheals, antivomitting agent, vitamins, nutrients, alternative.

(b) Multivitamin, vitamin with hormone

(c) Antibiotics under severe competitions

(d) Preparations containing adrenocortico steroids

(e) Habit-forming drugs

100. However, the ministry has enacted and proclaimed the rules of licensing items for special case. It only grants a license to a new application if it has satisfied one of the following requirements (1) exporting the entire amount produced; (2) providing more excellent facilities than the existing firms; (3) manufacturing raw materials only ; or (4) having other recognizable special interest.

101. To analyze the drugs registered to the medical insurance that started from 1977;

As of 1977	Number of item
Total licensed drugs	6,059
produced drugs	5,396
Drugs of medical insurance	2,998
(as drug components	1,112)

102. Market share of top brands

As shown in the table 2, the market share of the top brands has remained same for the recent 3 years. Furthermore, no change is seen in each aggregate group surprisingly.
Every year just 100 top brands occupied the 21% of the total production value, and 50% of the total production was occupied by 378 products, 7% of total product number (6,059) in 1977.
Therefore, the number of products of Korea seem to be too many; and the governmental effort to reduce the number may well be reinforced.

103. The number of manufacturers has repeated the same cycle as the number of the products. (see Table 1)
However, during the recent ten years the number has been decreased and seems to continue that way for the time being.
The table 3 shows the concentration by production value of the top manufacturers by the aggregate number. As shown in the table 3, the concentration pattern has been declined from 1972 to 1977, but the pattern seems to be almost similar to those of U. S. A. and U. K. It may be explained in this way; Korean pharmaceutical market environment may have been affected by these two countries.

104. Entering 1978, Korean government made a proposal to the drug manufacturers, particularly to the small-size manufacturers, to consolidate each other into one stronger & larger firm.
To promote this, some incentives were promised such as tax benefit and product licensing etc. Even if this plan succeeded, the concentration pattern would not be changed, for the consolidation may be happening among the groups not included in top 50 manufacturers.

C. Statistic Say:

105. How the Korean pharmaceutical industry has been growing up, what problems she has now and what she shall be etc. may be easily understood from the following tablets:

(a) Table 4 : Drug consumption/Manufacturing production/ GNP & per Capita (1960 - 1977)

(b) Table 5 : Production/Import & consumption (1960 - 1977)

(c) Table 6 : Import dependency of Korean pharmaceutical industry (1960 - 1977)

(d) Table 7 : Import-Export of herbal medicine (1960 - 1977)

(e) Table 8 : Changing pattern of market share (1972 - 1977)

TABLE 4

Drug Consumption/Manufacturing Production/GNP & Per Capita (R. O. K.)

Year	Population	GNP $ M	GNP per Capita($)	Drug Consumption per Capita($)	Total Manufacturing per GNP (%)	Drug Production per Manufacturing	Drug Consumption per GNP (%)	Dollar Exchange Rate (Won)
1960	24,954							65
61	25,498	2,124	83	0.60	13.4	5.04	83	127.7
62	26,231	2,271	77	0.93	14.5	6.21	77	130
63	26,987	2,641	98	1.68	14.9	9.39	98	138.7
64	27,678	2,811	102	1.17	15.9	7.14	102	213.3
65	28,327	3,005	106	0.93	17.9	5.96	106	265.4
66	29,160	3,655	126	1.11	18.5	5.47	126	271.3
67	29,541	4,236	143	1.54	18.8	6.38	143	270.6
68	30,171	5,052	168	2.23	20.5	6.97	168	276.6
69	30,738	6,399	208	2.77	20.7	6.93	208	288.3
70	31,435	7,558	242	3.38	21.6	7.29	242	310.6
71	31,828	8,747	275	3.48	21.7	6.98	275	347.7
72	32,360	9,824	304	3.45	23.4	5.25	304	392.9
73	33,177	12,374	376	4.92	26.2	5.44	376	398.3
74	33,789	16,759	483	6.85	27.9	5.44	483	404.5
75	34,688	18,702	531	7.70	28.0	5.74	531	484.0
76	35,860	24,967	698	10.04	29.3	7.01	698	484.0
77	36,436	31,423	864	12.30	30.9	7.61	864	484.0

TABLE 5

Production / Import / Export & Consumption

(Korean Drug & Pharmaceuticals)

Unit: $1,000

Year	PRODUCTION		IMPORT		EXPORT		Consumption of Drug
	Finished Drugs	Bulk Drug	Finished Drugs	Bulk Drug	Finished Drugs	Bulk Drug	
1960	19,076	400	2,784	2,479		341	21,860
61	14,133	400	1,509	648		384	15,642
62	21,699	220	2,777	4,943		62	24,476
63	44,251	600	1,069	3,347	12	443	45,308
64	31,736	659	628	3,513	20	277	32,344
65	26,096	991	522	3,938	16	11	26,602
66	31,475	1,803	1,090	5,963	108	7	32,457
67	42,885	3,401	2,508	6,087	3	3	45,390
68	64,533	3,614	3,326	9,178	481	1	67,378
69	82,824	3,562	2,654	11,173	319	625	85,159
70	103,586	5,319	2,996	14,692	374	645	106,208
71	108,579	6,274	2,629	17,087	507	650	110,701
72	110,916	9,791	1,329	16,143	819	218	111,426
73	161,588	14,676	2,483	27,299	687	3,428	163,389
74	229,127	25,551	3,108	43,896	742	10,337	231,493
75	265,065	35,800	3,194	40,005	1,270	10,064	266,989
76	358,258	56,559	4,233	38,424	2,304	13,347	360,187
77	445,635	71,231	5,834	48,379	3,319	16,605	448,150

TABLE 6

Import Dependency of Korean Pharmaceutical Industry

Year	PRODUCTION		IMPORT		Demand	Dependency on Import
	Finished Drugs	Bulk Drug	Finished Drugs	Bulk Drug		
1960	19,076	400	2,784	2,479	22,260	0.24
61	14,133	400	1,509	648	16,042	0.13
62	21,699	220	2,777	4,943	24,696	0.31
63	44,251	600	1,069	3,347	45,920	0.096
64	31,736	659	628	3,513	33,023	0.13
65	26,096	991	522	3,938	27,609	0.16
66	31,475	1,803	1,090	5,963	34,368	0.20
67	42,885	3,401	2,508	6,987	48,794	0.18
68	64,533	3,614	3,326	9,178	71,473	0.17
69	82,824	3,562	2,654	11,173	89,040	0.16
70	103,586	5,319	2,996	14,692	111,901	0.16
71	108,579	6,274	2,629	17,087	117,482	0.17
72	110,916	9,791	1,391	16,143	122,098	0.14
73	161,588	14,676	2,488	27,299	178,752	0.17
74	229,127	25,551	3,108	43,896	257,786	0.18
75	265,065	35,800	3,194	40,005	304,059	0.14
76	358,258	56,559	4,233	38,424	419,050	0.10
77	445,635	71,231	5,834	48,379	522,700	0.11

TABLE 7

Import - Export of Herbal Medicine

Unit: 1,000

Year	Import	Export	Export of Ginseng Product	Total Export	Balance
1960	932	407	294	701	-231
61	242	924	223	1,147	905
62	747	797	37	834	87
63	373	1,317	41	1,358	985
64	269	2,434	43	2,477	2,208
65	224	1,214	41	1,255	1,031
66	453	1,031	34	1,065	612
67	915	1,310	46	1,356	441
68	844	1,963	43	2,006	1,162
69	1,152	2,301	22	2,323	1,171
70	1,538	2,674	929	3,603	2,065
71	1,492	3,003	2,127	5,310	3,638
72	1,907	5,480	910	6,390	4,483
73	2,687	9,073	623	9,696	7,009
74	3,481	6,032	961	7,043	3,562
75	3,667	6,553	1,060	7,613	3,946
76	3,859	19,761	1,878	21,639	17,780
77	5,930	19,948	1,901	21,849	15,919

TABLE 8

Changing Pattern of Market Share

(By Some of Therapeutical Calssification)

	1972	1973	1974	1975	1976	1977	Trend
Antibiotics	21.72	23.83	24.45	25.45	24.79	22.29	~
Tonics	13.25	13.14	12.38	12.84	12.87	13.33	~
Analgesic & Antipyretics	7.42	7.32	7.34	7.51	8.32	8.06	~
Vitamines	5.27	5.94	5.58	5.40	5.55	6.06	
Hormones	4.52	4.29	3.77	3.82	3.63	3.69	↘
Steroids	2.84	2.52	2.33	2.21	2.33	2.6	
Antiacid	0.85	1.25	2.18	2.50	2.73	2.83	↗
Anti-TB drug	4.31	3.94	3.41	3.22	2.81	2.44	↘
Anthelmintics	1.2	1.15	1.29	1.43	1.54	1.07	
Sulfa Drug	2.48	2.44	2.55	2.00	1.76	1.55	↘
Cardiovascular Drug	1.64	1.66	1.47	1.46	1.63	2.14	↗
Anti-Cancer Drug	0.03	0.04	0.15	0.31	0.37	0.53	↗
Diabetic Control Drug	0.16	0.25	0.2	0.2	0.21	0.17	
Psychotropics	0.92	1.05	1.10	1.44	1.14	1.15	↘
(Unit $1,000)	$116,916	161,582	229,197	265,065	358,258	445,635	

TAPLE 9

Price Comparison

	Unit	Korea	Japan	U. K.	HongKong	India	Israel	Italy
Ampicillin.3H2O	250mg/Cap	1	5.98	0.69	0.52	1.44	1.88	2.21
Ampicillin-Na	250mg/Inj	1	8.71	1.12	1.73	2.21	2.66	3.50
Amoxycillin	250mg/Cap	1	4.82	0.59	1.14		1.23	"
Cephalexin	250mg/Cap	1	5.42	0.87	2.48		1.48	1.7
Kanamycin Sulfate	1g/Vial	1	2.22	4.91	0.98	1.97	1.71	3.42
Erythromycin estolate	250mg/Cap	1	3.38	1.05	0.67	1.82	1.39	4.16
Chloramphenicol	"	1	2.56	5.67	1.22	2.22	3.33	5.11
Oxytetracycline HCl	"	1	3.78	1.67	3.44	1.22	"	4.72
Gentamycin	80mg/Inj	1	2.14	2.90	5.42	"	1.55	1.55
Cephloridine	250mg/Inj	1	2.72	0.37	1.56	"	1.16	0.2
Rifampicin	150mg/Cap	1	4.98	1.35	1.71	1.34	1.03	1.03
Sulfamethoxazole Trimethoprim	400mg/80mg Tab	1	"	1.24	2.74	1.31	1.52	0.57
PAS-Ca	500mg/Tab	1	3.00	"	"	2.00	"	"
INAH	100mg/Tab	1	0.33	"	0.56	0.22	0.22	"
Saridon	Tab.	1	"	0.15	0.70	0.30	0.19	0.41
Darralgin	"	1	"	"	1.21	0.62	0.62	0.62
Bayer Aspirin	500mg/Tab	1	0.51	1.29	2.14	0.14	0.57	1.00
Lorazepam	1mg/Tab	1	"	0.43	1.11	"	0.61	0.58
Furosemide	40mg/Tab	1	2.48	1.30	1.72	0.61	0.81	1.61
Dexamethasone	0.75mg/Tab	1	2.11	4.11	1.22	1.33	2.33	6.78
Ethambutol	400mg/Tab	1	2.86	3.03	3.11	"	1.51	2.48
Propranolol	40mg/Tab	1	3.93	0.62	1.31	0.69	0.33	0.68

(f) Table 9 : Price comparison

D. Impact of Foreign Technology

106. The foreign technology particulary originated from the transnational corporations began to be induced from the year 1960. Until 1977, Korean market environment has been colored by almost 50 transnational corporations, of which 8 companies have been grafted upon each Korean partner in the way of joint-venture, and most of the technology inducement agreements settled between both partners have been expired remaining only one case to be also expired as of December 1978.

107. The transnational corporations in Korea can not be said well done at least until now, while Korean partners have been very much successful to absorb the necessary technology from them.

108. As shown in the below chronology, 24 transnational corporations entered the market during the ten years of 1960's.
And in the first half of the 1960's, the necessary techniques have been transferred as far as the techniques were concerned about the production know-how with bulk medicines. Such transferred technology has fast diffused throughout the country, too.
As a result, there appeared several Korean partners that began to ask more advanced technology like synthethic know-how. It was very short-sighted that the transnational corporations did refuse to accept such offer at that time. On the contrary, as bad luck often brings good luck, it was a strong stimulus for the Korean partner to try for themselves.

190. The Chronology (Transnational Corporation Entered)

(* ; J. V.)

1960	*	Hochst
1961	*	Pfizer
1962	*	Bayer.
	*	Lepettit
		Lederle
1963	*	C.H. Bohringer
		Organon
		Wellcome
1967		Roche
		Lakeside
		Bohringer(John)
	*	Shering
1968		I. C. I.
		Merck
		Nordmark
		U. C. B.
		Carlo erba
		Polichimia
1969		Ciba
	*	Upjohn
		Armour
		Beecham
		Solco
		Knol
1970		Squibb
		Cutter
1971		Lilly
		Stf
1972		Theraplix
1973		Wyeth
	*	Meiji
		Bristol Myer
1974		Pfrimmer
1975		Media
		Netherax
		Chemi chemi
1976		Sandoz
		Russel
		Syntex
1977		Kali chemi
		Serl
		Rhone Poulenc
		TAD

110. There were three as main objectives for which Korean partners entered the business relationships with foreigners;

(a) To take advantage of the brandname

(b) To monopolize the product in case it was patented and produced exclusively by the partner only.

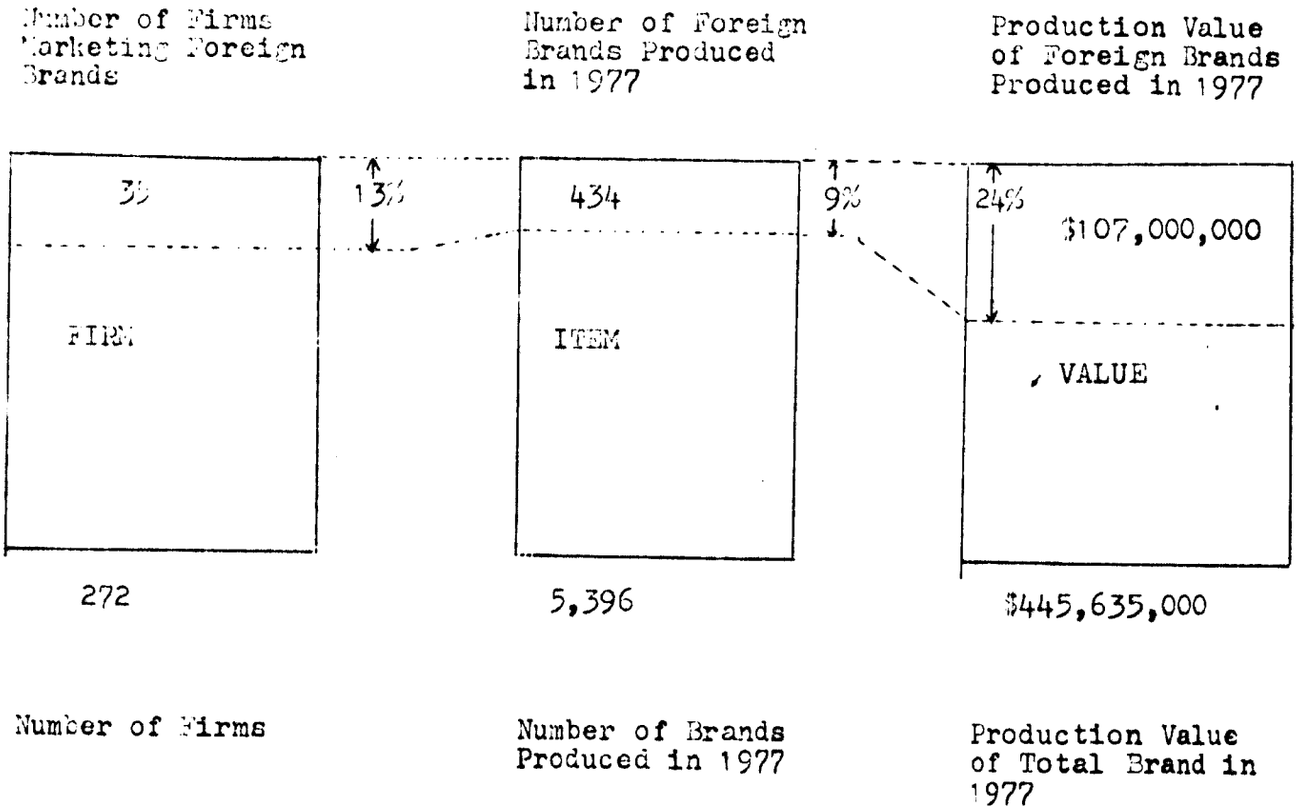
(c) To absorb the technology

But few foreign partners were qualified for all such requirements. Most of the transnational corporations tried to make the best of the first requirement (a), only and asked Korean partners to repay for it too much. It was disclosed shortly that the primary concern of the transnational corporations was the trademarks. The Korean partners began to recognize that the foreigner's trade mark should be managed by any means as long as the above two other requirements (b) and (c) are not met.

111. Fortunately, the Korean economic planning board never permitted to extend the technology inducement agreement further more than 2 or 3 years, since such period was thought to be sufficient to absorb the technology (production from bulk). And foreigner's trademarks were permitted to use only during the legally effective period of the technology inducement agreement (Official agreement).
Despite of the fact, the transnational corporations lost the chances to withdraw their tradenames from Korean market when the official agreement was expired. It was self-destructive delinquency that they allowed their partners to continue to use the trademarks without any legal protectio . As a result, most of their trademarks still on the market are in an extremely precarious position when any third party raised a claim to the law that the non-qualfied subjects have been using the trademarks of the others and the owner connived, therefore the trademarks being deserved cancellation.

112. Recognizing such situation, some of the transnational corporations try to save their trademark even by the complete concession to the Korean partner under the privately made promise, but it seems very difficult. Moreover, the product was already registered to the product license list of the pharmaceutical affairs department, by the name of the Korean partner. And the product name cannot be transferred to other for such registration purpose.

113. To look into the market power of such foreign brands;



As of the end of 1977, 65 manufacturers were marketing 434 products by the foreign brand names, 9% of total number of the products. This 9% occupied 24% of the total production value in 1977.
Since the analysis by the brands may stand for the maximum calculation of the foreign influence, Korean market may be said to be under the foreign influence by 24% at most.

On the other hand, to look into the 5 J.V. firms (Hoechst, Roussel, Schering(Ger), Pfizer, Upjohn, Bayer, Meiji, Boehringer), their market share was calculated as 12.5% of the total production value in 1977. This is very moderate compared with other countries. They are generally said to be not so good in Korea.
To analyze & compare their operations with those of the Korean firms of the same level.

	J. V.	Genuine Korean Firms
Salesmen	29.7	30.2
Production personel	44.9	35.2
Other management	25.4	34.6
	100%	100%
Monthly Production Value (Rate)	1	2.5
Monthly production value per capita	1	1.03
Monthly sales value per salesman	1	1.2

As shown in the above, the operational efficiency of the J.V. firms was lower than that of Korean Firms:

	J. V.	Korean Firm
Production Efficiency	97%	100%
Marketing Efficiency	83%	100%

It is generally commented that the transnational corperations fail to take necessary actions appropriate to the local environment, even though they are seemingly understanding the market and trying to assimilate thenselves to the environment, because they are doing so only on the condition that the fixed principles learnt from their past expierence are maintained.

116. The main reason that most of the transnational corporations have failed in Korea was not in the matter of marketing but in the matter of product development & the policy of technology. They should have taken the same developmental policy as the Korean firms did. There seem to appear several foreign firms that approach to Korean firms suggesting to depoly the completely assimilated policy from now.

E. Diffusion of Information & Technology

117. Entering 1970's, there appeared many kind of publication, such as 6 kinds of monthly professional journals each privately published, monthly pharmaceutical technology information published by the association, 7 kinds of weekly news, medical index (PDR Type), several kinds of drug compendia, price list (U.S. Red Book Style) etc. And everyweek pharmacy practitioners could have chance to participate in any seminar provided by the drug firms. The pharmaceutical continuing education program was reinforced. Accordingly, the information was diffused very fast. Such being the case, the drug manufacturers who have been enthusiatic to find a good new drug from the world market and to introduce it earlier than others stopped such old strategy and instead, started to compete through technology development and export-competition.

118. During the 1970's production of bulk medicine have been increasing at the faster rate than the bulk import. (As shown in the Table 5) Export has been also increasing with bulk medicine as well as finished products. The import has been continuously decreasing from 0.24 of 1970 to 0.11 of 1977. (As shown in the Table 6)
Such rapid growth can be also illustrated by drug consumption per capita. (As shown in the Table 4)
Eventually it was the technological development that the Korean drug & pharmaceutical industry has been developing up to the today's level. It was also owing to the fast diffusion of information & Technology among the manufacturers.

118. The Table 10 shows how the technology has been transferred and diffused in Korea by the term of Lag between the next follower from 1965 to 1977.

TABLE 10

Korean Technology Development/Transfer/Diffusion

Here below are listed the KOREAN PHARMACEUTICAL TECHNOLOGY DEVELOPMENTS in the chronological sequence.
The year in the first column shows the first development-year that the corresponding product was manufactured by chemical synthetic process or other relevant technology.
The years in the next column indicate each year whenever the follower started manufacturing owing to the technology-diffusion.

The 1st Year	Technology	Follower				
		2nd	3rd	4th	5th	6th - 9th
1955	Aluminum Hydroxide Gel	67	71	73		
1957	Ephedrine					
	Zinc Oxide					
1959	Dry Yeast	9/59	70			
	Lactobacillus Granule					
1961	Acetanilide					
	Acetylsalicylate	74	75	76		
	Glycerin	73				
1962	Menthol	11/74	12/74			
1963	Thiamin Propyl Disulfide					
	Iodine Tincture					
1964	T.T.F.D.	67	7/70	10/70	72	
1965	P.A.S. - Ca	73				
	S-lase					
	Biotise					
	Castor oil					
	Oxytetracycline HCl	3/72	3/72			
	Oxytetracycline	3/72	3/72			
	Chloramphenicol	67	75			
	CM palmitate	67				
	CM sodium succinate					
1966	Sulfadimethoxine					
	Choline sulfate					
	Biodiastase					

The 1st Year	Technology	Follower				
		2nd	3th	4th	5th	6th - 9th
1966	Nicotine-amide	8/67	9/67	74		
	Dl-methionine	8/67	9/67			
	Lysine HCl					
	Diastase					
	INAH	8/67	9/67	73		
	Ascorbic acid					
1967	Bismuth subnitrate					
	Magnesium silicate					
	CM Micro Powder					
	Tetracycline HCl(Fermen)	71				
	Tetracycline (Fermen.)	69	71			
1968	Soda-lime					
	Sulfadimethoxine Sod.					
	Lact-S					
	Caffeine	72	73			
	Acetaminophen	70	73	3/75	7/75	
1969	Tetracycline Phosphate					
	Syn. Aluminum silicate	75				
	Mercurochrome	71				
	Chlorpheniramine malate	69	73			
	Sod. INAH methan sulfo-nate	72	74			
	r-Oryzanol					
	Salicylic acid	76				
	Methyl Salicylate	74				
1970	Aminophyrine	8/72	12/72	73	75	
	Thiamin HCl					
	Sulpyrin	70	71	76		
	C.M.C. - Na	2/76	3/76			
	Ampicillin $3H_2O$	73	1/75	3/75	76	
	Ampicillin sodium	73	1/75	3/75		
	Glycine					
	Danisol B.E.M.P.					
	Inositol					
1971	Methyl Estronone					
	Methyl Estradiol					
	Rifampicin	73	1/74	5/74	4/75	6/75

The 1st Year	Technology	Follower				
		2nd	3th	4th	5th	6th - 9th
1971	Sodium Salicylate	72	76			
	Aspirin					
	Pyrabital					
	Ethenzamide	73	74	75		
	Thiamin mononitrate					
	Racemic Thiamin HCl					
	Magnesium Stearate	73				
	Calcium Panthotenate					
	Trimethoprim	6/72	12/72	74	76	
1972	Magnesium hydroxide	73				
	Thiamin disulfide powder					
	Prothionamide	72	74			
	Liquid Paraffin					
	Pyrithioxino HCl					
	Calcium phosphate dibasic	74				
	Soluble KM sulfate	6/72	12/72	73	9/74	10/74
	Lactobacillus acidophilus					
	Metoclopramide					
	Erythromycin estolate	73	74			
	Pancreatin	75	76			
	Phenacetin	72	75			
	Cinnamon Powder	74	76			
	Sod. Cloxacillin H_2O	12/72	73	74	1/75	8/75
	Benzoic acid	73	74			
	Sodium Benzoate	73	74			
	Bezoar					
	Potassium Hetacillin	72	3/73	9/73	74	
	Natto(Digestive strain)					
	Taurine					
	Spored active clostum butyrcum					
	Complase-A					
	Streptococcus pericus					
	Ethambutol					
	Glucose					
	Theophylline					
1973	Meclofenoxate					

The 1st Year	Technology	Follower				
		2nd	3th	4th	5th	6th - 9th
1973	Cephaloridine	5/73	3/74	7/74	3/76	8/76
	Sodium bicarbonate	75				
	Cephalexin	5/73	1/74	4/74	7/74	4/75 4/75 10/75 12/75
	Chloramphenicol stearate					
	Thimerosal					
	Ca-bile acid phosphate					
	Ampicillin anhydrate	11/73				
	Dimenhydrinate					
	Adenosylcobalamine					
	6-APA	8/73				
	Benzoyl P.A.S. - Ca	75				
	Berberine tannate					
	Magnesium Oxide	74	75			
	Magnesium Carbonate	74	75			
	Dl-α-Tocopherol					
	Dl-α-Tocopherol Acetate					
	Sulfamethoxazole	7/74	12/74	3/75	4/75	
	Ethambutol HCl	5/74	5/74	6/74		
	Albumine Tannate					
1974	Carbazochrome Na-Salicylate					
	Mel					
	Calcium Bile salt					
	Phenol					
	Sodium Chloride	75				
	Erythromycin					
	Phenol Zinc sulfate	74				
	Probenecid	75	76			
	Palaxin B.P.E.M.					
	Sodium Sulfate					
	Barium Sulfate					
	Furfuryl Acetnite					
	ETB HCl					
	Thioctic acid amide					
	Thioctic acid					
	Zingiberis rhizoma					

The 1st Year	Technology	Follower				
		2nd	3th	4th	5th	6th - 9th
1974	Coptis rhizoma					
	Platycodi Radix					
	Gentianae Radix					
	Gentianae scabre Radix					
	Glycyrrhizae Radix					
	Curcumae Rhizoma					
	Gelatin	2/75	10/75			
	Soluble Saccharin	2/75	5/75			
	Benzoyl Thiamin Disulfide					
	Salicylamide					
	Ox bile Extract	76				
	Medicinal Soap					
	Methyl Benzoic acid					
	Crude Urokinase	10/74	3/76	5/76	6/76	
	Calcium Soap					
	Kanamycin Sulfate					
	Human plasma Protein fraction					
	Salbutamol Sulfate					
	Al-Hydroxide+Mg-Carbonate					
	Rhemaniae Rhizoma					
	Water for Injection					
1975	Oxoamide					
	Aminocaproic acid	1/75				
	Saccharated Pepsin	12/75				
	Aluminum Phosphate Gel					
	Unsoluble Saccharin	8/75				
	C.M.C. - Ca					
	Sulfaisomidine					
	Boraben B.E.M.P.					
	Lauryl Prothion sulfate					
	Myristicae semen					
	EM Lactobionate					
	Protease					
	Thiamphenicol					
	Lipase					
	Pivampicillin HCl	10/76				

The 1st Year	Technology	Follower				
		2nd	3th	4th	5th	6th - 9th
1975	Chlorpramide					
	Metronidazole					
	Heavy Mg Oxide					
	Heavy Mg Carbonate					
	Ppted. Ca Carbonate					
	Calcium chloride					
	Exsiccated Ca sulfate					
	Blank Capsule					
	Sorbitol(70%)					
	Amoxycillin Trihydrate	9/75	11/75	12/75	76	76
	Procaine Penicillin G					
	Phenobarbital					
	Phenylamine malate					
	Glybenclamide					
	Dicloxacillin Sod.					
	Metopramide HCl					
	Amino capro Phosphate					
	Complase-B					
	Penicillin G Pot.(Inj.)					
	P. A. S.					
	Penicillin Sodium					
	Isopropylantipyrin					
	Complase-D					
	Cefazolin Sodium					
1976	Ursodeoxy cholic acid sulfide					
	Sulpiride					
	Mefenamic acid	6/76				
	Bisacodyl					
	Cephalothin Sodium					
	Dipyridamol					
	Cyproheptadine HCl					
	Sulfaisomidine					
	Sulfisoxazole					
	Calcium Saccharide					
	Sodium Saccharin Powder					
	Lysozime chloride					

The 11st Year	Technology	Follower				
		2nd	3th	4th	5th	6th - 9th
1976	Benzalchrome HCl Soln.					
	Sorbitol					
	Silver sulfadiazine					
	Aluminum flufenamic acid					
	Flufenamic acid					
	Oxycycline Hydrate					
	Dapson					
	Cyclamine sodium					
	Glucose-1-Ph.Diarginine					
	Bromelain					
	Sulfamonomethoxine					
	Cephapirin sodium					
1977	Cimetidine					

119. The Table 12 shows how the Korean antibiotic consumption pattern has been changed. Of these antibiotic categories, Semi-synthetic penicliins, Cephalosporins, Chloramphenicols, Tetracyclines, Erythromycines, Kanamycins, and Rifampicins are covered with almost 95% up by chemical synthesis & fermentations in Korea.

And the Table 13 also shows how such antibiotic production technology has been transferred & diffused among the next followers.

TABLE 12

Antibiotic Consumption by Kg Weight

(R. O. P.)

	1970	1971	1972	1973	1974	1975	1976	1977
Penicillin-G & -V	8,573	10,335	10,631	16,516	15,924	12,057	15,732	15,999
Semi Synthetic Penicillins	670	2,260	2,720	7,300	13,125	19,386	28,693	30,925.39
Cephalosporins	-	-	-	35	1,123	1,211	2,308	3,025.21
Chloramphenicols	35,800	32,340	32,600	43,730	41,340	37,600	55,400	54,620
Tetracycline Group	32,210	40,300	46,220	66,060	61,390	63,795	77,109.7	116,726.52
Erythromycins	230	457	1,039	1,710	4,680	5,750	8,299	13,998.53
Other Macloride Group	-	35	240	560	580	1,006	1,499	2,450.11
Streptomycin	14,500	13,400	19,600	26,200	25,500	15,100	12,580	22,465.07
Kanamycin Group	990	1,120	1,490	2,860	4,250	6,492	9,245	8,442.74
Gentamicin	1	7	15	35	70	76	291	185.91
Colistin	190	260	160	570	470	312	303	881.39
Rifampicin	-	-	150	680	1,370	3,000	3,000	4,281.79
	93,163	100,584	114,815	167,016	169,927	165,793	214,374.7	79,010.55

TABLE 13

Antibiotic Production Technology - FOR A -
(Transfer & Diffusion Lag)

Antibiotics	Year of Import		Year of Synthesis	Number of Synthetic Producers	Number of Finished Product Producer	Worldly first marketing year
	As finished drug	As bulk				
Penicillin G Sodium	before 1957	1958			5	
Procaine Penicillin G	"	before 1957			1	
Benzathin Penicillin G	1958	1970			1	
Penicillin V	1959	1959			3	
Novobiocin Sodium	1961	1964			1	
Ampicillin Anhydrous		1972	1973	2	1	1961(U.K.)
Ampicillin Trihydrate	1968	1969	1970	5	7	
Ampicillin sodium	1968	1970	1970	4	6	
Amoxycillin Trihydrate	x	x	1975	6	15	
Hetacillin Potassium	1969	1972	1972	4	6	1967(U.K.)
Cloxacillin Na $\cdot H_2O$	1968	1970	1972	5	4	1962(U.K.)
Licloxacillin Sodium		1975	1975	3	7	1968(U.S.)
Flucloxacillin		1976			1	1970(U.K.)
Pivampicillin HCl			1975	2	2	
Carbenicillin		1972			2	1967(U.K.)
Ciclacillin		1975			1	
Sulbenicillin		1975			2	
Methicillin		1975			4	

Antibiotics	Year of import		Year of synthesis	Number of Synthetic Producers	Number of finished product producers	Starting first production in the year
	As finished drug	As Bulk				
Colistin sulfate	1963				1	
Colistin Sod. methan sulfonate	1963	1967			2	
Streptomycin sulfate	before 1957	1961			9	
Kanamycin sulfate	1960	1960	1972	6	10	
Aminodeoxykanamycin		1973			1	
Gentamicin sulfate		1970		1	13	1966(U.S.)
Amikacin sulfate		1977			1	
Dibekacin sulfate					1	
Cycloserine	1960	1963			1	
Erythromycin	before 1957	1964	1974	1	2	
Erythromycin estolate		1971	1972	3	7	
Erythromycin stearate	1959	1972			5	
EM lactobionate	before 1957	1968	1975	1	2	
EM ethyl succinate		1975			1	
Leucomycin	1964	1965			2	
Acetylleucomycin	197	1970			1	
Oleandomycin phosphate		1963			1	
T A O	1965	1966			1	
Spiramycin	1964	1971			1	
Josamycin		1972			2	
Chloramphenicol	before 1957	before 1957	1965	3	8	
Chloramphenicol palmitate		1962	1965	2	4	

Antibiotics	Year of Import		Year of Synthesis	Number of Synthetic producers	Number of finished product producers	World's first marketing year
	As finished drug	As bulk				
CM sodium succinate		1962	1965	1	1	
CM stearate					1	
Tetracyclin HCl	before 1957	before 1957	1967	3	13	
Tetracycl n phosphate		1962	1969	1	1	
Oxytetracyclin HCl	before 1957	1962	1965	3	8	
Chlortetracycline HCl	"	before 1957			1	
Lymecycline				1	2	1963(U.K.)
Doxycycline hyclate		1970	1977	2	3	1967(U.S.)
Minocycline		1971			3	1971(U.S.)
Demeclocycline		1969			1	
Midecamycin		1975			1	
Cephlexin	1973	1973	1973	11	11	1969(U.K.)
Cephaloridine	1973	1973	1973	7	7	1964(U.K.)
Cephalothin Sodium		1975		1	5	1964(U.K.)
Cefazolin Sodium		1974	1975	2	4	
Cephacetrile					3	
Cephpirin Sodium			1976	1	2	
Rifampicin		1970	1971	6	5	1969(U.K.)
Linchomycin HCl		1971			1	1964(U.K.)
Clindamycin					1	1969(U.K.)
Spectinomycin		1975			1	1971(U.S.)
Ribostamycin sulfate		1975			1	
Aminosidine sulfate					1	

Antibiotics	Year of import		Year of Synthesis	Number of synthetic producers	Number of finished products producers	Yorldly first marketing year
	As finished Drug	As Fulk				
Griseofulvin	1960	1966			5	1959(U.S.)
Nystatin	before 1957	1972			3	
Varictin					1	
Mitomycin C	1969				2	
Bleomycin	1973				1	
Sulfamethoxazole			1973	5	1	1961(U.S.)
Sulfamethoxydiazine					5	
Sulfamethoxypyridazine	1959	1962			4	
Sulfamonomethoxine		1968	1976	1	1	
Sulfadimethoxine	1962	1961	1966	1	3	
Sulfamethizole					4	
Sulfisoxazole		1958	1976	1	2	
Sulfisomidine			1976	1	1	
Sulfamethoxypyrazine					2	1969(U.K.)
Sulfadiazine		before 1957	1976	1		
Salycylazosulfapyridin					1	
Prontosil					1	
Phthalylsulfacetamide					1	
Phthalylsulfathiazole		1960			1	
Sulfamethomidine		1965			1	
P A S - Ca		before 1957	1965	3	4	
Benzoyl PAS-Ca			1973	2	1	
I N A H		before 1957	1966	4	9	

Antibiotics	Year of import		Year of synthesis	Number of synthetic producer	Number of finished products producer	Locally first marketing year
	As finished drug	As bulk				
Sod.INAH methan sulfonate			1969	3	2	
Ethambutol		1970	1973	5	9	1967(U.S.)
Prothionamide	1966	1969	1972	3	6	1966(U.F.)
Dapsone		1961	1976	1	3	
Acetarsone					1	
Nitrofurantoin	1959	1962			6	
Furazolidone					6	
Nifuratel					1	1967(U.F.)
Metronidazole		1965	1975	1		1960(U.K.)
Tetramizole		1971				
Thiabendazole		1971				1967(U.S.)
Miconazole		1972				
Tinidazole		1973				
Mebendazole		1973				
Clotrimazole		1977				
Nimorazole		1977				1970(U.K.)
Trimethoprim	1970	1970	1971	5	27	1968(U.K.)
Nalidixic acid		1969			8	1963(U.F.)
Oxolinic acid		1976			6	

.. Impact of External Policy

120. In recent years Korean pharmaceutical society has been introduced to many new concepts flowed in from the external sources such as GMP (Good Manufacturing Practice), GPSP (Good Promotional & Supplying Practice), GLP (Good Laboratory Practice), Generic Equivalency, and Drug Efficacy Reevaluation, etc.

121. Of these GMP and drug efficacy reevaluation were already taken up by the Korean government to set in the long-term implementation policy.

122. GMP : Korea is preparing for the enactment of GMP according to the recommendation of WHO and the trends of other countries. It is the view of Korean government that the implementation of GMP system is inevitable for the promotion of export as well as for the control of manufacturing process.
The government organized the GMP expert committee to prepare the appropriate one by the name of KGMP feasible for all Korean manufacturers. However, while this committee will have finished the work, every manufacturer was asked to set up and voluntarily implement his own appropriate GMP.
It is expected that KGMP will be enacted by 1981 if the fourth economic 5 years development plan is successfully completed.
On the other hand, most of the drug manufacturers have somewhat different opinion on GMP from the view point of the past experiences. They agree in principle with GMP on the concept; "The better is better". However, appropiateness is more important. So started many drug manufacturers to study the GMP with different view to find out what is appropriate, what shall be modified or what is unnecessary.

It is a general tendency of the Korean drug manufacturers that the part of the facilities of GMP shall be untouched until the necessity is confirmed by the authority on the economic & sociological background as wellas on the practical value, since the current Korean regulation for facility-standard in force is appropriate, and instead, the part of the soft management shall be positively applied. Such conceptual approach to GMP seems to be wise, for the determination of facility-requirement must be based on the full understanding of the soft management. Furthermore, it is desirable if the government asks the applicant of the product manufacturing license to submit the data and/or the methods of manufacturing pre-pared on the basic of such GMP except the part of the facilities.

13. Drug Efficacy Reevaluation:

There were severe argument & controversy whether to implement such reevaluation or not. Finally in 1975 the Ministry of Health & Social Affairs decided to do it, and established the reevaluation Committee seperated from the current drug safety committee.
In 1976 the first disclosure of the reevaluation was made unfortunately to the public. The disclosed information was handled by non-professional news reporters so simply that most of the true meaning of the result were misunderstood by the public.
The re-evaluation was implemented in such way: all the data & clinical reports were collected not from the objective sources but from the manufacturers; only the printed matters were studied in the light of the logics & the statistics without any real experiments that is to say it was a paper screening. Therefore, the results turned out to be the working for standardzation of the terminology, for example gonoccoccus in place of gonorrhea, or three to four times a day in place of several times a day etc. But the non-professional news Reporters disclosed it by the number of correction. This misled the public to have the feeling that so many drugs were false or inferior.

'24. The pharmaceutical society, being surprised at such unexpected response of the public, started to interprete the true meaning of the result through the lay press. Since then, in 1977, and in 1978, the results of the reevaluations were disclosed to the public. These times the reaction of the public was somewhat tolerable.

'25. Still, the practical value of such reevaluation has been a big issue among the professionals. It is true that it is not a kind of true evaluation of the drug efficacy. But it works for the training of the manufacturers in preparing for the scientific documentation. This shall sometimes lead to the sufficient qualification of each manufacturers to be able to make up any protocol for a clinical investigation of a drug.

Chapter 7

Public Health & Medical Insurance

A. Public Health

126. Since 1960, the health status of the Korean has been improved with the rapid economic growth. As shown in the Table 14, the average life expectancy continued to increase:

1961	1970	1976	1986
60	65	67	80

And such improvement is ascribed to the decreased crude death rate, particularly to the declined death rate of the age group 1 through 4.

127. On the other hand, the nutritional state has been also greatly improved:

	1961	1970	1976	1986	
Daily calory intake	2,000	2,370	2,500	2,712	Cal

And the physical status of the students were improved.

Table 14

[illegible] Health Indicators

	1970	1976	1980	Low Middle Income Country	Developed Country
Average Life Expectancy	65	67.4	[illegible]	61.8	71.4
General Death Rate	8.5	6.6	5.9	10.5	9.1
Death Rate of 1-4	45.3	38	[illegible]	47.5	17.0
Daily Calorie Intake	2,370	2,290	2,190	117.9%	130.3%
Daily Protein Intake	65.1	71.1	77.6	88.8	91.8
Daily Animal Protein Intake	10.6	15.2	17.7	39.6	59.8
Population per Physicians	2,107	2,011	1,245	1,382.5	868.7
per Nurse	1,742	572	405	830.3	194.6
per Dentist	14,830	13,799	6,000	...	...
per Pharmacist	2,147	2,140	2,140		
Population per Hospital Bed	969	742	550	171.6	91.1
Bed Occupancy	58.4	64.3	75	...	...
GNP per Capita ($)	242	698	1,512	1,285	4,296
Drug Consumption per Capita ($)	3.38	10.04	22	...	...

129. According to the World Economic and Social Indication (1977), it is reported that Korea stands ahead of the similar health indicators to those of the countries belonging to the upper middle income country.

130. As supplementary data for the above improvements the Korean Health Service Resources are also illustrated in the Table 14.

• Some Statistics

130. Table 15 : Number of Health Delivery System (1960 - 1976)

131. Table 16 : Korean Health Personnel Training Institution and yearly graduate as of 1977.

132. Table 17 : Number of registered health personnel & yearly increase rate. (1961 - 1973)

133. Table 18 : Patient classification of Disease (Urban vs rural) in 1975

TABLE 15

Number of Health Delivery System

(... No. ...)

Classification \ Year	1960	1963	1970	1975	1976
General Hospital	[illegible]	[illegible]	12	56	52
Hospital	128	128	233	138	144
Clinic	3,863	5,082	5,402	6,111	6,154
Dental Hosp. & Clinic	753	1,079	1,344	1,609	1,671
Sanitoria			121	208	246
Welfare Institution			912	1,[illegible]	1,137
Herb Clinic	1,779	2,247	2,443	2,385	2,378
Private Midwives			756	727	683
Health Center		189	192	1,586	1,584
Pharmacy	2,515	6,163	8,439	9,743	10,519
Druggist	11,274	1,286	3,624	3,328	3,041
Herb Drug Dealer	3,770	4,254	3,120	3,448	3,176
Restricted Drug Dealer	3,314	4,638	1,314	955	829

Korean Health Personnel Training Institutes

Classification	No. of School	No. of Yearly Graduate
Medical College	14	1,270
Pharmaceutical College	13	950
Dental College	5	240
Sub Medical College	2	80
Nursing College	14	760
Nursing Technical School	35	2,520
Nursing High School	3	146
Mid Nurse Training School		4,287
Laboratory Technical School	6	520
Laboratory Technician Junior College	1	70
Dietitians Technical School	6	400
Dietitians Junior College	1	40
X-ray Technician School	5	200
X-ray Technician Junior College	1	70
Dental Tecnicians School	3	240
Dental Technician Junior College	1	40
P. T. Technician School	1	80
P. T. Technician Junior College	1	40
Health Administration Technical School	2	160
Health Administration Junior College	1	50

TABLE 17

Number of Registered Health Personnel

	61	65	70	75	7[illegible]	Yearly increase rate (%)
Physicians	8,405	10,85[illegible]	14,932	16,26[illegible]	18,91[illegible]	8.1
Dentists	1,510	1,78[illegible]	2,122	3,51[illegible]	2,[illegible]	9.9
Nurses	8,144	8,89[illegible]	14,506	23,03[illegible]	30,2[illegible]	15.6
Aid Nurses			3,541	22,34[illegible]	10,21[illegible]	15.8
Pharmacists	5,025	10,02[illegible]	14,64[illegible]	16,58[illegible]	21,38[illegible]	1.6
Herb Doctors	3,205	2,849	3,552	2,551	2,231	1.3
Mid Wives	6,391	5,714	6,182	3,[illegible]75	4,22[illegible]	10.2
Laboratory Technicians			1,119	1,774		14.2
X-ray Technicians			678	1,213		15.8
Dental Technicians			562	930		6.1

TABLE 18

Patient Classification of Diseases (Korea)

(Urban vas Rural) 1976

	Whole Nation		Big City		Medium & small City		Rural City	
	No. of Case	%	No. of Case	%	No. of Case	%	No. of Case	%
Diseases of Digestive System	55,387	21.08	16,945	16.02	17,120	15.30	21,422	33.62
Diseases of Respiratory System	51,220	19.49	23,825	22.67	17,480	15.58	9,915	15.56
Diseases of the Skin and Subcutaneous Tissue	16,461	6.27	6,300	6.00	5,850	5.20	4,326	6.79
Diseases of Female Genital Organs	15,554	5.92	6,760	6.46	6,730	7.16	2,064	3.24
Diseases of E.N.T. Areas	14,645	5.58	5,795	5.51	6,040	6.42	2,810	4.41
Diseases of the Eye	11,468	4.37	3,355	3.19	6,915	7.35	1,198	1.88
Hypertension	11,457	4.36	4,910	4.67	3,450	3.67	3,097	4.86
Diseases of Auditory Organ	8,825	3.36	3,245	3.09	4,325	4.60	1,255	1.97
Complications of Childbirth, Pregnancy & Puerperium	8,505	3.24	3,370	3.21	3,740	3.98	1,395	2.19
Diseases of Nervous System	8,452	3.22	3,300	3.14	3,005	3.19	2,147	3.37
Other Diseases of Circulatory System	8,189	3.12	4,205	4.00	2,060	2.19	1,924	3.02
Accidents, Poisonings and Violence	7,847	2.99	3,120	2.97	2,805	2.98	1,922	3.02
Diseases of Male Genital Organs	6,457	2.46	3,565	3.39	1,860	1.98	1,032	1.62
Infective Diseases	6,148	2.34	2,740	2.61	2,185	2.32	1,223	1.92
Diseases of Musculoskeletal System and Connective Tissue	5,472	2.09	1,855	1.77	2,075	2.21	1,542	2.42
Other Diseases of Urinary System	5,437	2.07	2,890	2.75	1,018	1.08	1,529	2.40
Endocrine, Nutritional & Metabolic Diseases	4,704	1.79	1,660	1.58	1,700	1.81	1,344	2.11
Mental Disorders	4,685	1.79	2,495	2.37	1,540	1.64	650	1.02
Parasitic Diseases	4,398	1.67	1,360	1.29	1,590	1.69	1,338	2.10
Symptoms and Ill-defined Conditions	2,469	1.01	1,189	1.12	845	0.90	624	0.98
Diseases of Blood and Blood-forming Organs	2,444	0.93	1,085	1.03	815	0.87	544	0.85
Neoplasm	1,514	0.58	745	0.71	495	0.53	274	0.43
Congenital Anomalies	535	0.20	215	0.20	335	0.36	109	0.17
Certain causes of Perinatal Morbidity and Mortality	318	0.12	108	0.1	115	0.12	95	0.14

C. Medical Insurance

134. The Korean National scale medical insurance system was materialized in July 1 in 1977.
And the period of one full year from July 1977 to June 30 1978 was analyzed to evaluate the efficiency of the system.
As a result, it was announced that the first year of the Korean Medical Insurance was successful, and the basic policy of the government should be continuosly implemented.

135. During the first year period, the compulsory system was applied to every employees working in the big scale enterprises, which has more than 500 employees:

The total policy holder	1,232,000
The dependent	2,027,000
Sum	3,259,000

The number of men treated annually was / 9,300,000 during the term through 212 insurance hospitals, and the financial state was found to be still far from being in shortage.

136. The government's plan was to increase the number of the insured from 3,259,000, 10% of total population in 1977 up to 10,102,000, 20% of the 1979 - population.
To achieve this, the compulsory system must be applied to the small scale enterprise who has more than 200 employees.

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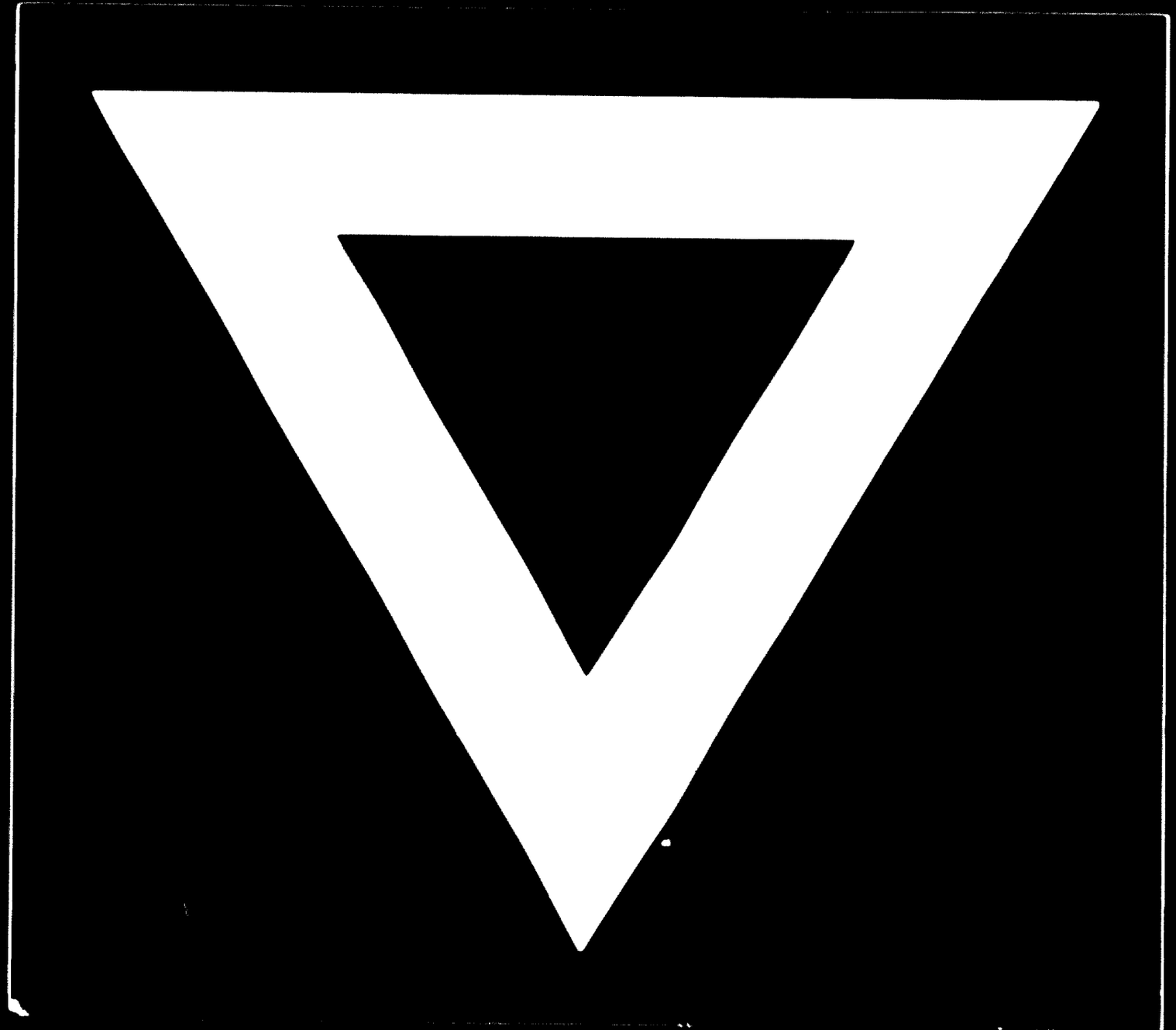

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