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STUDIES ON THE TRANSFORMATION OF THE RUSSIAN PHARMACEUTICAL INDUSTRY TO A MARKET ORIENTED SYSTEM

TF/GLO/92/010

The Russian Federation and the City of St. Petersburg

TERMINAL REPORT*

VOLUME 2

Prepared for the Government of the Russian Federation
and the City of St. Petersburg
by the United Nations Industrial Development Organization

Based on the work of ICN Pharmaceutical Inc.

Backstopping Officer: Dr. Zoltan Csizer
Chemical Industries Branch

* This document has not been edited.

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THE PROCESS OF CONVERSION - CHALLENGES TO THE CONVERSION OF THE PHARMACEUTICAL INDUSTRY IN RUSSIA

ACKNOWLEDGEMENT

In May 1992, Anatoli Sobchak, Mayor of the City of St. Petersburg, Russia, submitted a request to United Nations Industrial Development Organization (UNIDO) that a study of the current state of pharmaceutical production and distribution in that city be conducted. Due in large measure to the encouragement of Jack L. Gosnell of the Consul General of the U.S., resident in St. Petersburg, UNIDO engaged a western pharmaceutical firm as a partner in this project, ICN Pharmaceuticals, Inc. of Costa Mesa, California. The Russian Ministry of Health requested UNIDO to expand the scope of the project to include the entire Russian pharmaceutical industry sector. In April 1993 the UNIDO/ICN study team completed the project report in draft form. In June 1993, the preliminary findings and recommendations of the UNIDO/ICN study team were presented at a briefing for Member States at UNIDO headquarters, Vienna, Austria, co-chaired by Mr. Charles W. Warner, Deputy Director General, UNIDO and Mr. Milan Panic, Chairman, ICN Pharmaceuticals, Inc.

Detailed industry sector analysis require a broad range of expertise in a myriad of subjects. Assembling such a team of experts is as unique a challenge as an intended study, and equally important. UNIDO and ICN take particular pride in the team of international experts assemble for their study of the Russian pharmaceutical industry sector. The UNIDO/ICN study team was unique in both its composition and contribution, bringing together for the first time international pharmaceutical experts, as well as political, economic and regulatory specialists. The contribution of this uniquely qualified team is evident in the following project report, *"STUDIES ON THE TRANSFORMATION OF THE RUSSIAN PHARMACEUTICAL INDUSTRY TO A MARKET ORIENTED SYSTEM".*

This UNIDO report should be considered significant in its content. Not only does the study present a candid assessment of the current state of the Russian pharmaceutical industry (the first of its kind), it also makes a series of recommendations, believed by most participants in the project to be fundamental to the transformation of this former state-controlled industry into a more market-oriented system.

In addition to these recommendations this UNIDO report contains a detailed business strategy developed by ICN for a proposed joint venture with a specific Russian pharmaceutical firm, OKTYABR. The ICN OKTYABR joint venture is the first attempt to implement many of the UNIDO/ICN study team recommendations in an actual commercial project. Although the success or failure of the ICN OKTYABR joint venture will be influenced by a variety of factors, the project will shed some light on the effectiveness of the recommendations in the report and the seriousness of the Russian Federation in market reforms. In short, the ICN OKTYABR joint venture is a benchmark by which to measure Russia's progress in its transition to a more market-oriented economy.

All which follows is the result of the efforts of the UNIDO/ICN study team. UNIDO/ICN take pleasure in acknowledging those organizations and individuals who comprised that team:

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SECTION I

OVERVIEW OF THE PHARMACEUTICAL INDUSTRY IN RUSSIA

A. LEGAL ASPECTS

1. Structure of the Ministry

Upon the dissolution of the former U.S.S.R. and the formation of new independent states, the Government of the Russian Federation decided to develop new structures for the management of the national economy. The former Soviet Ministry of Medical Industry was restructured and transferred to the jurisdiction of the Russian Ministry of Public Health Care (hereinafter the "Health Ministry").

By a decree of President Yeltsin dated December 5, 1991, the Medical Industry Committee ("MIC") was created within the Health Ministry and given authority over the development and production of drugs and medical and related articles. The MIC is charged with improving the system of supplying health care and medical products to health care institutions and to the public.

The functions of the MIC are the following:

- promulgating measures to apply international standards in the development, production, testing and quality control of drugs and medical equipment;

- determining, in collaboration with other subdivisions of the Health Ministry, the state needs for pharmaceutical products, medical equipment and related articles; determining supplies of these products in Russia;

- arranging delivery of medical products for the state needs of the Russian Federation;

- preparing suggestions for state divestiture and privatization of medical industry enterprises;

- preparing suggestions on price regulations for medical products.

- carrying out state investment policy in the field of medical industry;

- preparing suggestions on the use of foreign currency funds for the purchase of vital imported drugs and medical equipment, as well as for the import of raw materials and production equipment;

- developing regulations and other measures applicable to the medical industry;

- organizing international cooperation and foreign economic relations, including recommending joint ventures.

Several state-owned corporations are within the jurisdiction of the MIC, as well as state organizations charged with the distribution of pharmaceutical and related products to the hospitals and medical institutions of the Russian Federation and to the public. Although previously formed as joint ventures under the laws of the USSR, the preferred form of business currently is the joint stock company or limited liability company. Joint ventures do remain viable where required to re-register in either of these forms. (See Presidential Decree No. 721 of 1 July 1991, "On measure to transform state enterprises and their free associations into joint stock companies".)

Under the present structure, the entire cycle of pharmaceutical product design, production and delivery is controlled and coordinated by the Health Ministry, through the MIC. Over 90% of the total amount of drugs produced in Russia are produced at enterprises which are part of the Health Ministry.

A presidential decree, "On the liberalization of external economic activity in RSFSR" of 15 November 1991, has significantly increased the opportunity for cooperation with foreign pharmaceutical companies. The monopoly of the state has been abolished and many limitations on purchasing drugs abroad have been eliminated. The state has kept the control over the quality and assortment of drugs imported into the country. The Health Ministry, during a two-month period in 1992, granted licenses for the import of drugs valued at over $33 million to over 150 organizations.

2. Effects of Central Planning

Under the regime of the former U.S.S.R., the pharmaceutical industry was subject to a centralized system of planning, distribution and supply. During the current period of transition to a market economy, the system of centralized determination of the need for drugs and medicinal products has been maintained. This function rests with the Health Ministry which sets orders for the amount of domestic production, for the import of essential products not produced in the country, and for the distribution of imported and domestically produced drugs.

3. Company Law

The Russian Law, "On enterprises and entrepreneurial activity", of 25 December 1990 provides for different forms of business entities: state enterprise, municipal enterprise,

individual private enterprise, full partnership, mixed partnership, joint stock company of closed type (company with limited liability), joint stock company of open type, leased enterprise and associations of enterprises.

Enterprises may engage in any activity unless it is specifically restricted or forbidden by law. Certain types of activities, e.g. production and distribution of narcotics, poisons and other substances of strong effect, may be conducted only by state enterprises. The Council of Ministers may require licenses for conducting certain activities.

At present practically all pharmaceutical enterprises are state joint stock companies, though drugstores (apotekas) in many cases are owned by municipalities or by private companies.

The Presidential decree #721, "On measures to transform state enterprises and their free associations into joint stock companies" of 1 July 1991, obliged state enterprises to reorganize as joint stock companies, except those which cannot be privatized in 1992-1993. All shares in such joint stock companies are considered as state property until they are privatized in accordance with the laws on privatization.

4. Antimonopoly Laws

The existence of Antimonopoly laws is important in a country like Russia with its exceptionally high degree of vertical and horizontal concentration. The set of laws in this area includes the Law "On the Competition and Limitation of the Monopolistic Activities on the Commodity Markets" of 22 March 1991 and a number of regulations, including procedures for the regulation of prices of the products of monopoly enterprise and procedure for the formation of the State Register of monopoly enterprises.

The Law prohibits both horizontal and vertical agreements. However, it exempts agreements if the parties can show that they promoted large supply of the commodities for domestic market, improved the quality of goods and increased their competitiveness. This provision allows much room for interpretation.

The Law provides for the possibility of a forced break-up of monopoly enterprise by the Antimonopoly Committee, requires it to monitor merger of enterprises for Antimonopoly implications, and allows it to set prices or price ceilings for goods produced by monopolies.

The Antimonopoly Committee, following the criteria established in the Law "On Competition and Limitation of the Monopolistic Activities on the Commodity Markets" and regulations may include an enterprise in the State Register of Monopoly Associations and Enterprises, regardless of the form of ownership. The prices of certain types of goods and services produced by such enterprises are controlled either by setting maximum prices or maximum multiples for any price increase. The prices of any other goods produced by monopoly enterprises are set by applying a maximum allowable level of profitability for 1992-1993. For monopoly enterprises producing pharmaceutical and medical equipment, the level of maximum profitability is set at 30%. However, the Ministry of Economy has the right to change the allowable profit margins upon agreement with relevant ministries and departments if conditions for the cost of producing and marketing goods change.

The government can waive the maximum profitability levels for goods that represent an increase in quantity from the previous year. It may also waive the limits for three years for new products made under patented invention or a new high-cost production process.

The Law provides for financial, administrative and criminal liability for violating Antimonopoly regulations.

5. Property Law

The Law, "On ownership in the RSFSR" of 24 December 1990, was a major shift from the dominance of state property: it introduced the principle of private property on land, buildings, securities, enterprises, equipment, means of transportation, etc. The Law abolished the preferential treatment of state property and guaranteed equal protection for all forms of property. Foreign individuals and legal entities are granted the same property rights as Russian nationals unless the law specifically states otherwise. (See, generally, the Law In Foreign Investment.) Thus, foreigners may acquire in their own names enterprises, buildings, intellectual property, inventory, etc.

The private ownership on land remains to be quite a controversial issue. The 1991 Land Code recognized the right to use land under lease agreements; a right to permanent or temporary use for a specific purpose; an inheritable right of lifetime possession without right to sell and right of ownership. The privatization legislation significantly enlarged those rights. Pursuant to the 14 June 1991 Decree, "On procedure of sale of land plots during privatization of the state and municipal enterprises, expansion and construction of these enterprises, as plots granted to individuals and their associations for entrepreneurial activity", Russian companies as well as foreign investors are allowed to purchase both the enterprise which is subject to privatization and the plot of land this enterprise is located on. The Decree also permitted the acquisition of land for expansion of enterprise but only through competitive tenders or auctions. The Decree "On Urgent Measures to Implement Land Reform in Russia" of 27 December 1991, provided for giving farm land to private farmers.

Russia has a law on security interests ("Law on Pledge" of January 1992) which provides for the securing of obligations with a broad range of property and property rights, including interests in land with a variety of commercial arrangements (loan and sale agreements, rental and transport contracts, etc.).

6. Intellectual Property

i) Patent protection

The Supreme Soviet of the Russian Federation adopted the Patent Law of the Russian Federation of 23 September 1992.

Under the Patent Law, the Russian State Patent Department is charged with carrying out the policy of protecting industrial property as determined by the Patent Law. A patent is valid for 20 years from the date the patent application is received by the Patent Department. When a patent application is received, the Patent Department is required to begin its formal examination within 2 months. The Patent Department is required to publish its decision within 18 months of the receipt of the patent application.

The following items may be the object of a patent: a new device, method, substance, micro-organism or biological strain, or culture of plant or animal cell, or a new application of a known device, method, substance or biological strain. New sorts of plants or breeds of animals are not patentable inventions. An invention will be granted legal protection if it is new, reflects a requisite level of invention, and has industrial application. A patent may be granted directly to the author of the invention, or to the author's employer where the invention was developed in fulfilment of the author's duties as an employee.

If the patent owner does not sufficiently apply the invention during a 4-year period, any person can petition to the Higher Patent Chamber to grant a forced non-exclusive license, where the patent owner has refused to sign a license agreement. If the patent owner cannot demonstrate that the non-application or insufficient application of the patented object is warranted by substantial cause, the Higher Patent Chamber may grant a license and will set the terms and conditions of the license, including time period and payments.

ii) Trademark protection

The Law on trademarks, service marks and signs of origin of goods was adopted on 23 September 1992.

This Law recognizes the registration of the trademarks and service marks made by the USSR authorities with certain exceptions. According to the Law, a trademark is a verbal, graphic, volumetrical or other designation or their combination. A trademark may be registered in any colour or combinations of colours.

The Law specifies the list of cases when the trademark may not be registered. There are several "absolute grounds" for declining the application: the trademark may confuse the customer in respect of the goods or their qualities; it is against morality or the public interest; it represents common symbols and definitions; it does not have the capacity to distinguish goods, etc.

The Law provides for other grounds for refusal of registration. A trademark may not be registered if it is identical or similar to the extent of being confused with: a) trademarks previously registered or applied for in the

USSR in the name of another person with respect of goods of the same kind; b) trademarks of other persons protected without registration by virtue of international treaties of the Russian Federation; c) names of places of origin of goods protected in Russia except when they have been incorporated as a non-protected element in a trademark registered in the name of the person having the right to use this name; d) registered certification marks. Designations may not be registered as trademark if they: reproduce industrial designs; are names of works of art and science well-known in Russia without consent of the copyright owner; or are names, pseudonyms, portraits, etc. of well-known persons without the consent of the latter.

An application for a trademark registration must be filed at the State Patent Agency of the Russian Federation ("Agency"). Foreign legal entities and individuals must conduct all related activities through the patent agents registered at the Agency.

The priority of a trademark is established at the date of the receipt of the application by the Agency, or at the date of filing the application in a foreign country which is a participant of the Paris Convention for the Protection of Industrial Property of 1883 (USSR joined the Convention in 1973) if the application was received by Agency in Russia within six months of the said date. The Law also provides as well for the possibility of exhibition priority.

The application goes through expertise, the results of which can be appealed. If the decision is made to register the trademark, the Agency includes the trademark and relevant information in the State Register of trademarks and service marks of the Russian Federation and within three (3) months of such registration issues a trademark

certificate. The information on the registration will be published by the Agency in the official bulletin.

The certificate protects the trademark during a ten (10) year period counting from the date of the receipt of the application at the Agency. This period may be extended upon the application of the owner of a trademark, each time for ten (10) years.

A certificate certifies the fact of the registration of a trademark, its priority, the exclusive right of the owner to a trademark with respect to the goods specified in the certificate. No one else can use registered trademark without the consent of its owner. A trademark infringement includes unauthorized manufacture, use, import, offer for sale, sale, other introduction into the stream of commerce or storage with this purpose of a trademark, or a good designated with the registered trademark, or designation similar to the extent of produce confusion with respect to the similar type of goods. However, the owner of the trademark cannot prevent the use of the trademark by other persons, in respect of the goods introduced into the stream of commerce with the consent of the owner of the trademark.

Trademark infringement may generate civil and criminal liabilities. The legal remedies include injunction and compensatory damages; the publication of the court decision in order to restore the business reputation of the plaintiff (an extremely unusual measure for the Russian law); as well as removal from the goods of the illegally used trademark.

To preserve a trademark, the owner must use it. Any interested legal or physical person may file an application with the Patent Chamber asking to terminate the registration if the owner fails to use the trademark

uninterruptedly for five years from the date of registration or five years preceding the filing of such application.

The Law gives the description what is considered to be the use of trademark. The list includes the application of the trademark on the goods (and/or on their packing) for which the trademark has been registered by the owner of the trademark or by the person who has a license to use it; the application of a trademark in advertisements, printed publications, letterheads, signboards at exhibitions, etc.

Legal entities and individuals conducting middleman activities may use their own trademark together with the trademark of the producer of the goods, or instead of the trademark of the latter, if there is a corresponding contract between them.

A trademark may be transferred to any legal or physical person with respect to all or part of the goods for which it has been registered. The transfer is not permitted if it might deceive a consumer as to the goods or their manufacturer.

The right to use the trademark may be included in a license contract, which in this case must include a condition that the quality of the goods of the licensee will not be lower than the quality of the goods of the licensor and that the latter will effectuate control over the fulfilment of this condition. Both the agreement on transfer of trademark and license contract must be registered at the Patent Agency. Otherwise, they are void.

Foreign legal and physical persons enjoy the rights provided for by the Law equally with Russian citizens by virtue of the international agreements signed by the

Russian Federation or the principle of mutuality. If an international treaty signed by Russia provides for different rules than established in this Law, the rules of the international treaty will apply.

7. Currency Regulation

The monetary system of Russia and the scope of permissible use of hard currency is governed by the Law on Currency Regulation and Currency Control of 9 October 1992, the Law on Monetary System of Russian Federation of 25 September 1992 and certain instructions of the Central Bank of Russia.

The ruble is a primary currency in Russia, but limited legal circulation and use of foreign currency is permitted. Significant distinctions are made between residents and non-residents of Russia. Residents may have foreign currency accounts only at authorized Russian banks; foreign currency accounts abroad may be maintained outside Russia only by special permission of the Central Bank.

Foreign currency may be purchased and sold in Russia through the network of authorized Russian banks. Residents and non-residents are subject to different levels of restrictions on currency trading and remittance of foreign currency abroad.

A new Presidential Decree #1306, "On goods (work, services) for sale to citizens for hard currency on the territory of the Russian Federation", of 27 October 1992, and related instruction of the Central Bank of Russia dated 20 January 1993, No. 11, intended to tighten control over foreign currency settlements for the sale of goods and services within Russia, and particularly such settlements between resident entities and individuals. In various ways, including imposition of new registration

requirements upon sellers of goods and services for hard currency, the new rules attempt to advance the government goal of replacing hard currency transactions with ruble payments.

All resident companies in Russia, whether they are wholly or partly owned by foreigners, are subject to the mandatory conversion to rubles of 50% of their gross hard currency revenues from export of goods and services. Companies with 30% or more of the foreign ownership are, however, permitted to sell the entire 50% portion at the rate of exchange they might negotiate with authorized Russian commercial banks, while all other companies have to sell 30% of the 50% to the Central Bank at the official rate of exchange. Currently there are discussions on increasing the portion of mandatory conversion to up 100%.

8. Export and Import Regulation

Decree "on licensing and quotas for export and import of goods (services) on the territory of Russian Federation in 1993", No. 854, of 6 November 1992, established a uniform procedure for licensing and obtaining quotas for the export and import of goods and services for 1993. The Decree covers operations with all foreign countries including republics of the former Soviet Union.

Licenses are granted by the Ministry of Foreign Economic Relations after the contract with the foreign trading partner is already signed or has been initialed. The shipment of goods for export is allowed only after the license is granted.

There are four categories of goods where licenses, and sometimes quotas are needed for export or import operations. Seventeen (17) groups of goods representing the most significant part of Russian export (metals, timber, some chemicals, fish, etc.) can be exported with a license only within quotas established by the Ministry of Economics. Quotas not used by its

holder can be sold by the Ministry of Foreign Economic Relations at auctions.

Nine (9) groups of goods may be imported and exported only with licenses granted pursuant to special procedures approved by the Russian government (arms, military equipment, precious metals and stones, narcotics, etc.).

Three (3) groups of goods (wild animals and plants, drugs and collection materials on mineralogy) and one group of services (information on mineral, oil and gas deposits on Russian territory) require export licenses.

Two (2) groups of goods need import licenses (chemical substances for the protection of plants and industrial waste).

Export and import of pharmaceutical products is carried out only after receiving the approval of the Health Ministry.

Not every owner of certain products can export them. There are a number of so called "strategically important goods" which, according to the Presidential Decree "On export procedure of the strategically important goods", of 14 June 1992, can be exported only by the companies registered specifically for this purpose at the Ministry of Foreign Economic Relations. All other owners of the goods on this list, in order to export them, must use these registered companies as intermediaries, paying a commission rate established by law.

The import of certain products, including pharmaceuticals, are subsidized by the government if these goods are part of the centralized import, i.e. purchased with state hard currency resources either allocated for these purposes by the government or with resources obtained as loans guaranteed by the Russian government ("The Procedure for Settlements and Subsidies applied

to centralized imports" #73 of the Ministry of Finance of 14 August 1992, effective as of 1 September 1992).

Russia has new rates of custom duties on import tariffs introduced by Presidential Decree No. 340 on 15 March 1993, as applied since 1 April 1993. All pharmaceuticals are exempt of import duties.

There is a vast list of goods subject to export duties. This list is periodically changed by the Government (Decree No. 461 of 30 June 1992) and by the State Customs Committee (Order No. 603 of 11 December 1992). The export duties are 30% higher if goods are exported as part of a barter transaction. After 1 January 1993, the differential increases to 50%. Export duties are levied on raw goods and materials. Industrial production is exempt from export duties.

9. Environmental Law

Russian environmental law is still very weak and undeveloped. Until 1988, when the State Committee for Nature Preservation was created, there was no state agency responsible for development of environmental policy. Though there were several statutes, they were rarely enforced since the state was both regulator and owner of all enterprises causing major pollution.

The Russian Law, "On protection of environment", was adopted 19 December 1991, which has tighten the environmental regulations and increased to a certain extent the strength of some sanctions. In August 1992, the Russian Government approved the Decree "On procedure for establishing ecological norms for the emission and discharge of pollutants into the environment and the limits for the use of natural resources and for dumping waste". Now the Ministry of Ecology and Natural Resources will

be establishing certain limits of using the natural resources by every industry and, in accordance, with those limits, each enterprise will be given a permission for the emission of pollutants, the use of natural resources and for dumping waste to a certain amount only. Fines and their rates are established for exceeding of those limits. The payments for dumping within limits are considered the costs of production, while payments for extra dumping are not tax deductible.

The major problem in Russia is lack of available resources and technology for evaluation and cleanup. The enterprises forced by legislation to cleanup damage very often are unable to do it because they lack technology and expertise.

10. Consumer Protection

Russia has a "Law on the Protection of Consumer Rights" of 7 February 1992, which sets up rather high standards of protection. According to the Law, the quality of manufactured goods or services should comply with state quality standards or "common standards". If the goods may affect the health and safety of people or environment, they are subject to compulsory certification. The Procedure on Confirmation of Safety of Goods manufactured or imported into Russia adopted under this Law became effective 1 September 1992. This Procedure is also applicable to pharmaceutical products.

A manufacturer has an obligation to inform the consumer about the goods and their possible effect on health and safety. For food products, pharmaceuticals and other goods whose quality may deteriorate with the passage of time, the term of fitness for use or sale must be marked.

The manufacturer and/or seller are strictly liable for full compensation of damages sustained by a consumer as a result of

violation. In some cases, laws of Russian Federation or its republics may provide for higher degree of liability. Moral harm (i.e. pain and suffering) shall be compensated by the manufacturer or seller only if there was "fault" (presumably, it includes intent as well as negligence, but the concept is not very well developed).

There are several government agencies which control the compliance of producers and sellers with this Law: Antimonopoly Committee, Ministry of Ecology, State Committee on Standardization and Certification and others within their competence. The Law established a series of sanctions these agencies can impose on the violators of this Law.

11. Privatization

The legal basis for privatization in Russia consists of the complex and often inconsistent set of laws, decrees and regulations designing privatization procedures for state and municipal property in general as well as privatization of the specific sectors of economy (e.g., fuel and energy sector or railroad system). There are no specific laws concerning privatization of pharmaceutical industry.

A two-tiered administrative system was established in which the State Committee on the Management of State Property determines privatization priorities and reorganizes enterprises and its local subdivisions, while the newly reorganized property is held by the State Property Fund (or its local subdivisions) which is a lawful seller of shares and certificates of state property. Besides, the Law provides for the creation of privatization commissions allowing for input from labour, management, local authorities and privatization experts.

The Law recognizes four methods of privatization: sale by competition, sale by auction, stock offerings and buying-out of the leased property. The State Privatization Program for 1992, adopted on 11 June 1992, establishes criteria for determining privatization methods; categories of enterprises subject to privatization in 1992 and those which can not be privatized; benefits offered to employees; payment arrangements and use of privatization proceeds; use of foreign investments in privatization, etc.

The privatization of a large enterprise involves necessarily the corporatization, i.e., transformation of the state enterprise into a joint stock company of open type. The Law provides for three basic options: according to the first one, employees are given, free of charge, non-voting preferred shares representing 25% of the face value of the capital of the new corporation; they have the right to purchase another 10% at 30% discount, and managers have the right to purchase another 5% of the stock. The second option gives the employees, including managers, the right to purchase common shares representing 51% of the face value of the new corporation. (The nominal price is determined by a coefficient of 1.7 times the 1992 prep value.) The third option gives a right to purchase 20% of the voting shares at 30% discount; the right to vote 20% of the stock held by property fund; the remaining 60% will belong to the state. Whatever option is chosen, shares are to be sold to the employees in a closed subscription. The shares may be sold by the employees to third persons without any restrictions.

The rest of the shares are to be sold to outside investors in a competitive tender organized by the State Property Committee. Direct sale to a single bidder through negotiations are not permitted. The terms of the tender may impose obligations such as maintenance of employment levels, future investments in the enterprise, continuation of the product lines, etc.

Pursuant to a Decree of the Government, #490, "On procedure of introducing the system of privatization checks" of 15 July 1992, on 1st October each Russian citizen is entitled to receive a voucher (privatization check) with a face value of 10,000 rubles. The vouchers may be used by the holder to purchase the shares in a privatized enterprise or in specialized investment funds. The Presidential Decree #914 (of the same name as the Government's Decree) of 14 October 1992, established that depending on the property (federal or republican), from 35% up to 80% of the shares of privatized enterprises may be purchased with vouchers.

12. Taxation

The Enterprise Tax Law was the USSR's first tax law of universal application, applying to all forms of business, including both foreign and domestic enterprises of all types. It was adopted in June of 1990. The law provided for worldwide taxation of income of USSR enterprises and for an excess profits tax, an import-export tax, and other changes. The law contained a large number of favourable provisions designed to attract foreign capital. These provisions applied to enterprises with more than 30% foreign ownership and included tax holidays in special trade zones and other special rules.

In December 1990, Russia, in line with its declaration of sovereignty, adopted legislation that replaced the USSR's Enterprise Tax Law with a Russian tax law.

A brief description of the elements of taxation of various entities under the current Profits Tax law follows.

i) Joint Stock Societies, Joint Enterprises and other "Corporate" Business Forms

Until 1990, joint stock societies did not exist. In addition to State Enterprises and Cooperatives, joint

enterprises were possible between Russian and foreign persons under USSR Decree 49. Russian law eliminated the USSR joint enterprise as a business form, though thousands of "grandfathered" joint enterprise continue to exist and operate.

The tax rates under the Profits Tax Law for all foreign and domestic enterprises is 32%, regardless of the level of foreign ownership. Profit from "middleman" activities, however, is taxed at the higher rate of 45% (apparently, middlemen do not include entities that buy and resell, but only commission agents). (The proposed Income Tax Law would substantially lower the tax rate to 18%. Under the proposed law, the Republics within the Russian Federation would be permitted to vary this rate, not to exceed 18%. Also under the proposed law, income from auditing and consulting services is to be taxed at 25% and income from trading, brokerage and middleman activities at the 45% rate. A special five (5) year exemption would be provided in connection with gain from the use of new technology licensed or created by an enterprise.)

Limited tax privileges are provided under the Profits Tax Law in the case of reinvestment of an enterprise's current profit in certain areas; for example, to increase production capacity in the oil sector or to reconstruct facilities previously engaged in military production. However, unlike privileges granted taxpayers under the prior Enterprise Tax Law, there is now a cumulative limitation on all special privileges, which may not, in the aggregate, decrease the tax otherwise due by more than 50% in any year.

In order to attract foreign investors to invest in Russian enterprises, the former Enterprise Tax Law contained tax holidays, preferential rates as well as substantial

benefits that came from the methods of calculating expenses such as depreciation, and in paying the tax in rubles using favourable exchange rates that were available to foreign owned Russian enterprises. The former Enterprise Tax Law allowed an expanded list of deductible expenses to more than 30% foreign owned joint enterprises. For example, in addition to deducting costs of labour and materials and other direct costs, the law allowed those enterprises deductions for interest on non-shareholder debt, special, favourable depreciation rates, deduction for employee social insurance costs, R&D, environmental clean-up expenses, and other expenses. Rent was also specifically deductible.

A critical five year tax loss carry forward was also available to these joint enterprises as a means of recouping anticipated start-up losses.

The current Profits Tax Law reduced or eliminated almost all of these significant benefits. In fact, under one particularly troubling provision of the Profit Tax Law, there is an <u>increase</u> to an enterprise's taxable income of amounts paid to workers in excess of a multiple of certain Russian minimum wage levels. The provision is the equivalent of making non-deductible salaries paid to workers in excess of four times the Russian minimum wage, thereby artificially increasing taxes.

This limitation on the deduction of wages does not apply to foreign persons with Russian branch operations or to wholly foreign-owned Russian joint stock societies, making these forms of doing business substantially more desirable than a Russian company of Russian ownership or of mixed Russian-foreign ownership.

ii) Foreign Entities: Russian Branch Operations

Under the Profits Tax Law, if a foreign company "effectuates economic activity" through a local "representation" (including either an office or other place of business as defined under local Russian rules), it will be subject to tax on "net income." Otherwise, under the Profits Tax Law, a foreign company will be taxed at a rate of 15% on gross interest and dividends and 20% on gross on other items of Russian source income (including rent, royalties, etc.), collected through a withholding mechanism.

Russia has taken the position that it wishes to succeed to the rights and duties of the Soviet Union's income tax treaties. Consequently, if a foreign investor were incorporated in one of approximately twenty-five countries that had an income tax treaty with the USSR, the foreign company would still be protected by the treaty with the USSR. Generally, this means that the company would not be subject to a tax on net income unless its Russian presence constituted a "permanent establishment" under the terms of that particular tax treaty. Additionally, an income tax treaty might reduce or eliminate some or all of the withholding taxes. For example, the UK-USSR Treaty completely eliminates the withholding tax on dividends.

Operating branches of foreign companies, typical in the West, were not permitted in Russia until very recently. Foreign companies could, in effect, perform economic activities in Russia only to fulfil specific contracts, usually involving performance of services under contracts with Russian parties. Now legislation permits the possibility of foreign enterprises engaging in trading and even manufacturing activities or other business in Russia

in branch form, requiring registration of the branch in each jurisdiction in which it operates.

If a branch arranges its activities in Russia in such a way as to cause it to have a representation for tax purposes, it must file a tax return. Under the Profits Tax Law, it would be subject to a 32% tax on net income by attributing both income and expenses to the operation under Russian rules. Middlemen are subject to tax at rates of 45% but, as noted earlier, it may be that only commission agents are included in this designation. A foreign company with a taxable Russian presence can apply for a tax ruling to permit the foreign company to pay its tax on a base of income equal to 25% of gross receipts or gross expenses (up from 15% in 1991), provided it can convince the tax authorities that net income cannot otherwise reasonably be determined.

iii) Foreign-Owned Joint Stock Societies

The former Enterprise Tax Law afforded 100% foreign-owned Joint Stock Societies the same favourable tax treatment afforded by the USSR to joint enterprises with foreign ownership in excess of 30%. As noted, that included interest and wage deductions, a two-year tax holiday, special depreciation allowances, a five-year net operating loss carryforward period, without any 50% aggregate limitation on the use of such tax "privileges." Practically, however, there is no favourable taxation treatment for foreign-owned joint stock companies, except in special trade zones.

iv) Export Tariffs

On 30 June 1992, the Russian Government established a list of export tariffs for a range of goods. The tariffs apply

from 1 January 1993. They replace the Export-Import Tax originally imposed under the USSR's Enterprise Tax Law and later incorporated into the Russian tax system (for 1991) by a decree of the Russian Council of Ministers. (See, Order No. 603 of Custom Committee of 11 December 1992.,

The tax applies to almost all natural resources and in some cases is measured in ECU's per unit of weight or volume and can be quite high - for example, almost $5 per barrel of oil or 30 ECU per ton. These amounts have been (and will continue to be) regularly changed by the Russian government. Some exceptions have been made. For example, in Karelia, by special decree of President Yeltsin, the tax can be eliminated where the production is sold to pay for certain goods - such as equipment, food, etc.. Similarly, in certain oil investments in joint enterprises registered prior to 1992, the tax on exports is eliminated until start-up expenses have been recouped.

Pharmaceuticals are subject to tariff in the amount of 5% per unit cost, also raw materials and chemicals used in their production may be subject tc tariffs.

v) Value-Added Tax (VAT) and Excise Tax

In December 1991, the text of Russia's first value-added tax was published. It replaced an existing turnover tax and a national sales tax. The VAT was initially set at a 28% rate for sales at unregulated prices and at 21.88% for regulated ones. The rate was reduced to approximately 20% for most goods from January 1, 1993. The VAT applies to barter exchanges as well as to cash sales and, like Western European VATs, does not apply to exports (sales of goods outside of the CIS Economic Community). The VAT has applied to imports since 1 February 1993. A list of goods

such as medicines is to be maintained the sale of which is exempt from VAT.

No VAT exemption appears to apply to capital goods so that their acquisition from domestic persons results in a permanently non-recoverable charge. This appears to be unusual in the case of European VAT laws which generally appear to permit recovery of all VAT paid against VAT received on sales of the manufacturer's goods. (All VAT is ultimately borne by the consumer.) Some consideration appears to be ongoing to permit recovery of VAT paid on capital goods against VAT received from the sale of a company's production, over a period of time. It is unclear whether consideration is being given to granting relief from current rules in the case of a producer of goods, the sale of which is exempt from VAT.

vi) Import Tax

An import duty of 15%, up from 5%, applies to most goods. Medicines, food stuff, medical materials and equipment; and non-ferrous metals products are exempt.

vii) Property Tax

The recently enacted Property Tax that calls for an additional tax of 1% per annum on the gross asset value of a Russian enterprise will also discourage investment. For example, in connection with a new investment of $50 million in plant and equipment, an enterprise would pay $500,000 per year in property tax.

viii) Enforcement and Penalties

There are extensive provisions on enforcement with administrative, civil and criminal penalties. For example,

the penalty for late tax payments is calculated at a rate of 0.2% per day - over 70% per year. Wilful failure to register for tax purposes can result in a forfeiture of all profits and criminal sanctions.

ix) Taxation of Foreign Investors

Under the Profits Tax Law, withholding taxes at 15% rate are imposed on interests and dividends. Royalties and lease payments are taxed at 20%. USSR tax treaties may provide that royalties and interest are to be low taxed or exempt from withholding tax, assuming the recipient does not otherwise engage in business in Russia through a Russian "permanent establishment". A joint enterprise or joint stock society would not itself constitute a permanent establishment for this purpose.

B. TECHNICAL ASPECTS

1. Size of the Industry; Types of Production

The pharmaceutical industry in Russia consists of over sixty different enterprises, many of which are made up of several "subsidiary" enterprises. Over 50% of these pharmaceutical enterprises, constituting approximately 66% of the total productive capacity of the pharmaceutical industry, are located in the European part of Russia. In 1991, the value of the total output of goods by the pharmaceutical industry was equal to 6.6 billion rubles. It has been estimated, however, that this production accounted less than 50% of the total health care needs of the country.

The Russian pharmaceutical industry produces over three thousand different types of products. About sixteen thousand

types of raw materials or semi-finished products are used in the production of pharmaceuticals and related products.

2. The System of Selling Pharmaceuticals on the Russian Market: the Wholesale and Retail Network

The appearance of new forms of ownership and the new economic relations being established in Russia are causing serious structural and organizational changes in the system of selling pharmaceutical products in Russia. At the time of this writing many new laws and regulations are being considered that will affect wholesale and retail distribution of pharmaceutical products, as well as the price of these products. The government's policy of price liberalization has caused the prices of many drugs to rise considerably, which in turn has led to a significant reduction in demand and in the volume of sales.

The network for selling pharmaceuticals in Russia is a multi-level structure. Within the Health Ministry, two state associations, "Pharimpex" and "Rospharmacya", play the leading role. Pharimpex is in the process of transforming into a joint stock company which will subsequently be privatized. Pharimpex is charged with organizing the drug supply for health care institutions and for the public and with developing the price structure for the products supplied through its system. It also supplies imported drugs and medicinal articles, and is authorized to enter into contracts with foreign firms. Rospharmacya fulfils the function of supplying the health care institutions and the general population with domestically produced drugs and medicinal products. Distribution is carried out by 88 territorial production associations known as "Pharmacya". In addition, there are 140 pharmaceutical depots throughout Russia. The retail network consists of approximately fifteen thousand drugstores, over six hundred pharmaceutical shops, and approximately four thousand pharmaceutical stations. Many other specialized structures exist; for example, the Ministry of Communications,

Ministry of Defense and other administrative agencies operate pharmaceutical administrations.

Russia must import a considerable amount of drugs which are not produced domestically. The Russian pharmaceutical industry does not produce, for example, insulin preparations, certain hormonal drugs, and many types of drugs for the treatment of cancer. The industry satisfies approximately 50% of domestic need; with the allowance of import purchases, approximately 70-80% of public demand can be satisfied.

3. Quality Control

The quality of pharmaceutical products on the territory of the Russian Federation is carried out by the Health Ministry. In 1992, the Board for Standardization and Control of Drugs and Medical Equipment (hereinafter the "Board") was organized within in the Health Ministry. The Board has jurisdiction over the domestic pharmaceutical industry, pharmaceutical factories, production departments of drug stores, pharmaceutical operations of other ministries, and over imported products.

The principal responsibilities of the Board are as follows:

- organizing and carrying out state control over the quality of drugs and medical equipment, including imports;

- organizing and undertaking the examination of new drugs;

- registering pharmaceutical products and medical equipment, including imported products.

The Board facilitates the activities of the enterprises and organizations of the Russian Federation including many scientific research institutes and others which are involved in the design, production and distribution of pharmaceutical products. The Board's other major responsibilities include:

- drug standardization;
- drug quality inspection;
- laboratory analysis;
- regulation and oversight of pharmaceutical enterprises.

Another department of the Health Ministry, the State Pharmaceutical Committee, is responsible for carrying clinical trials of all new domestic and foreign pharmaceutical products. No independent clinical trials of new drugs may be undertaken without the permission of State Pharmaceutical Committee.

The leading institution is the state system of quality control in the area of pharmaceuticals in the State Scientific-Research Institute for Standardization and Quality Control of Drugs (the "Institute"). The Institute is charged with overseeing quality control for all pharmaceutical products or other products related to medical care. The Institute facilitates the establishment of quality control standards.

C. FINANCIAL ASPECTS

The system of accounting which Russia inherited from the former Soviet Union was primarily one which had been geared for years to the demands of controlling the centralized command economy and therefore the requirement to produce information for

planning purposes - to meet the plans set each five years, and to plan for the future needs. In terms of the vastness of the former Soviet Union's territory, covering eleven time zones, this was considered the most effective way of managing the country and of harnessing the resources to be found in each of the (non independent) republics. The gathering of information was therefore concentrated on details of production and operational statistics, rather than any aim for fiduciary responsibility of financial reporting of the enterprise to the controlling bodies.

Furthermore, Russian and Soviet accounting is not set in a conceptual framework such as had been developed in the West. Instead, it focuses on technical accuracy in the context of a detailed chart of accounts and instructions. Accounting and bookkeeping techniques are thus based on a very standardized, clearly-defined chart of accounts and bookkeeping requirements, characterized by a cash-based double entry system and heavy reliance on statistical data. Uniformity of accounting and presentation of regular information from enterprises operating in the same type of business was paramount. In view, therefore, of the significance of such data for central planning purposes, the Chief Accountant played an important role. However, much of the monitoring of actual performance was prepared by a completely separate department, the planning department, with often little reference to the work of the accounting department.

In the context of "audit," a concept introduced by the initial law on joint ventures in 1987, the verification of the accounts was principally tax-driven, concentrating on ensuring that transactions had been posted to the correct account in the plan of accounts, rather than considering some of the principles of western audit techniques, for example, checking of accounting and management controls and validity of accuracy of transactions. This is particularly important from the viewpoint of the needs of foreign investors - a Russian statutory tax audit does not

address and cannot be seen to provide comfort on the areas traditionally regarded in the West as covered under audits.

1. Recent Developments

One of the main benefits of perestroika was that it enabled foreign investors to take advantage of the opportunities in the huge market that became available to them by encouragement of investment through preferential tax advantages and holidays for enterprises with certain levels of foreign investment, and specific rules on customs and other duties. Accounting for the operations of these enterprises in this environment acquired a new importance, with the foreign partner necessarily requiring regular and comprehensible financial information, prepared on a basis that was consistent with the accounting principles with which they were already familiar. Soviet accountants were often unfamiliar with these demands, and unable, without the guiding hand of a foreign expert, to meet these requirements.

As a first step in the new direction, on 1 January 1992, a new chart of accounts and an accounting instruction were adopted. This heralded important new developments towards western accounting principles, including many expense accruals, recognition of sales on an accruals basis and, therefore, debtors. There was also the removal of the confusing use of an unrealistic exchange rate for the rouble for accounting purposes. In 1992, a much more realistic rate set by the Central Bank of Russia has been used. The new accounts have been developed partly as a result of the demands of the foreign investors, and are seen by the authorities as an attempt to bring the accounting and reporting environment more into line with international practice. Further revisions are expected as the new requirements receive close attention from all enterprises operating in Russia.

2. Key Differences Between Russian and Western Accounting Principles

A brief description of the key differences between Russian and western accounting principles set out below concentrates on the principal elements which will be of interest to the western investor or reader of Russian financial information. It should be remembered that, as mentioned above, the practice of regular financial reporting through financial statements (including balance sheets and detailed profit and loss accounts) did not exist as we know it in the West. In the first instance, the main differences in accounting existed in the context of a lack of an overall conceptual framework for Russian accounts, that is, no consideration for the western accounting concepts of prudence, accruals/matching and going concern. Consistency of information could be considered to exist at least in part, owing to the strict allocation of transactions to designated accounts within the detailed chart of accounts. No concept of materiality, in the nature of the financial statements as a whole, existed in any form. Above all there was no western-style market to provide a basis for reliable valuations of either assets or liabilities.

Principal differences are as follows:

i) Revenue/Income Recognition

Revenue was not recognized until payment had been received. Instead, a form of "realization" account was used to record the dispatch of goods. In other words, instead of debtors (including profit), there was "goods dispatched" at actual cost (without the profit element). As a result, accounts receivable in the western sense did not exist - this had important implications for the concept of the need for provisions for bad and doubtful debts. In fact, there was no concept of a bad debt, the need for provision, or more importantly, the need for any kind of credit control.

Current practice requires recording of the sales and receivables on dispatch, and the review and valuation of accounts receivable for required provisions. This change has alone had profound implications throughout Russian enterprises this year, particularly in the context of the massive problems with the settlement of inter-enterprise debt, hyperinflation and potential bankruptcies of enterprises.

ii) Valuation of Assets and Liabilities

All assets and liabilities were recorded at their cost. No reference was made to the realizable value of replacement costs of inventories, and therefore to the concept of prudence in the preparation of accounts on a conservative basis. Thus, for inventory, there is no custom of estimating provisions for damaged, obsolete or slow-moving inventory (at a time when many enterprises are over-producing and cannot sell their inventory.) For fixed assets, the Government has recently introduced special valuation methods for enterprises undergoing privatization, which attempt to cope with inflation by indexing with various coefficients. This still falls far short of yielding reliable valuation.

iii) Cost Accounting

No system of standard costing or responsibility by profit centre existed - in addition, "cost" of an item including different costs (no distinction was made between fixed and variable costs), regardless of whether these were direct production costs or general overheads. When Russian enterprises refer to their standard costing system, they usually mean their planning department's system for developing its budget. Planning information, however, is kept largely isolated from financial reporting.

iv) Fixed Assets and Depreciation

Accounting for acquisition and depreciation of fixed assets involved not only the recognition of an asset and depreciation expense over the useful life, but also the setting up of an individual reserve in the capital section of the balance sheet. The estimated cost of capital repairs over the life of the asset was posted to a reserve, and released to expenses over the life of the asset. Depreciation was both charged as an expense as well as included in a special fund to allocate cash for the repair and replacement of fixed assets.

v) Accruals

Accounts were prepared on the basis of the cash transactions in the period, rather than any consideration of income and expenses applicable to the period irrespective of when the cash payment or receipt actually took place. Thus, for example, an annual insurance premium would have been charged to the income statement in full on the date it was paid. The change to the accruals basis of preparing accounts is one of the main recent developments.

Furthermore, there is no assessment of contingent liabilities, commitments, or provision for future losses. In other words, prudence does not form a basis for preparing Russian accounts.

vi) Funds and Reserves

Several specific funds were created in the balance sheet, and treated as capital of the enterprise. These included:

Reserve Fund - A transfer of a specific proportion of pre-tax profits, to act as a kind of general reserve against losses, etc.

Economic Stimulation Fund - This is a fund sourced from post-tax profits and created for the welfare of employees, including bonuses, social and cultural amenities, and other benefits.

One significance of these funds from a western perspective is that several categories of expenditure (which would normally be deducted from profit before taxes) are treated as movements on reserves in Russian accounts. This in effect "hides" certain income statement items that would be of interest to a western investor.

Significant differences also exist in the treatment of certain expenses for tax purposes, for example, there is a maximum amount of salary expenditure that is deductible for tax purposes.

3. The Way Forward

As discussed above, partly as a result of the need to meet the demands of foreign investors and to provide a framework consistent reporting for Russian enterprises as well as a bridge between Russian and western accounts for financial reporting of the results of joint venture, there has been a significant move towards western accounting principles in the recent legislation. International Accounting Standards form a convenient basis for this development, however, the conceptual framework has not yet been addressed. Laws on accounting and financial reporting are currently being drafted and discussed by the legislature and their advisors, but they still have a long way to go to reach broad application to all enterprises.

In addition, the need for consistency of reporting and accountability has highlighted the need for qualified auditors and auditing firms to provide opinions on the financial statements. As indicated above, "auditing" has always been more of a verification of accuracy of posting of transactions for the purposes of assessing the reliability of the reported annual profit figure. Foreign investors are demanding more detailed western-style audits. Furthermore, with these demands comes the need to regulate and provide a framework for the auditing companies themselves. The Parliament and legislative bodies are currently working on a project to establish a Russian auditing and accounting professionals, taking into consideration also the legal requirements for financial reporting.

D. CONCLUSION

The accounting and financial reporting environment in Russia has developed positively from that which existed under the former Soviet Union, more as a result of the needs and requirements of foreign investors than any indigenous desire for radical change. It still has a long way to go. The lack of experienced Russian accountants who can easily fit into the environment of the operations of a joint venture has left a gap which has needed to be filled, albeit temporarily, by western experts. The passing of their knowledge and experience to both accountants and to the training establishments and academies is critical in the nurturing of a new generation of aware and competent students of accountancy. New challenges, including price liberalization, currency convertibility, banking reform and the growth of a market economy need to be met also in the context of these developments, to ensure that Russia benefits from all aspects of foreign investment. Perhaps more importantly, foreign investors need to be comfortable that their investment can be controlled, is profitable and will show a return. Accounting and financial reporting is but a small element of this.

SECTION II

OVERVIEW OF THE PHARMACEUTICAL INDUSTRY IN THREE OTHER COUNTRIES

In an effort to provide some context and comparison for the review of the Russian pharmaceutical industry, this section briefly describes some of the legal, financial, and technical aspects of the pharmaceutical industries in what was formerly Yugoslavia, Spain, and the United States.

A. YUGOSLAVIA

The following analysis is based on statistics derived from the period immediately preceding the break-up of Yugoslavia.

1. Regulatory and Legal Issues

Yugoslavia was a Federation comprised of six republics and two autonomous provinces within the Republic of Serbia. As discussed below, the regulation of the pharmaceutical industry occurred at the Federation, republic and local level.

i) Federation

The regulatory scheme at the Federation level for the method of release of drugs, the registration of drugs, and related matters is outlined below:

(a) The 1988 Regulations detail conditions to be met by the organizations that produce drugs for marketing, these organizations have to coordinate production process, quality control, storage and distribution of drugs with the international GMP. Employees, supervising the production of drugs and raw materials

and quality control process, must be university graduates (pharmacy, chemistry, medicine).

The Regulations also regulate the storage of raw materials, packaging materials and finished drugs, as well as construction and technical conditions of the premises. The conditions for the production of sterile products are also precisely defined. Quality Control Department is an independent unit with precisely defined conditions and method of work.

The Regulations also prescribe the conditions that have to be met by the organizations performing the import and turnover of finished drugs (including the employees, space, warehouses and control).

It is also prescribed by the Regulations that all conditions of trials must be determined based on the regulations prescribed for a particular preparation and according to previously prescribed Yugoslav pharmacopoeia or according to a special method of trials established when giving the approval for release of drugs. See, The Official Gazette of the SFRY, No. 55/58.

(b) The 1989 Regulations on clinical studies of drugs prescribe the conditions under which the clinical trials can be performed. See, The Official Gazette of the SFRY, No. 2/89.

In order to perform clinical trials it is necessary to provide the following:

- laboratory findings and a list of pharmacological-toxicological trials in the factory;

- explanation of the justification of clinical trials and advantages over the therapy currently applied;

- protocol of clinical trials based on the adopted principles of clinical pharmacology;

- approvals of the republic and federal institutions competent for public health.

The trials should be organized at two clinics at least.

For a licensed drug the results of clinical trials performed in the licensor's country can be also submitted.

The Regulations also prescribe the documentation and material required for laboratory and pharmacological-toxicological trials.

A written report stating the date of commencement and competition of trials must be submitted to the Federal Ministry of Health.

(c) The Regulations on marketing of human blood, its elements and products prescribe the method of collection, processing, storage, quality and distribution of the blood. See The Official Gazette of the SFRY, No. 35/89.

A blood donor may be every healthy person from the age of 18 to 65 provided that medical checks and laboratory tests show that neither the donor's nor the recipient's health will be jeopardized.

The patients with chronic systemic or malignant diseases, persons recovered from hepatitis, type H, patients with positive test result to MBSAg, HIV positive patients and other human retroviruses along with drug addicted, homosexual intimate connections and in all other persons when transfusion of such blood causes transmissible infections.

The Regulations also prescribe the reasons for temporary exclusion of some persons from the list of blood donors.

The maximum amount of blood that one can give is 450 ml. Men may be admitted for transfusion every three months, and women every four months, monitoring hematocrit and hemoglobin count.

The Regulations prescribe the blood products, their processing, facilities and conditions required by the blood processing centres as well as storage and distribution.

(d) The Regulations on monitoring and reporting system and data to be produced relating to the established side effects in drug application, relevant forms to be submitted by the health organization. See, The Official Gazette of the SFRY, No. 57/87.

The report on side effects contains both description and laboratory findings of respective side effect, its occurrence and outcome, name of the drug (dosage, mode of administration, the beginning and the end of the therapy), drugs simultaneously used, previously reported reactions to drugs, treatment of the side effect occurred, disappearance of side

effects upon discontinuation of the therapy, repeated side effects and other significant data.

The Republic and Provincial centres monitoring the side effects submit their reports to the Yugoslav Centre for Clinical Pharmacology of the Internal Clinic - REBRO, Zagreb.

Should the side effects cause severe outcomes (death, permanent damage, hospital treatment of the patient), the Federal Ministry of Health is informed by telex immediately.

(e) The Decree of the drugs subject to a special control prior to release stipulates that each batch of the following drugs (domestic or imported) must undergo the control:

- finished drugs containing serums and vaccines,
- finished drugs containing direct blood products,
- finished drugs containing antibiotics,
- finished drugs containing cardiotoxic glucosides,
- finished drugs containing insulins,
- the first batch of each newly produced drug prior to release.

See The Official Gazette of the SFRY, No. 22/88.

(f) The Decision determining the Yugoslav pharmacopoeia - the Yugoslav pharmacopoeia was established in 1984 (The fourth edition). See, The Official Gazette of the SFRY, No. 30/84.

(g) The Regulations on prescribing and dispensing of drugs stipulate that drugs may be prescribed only by full fledged doctors and dentists. See, The Official Gazette of the SFRY, No. 57/87.

Drugs are prescribed and dispensed only on a doctor's prescription. Only special categories of drugs may be dispensed without a doctor's prescription.

Whether a drug is to be dispensed on a doctor's prescription or not, it is determined in the process of registration of the drug by the Federal Ministry of Health.

It is stipulated by the Regulations what a physician's prescription must contain, then how to write a prescription for magistrals and how and when the medicines containing intoxicating drugs are prescribed.

The Regulations further stipulate when the authorized persons (pharmacists) should sell a prescription drug, what actions the pharmacist is obliged to undertake when the prescription is not clear either in view of form of the drug, its strength, package size, etc. When dispensing a drug, the authorized person puts a pharmacy stamp, date of dispensing, drug price and his signature on the prescription.

(h) The Regulations on specific conditions for marketing OTC products. See, The Official Gazette of the SFRY, No. 73/87.

These Regulations stipulate the conditions under which OTC products can be released for marketing and this will not be the subject matter of this study.

After fulfilling all legal conditions, drug producing factories and distribution organizations are

registered by the founder with the republic Commercial Courts.

Inspection is imposed by the republics and provinces and its function is to verify that the federal regulations have been complied with.

On the federal level, health care for military persons is realized from the Army budget out of the Federal budget. This budget provides the funds for full and separate health care for all military persons and members of their family. Military health care institutions secure their income from the Federal budget, and in cases of hospitalization of civilians who are not covered by the military health insurance, by getting reimbursement for their services from the fund of the region where the person has his permanent residence. In such cases, before hospitalization or examination in a military institution, the regional fund decides whether to cover the costs of the medical treatment.

ii) The Republics

The regulatory scheme as it existed within the six republics is discussed below.

Within each of the Republic governments there is the Ministry for Health. Taking into consideration that the legal regulations stipulating the conditions to be complied with by the organizations dealing with the production and sales of drugs, as well as other above mentioned enactments, are brought on the federal level, the jurisdiction of the Republic Ministry concerns the development and maintenance of the system of health organizations, ensuring the functioning of these

organizations, and the legislative sphere in the domain of social, health and retirement insurance of the Republic's population. For this reason, there were considerable differences in the health care systems and participation levels in the Yugoslav Republics. These differences were even more marked in the last few years.

It is also in the jurisdiction of the Republics to finance out of their own funds the vaccination of the population and provide health care for that part of the population exposed to a higher risk of falling ill. The Republics provide funds in their budget for all persons who do not have retirement insurance or some other form of health care covered by social insurance on the basis of employment and private business activity.

Therefore, the priority task of each Yugoslav Republic is to organize a system of health care for persons who are not covered by health insurance through special activities of the health care institutions and for specific illnesses.

Allocation of funds for the health care of the population is conducted through social and health care funds. The funds are organized differently in each Republic on a municipal and regional level.

Health care funds generate their income from taxes levied on personal incomes of the workers employed in the state and private companies, on landowners and other private activities.

Tax level is proposed by the Fund Assembly, with receipts and expenditures balance taken into account the Municipal or Regional Assembly approves the budget and sources of revenue of the Municipal or Regional Fund. Funds are incomplete organizations. Surplus or deficit of the Fund

resources are balanced in the course of the following fiscal year.

The Social Accountancy Service and competent municipal or regional institutions (financial function) supervise utilization of the Fund resources, while the Fund Annual Financial Statement is adopted by the Fund Assembly and the Assembly of the respective political community.

The funds allocated for the health care service amounted to 5% of the national product, but the economic crisis caused their reduction even to less than 3% of the national income.

There are no other statutory provisions on the regional or municipal level other than those regulating collection and utilization of the funds.

Payments to medical organizations (hospitals, medical centres) for services rendered on the basis of given evidences of the service supplied are made through the Funds. Service charges are negotiated by between medical organizations and the funds.

In the event that it is impossible to provide adequate medical treatment for individuals in municipal or regional medical centres, a medical commission appointed by the Fund Assembly, with reference to medical supporting documentation, will recommend the treatment in other organizations, in that case the Fund pays this service. The same principle is used for the treatments in spas and rehabilitation centres.

The Fund provides the means for payments to pharmacies for the prescribed drugs. The pharmacy or wholesale drug distributor makes out an invoice for the issued drugs.

Prices of drugs are determined by the Federal Statutory Act, which is not the case with medical services.

2. Economic and Financial Factors

As the following charts highlight, according to the 1981 census, Yugoslavia was a country of approximately 45 million, 63% of these people lived in urban centres while the remaining 37% lived in Yugoslavia rural areas. 42% of the population was located in Serbia.

POPULATION FLOW

	SFRJ	BIH	Monte-negro	Croatia	Macedonia	Slovenia	Serbia
Total Population according to 1981 census (in mil.)	22.40	4.12	0.58	4.60	1.90	1.89	9.30
Born alive (1983)	374,610.0	74,296.0	10,657.0	65,599.0	39,210.0	27,200.0	137,648.0
Born alive/1000 inhabitants	16.40	17.60	17.80	14.20	19.90	14.20	16.70
Died (1983)	218,980.0	29,999.0	4,194.0	65,147.0	14,391.0	20,703.0	94,546.0
Died/1000 inhabitants (1983)	9.60	7.10	7.00	11.90	7.30	10.80	10.00

B. Structure of the Yugoslav Market

Four companies, ICN-Galenika, Pliva, Krka and Lek, have a research institute within the organization. These institutes are organized as separate entities and are registered as research institutions.

The other companies instead of research institutes have only research laboratories.

By registering the research institutes in compliance with the legal provisions, the institution is exempted from paying

customs fees when importing equipment and at the same time the institution acquires the right to apply for scientific research projects announced by the Federal and Republic Departments of Science and Technology.

Thirty to fifty percent of the sum for the project was provided by the State. This was a means of the State institutions financing whereas the pharmaceutical industry development was not subsidized by the State.

All pharmaceutical industry projects were self-financed. The previous chapters describe the development of this industry.

The pharmaceutical industry used 1.5% of the turnover to provide funds for its budget for financing its institutes and projects. The annual sum amounted to 40-50 million US dollars.

In compliance with the existing law the pharmaceutical organizations that have registered a product with an identical generic name must follow the registration succession and only the first three organizations may use a trade name. A product that comes after may be sold only under generic name. This is established in the course of product registration.

The tabular review shows that four companies have a major share of the Yugoslav market.

Some ten years ago the pharmaceutical industry started the process of forming joint ventures with foreign companies which resulted in the formation of:

- ICN-Galenika, a stock company, founded by Galenika Holding Company and ICN Pharmaceuticals (USA)

- Jugoremedija, a joint venture of Hoechst (Germany) and Servo Mihalj (Jugoremedija)

- Bayer Pharmo, a joint venture of Lek (Yugoslavia) and Bayer (Germany).

The selection of products is made on the basis of market evaluations conducted by producers themselves, recommendations of the Federal Ministry of Health, suggestions of physicians and foreign pharmaceutical companies. Based on legally applied procedures the commission of the Ministry of Health accepts or rejects registration applications.

The Yugoslav drug factories have relatively insufficient materials basis. The reasons are above stated.

The following raw materials are manufactured by pharmaceutical companies: Penicillin, Vitamin C, Vitamin B, animal origin extract based-products, human origin extract based-products and some pharmaceutical active substances. Out of auxiliary materials, paper packaging material, alu and plastic tubes and glass packages are manufactured in Yugoslavia.

With regard to the size of the domestic market, capacities in the pharmaceutical industry are significant:

-	ampoules	260 million
-	tubes	130 million
-	syrups	30 million
-	antibiotics in vials	230 million
-	tablets	6 billion
-	capsules	15 billion

The four largest manufacturers have all above indicated dosage forms in their range.

The production costs amount to approximately 50% of the selling price. In view of relatively insufficient raw material basis, over 70% of active pharmaceutical materials are imported

and the cost of active substances accounts for 30-35% of the selling price.

1. Distribution

The price of a drug offered to wholesale by drug manufacturers is state-controlled. The manufacturer states the wholesale price on the invoice, allowing 10% discount. The wholesale cannot change this price.

In 1989, there were 28 wholesale pharmaceutical organizations in Yugoslavia. Since 1990 the process of privatization has started and in 1991 about 80 private wholesale pharmaceutical organizations were set up.

Each wholesale organization has to meet the above stated regulations in order to be allowed to handle sales of drugs.

The wholesale organizations supply hospital, medical centres and pharmacies with drugs.

Pharmacies dispense a drug to the patient on a physician's prescription, and the patient has to pay either part or the full amount of the cost, if the cost of the drug is not covered by the social insurance fund. The pharmacy may add 25% trade margin to the wholesale price.

In 1990, there were 1350 pharmacies in the territory of Yugoslavia. In 1991, the process of setting up private pharmacies started, and this trend differs from republic to republic. Most private pharmacies have been set up in the Republic of Serbia and it is estimated that now there are 600 socially-owned and about 300 privately-owned pharmacies.

The import of drugs is subject to a prior approval of the Federal Ministry of Health. The import is allowed only when a drug is not locally manufactured or in case of short supply.

In principle, the importers are wholesale organizations which form the price of the drug including all expenses (drugs are exempted from customs duty). The distribution of imported drugs is handled in the same way as of the locally manufactured drugs.

2. Technical Issues

All major Yugoslav drug manufacturers have their own research centres (ICN-Galenika, Pliva, Krka, Inex Hemofarm). However, the Yugoslav drug industry has not been very successful in developing new molecules.

The development of the pharmaceutical industry was subject to the state requirement which put an imperative on the supplying of the market with all necessary drugs. Consequently, all pharmaceutical companies instead of opting for long-term development of new molecules turned to the use of license rights and generic preparations.

In view of the fact that primary chemical production and production of fine chemicals in Yugoslavia has not received much attention, the pharmaceutical industry relied more and more on the importation of finished raw materials. Because of that, all research laboratories had qualified staff for the formulation of products but did not pay much attention to personnel policy in other developing functions. The pharmaceutical companies worked on the development of their own raw material base until the mid-seventies.

Concentrating on the organization of their own development, cooperation with universities and institutes was neglected, and the only form of cooperation that existed was with clinics. Much attention was paid to developing this relationship as there was a legal stipulation stating that drugs whose generic name was not registered in Yugoslavia had to be clinically tested.

The law on patent rights protection, amended two years ago, permitted the creation of one's own patent by technology change, contributing as well as to the development of the pharmaceutical industry. However, the low price policy also hindered the development of new drugs.

By sustaining the process of regular registration of new drugs and by occasional reduction of production, the pharmaceutical industry managed to meet the state requirement for the necessary supplying of the market with drugs. The importation of finished drugs accounted for less than ___ of the total market share.

On the other hand, due to growing competition between pharmaceutical companies sales became a top priority. As a result, all manufacturers nowadays have a relatively well developed field force employing doctors and pharmacists.

C. SPAIN

This section briefly discusses some of the basic legal, regulatory, economic and technical aspects of the health care services and of the pharmaceutical industry in Spain.

1. Regulatory and Legal Aspects

Background

The Spanish Constitution recognizes the rights of citizens to have health protection and charges all public services to organize and protect the public health by means of enforcing the preventive medicine and establishing a system of social benefits and health services.

The General Law on health provides for the universal system of health protection and integral organization of health services. The Law enacts actually the National Health System, which is organized and coordinated by both health authorities of the central government and autonomous local governments. There are 17 Territorial Autonomies in Spain.

The configuration of the national health System, its consolidation as a system of universal coverage, which is financed publicly and is oriented towards the health protection and the prevention of illnesses, requires that the health authorities make a clear definition of what are, on the one hand, limits for ensuring the rights for health protection and, on the other, what are the provisions of resources for health care services.

On this basis, the General Law on health is specifying this distinction in such a way that it attributes the development of health protection to the state health authorities, while charging the National Institute of Health with the organization of health services. The Institute has the instrumental role to organize these services and to transfer corresponding services to the autonomous communities to the extent of their rights and responsibilities in this field.

Since the enactment of the General Law on Health twofold activities and developments have taken place. One was aimed to thorough studies and the design of the function of the health authorities, and the other to the administration and management of health services. These two different areas were divided between the Ministry of Health and the National Institute of Health.

2. Regulation of Health Care

Within the limits of duties and responsibilities of the State, the health authorities are encompassed in the Ministry of Health, which carries on abiding functions of ensuring rights for health protection. This function is oriented so as to guarantee the equality of all Spanish citizens in regard to this fundamental right.

Therefore, the State has to exercise the regulatory function in creating conditions for citizens to exercise these rights, but keep independent the entities or establishments which provide the organization and funding of health care services. The function of providing health care services may correspond to the institution at the State level (The National Institute of Health) or at the level of autonomous communities, as well as to the local organizations or private health care services. But in any case, the Ministry of Health bears the sole responsibility to establish and finance the basic rights for health protection and to provide general planning and coordination of the entire System.

On one hand, the analysis and diagnosis of the public health situation and the planning of health services have the objective of programming and orientation of the health resources, as well as the proper and rightful allocation of the resources to the proposed objective. It also includes such sensitive

functions like insurance, planification, economic programming and orientation of the system of health care and, consequently, definition of benefits and evaluation of resources to make them effective.

On the other hand, the Ministry of health has to develop the policy of health protection, to harmonize it and coordinate with the policies of public health protection of autonomous communities. It has to create the global strategy of health care promotion and of prevention of illnesses, to arrange the research in health care services and health care products, particularly drugs, and to develop the concrete policy in arranging the health care professions and the system of permanent information of citizens.

The Ministry of Health is basically divided into four departments (secretariats), according to the corresponding fields of activities:

- General Secretariat for Health;

- General Secretariat for Planification;

- Delegation of the Government for the National Drug Plan; and

- Under Secretariat for Health and Consumption.

The major government authorities which deal with the pharmaceutical industry and perform administrative duties in this field are organized within the frames of the General Secretariat for Health. Large department of this Secretariat covers all regulatory, legal, administrative, supervisory and related issues of pharmaceutical field and health care products.

This department is responsible, for example, for introduction of new drugs, their evaluation, control and official approval. It is authorized for the inspection and control of the manufacturing and distribution of drugs, including narcotics and drug-trafficking. The department establishes rules for practices in studying adverse effects of drugs, supervises rational use of drugs and proper information for patients, sets the rules and regulations for the evaluation of clinical efficacy of drugs. Other rules set up by this department include ways and systems of price fixing and of state participation in financing prescription drugs.

3. The National Institute of Health

The National Institute of Health (INSALUD) is administratively the part of the General Secretariat for Planification. This Institute is directly responsible for the administration and allocation of state funds for health care and also for planning and ensuring of fund allocated to autonomous governments.

Being a part of the Secretariat for Planification, which is the state body for planning national health care standards, needs, requirements, level and quality of health care services, INSALUD is responsible for the design, forecasts and development of the entire National Health System. Based on its planning and forecasts, INSALUD proposes the national budget for health care, social security, medical care and all related services. This budget is the part of the Ministry of Health budget, but in its spending and allocation it is separated and cannot be used for other purposes than those described.

INSALUD is directly responsible in negotiating needs and requirements of those autonomous governments in Spain which have overtaken full responsibility for the development and financing

of health care services in their respective territories. Based on this, INSALUD plans and thereafter allocates state funds for health care to autonomous governments. Budget forecasts and spending are established for each of autonomous governments individually, taking into consideration their economic levels, standard of living, standard and needs of health care services, etc.

For those autonomous territories which have not undertaken such rights and responsibilities, INSALUD directly administers and manages all health resources coordinating its activities with their respective autonomous governments. The extension of its competencies and authorities for direct administration of health resources in autonomous territories, requires a strong and well organized structure of INSALUD.

The Institute must take care of all needs of health care services in those territories, for which it establishes its own departments, territorial bodies and administration. Through various forms of local co-participation in the administration and management of services, INSALUD endeavors to attract the attention of citizens and get their voice in planning, setting up of health care facilities and services to meet demands and to ensure the fulfilment of the constitutional rights of citizens for health care needs and protection.

4. Autonomous Government

The Spanish Constitution makes a clear-cut definition of the separation of rights and responsibilities between the central state and the autonomous communities. The Constitution provides that the central government, in transferring to autonomous communities some of its rights and authorities in certain fields of economic and social life, reaches an agreement with local

governments by which this transfer becomes the part of the entire constitutional system.

Spain has the following 17 territorial autonomies:

* Andalucia	Extremadura
Aragon	* Galicia
Asturias	* Madrid
Baleares	Murcia
Canarias	Navarra
Cantabria	La Rioja
Castilla-la-Mancha	* Valencia
* Castilla Y Leon	* Pais Vasco
Catalonia	

The Constitution establishes that "matters not expressly attributed to the State by this Constitution may correspond to the Autonomous Communities, subject to their respective Statutes. The competence over the matters not included in the Statute of the Autonomy belongs to the State".

Out of 17 territorial autonomies, 6 autonomous governments have overtaken until now rights, duties and responsibilities in the field of health care and social security: Andalucia, Catalonia, Galicia, Madrid, Valencia and Pais Vasco. They all have signed separate agreements with the central government, by which all the obligations regarding health care services, social security, hospital network and alike are transferred from the State of the Autonomous Government.

All these governments have not their own planning, budgeting, providing and supervising all health care services and social security benefits in their territories. But the major parts and sourcing of their health care budgets originate from the central State funding, provided and distributed basically through the National Institute of Health.

5. Economic Factors

Background

The Spanish economy keeps the moderate growth rate in the past several years after 1989. Such a growth is the result of consequences of the restrictive regulations of Spanish economic policy, introduced to halt the basic unbalances created by the rapid growth in previous years.

The moderate growth rate resulted in the following increase of the Gross National Product (GNP): 3.7% in 1990, 2.7% in 1991 and 3.3% (estimate) in 1992. Based on such a growth, all planning and budgeting of health care services and social security benefits have undergone serious reconsideration and restructuring in the past three years.

It is expected that Spain shall have more dynamic economic development in the years to come than other countries of the European Community. But Spain is also facing some serious challenges resulting from the establishment of the unified European Market as of the beginning of 1993, as well as the introduction of the second phase of the Economic and Monetary Union scheduled for 1994. Spanish economy must eliminate some disparities which exist in comparison to the other European Community countries, such as inflation, unemployment, public deficit and foreign trade deficit, if it wishes to keep the pace and have comparable economic levels with other countries of the European Community. This will particularly affect public spending, of which the health care services and social security benefits are one of the most important parts.

Financing of Health Care Services

The increase of the public spending in recent years was the main feature of the State Budget of Spain. Such trend has to be stopped and harmonized with the economic potentials and overall rate of economic development. Predominant parts of the public expenditures are spending for health care services, social security benefits, retirement, and unemployment benefits, which in the last two years were growing at a much higher rate than the growth of the Gross National Product. The following chart which presents the major parts of state spending (in millions of pesetas) in 1991 and 1992 illustrates this trend:

Description increase	1991	1992	% of budget	%
Pensions	4,706,055	5,458,895	23.1	16
Unemployment and Social Security	2,090,883	2,646,362	11.2	26.6
Health Care	2,258,776	2,548,926	10.8	12.8

Only these three categories represent 45.1% of all state public spending. Other budgetary categories that show substantial increase are: public debt (14.8% of the budget, 34.1% increase), financing of territorial administrations (10.6% of the budget, 16.8% increase) and education (4.7% of the budget, 7.9% increase). Savings and budget cuts had to be made in all other sectors, including national defense and foreign policy (3.4% of the budget, decrease of 9.2%).

In spite of rapid growth of public spending for health care and social security benefits, Spain is still behind most of the developed countries of the West in the ratio of public health versus gross national product. Spain is even below the average of the 22 countries of OECD. Whereas in 1989

the health care spending in the United States represented 11.8% of the GNP, in Sweden 8.8%, Canada 8.7%, Holland 8.3%, Austria 8.2%, Germany 8.1%, Switzerland 7.8%, Italy 7.6% - Spain was at the level of 6.3%. The average for the 22 countries was 7.6%.

The public spending for health care services goes almost exclusively through the National Institute of Health. In the budget for tne health care in 1992, in the amount of 2,467,516 million of pesetas, the national Institute of health administers 2,389,061 million of pesetas, or 96.82% of the total budget. The Institute transfers 56.46% of this amount to the autonomous governments which run health care services and social security benefits in their respective territories (Andalucia, Catalonia, Galicia, Madrid, Pais Vasco and Valencia).

The increase of the budget of the National Institute of Health, which for many years was constant, recorded slight decrease in the past two years. This comes as the result of the cutting of public expenses in spite of badly needed increases for the improvement of health care services. The trend of the per cent increases on INSALUD budgets (not adjusted for the inflation), was as follows:

1985-86	1986-87	1987-88	1988-89	1989-90	1990-91	1991-92
8.11	10.10	16.93	16.54	17.57	13.95	13.29

However, the slower increases in funding health care services and social security benefits do not decrease the ratio of health care spending versus the GNP. The following table gives the ratio of the health care spending (INSALUD budget) versus the GNP (in million of pesetas):

Year	INSALUD budgets	GNP of Spain	% ratio to GNP
1985	970.354	27,788,803	3.49
1986	1,049,032	31,350,147	3.35
1987	1,155,019	36,191,324	3.19
1988	1,350,632	40,658,549	3.32
1989	1,574,055	45,864,284	3.43
1990	1,851,145	51,160,425	3.62
1991	2,108,863	56,122,986	3.76
1992	2,389,061	61,174,055	3.91

It should be noted that the budget of the INSALUD is not totally financed by the state. In 1992, the state contribution to the budget was 69%. In addition, social security contributions represented 27.2% of the budget, revenues from certain health care facilities 2.7%, depreciation 0.7% and an outside contribution for the development of the national health care programme 0.3%.

Health Care Costs

The structure of health care costs in Spain shows that the major part of spending is allocated for the specialized medical care and treatment, including hospitals, then for the primary medical care and treatment (outpatient medical institutions, GP's and other) and for the prescription drugs.

The following chart shows how the health care costs in Catalonia are split. As discussed above, Catalonia is one of the six territorial autonomies which have undertaken all rights and responsibilities to organize, maintain and finance all health care services (beginning in 1991).

Health care costs structure in Catalonia:

Specialized medical care	55.27%
Primary medical care	25.00%
Prescription drugs	16.35%
Admin· ration, general services	2.37%
Health care personnel training	1.01%
	100.00%

The structure of health care costs in Catalonia can be taken as representative for other autonomous governments, as well as for spending on the national level through the National Institute of Health.

6. Technical Aspects

Certain technical aspects of the pharmaceutical industry in Spain, including issues regarding manufacturing of raw materials and finished products, production requirements, quality control, research and development, human resources and management are discussed below.

Manufacturing

Spain has been traditionally a country with a low level of research and development investments. The pharmaceutical industry as well was lacking its own fundamental research and development. Therefore, it had to be developed along the lines of certain requirements to meet domestic needs and demands for drugs.

The study and analysis of the actual pharmaceutical needs of the country was based on hospital requirements but, more essentially, on the requirements of private medical

practices which for many years were a driving force for the application of new drugs.

Evaluating needs for pharmaceutical products, such a study was basically oriented towards the development of new drugs from the U.S.A. but also to many drugs developed in technologically advanced European countries, and their possible application to the Spanish market.

The development of the pharmaceutical industry was also based on cost-effectiveness of products, evaluating drugs with a higher consumption and analyzing their production costs in order to determine whether they are profitable, i.e. whether their gross margins are sufficient enough in comparison with the sale prices which were always controlled by the State health authorities.

International pharmaceutical patents were instrumental in developing the Spanish pharmaceutical industry, either by ways of acquiring patent rights for domestic manufacturing of drugs, or obtaining licenses from proprietors, or by developing on process patents.

It should be underlined that most of active substances used in drugs manufacturing in Spain have been developed by big multinational chemical and pharmaceutical companies. In many cases, these companies protected their patents not only for the manufacturing of active substances but also covering process, part of the process or transformation of substances into derived products and drugs.

Such a development could be characterized even as the cultural aspect of the Spanish pharmaceutical industry. The entire pharmaceutical industry was inclined to think in terms of manufacturing under licenses, perhaps due to

economic circumstances and potentials. Consequently, most of pharmaceutical companies, both in the manufacture of raw materials and finished products, as well as those specialized in blood processing and fractionating, have found their market share based on their agreements negotiated with the owners of first brands and/or, as already discussed above, on the development of their own process patents.

The pharmaceutical industry of Spain enlists now 290 companies altogether. 240 are manufacturing finished pharmaceutical products and 50 are manufacturing pharmaceutical raw materials.

The major concentration of the Spanish pharmaceutical industries is in the more industrialized regions of the country, where it is easier to find the adequate industrial infrastructure and labour force. These industries are located as follows:

Madrid	23 raw materials	129 finished products
Catalonia	27 raw materials	111 finished products

In view of the fact that pharmaceutical companies have opportunities to select products for manufacturing based on their cost-effectiveness, the entire pharmaceutical industry has reached relatively high level of profitability. In general, costs of production (costs of goods) in the pharmaceutical industry in Spain are between 35% and 40% of ex-factory sales prices. That gives 60% to 65% gross margin to the industry as a whole.

Before reaching consumers, the pharmaceutical products are loaded with additional costs, which include an average for wholesalers of 13.6%, for retailers (pharmacies) 48.5% and taxes of 9.7%.

Retail sales price composition, therefore, includes the following elements:

- manufacturing cost of unit	24.4%
- Gross profit of manufacturer	33.8%
- Gross profit of wholesaler	7.9%
- Gross profit of pharmacies	28.2%
- Taxes	5.7%
Total	100.0%

The Spanish government does not grant any subsidies to the pharmaceutical industries if the subsidies concept is understood as a system of bonuses or allowances to compensate high manufacturing costs for products of low consumption or high technology products. Due to this, there is a trend to import those finished pharmaceutical products which due to a low profitability were not included in the selection of products to be manufactured.

Subsidies projects, however, have started to be developed in the last five years for future training programs, for the research and development of GMP projects and for increasing the productivity.

It is worth mentioning that there are subsidies available for projects aimed to reduce or eliminate environmental pollution caused by pharmaceutical industries. This is an

area where Spain becomes a part of the great international attention paid nowadays to the industrial contamination.

Production Requirements

Spanish government has introduced very extensive and detailed legislation on production requirements in the pharmaceutical industry, regulations on the Good Manufacturing Practices (GMP) and the Good Laboratory Practices (GLP), quality control (QC) and other requirements in this industry.

In accordance with the "Ley del Medicamento", art. 72. the Good Manufacturing Practices (GMP) promulgated by the Ministry of Health and the Good Laboratory Practices (GLP) should be fulfilled by the holders of a pharmaceutical laboratory authorization. These regulations are those from the European Community Committee and related both to the production and quality assurance.

Essential regulations of the GMP in Spain require that all manufacturing procedures should be clearly defined and reviewed systematically bearing in mind the experience and to show that they are able to manufacture homogeneously drugs with the required quality and in agreement with the specifications.

The critical phases of the manufacturing procedures and the significant changes of these procedures should be regularly validated.

Everything required for the fulfilment of the GMP should be available at the pharmaceutical facility:

- Trained personnel
- Appropriate place and premises

- Appropriate equipment and services
- Correct materials, packages and labels
- Approved instructions and procedures
- Appropriate storage and transport

All data obtained during the manufacture should be recorded by hand and/or by means of recording instruments. The quantity and quality of product should be as scheduled. Any significant deviation should be recorded and thoroughly investigated. The manufacture protocol and the distribution data should be kept complete and accessibly in order to reconstruct the whole history of any batch.

The distribution of the products to wholesalers should minimize the risk to decrease the quality. A withdrawal system of product batches from their distribution and sale points should be available. Claims concerning commercialized products should be studied. The reasons for quality faults should be investigated and to take the appropriate measure with regard to defective products as to prevent their recurrence.

The supervisors from the Ministry of health inspect thoroughly each laboratory as to check the fulfilment of these regulations. If an unfavourable report is issued after the inspection, the facilities, procedures, documents, etc., should be adapted within a certain delay before a new inspection. If after this new inspection the GMPs are not fulfilled by the laboratory, the manufacture of those pharmaceutical forms without the required facilities, will be forbidden by the Ministry of Health.

Production requirements should follow clearly defined procedures and to comply with the GMP. The production should be performed and supervised by reliable personnel.

The responsible for the Production Department, according to the law, has the following duties:

- To guarantee that the products are manufactured and stored in accordance to the relevant documents.

- To approve the instructions related to production operations and to guarantee their strict fulfilment.

- To guarantee that the production protocols are evaluated and signed by an authorized person before their sending to the Quality Assurance Department.

- To verify the maintenance, premises and equipment.

- To guarantee that the personnel in his Department is receiving an initial and continuous training.

Production requirements indicate that all handling of materials and products such as reception and quarantine, sampling, storage, labeling, fractionation, manufacture, package and distribution should be performed in accordance with written procedures or instructions.

All entry materials should be subjected to tests in order to guarantee that the shipment corresponds to the order. Any impairment in packages or other problems which could affect negatively the quality of any material should be investigated, recorded and a report to the Quality Assurance Department should be issued.

Starting materials and finished products should be kept in quarantine, physical and administratively, immediately after their reception or manufacture until the approval of their use or distribution. Intermediate and in bulk

products should be treated on their reception as starting materials.

All materials and products should be stored under the appropriate conditions established by the manufacturer and in an orderly way as to allow the separation of the batches and the turnover of the stock.

Verifications of the yield and balance of quantities should be made in order to guarantee the non-existence of discrepancies exceeding the acceptable limits. As far as possible, any deviation from the instructions should be avoided. If deviations are observed, these should be approved in writing by an authorized person. Operations with different products should not be made simultaneous or consecutively in the same room in order to prevent the risk of confusions or crossed contaminations. In all production operations, the materials and products should be protected from microbial and other type of contamination.

During the work with dry materials and products, special precautions should be taken as to prevent the production and diffusion of dust. This must implemented specially to the handling of very active or sensitizing materials.

During the whole process, all materials, in bulk packages, important equipment and, where appropriate, the used rooms should be labeled or identified. These indications should mention also the production phase. All labels applied to the packages, equipment or premises should be clear, unequivocal and with a format approved by the company.

The access to the production premises has to be limited to the authorized personnel only.

The use of areas and equipment devoted to the production of drugs should be avoided for the production of non-pharmaceutical products.

Quality Assurance

It is regulated by the law that every holder of a pharmaceutical manufacture license in Spain should have a Quality Assurance Department in order to secure high quality standards of pharmaceutical products equaled to other European Community countries. This Department should be independent from others and under the management of a qualified and trained person and with one or more control laboratories at its disposal.

Essential requirements for Quality Assurance include the availability of facilities, qualified staff and the necessary approved procedures for sampling, inspection and control of starting materials, conditioning materials, intermediates, bulk and finished products and, where appropriate, to control the environmental conditions to comply with the GMP.

Sampling or starting materials, conditioning materials, intermediates, bulk and finished products should be carried out by the staff and methods approved by the Quality Assurance. Test methods should be validated.

Finished drugs, according to this procedure, should contain the active substances according to the qualitative and quantitative composition in the Marketing License, to have the required purity and to be duly packaged and correctly labeled.

A recording with the inspection results should be maintained and available to evaluate the performed tests

with the materials and intermediates, in bulk and in finished products in agreement with the specifications. The evaluation and review of the production documents will be included in products evaluation. Reference samples of the starting materials and of finished drugs should be kept for the future examination of the product, if required. The products must be always kept in their final packages.

The sale and distribution of any batch is forbidden unless that the Pharmaceutical/Technical Director has confirmed that this product complies with the requirements in the Marketing License.

Duties and responsibilities of the Head of the Quality Assurance in Spanish pharmaceutical companies are very broad, but so is his authority to fully exercise these duties and responsibilities. Duties include but are not limited:

- To approve or reject the starting materials, conditioning materials and intermediates, in bulk or finished products.

- To evaluate the protocols from each batch, to approve the specifications, sampling instructions, test methods and other quality assurance procedures.

- To guarantee that all required tests and required validations have been performed.

- To verify the maintenance of the department, facilities and apparatus and to guarantee that the staff in the department has been duly trained and that this training is in accordance with the requirements.

Special conditions are required for the Quality Assurance laboratory facilities. First of all, they must be separated from the production areas. This fact is specially important in case of control laboratories for biologicals, microbiologicals and radioisotopes, which must also be separated from each other.

Quality Assurance laboratories must be designed in accordance with the operations to be performed. There should be enough room as to prevent mistakes and crossed contamination. There should also be enough room for storage under appropriate conditions for samples and files. The staff, facilities and equipment in the laboratories should be appropriate to the work and manufacture operations. The recourse to external laboratories (analysis under agreement) may be accepted only in special circumstances.

All documents related to the quality control of a batch of any product should be filed for one year after the expiry date of a batch. The recordings of some data, the results of the analytical tests, yield, environment control should be filed in order to evaluate future trends. Besides the information in the Batch Protocol, other original data such as laboratory notebooks and/or recordings should be filed for an easy consultation.

The regulations provide that reference samples should be representative of the materials or products batches from where they have been obtained. The sample-containing packages should be labeled showing the contents, batch number, sampling date and packages from where samples have been obtained.

Reference samples from each batch of finished products should be kept until one year after their expiry date.

Finished products have to be normally kept in their final package and under recommended conditions.

Research and Development

The pharmaceutical industry in Spain constitutes the industrial sector with relative highest level of investment and expenses in research and development. In 1990, more than 50 laboratories that were working within the Plan of development and research in the pharmaceutical industry spent 30,000 million of pesetas for these purposes. Out of those 50 laboratories, 30 belong to multinational companies and 20 to domestic companies. All of them together employed about 2,000 people in direct research and development.

The Law of Science which regulates this field in detail, attaches special attention to the research at universities. The concept is that the universities should be the driving force in scientific research, but they should be closely connected with enterprises in respective fields in order to assure the implementation of scientific achievements. In particular, university research should be closely connected with research and development in pharmaceutical industry, whether private or public. In that way the fundamental research performed within universities becomes instrumental in supporting the modern scientific concept of pharmaceutical development.

The connection of the pharmaceutical industry with University research centres is of particular importance, since the pharmaceutical research requires very broad and complex types of research to obtain new medicines, which is their final objective. The multidisciplinary concept of the research in the pharmaceutical industry in Spain includes the following:

- Bibliography, documents and patents,
- Molecular design,
- Chemical synthesis,
- Analytical Chemistry,
- Pharmacological Screening,
- Toxicology research,
- Microbiology research,
- Biochemistry research,
- Biotechnology,
- Pharmacokinetics and metabolism,
- Immunochemistry and Immunopharmacology,
- Clinical studies.

Spain has an extensive network of hospital centres which can perform various clinical trials and which have Ethical Committee for Clinical Trials. Altogether there are 122 hospital centres which are approved for clinical trials.

There are 13 specialized schools and colleges within the field of pharmaceutical science and 12 colleges and schools of chemistry. All of them have research capacities.

Human Resources

The pharmaceutical industry in Spain employs 40,000 workers, as shown in the following chart:

Region	Raw materials	Finished Products	Total
Catalonia			
No. of companies	27	111	136
No. of employees	1,430	16,996	18,426
Average no.per company	53	153	132

Region	Raw material	Finished products	Total
Madrid			
No. of companies	23	129	152
No. of employees	3,490	17,410	20,900
Ave. No. per company	151	134	137
Industry Total			
No. of companies	50	240	290
No. of employees	4,920	34,406	39,326
Ave. No. per company	98	1443	135

It may be noted that an average sized pharmaceutical company in Spain employs only 135 workers. It shows, on one hand, that the labour in the industry is not very intensive, but on the other hand, indicates also that there is a strong competition in this industry which brings companies to cut down expenses as much as possible to stay in business.

There are no specialized schools for the training of skilled personnel for running and managing operations in the pharmaceutical industry. Therefore, the technical personnel have to be hired from the ranks in the fields of medicine, pharmacies and chemistry. Anyone with elementary education in these fields and with good training can perform these kinds of jobs. There is no difficulty in filling this category. However, due to the complexity of job positions companies are facing the situation to either offer high salaries to experienced and trained personnel or to invest large amount of time and money for training.

During the 1980's when Spain entered the new era of international opening, there was a strong demand for highly skilled and internationally oriented managers in the pharmaceutical industry who could bring to the production increase, higher productivity and open competition from abroad. This was particularly evident in the sphere of pharmaceutical marketing.

Thanks to the Spanish Business Administration Schools and through highly specialized courses of post-graduate studies, now Spain has very qualified pharmaceutical executives nationally and internationally renowned.

D. THE UNITED STATES

This section briefly discusses some of the basic regulatory, economic and technical aspects of the pharmaceutical industry in the United States.

1. Regulatory and Legal Aspects

Background

The United States of America is a federation of 50 states and the Federal District of Columbia. U.S. overseas territories include the Commonwealth of Puerto Rico; the U.S. Virgin Islands; and several Pacific Island groups, the largest of which are Guam and American Samoa. The United States mainland is bordered by Canada, Mexico, the Pacific Ocean, the Atlantic Ocean, and the Gulf of Mexico. The total area is about 3,543,900 square miles (9,178,700 square kilometres).

The United States federal political system is a representative democracy which is established, defined, and guaranteed by the Constitution. The three main branches of U.S. federal government - executive, legislative, and judicial - are represented by the President, Congress, and Supreme Court, respectively. The President may be elected to a maximum of two four-year terms via an electoral college system. The national government is administered by 13 executive departments, the heads of which report to the President and form the President's Cabinet.

National legislative powers are vested in the Congress, a bicameral body which makes, repeals, and amends federal laws; levies federal taxes; and appropriates funds for the government. The upper house, known as the Senate, has 100 members (two from each state) who serve six-year terms of office. The lower house, the House of Representatives, has 435 members elected every second year. Its membership may change or be redistributed as state populations fluctuate.

The Supreme Court consists of nine Justices who are appointed by the President for indeterminate terms. New Justices may only be appointed when a vacancy is created through death or voluntary resignation of an existing Justice. The Supreme Court is charged with interpretation of the Constitution as it pertains to cases presented to it and of other laws promulgated by Congress. A majority vote of member Justices is required for a decision to formally be rendered by the Supreme Court.

Each state also has its own Constitution and an independent government which shares certain powers with the federal government. As with the federal government, all states have a bicameral legislature; a Governor and other executive officers; and a Judicial system. The Governor is

chosen by direct popular vote, as opposed to Electoral College vote for the President, for a term of office of between two and four years.

Regulation of Health Care

Overall responsibility for health matters rests with the Department of Health and Human Services. Governmental funding of health care is not comprehensive, but is generally designed to provide basic services for the poor and elderly through Medicare and Medicaid programmes, which are administered by the Health Care Financing Administration (HCFA), certain other programmes administered by the Social Security Administration, as well as individual state health care funding programmes. The Department of Defense and the Veterans Administration provide a comprehensive health insurance programme, particularly for hospital care, to active and former members of the armed forces.

The Department of Health and Human Services embraces three main divisions - the Public Health Service (PHS), the Social Security Administration (SSA), and the Health Care Financing Administration (HCFA).

The Public Health Service includes the Food and Drug Administration (FDA); the National Institutes of Health (NIH); the Alcohol, Drug Abuse and Mental Health Administration (ADMHA); the Centres for Disease Control (CDC); the Health Services Administration (HSA); and the Health Resources Administration (HRA). The functions of the PHS are defined as follows: "To identify health hazards and assure compliance with the standards established to control these hazards; to improve the organization and delivery of physical and mental health care services for entitled individuals; to conduct research

in medical and related sciences; and to encourage health education and training."

Food and Drug Administration: As stated above, the Food and Drug Administration (FDA), a division of the Department of Health and Human Services, is responsible for all matters related to pharmaceuticals. A relatively new regulatory body with FDA, the National Centre for Drugs and Biologies, was created in 1982 to replace the old Bureau of Drugs. Within the Centre, the Office of New Drug Evaluation has specific responsibility for new drug approvals.

The Food, Drug and Cosmetic (FD&C) Act and its amendments cover most aspects of drug control. The FD&C Act was first enacted in 1938 and has been subjected to virtually constant modification and amendment since. Amendments to the Act and new legislation pertaining to pharmaceuticals generally result from evidence and testimony submitted to congress committees or in response to specific requests from Congressional oversight committees. Prior to enactment as law, new drug regulations are published in the Federal Register which serves as an invitation for comment from all interested parties.

Registration of Drugs

All "new drugs" are subject to a registration procedure. Within the context of U.S. pharmaceutical regulations, a "new drug" is defined as any drug with a composition not yet generally recognized to be safe and effective for the use being proposed, excluding those drugs marketed prior to 1938 (the date the FD&C Act became effective). Changes in the dosage form or therapeutic indication of existing approved drugs also require prior approval of another New Drug Application (NDA). Certain groups of products are

subject to special provisions. Vaccines, blood and blood products require bath certification; biological product manufacturers must obtain specific licenses; and manufacturers of narcotics and controlled substances must be specially registered with the Drug Enforcement Administration. Diagnostics and medical devices are also regulated by FDA, and have recently been the subject of proposals for increasing levels of control.

The Office of New Drug Evaluation at FDA is responsible for product registration. Although medical and scientific reviewers are on staff to evaluate NDA submissions, outside medical committees are periodically consulted during this period.

The Process for Approval of Prescription Drugs

The process for the approval of a prescription drug in the United States is time-consuming and highly regulated. All drugs must be determined to be safe and effective for the intended use. In general, required laboratory and animal testing on a newly discovered compound takes one to two years. If after this initial testing the drug shows some therapeutic promise is determined to be safe for limited controlled clinical trials in humans, the company must file an Investigational New Drug (IND) application with the FDA. This informs the FDA that initial human clinical studies will be initiated within 30 days, unless FDA objects. Approximately 10% of drugs for which an IND is issued completes all phases of testing. From 1963 through 1987, between 671 and 2,112 IND's were submitted annually, about half of which were abandoned by the sponsor.

After the IND is filed, clinical studies with the drug are undertaken in humans and are divided into three phases.

Phase I trials are initial studies of a new drug in a few healthy volunteers. These studies are carried out to determine the pharmacological profile of the drug and take, on average, about one year to complete. Phase II trials study the effects of the drug in a population who have the disease which the drug is intended to treat. These studies are principally used to define an optimum dose and take approximately two years to conduct. Phase III trials are usually constructed as double-blind, placebo-controlled studies in which the drug is tested in a diseased population and efficacy and safety are measured against a similar group of patents who receive an identically appearing product which contains no active drug substance. The FDA generally requires that two well-controlled phase III studies show statistically significant efficacy, and reasonable safety, before an NDA can be approved. Such studies average three years to complete.

After the clinical studies have been completed, the resulting data is compiled into a New Drug Application (NDA) together with relevant data on manufacturing, process control, quality control, and animal toxicology. The FDA review of the resulting document, which may contain several hundred thousand pages, takes two to three years. Thus, on average, the time elapsed from discovery to marketing of a new drug in the United States is ten years. Once granted, NDA approval is valid indefinitely.

Dispensing a Prescription

All drugs designated as "legend" drugs require a prescription. Prescription drugs can only be dispensed by a licensed pharmacist or an authorized health care practitioner, such as a physician or dentist. Over 15 billion prescriptions are dispensed in the United States each year through various channels, including independent

(privately-owned) pharmacies, chain pharmacies (large consortiums, also usually privately-owned), hospitals, nursing homes, clinics, mail order pharmacy, and mass merchandising outlets. Only a few prescriptions are dispensed directly to patients by physicians, the remainder come through one of the previously mentioned outlets which must have a licensed pharmacist who is designated "in-charge" and who is responsible to ensure that all applicable state and federal laws are observed.

2. Economic Factors

Background

Health care in the United States is provided principally through the private sector and financed through a system of federal government, local government and private health insurance. The system provides access to care for virtually all U.S. citizens, provides incentives for maintenance of good health, and provides incentive to the pharmaceutical industry to develop improved and more cost-effective therapies.

The health care system in the United States today is still largely based in the private sector, with private insurance as the primary mechanism for financing care. However, the federal government has played an increasing important role in financing and regulatory health care in the United States.

Financing of Health Care Services

Despite the increased role of the federal government in health care management, there is still no single system available to provide health care to the entire U.S.

population. Health care is made up of many sub-systems which serve different segments of the population. The employed segment and their dependents generally have private health insurance which is provided by the employer and which pays for health care provided through the private sector. Employees usually may select the insurance plan and method through which health services will be provided from a variety of options, some of which provide all services at no charge to the employee and his dependents and others which may require the employee to pay directly for some portion of the costs.

For the poor, the unemployed population, and others with no private health insurance coverage, the federal government gives responsibility to the state and local governments for providing health care. State Medicaid programs, which are managed by the state but which obtain some funding from the federal government provide health care financing specifically for the poor and unemployed, such as disabled individuals and families with dependent children who meet poverty-level eligibility requirements. Medicaid recipients, depending upon the state and locale, may use the private sector to obtain health care services or they may use local public hospital and clinic facilities. Although most state Medicaid programmes, in an effort to reduce costs, have begun to limit the amount of funding available to the private health care providers, thus forcing Medicaid recipients to utilize government-run facilities. Additionally, many of the poor remain ineligible for Medicaid programs and must rely on local government facilities, which are often poorly organized and overburdened.

Medicare provides federally-sponsored health insurance coverage to individual 65 year of age and over. Care is provided through the same private system as utilized by the

employed population. Other populations, such as Native Americans and the military and their dependents have separate systems for providing health care.

Although these separate subsystems exist, there is considerable overlapping of service. Public health services are provider for all by local and state governments. The private system is sometimes used by government programs through contractual arrangements. However, in general the whole system lacks an overall scheme to coordinate services and ensure proper utilization. Many aspects of this system are inadequate for those with no insurance and who are unable to pay for care. There is also a general problem with inefficient and sometimes ineffective utilization of available resources. Proposals for federal legislation to reform and more thoroughly integrate management of the total health care system have become increasing important issues in recent elections.

Health Care Costs

In 1987, $500 billion was spent on health care in the United States, an average of $1,987 per capita. This amount represents 11.1% of the U.S. gross national product (GNP). Health care spending has been increasing steadily since 1965, after the introduction of Medicare. Figure 1 shows the rise in health care spending in the U.S. as a percent of GNP. Table 1 shows the relative amount of that total spent for various components of health care in 1987. Drugs and medical sundry costs were $34 billion in 1987, or 6.8% of GNP, a ratio which has been stable since 1980. Spending on drugs and medical sundries, which includes OTC drugs and devices, is generally considered to be one of the best controlled aspects of health care cost and has

declined as a percent of GNP to 6.8% in 1987 from 12.45 in 1965.

Payment and Reimbursement of Health Care Costs

The following table shows the sources of health care financing in the United States for 1987. These percentages have not changed appreciably in the last five years. Prior to the establishment of Medicare and Medicaid in 1965, private insurance played an even greater role in financing health care.

Public sources provided less than 30% of financing in 1965, but have increased to 40% since 1975.

TABLE 1

Sources of Health Care Financing (U.S.)

	Percent of Funding 1987	1965
Source of Health Care Funds		
Private Insurance	32%	
Direct Consumer Payment	25%	
Other Private and Charity	2%	
		78%
Total Non-Government Sources	59%	
Medicare	17%	
Medicaid	10%	
Other Government Payment	14%	
		22%
Total Government Sources		100%

Funding for various health care services is dependent upon the payer. For example, Medicare provides health care financing primarily for hospital care. Medicaid is almost the only source of third-party financing for nursing home care (there is almost no private insurance coverage for long-term care). Most financing for nursing home care comes from direct patient payment.

Private insurance is generally regarded as providing the best coverage for hospital and physicians services and the worst for drugs, eyeglasses/appliances, and nursing home expenses.

Fairly recently, private insurance has begun to provide payment for out-of-hospital drug use. However, direct patient payment still accounts for 75% of funding for drugs and medical supplies.

Coverage

Approximately 18% of persons less than 65 years old do not have health insurance. Studies have indicated that the uninsured are generally poor, minorities, young adults, rural residents, and employees of small companies. Although care is available through local government clinics and hospitals for those not eligible for federal government sponsored health insurance programmes, studies have shown that the uninsured tend to utilize preventive services less and have no usual source of care. The issue of uninsured or uncovered populations is the focus of considerable attention and hopefully will be resolved in the near future.

Price Regulation

In general, the U.S. pharmaceutical market relies on free-trade and competition in the marketplace to determine pharmaceutical prices through the principles of supply and demand. There are no uniform price regulations; however, many payers are instituting programs designed to limit or control drug costs. Federal and state regulations control the amount the government pays for drugs in the Medicare and Medicaid programs through various mechanisms including mandatory substitution of high-priced non-patented brand name products for generic equivalents and a requirement for a rebate to the federal government by pharmaceutical manufacturers in exchange for the right to participate in the Medicare system.

Competition (Brand and Generic)

To market a generic drug in the United States, a company must first submit an Abbreviated New Drug Application (ANDA) to the FDA and the ANDA must be formally approved. Further, generic drugs may only be marketed after expiration of any patents covering the original product. As long as the generic product is identical in potency, dosage form, and labelling to the original product, the sponsor of the ANDA need not repeat the preclinical and clinical testing that the manufacturer of the original product was required to conduct. However, prior to marketing of generic versions, bioequivalency to the original product must be demonstrated and must not deviate from that of the originators by more than 20% with regard to the mean extent of absorption. The time to approval of an ANDA ranges from nine months to two years and the expense associated with developing the required data is significantly lower than for an NDA.

When one looks at the dynamics of growth in the generic (multi-source) versus brand segments of the U.S. pharmaceutical markets several points become clear. The brand segment grows principally as a result of new product introductions and price increases, true unit growth is relatively modest. The generic segment, on the other hand, grows almost entirely as a result of unit volume increase, with pricing actually eroding over time and new products constituting a minor portion of growth.

3. Technical Aspects

Certain technical aspects of the pharmaceutical industry in the United States, including issues regarding manufacturing, research and development, licensing, advertising and promotion, distribution, and import and export are discussed below.

Manufacturing

While there are no specific limitations on where drug manufacturing facilities may be located within the United States, there are specific tax incentives to locate such facilities in Puerto Rico. Other than Puerto Rico, where most major manufacturers have located at least a portion of their production facilities, drug manufacturing is concentrated in nine states: New Jersey, New York, Pennsylvania, Indiana, Illinois, Michigan, Missouri, Ohio, and California. It is generally regarded that the overall manufacturing capacity of U.S.-based pharmaceutical facility exceeds the annual prescription volume, hospital orders, and demand for non-prescription drugs by at least thirty percent. Recently, there has been a trend among several of the larger pharmaceutical manufacturers to consolidate their smaller manufacturing facilities into fewer, larger sites.

Research and Development

The pharmaceutical industry continues to have a major commitment to research of new pharmaceutical products. Since 1965, industry expenditure on research and development has exceeded 105 of revenue and currently approached 15%. Both the private sector and government play key roles in financing and conducting pharmaceutical research in the United States. In 1987, 42% of pharmaceutical research funding was invested by industry, 34% by the National Institutes of Health (NIH), a federally government agencies and academic institutions using both government and private financing.

The decision of the U.S. pharmaceutical industry to pursue research and development has been linked to consideration of four factors: medical need; probability of success for time and funds required; a balanced portfolio; and profitability.

Patents and Licensing

Patents in the United States may be obtained for new chemical entities, for novel manufacturing processes, and for new uses of existing compounds. In the United States, a patent provides its owner with the exclusive right for 17 years to sell the covered invention. This period of market exclusivity provided by a patent provides a powerful incentive for investing in research and development.

A patent application is usually filed as promising new chemical entity is discovered. Testing and Food and Drug Administration review of a New Drug Application usually takes seven to ten years. Thus, the patent protected marketing time for a pharmaceutical products is significantly reduced. Following discussion on how this

reduction in effective patent life may adversely affect a manufacturers' ability to recover costs and generate reasonable profit from a newly discovered compound, and thus limit the incentive to conduct research into new pharmaceuticals, legislation was promulgated which extends the effective life of a patent on pharmaceutical products or technology for up to five years to compensate for time during review of a New Drug Application by FDA. In 1986, 2,504 patents covering drugs and medicines were issued by the United States Patent Office covering. Of these, 1,198 (48%) were of U.S. origin and 1,306 (52%) were of foreign origin.

Advertising and Promotion

There are strict controls over advertising and promotion of pharmaceutical products in the United States. In 1962, amendments to the Food, Drug, and Cosmetics Act were introduced which regulate the claims that a company may make regarding its pharmaceutical products. The amendments require companies to include the generic names on drug labels as well as brand (Trade) names, and restrict all advertising claims in labelling and package inserts to those approved by the FDA. Traditionally, physicians and pharmacists have been the primary target audience for pharmaceutical advertising and promotion. However, a recent trend has emerged in which some pharmaceutical companies have targeted prescription pharmaceutical advertising at consumers. Although this trend has generated some controversy, it is expected to continue.

Distribution

In 1991, there were approximately 950 companies in the United States engaged in the manufacture and sale of prescription and non-prescription pharmaceuticals. About

150 of these companies were actively involved in research and development and produce patented pharmaceutical products. The value of the products shipped by these manufacturers in 1991 was $49.5 billion, eighty-nine percent of which is shipped through drug wholesalers. The remaining eleven percent is shipped directly from the manufacturer to hospitals and retail pharmacy outlets.

Of the 950 manufacturers, virtually all ship some portion of their product through pharmaceutical wholesalers, who are highly automated, efficient warehousing operations. Approximately four hundred and fifty (450) of such wholesale distribution centres are located throughout the United States, they ship pharmaceuticals to over 200,000 retail outlets. Such outlets include chain and independent retail pharmacies, hospitals, mail order pharmacies, nursing homes, clinics, physician offices, food stores, and mass merchandise outlets. Table 2 shows the distribution of pharmaceutical produ ts in terms of value through these outlets during 1991.

TABLE 2

Distribution of Pharmaceuticals by Market Segment at Ex-Factory Pricing, United States 1991 (in U.S. $, billions)

Market Segment	$ 1991	% Change
Retail Pharmacies:		
Independents	12.7	+16.5%
Chains	12.3	+17.0%
Food Stores	3.1	+23.1%
Mail Order	2.9	+37.3%
Mass Merchandise	2.1	+16.7%
Hospitals	11.4	+19.0%
Clinics	1.6	+42.3%
Nursing Homes	1.4	+31.0%
HMO's (Staff Model)	1.2	+28.3%
Miscellaneous	0.8	+13.85
TOTAL	49.5	+20.0%

Import and Export

Since 1984, the United States has been the largest importer and exported of pharmaceutical products and technology. Japan is the largest recipient of U.S. pharmaceutical exports, receiving more than 205 of the total. Europe, as a total, receives approximately 50%. In 1987, exports from the U.S. were valued at 3.2 billion, and imports totaled $2.8 billion, yielding a position net balance of pharmaceutical trade. Most exports consist of raw materials and intermediate ingredients which are processed and packaged abroad.

SECTION III

CASE STUDY
OKTYABR - A STATE-RUN PHARMACEUTICAL ENTERPRISE

This section provides a case study of one state-run pharmaceutical enterprise in Russia. This case study, and the challenges faced by OKTYABR to conversion to a private commercial enterprise (discussed in Section IV), offer important insights into the conditions and issues that need to be addressed should the Russian pharmaceutical industry move toward private commercial operation.

A description of the operations of OKTYABR is provided in this section. The description is organized into three categories:

A. Legal and Regulatory Issues relating to the operations of OKTYABR:

B. Financial and Economic Issues relating to the operations of OKTYABR; and

C. Technical Issues relating to the operations of OKTYABR.

Each of these categories is discussed in detail, below:

A. Legal and Regulatory Issues

1. Creation of "OKTYABR"

On 2 November 1976, the Leningrad Chemico-Pharmaceutical Production Association "OKTYABR" was organized by an order #449 of the USSR Ministry of Medical Industry. This order caused the

consolidation of several pharmaceutical enterprises that were located in the territory of Leningrad. In addition, the order of the Ministry of Medical Industry confirmed the "OKTYABR" articles and no other agreements with other Agencies of the State were required.

In accordance with the Order of the Russian Federation Ministry of Public Health Care, N 124, dated April 13, 1992, "OKTYABR" is under the authority of the Medical Industry Committee of the Russian Federation Ministry of Public Health Care. By Order of the Committee on the State Property Management of the Mayor of St. Petersburg No. 47-R "OKTYABR" was reorganized into a joint stock company, open type, on December 10, 1992.

"OKTYABR" was a state enterprise and its production units did not possess the rights of a legal person. As a state enterprise, "OKTYABR" was permitted to produce drugs without obtaining any permissions or licenses.

2. Regulation of OKTYABR Production Activity

Antimonopolistic Activity

OKTYABR is subject to a broad range of regulations issued by a number of State organizations, including the Russian Federation Ministry of Public Health Care and the Russian Federation Committee on antimonopolistic Policy.

"OKTYABR" produces 14% of the pharmaceutical products in the Russian Federation and its market share exceeds 35%. However, since it does not abuse its market power, it has not been included in the "State Register of the Monopoly Enterprises" and therefore is not subject to the special

measures of antimonopolistic regulation.[1] Nonetheless, OKTYABR's observance of antimonopolistic legislation is supervised by the St. Petersburg agency of the State Committee on Antimonopolistic Policy and Support of New Economic Structures.

Creation of New Enterprises

OKTYABR as a joint stock company has no right to take part in the capital of other companies and organizations without the agreement of its shareholders. Currently, as the privatization process is not yet complete, the Fund of Property of St. Petersburg is the sole shareholder. The prohibition to participation in capital includes the creation of new enterprises and the participation of foreign investments in the purchase of shares of any company or operation with real property belonging to OKTYABR.

Taxes

The regulation of taxes is controlled by the tax inspection of the Petrograd District of St. Petersburg. This includes payments to both the Federal and local budgets. The authority of the inspection includes requiring the presentation of complete financial documentation, the application of penal sanctions, and the right to stop the operations of OKTYABR.

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[1] An enterprise is considered monopolistic, if it has a dominant position in the market and abuses its position. If monopolistic, an enterprise is included in the "State Register of Monopolistic Associations and Enterprises, acting on commodity Markets." If on this Register, an enterprise is subject to a number of measures to eliminate monopolistic actions. These measures can include: Forced recovery of the formed economic relations, price declarations, compulsory production and distribution, suspension of quota and export licenses, reorganization. This regulation is conducted by the Russia Federation Government Committee on Operative Regulation of Resources Supply.

Other Applicable Regulations

The control of the observance of ecologic legislation of "OKTYABR" is given to the Committee of Ecology and Nature Utilization of the Mayor of St. Petersburg, the territorial agency of the Russian Federation State Committee of Ecology and Nature Utilization.

St. Petersburg Council of People's Deputies (the representation power organ) and its Presidium regulate wastes of harmful compounds and limits on concentrations of harmful compounds. For violations of these rules, the Committee of Ecology and Nature Utilization or St. Petersburg Council of People's Deputies has the right to limit or stop OKTYABR's activity.

The observance of sanitary and medical requirements during the production of drugs is controlled by the Sanitary-Epidemiological Station of St. Petersburg. They too have the right to stop production for violations of sanitary and medical regulations.

The North-West District of the Russian Federation State Committee of Safe Operation Performance Supervision in Industry and of Mountain Supervision checks the operations of explosive productions by "OKTYABR". This includes synthesis of medicinal substances. (See, Presidential Decree No. 234 from February 18, 1993.)

3. "Standards" governing OKTYABR's Activity

"Standards" establish the required level of quality for pharmaceutical production. These "standards" consist of a complex set of norms, rules and requirements that are overseen

by a state agency. In the pharmaceutical industry, there are three types of standards:

i) State standards; set by the former USSR and confirmed by the USSR State Committee on Standardization;

ii) Branch Standards (OST) or Leading Normative Documents (LND); confirmed by the Russian Federation Ministry of Public Health Care; as applied to pharmaceutical production;

iii) Standards of "OKTYABR"; confirmed by internal administration; certain concrete technology processes, relations between departments, production control, quality control; however, does not set standards for the finished product.

With respect to the standard of quality of producing pharmaceuticals, OKTYABR uses standards from:

- State Pharmacopoeia;
- Registry Certification;
- pharmacopoeia articles and regulations;
- standards for other production in use in the Russian Federation.

Application for the production of new drugs and the nature of their production is directed to the Russian Federation Ministry of Public Health Care. Production is carried out consistent with industrial regulations which establish technological methods, and means for conducting the process of drug production.

Quality is measured by the requirements of the State Pharmacopoeia, registry certification and pharmacopoeia

articles.[2] This quality control is regulated by the Pharmacopoeia Committee of the Russian Federation Ministry of Public Health Care.

Within OKTYABR, supervision of the drug production process to ensure satisfaction of standards is done by the technical department from the central laboratory's Department of Technical Control and Safety Engineering. Their supervision assist fulfilment of intraplant, operative and complex controls.

On a day to day basis, control is the responsibility of technologists and masters within the OKTYABR plants.

Tests performed to measure the satisfaction of standards, include the following:

- controlling tests: conducted by the state scientific-research institute of standardization and control; done at the beginning of the production process

- approval tests: conducted by the department of technical control of OKTYABR; done at the time of raw material delivery and when the process yields a finished product.

- periodic testing: conducted by the State scientific-research institute of standardization and control of medicinal means.

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[2] The pharmacopoeia articles include the description of the drug, its destination, tests of qualitative and quantitative characteristics, requirement for packing and marketing, transportation and storage.

4. Certification

Certification means the confirmation by the competent supervising entity that the product satisfies the required standards. At OKTYABR, the supervising entity is the technical control department. This department conducts the tests and if the standards are met issues the quality certificate.

Every type of drug is subject to testing and certification. If certification is absent, realization of the product is banned.

5. Intellectual Property[3]

Russia's current intellectual property legislation is consistent with world practice though its enforcement still may face some difficulties. The law allows for the protection of the intellectual property of OKTYABR.[4] In order to protection production secrets and confidential information, OKTYABR has created the Department of Protection and Economic Safety. Among other things, this Department regulates the use of OKTYABR's commercial secrets and all subdivisions of OKTYABR must conform to the restrictions.

In addition, OKTYABR has a registered trademark, name, and emblem, registered with the patent department of the Russian Federation - good through the year 2000 and extended at will.

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[3] The following laws relate to Intellectual Property in Russia: Law of the RSFSR of 24.12.90 "on property in the RSFSR"; the law of RF of 14.05.92 "on trademarks, service marks and names of the places of the origin of goods"; laws of RF of 18.06.92 "Patent Law". Intellectual Property means the works of various kinds of creative activity, discoveries, inventions, rationalization proposals, production samples, programme for computers, know-how, trade secrets, trademarks, firm names and service marks.

[4] Prior to 1992, rights for inventions were transferred to the State.

Furthermore, in 1992, five patents for inventions were obtained and OKTYABR has agreements on the use of these inventions with the inventors who hold the patents. OKTYABR does not hold exclusive rights on trademarks for finished products since these products resulted from efforts of both scientific-research institutes and OKTYABR.

B. Financial and Economic Conditions

OKTYABR produces pharmaceuticals and vitamins. It has:

- 1,901 employees
- $147 million in sales revenue, 1991
- $23 million in income, 1991
- $54 million in assets, 1991.

However, like most Russian enterprises, it is encountering a number of economic and financial issues. These include:

1. inflation
2. limited customer base
3. shortages on cash flow
4. uncertainty in sales

1. Inflation

Prior to 1 January 1992, the central government set price and production levels and assigned suppliers and customers. As of 1 January 1992, OKTYABR is free to set prices, choose its suppliers and customers, and based on these factors, determine production levels. The Government of Russian Federation adopted a 30% maximum level of profitability to the basis cost) of producing pharmaceuticals by Decree No. 970, December 11, 1992. (See also Decree of Health Ministry, No. 16 from January 21, 1993.)

However, hyper-inflation existing at the moment makes pricing and supply decisions more difficult. With hyper-inflation, businesses face the risk that sales prices will not be sufficient to allow for the repurchase of raw materials. Overall inflation has been in the range of 30% per month for the first six months of 1992, but it is not clear whether it will stay at this rate or increase. Items that were under a fixed price system prior to 1 January, such as food have risen the most, up to thirty (30) times, while items that were under a free price system prior to 1 January have risen by two to six times.

A detailed discussion of inflation is beyond the scope of this report but some of the underlying causes include:

- Removal of state controls
- Removal of state subsidies
- Move to market prices for imported goods
- Excessive trade deficit
- Excessive public sector borrowing
- Shortages of essential goods
- High tariffs, customs duties on imported raw materials and equipment
- Loss of production due to breakdown in economic co-operation between some states of the former Soviet Union.

Thus far, for the bulk of production, OKTYABR has been able to pass on the monthly increases in the cost of materials and wages to its customers on a quarterly basis and maintain the same overall profitability. In cases where they have been unable to pass on increases in costs of material and labour (material costs make up 75% of the cost of production) for certain types of production the options are as follows:

- The production of a certain drug may be discontinued if a cheaper substitute for this drug exists.

- If no substitute exists, production usually continues as they are required by the government to maintain production of unique drugs.

However the bulk of their products have a relatively high demand and good profitability and as a result profit margins have not suffered. The abolition of centralized production controls has meant that demand for some of their products has changed. For example, demand for non-essential products, such as vitamins, has been reduced as the main users are senior citizens, who can no longer afford them. To date OKTYABR has been able to overcome this problem by using the excess capacity to produce new products such as a powered lemonade drink.

2. Customer Base

At present OKTYABR has around 4 0 customers, most of whom are under the umbrella of the state chain of pharmacies, Ros Pharmacia ("RP"). Because RP has financial difficulties and cannot always pay for products, OKTYABR would like to increase their sales outside Russia. In order to do so, OKTYABR requires additional export approvals from the Health Ministry, both for exports world-wide and to the former republics of the Soviet Union. Currently, the Russian government and Health Ministry is unlikely to grant export licenses as exporting significant amounts of most essential pharmaceuticals would mean shortages in Russia. In turn, however the republics that are not getting medicines from Russia may prevent the export of raw materials to Russia. Finally, Russian raw material suppliers have a virtual monopoly due to freed prices to producers and high customs duties for alternative sources of supply.

It is expected that approvals will be granted first for those products with excess capacity and products that can be sold

for hard currency. For example a license was obtained to export to Hungary for hard currency in 1992.

3. Cash flow

As noted above, OKTYABR's main customer has not had funds to pay OKTYABR. This is due to the near collapse of the banking system whereby transactions are not being settled. This has resulted in all state enterprises having significant receivable and payable balances. OKTYABR is no exception. As of July 1, 1992, total receivables were 24 times higher and total creditors were 33 times higher than at 1 January 1992.

All balances between state enterprises (the bulk of OKTYABR's receivables and payables) as of July 1 were scheduled to be settled by August 10 as part of a nationwide clearing operation. Under this program, OKTYABR received all debts. But the nation-wide clearing program was not entirely successful because inflation increased receivables and credits several times. After settlements, the absolute meaning of the receivables increased but the relative meaning of the receivables of OKTYABR were reduced. Now OKTYABR has seven percent (7%) of its receivables from volume of sales of pharmaceuticals, which is a better result from 1992.

Since July 1992, OKTYABR instituted a payment in advance policy whereby goods are not shipped until a payment notice is received from the bank. The policy has been effective in some cases, but in others they have shipped goods without payment as they do not have sufficient warehouse space to stockpile production and are loathe to stop production.

At the moment, OKTYABR is still willing to ship without payment, and OKTYABR's suppliers are willing to extend credit, because the general consensus is that the state will continue to

support key industries such as pharmaceuticals (including the distribution network RP) by the granting of loans or by some other means.

To replace existing loans and to finance working capital and investment OKTYABR has applied for government loans, the conditions of which are as follows:

- Repayment of the loans begins after 2 years.
- If the loans are used to increase salaries rather than for investment the 2 year repayment period is shortened. (OKTYABR's term was so treated.)
- Interest rates are as follows:
  - no increase in selling prices - interest free
  - price increases < 10% - 10% interest
  - price increase > 30% - 70% to 80% interest
- Under the programme up to R300m would be available.

In current circumstances the 70% to 80% interest rate is likely to prevail. OKTYABR has increased its selling price because of rising prices on raw materials and 80% interest.

4. Sales

For most major products, production in volume terms for the first 6 months of 1992 is broadly in line with that of last year and the 1992 plan. This indicates that the major product lines have not been significantly affected by the removal of state controls. The exceptions are discussed below.

Dimedrolum ampoules	Production has been increased from plan in order to satisfy demand.
Aerosol inhalipt	Production is below plan due to difficulties in obtaining the containers from the Ukraine.

Citromonum tablets	Production is below plan due to a lack of hard currency to pay for the cocoa component.
Vitamin C tablets	Production of this product has been curtailed by a ministry order because it contains sugar which is in short supply. In addition production of vitamin C itself has been stopped. It is not known when production will restart.
Phenacetinum - bulk	Production is under plan due to a lack of hard currency to pay for ingredients.

In general, gross profit margins have increased significantly as a result of selling in a highly inflationary environment. The exceptions are discussed below.

Dimedrolum - ampoules	Margins have been allowed to shrink from the prior period in order to reduce the possibility of being named as a monopoly supplier.
Proserinum - ampoules Dimedrolum - bulk Calcium gluconite - bulk	These products, along with many others, are produced at site N3 (Vasileostzovsky Island). This site also used to produce Vitamin C but Vitamin C production was stopped due to environmental reasons and as a result the remaining products absorb

additional overheads formerly borne by Vitamin C production.

Aerosol inhalipt — OKTYABR has been able to pass on increases in cost for this product and the margin has suffered accordingly.

OKTYABR's correct configuration with respect to the allocation of space and employees to its products appears on the following tables.

Table 1

OKTYABR
MANUFACTURING
CURRENT PRODUCTION

	Production	Area sq. m.	Employees	Million units
Ampoules	Basic Vitamins	3,000 2,500	280 160	234 320
Aerosols	Basic			12
Tablets (20 units/pack)	Basic Vitamins	2,500 1,600	280 160	7,100 1,280
Capsules (20 units/pack)	Vitamins	660	50	700
Vitamin C + Calcium Gluconate			320	4,200
TOTAL		10,260	1,250	

These issues (1-4, above) are discussed in Section 3, below, as the challenges which must be addressed if OKTYABR is to convert into a private commercial enterprise. However, its current financial condition is reflected in the following tables:

Table 2

SPI PHARMACEUTICALS, INC.
OKTYABR
INCOME STATEMENT
(DOLLARS 000)

	1990	1991	Six Mos June 30 1992
SALE	39,983	146,902	4,080
COGS	112,768	86,953	40,401
GROSS PROFIT	27,215	59,949	(36,321)
GROSS PROFIT %	19	41	(890)
OTHER EXPENSE	15,70	613,169	(7,867)
INCOME BEFORE TAX	11,509	46,780	(28,545)
INCOME TAX	14,489	23,604	697
NET INCOME	(2,980)	23,176	(29,151)
NET INCOME %	(2)	16	(714)

Table 3

SPI PHARMACEUTICALS, INC.
OKTYABR
INCOME STATEMENT
(RUBLES 000)

	1990	1991	Six Mos June 30 1992
SALES	114,786	255,610	587,486
COGS	92,470	151,299	270,735
GROSS PROFIT	22,316	104,311	316,751
GROSS PROFIT %	19	41	54
OTHER EXPENSE	12,879	22,914	54,594
INCOME BEFORE TAX	9,437	81,397	262,157
INCOME TAX	11,881	41,070	100,412
NET INCOME	(2,444)	40,327	161,745
NET INCOME %	(2)	16	28

Table 4

OKTYABR
INCOME STATEMENT
(000 RUBLES)

	12-31-90	12-31-91	Six Mos June 30 1992
CASH	619	2,460	2,243
ACCOUNTS RECEIVABLE	4,028	11,065	245,873
INVENTORIES	26,296	63,995	330,100
TOTAL CURRENT ASSETS	30,943	77,520	578,216
FIXED ASSETS NET	10,917	14,953	35,114
TOTAL ASSETS	41,860	92,473	613,330
ACCOUNTS PAYABLE	5,971	6,862	235,582
SHORT TERM BANK DEBT	7,730	4,336	92,000
ACCRUED LIABILITIES	2,747	15,536	58,264
TOTAL CURRENT LIABILITIES	16,448	26,734	385,846
EQUITY	25,412	65,739	227,484
TOTAL LIABILITIES & EQUITY	41,860	92,473	613,330

Table 5

OKTYABR
INCOME STATEMENT
(000 DOLLARS)

	12-31-90	12-31-91	Six Mos June 30 1992
CASH	369	1,439	16
ACCOUNTS RECEIVABLE	2,398	6,471	1,707
INVENTORIES	15,652	37,425	2,276
TOTAL CURRENT ASSETS	18,419	45,335	3,999
FIXED ASSETS NET	6,499	8,744	7,973
TOTAL ASSETS	24,918	54,079	11,972
ACCOUNTS PAYABLE	3,555	4,013	1,635
SHORT TERM BANK DEBT	4,601	2,536	639
ACCRUED LIABILITIES	1,636	9,086	405
TOTAL CURRENT LIABILITIES	9,792	15,635	2,679
EQUITY	15,126	38,444	9,293
TOTAL LIABILITIES & EQUITY	24,918	54,079	11,972

C. Technical Conditions

Technical conditions and issues are related to the full spectrum of matters relating to the development, production and distribution of product. The state of these issues, as they relate to OKTYABR, are discussed below.

1. Products

OKTYABR specializes in the output of finished medicinal means; ampoules, tablets, medicinal aerosols, vitamins in ampoules, tablets and capsules, liquid medicinal preparations, and also raw materials for the drugs production.

OKTYABR produces medical products, divided into following therapeutical groups:

Name	Unit	Output Volune in 1991	Specific weight of the total output
1. Cardiovascular drugs	thous. amp thous. pack	943 56549	0.2 12.7
2. Oncologic disease treatment	thous. pack	25281	5.7
3. Psychoneuro-logic disease treatment	thous. pack	14764	3.3
4. Analgetic and febrifuge drugs	thous. amp thous. pack	42243 183192	7.8 41.3
5. Anti-tuberculosis drugs	thous. pack	11503.8	2.6

Name	Unit	Output Volume in 1991	Specific weight of the total output
6. Antiasthmatic drugs	thous.amp thous. pack	44108 8804	8.2 1.9
7. Preparations for narcotics and local anaesthesia	thous. pack	1604	0.4
8. Vitamin preparation	thous. amp thous. pack	285094 45877	52.8 10.3
9. For treatment of endocrine system diseases	thous. amp. thous. pack	8230 5564	1.5 1.5
10. Others	thous. amp thous. pack	159381 90859	29.5 20.5

In all, OKTYABR produces 201 names of medicinal means, including:

40 mln ampoules of 36 names per year;

44 mln packages of finished medicinal means of 102 names per year;

1863.2 t substances of 63 names per year.

Among the produced assortment, the following medicinal means have the most specified weight by the volume of production:

Drug name	Output Volume in 1991	Specific weight of total output
AMPOULES		
Novocaine 0.5% 5 ml	82650.5 th.	15.3
Dimedrol 1.0% 1 ml	44108.0 th.	8.2
Proserine 0.05% 1 ml	35413.0 th.	6.6
Vitamin C 5% 1 ml	141585.0 th.	26.2
Total	303756.7 th.	56.3
FINISHED DRUGS		
Citramon N6 tab.	188502.92 th. pack	42.4
Nitroglycerinum 0.0005 N40 tab.	30399.10 th. pack	6.8
Cyclodol 0.002 tab.	9919.69 th. pack	2.2
Dibasol 0.02 tab.	17386.10 th. pack	3.9
Inhalipt aerosol	5564.00 th. pack	1.3
Validol caps.	15000.00 th. pack	3.3
Nitroglycerinum caps.	7924.00 th. pack	1.8
Vitamin C 0.025 tab.	34149.24 th. pack	7.7
Total	308845.05 th. pack	69.5
MEDICAL MEANS SUBSTANCES		
Phenacetine	660.31 t.	35.4
Methyluracyl	93.60 t.	5.1
Dimedrol	45.245 t.	2.4
Calcium gluconate	219.78 t.	11.8
Total	1018.935 t.	54.7

2. Raw Materials

OKTYABR uses over 8000 different chemicals for the production of its products. These raw materials are supplied by 2000

enterprises in Russia, countries of the CIS, and foreign partners. The raw material supply is carried out according to direct agreements.

In addition, OKTYABR has substances for its own production that can be partially used for the production of finished drugs. Intrafirm gross output circulation of the "Pharmacon" plant is about 20%. 26 of 63 kinds of substances, produced at OKTYABR are used.

OKTYABR has railway approach lines for the receipt of liquid raw material, delivered in tanks, and large storehouses (the total square of storehouses is 2450 m^2).

3. Labour Resources

There are 3,479 employees. According to the type of activity they are divided into:

Total number	3479	
including:		
production workers	2783	
nonproduction workers	696	

According to the qualification level:

qualified workers	1799	64.6%
workers of low qualification	984	35.4%
Nonproduction workers:		
with higher education	466	66.9%
with incomplete higher education	11	1.6%
with secondary technical education	181	26.0%
with secondary education	38	5.4%

According to the length of service at OKTYABR employees are divided as follows:

from 1 to 3 years	612	17.6%
from 3 to 5 years	850	24.4%
from 5 to 10 years	1133	32.6%
over 10 years	884	25.4%

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4. Training

Training at OKTYABR is carried out according to a long-term plan of training, retraining and qualification improvement of workers, specialists and leading officials of the enterprise. It occurs both directly at the enterprise and at training course centres, faculties of qualification improvement at higher education institutions, and at the institute of qualification improvement.

During 1991, there were 364 people involved in training of all kinds, including:

new workers training	33 persons
second (adjacent) job training	20 persons
tariff category raising	108 persons
newly adopted retained workers	150 persons
leading officials and specialists improved professional skills at the courses of qualification improvement	22 persons
trained at purpose destination courses for the lift operator specialty	31 persons

Together with the services of labour protection and safety engineers, subjects included: special rules (on service and safe

work in gas economy, in service, repair and safe employment of vessels, operating under pressure, on service, repair and safe employment of load lifting equipment), and fire engineering. The studies are carried out with the participation of the city and state technical observance workers, LOGS VDPO, and by the specialists of OKTYABR.

5. Production Planning

Three kinds of plans are being developed by OKTYABR: long-term (5 years), current (1 year), operative (3 months). The planning is carried out at present with the consideration of the following priorities:

i) market demand;

ii) raw material supply possibilities;

iii) production capacities;

While planning production activity, two aspects are taken into account:

a. The satisfaction of need of the population of Russia for a particular product; and

b. Maximization of Profit.

The current planning of production has been performed by the development of an industrial technical plan, which embraced the detailed planning of all operations and was the principal planning document for the work during a year. Due to the sharp change of the economic situation, the primary planning became the operative or three month plan, which responds to the changing market demand for the drugs and the available production resources.

According to the results of its activity, OKTYABR presents operative reports (once per month) to the organs of state statistics, and current reports (once per quarter and annually) to the organs of state statistics, bank and tax inspection. This schedule is based on the legislation of the Russian Federation and the oversight of OKTYABR's activity is carried out by the bank and tax inspection.

6. Costs of Production

OKTYABR's prices result from agreements with purchasers. The prices sought are formed internally, according to plan expenses and plan profitability of 30-50%.

Costs of production include the following groups of costs:

Cost article name	Spec.w. of art.in amp.cost, cost.cont.	Spec.w. in tablet content cont.	Spec.w. in aer. cost cont.	Spec.w. in vit.cost	Spec.w. in subst. cost cont.
1. Raw and main material	40.4	61.2	36.5	48.9	66.4
2. Auxiliary materials	18.5	10.5	40.8	17.5	0.9
3. Transport-procurement costs	1.7	1.1	2.0	2.0	0.5
4. Main salary of production workers	5.7	3.9	2.3	6.2	2.9
5. Additional salary	0.8	0.5	0.3	0.9	0.4
6. Social insurance assignment	2.9	2.1	1.4	3.1	1.9
6a. Energetics	-	-	-	-	-
7. Equipment maintenance & operation costs[5]	11.3	5.9	6.5	8.4	3.8

[5] power costs of finished forms are included into cost articles N7, 8, 9 due to low specific weight.

Cost article name	Spec.w. of art.in amp.cost, cost.cont.	Spec.w. in tablet content cont.	Spec.w. in aer. cost cont.	Spec.w. in vit.cost	Spec.w. in subst. cost cont.
8. Plant costs	3.7	2.6	3.3	2.4	7.9
9. Whole plant Costs	12.5	9.9	4.0	8.2	6.8
10. Extra-production costs	2.5	2.3	2.9	2.4	1.1

Production prices are revised each quarter due to the constant changes of prices for the raw material, auxiliary materials, power carriers, etc. When changing prices, it is necessary to agree with purchasers. Production costs planning and price formation are carried out by economists. Cost accounting is carried out by the accounts department. Costs charging to the production and cost formation is performed according to the legislation of Russia.

7. Production Requirements

All the medicinal means produced by OKTYABR have a registration number and are included in the State Register of medicinal means. As such, they can be used in medical practice and industrial production.

The production of medicinal means is performed in accordance with the requirements of the XIth edition of the general plan (i.e. aerosols, injection drugs, capsules, tablets) of the State Pharmacopoeia. Additionally, the requirements of separate Pharmacopoeia articles, applicable to specific medical means, are also satisfied.

All auxiliary substances used in the preparation of finished product, are qualified from medical application at their quality satisfies the requirements established in the current regulatory documentation. See, e.g. GOST, OST, TU, FS.

8. Quality Control and Testing

Quality control and testing is conducted by both the State and OKTYABR:

State Control and Testing is carried out by the State Inspection of the quality control of drugs and medical equipment articles, and by the State scientific-research institute of standardization and control of medicinal means (GNIICKLC).

GNIICKLC carries out:

i) Preliminary control of all preparations, for the first time produced serially at OKTYABR.

ii) Subsequently selective control of all the preparations, produced serially.

iii) Arbitral control in case of disagreements about the quality between a supplier and a customer.

Controls at OKTYABR: Production quality control at OKTYABR is carried out by the technical control department (TCD). The functions of TCD include:

- input control of the received raw material; control of its storage in the storehouses;
- acceptance inspection of the finished products and supervision of preparation stability at their storage during the established service life;
- selective control of the observance of technological discipline and production operations in compliance with the requirements of applicable regulations.

9. Research and Development

Production Development

The central laboratory at OKTYABR works to:

- conduct research;
- develop new technological processes to increase production levels; and
- develops new substances and finished drugs.

The central laboratory includes both the organic synthesis laboratory and the laboratory of finished medicinal forms. These laboratories are staffed with highly qualified specialists, including 18 nonproduction workers with higher education who graduated from the technological and Chemico-Pharmaceutical Institutes. Three of the specialists are candidates for degrees in chemical science.

The laboratories currently concentrate in the following areas:

- technological improvement of the synthesis of drug substances;
- development of new drugs;
- development of new technologies for the processing of finished drugs;
- improvement of current production technology;

- improvement of control methodology for both technological processes and finished product production; and

- creation of regulatory documentation regarding finished medicinal forms, and substances and semiproducts.

The work on development of new medicinal preparations and substances is carried out in close creative co-operation with a number of scientific-research and training institutes of Russia and countries of the CIS including: VILR, VNICFI, NPO "Vitamins", VNIICTLC, St. Petersburg Technological Institute, St. Petersburg Chemico-Pharmaceutical Institute, Moscow Chemico-Pharmaceutical Institute, St. Petersburg Institute of Toxicology, Kiev Institute of Toxicology, Institute of Highmolecular Compounds, Army-Medical College, Oncologic Scientific Centre, etc.

During the period of 1990-1992, the Laboratory of the Finished Medicinal Forms introduced and prepared for production twelve kinds of finished medicinal preparations (seven in tablet form, four for injection).

The Laboratory of Organic Synthesis has developed the technology for the production of new medicinal preparations, including: catapol (together with the Institute of Highmolecular compounds), gemithiamine (with St. Petersburg Chemico-Pharmaceutical Institute), oximethacyl (with Army-Medical College).[6]

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[6] Technological processes of production for a number of preparations have also been developed, e.g., prospydine, sarcolysine, ethadene, amicasol, naphthamon, bathylol, camphonium, damoxine, pyrroxane, dioxidine, chinoxide, glyformine, sydnophene, sydnocarb, spirobromine, prodimine, hydrotatrate adrenaline. There are author's certifications for a number of developed technological processes: N 620482. The method of 1-phenyl-3-oxibutyronitrile production; N 672202. The method of 1,4-diazo-bucyclo (4,3,0)-nonane production; N 738319. The method of vitamin D_3 production; N 690008. The method of sydnonimine production. N 908019. The method of hydrochloride 6 (3-phenylpyrrodidine-1') propyonile) - benzo - 1, 4-dioxane

In the field of production of injection solutions, the laboratory is working on vitamin fine filtration preparation development, the tableted form production, and studies the possibilities of development of a film coat technology for tablets in the "boiling layer".

In addition, the laboratory works on applications, articles, and new control methods. For the period 1990-1992, eighteen pharmaceutical articles have been revised; the application time of six preparations has been increased; three pharmarticles for new preparations have been developed; and new methods of the finished medicinal means control are being developed according to the requirements of XIth edition of Pharmacopoeia.

In addition, the laboratory carries out the development and preparation of consumer goods production, including nutritional tablets, vitaminized dry drinks and shampoos.

Development of Equipment

The section on non-standardized equipment at OKTYABR is charged with introducing new equipment and improving the current facilities for the production of the finished medicinal means.

A chart of OKTYABR's power resources is attached as Annex 2, hereto.

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production. N 944276, The method of 1,4 - di- -oxi-2,3-bis(bromethyl) - chinoxaline production, N 670594. The method of dichloride, -di- benzoyl-, -dispirotripiperazine production. N 1060617. The method of phthalazoncarbonic acid production. N 1115435. The method of di-iodomethylate-(dimethylaminopropyl) camphidine, N 1114022. The method of 3-3'-dimethylamino)propylamino) propylamide of oximinoacetic acid production. N 1103506. The method of production of photoresin, containing vitamin D. N 1365679. The method of 8-bromadenine production. N 1405265. The method of hydrotartrate adrenaline production. N 1489149. The method of dichloride dihydrochloride 6,9 - diazonium-3,12 - diazadispyro (5,2,5,2) hexadecane production.

SECTION IV

LEGAL AND REGULATORY CHALLENGES TO THE CONVERSION OF OKTYABR INTO A PRIVATE COMMERCIAL ENTERPRISE

A. Legal and Regulatory Challenges

Taking into consideration the existing legal regulations and business plans of OKTYABR, the latter may face some challenges which may arise due to the process of privatization itself, as well as challenges generated by the legal environment in which OKTYABR as a private entity will have to operate.

1. Creation of a corporate and financial structure

As a result of privatization, OKTYABR must become a viable and well-managed enterprise. It may happen only if it is structured adequately and handles effectively numerous challenges of this process.

During the privatization process and afterwards, OKTYABR may be confronted with the issue of separating certain welfare or consumption aspects of enterprises from their productive elements. Continued ownership and maintenance of housing for OKTYABR's employees and other non-operating business assets are in effect expensive subsidies to employees that not every enterprise can afford. The burden placed on newly privatized enterprises threatens their economic viability and certainly distorts their economic efficiency.

Even though the privatization options provided by the legislation give significant benefits to the employees of the enterprise subject to privatization in terms of purchasing the stock in the enterprise, the subsequent restructuring of the enterprise in order to make it more efficient economically may

have a high social cost, for instance, the lay-off of potentially large number of employees. It is not clear whether OKTYABR management will be willing to make tough economic decisions and cut labour costs in the pursuit of profits.

Since the recent privatization legislation provides for the possibility for purchasing with vouchers at a market price (above or below the voucher face value of 10,000 roubles) from 35% to 80% of the stock, the privatized enterprise will need a serious injection of capital to modernize the production, comply with new environmental requirements, etc. After privatization, the enterprise may no longer be able to look to the State for its capital, but will have to try to obtain it in the market through equity or bank financing. Both ways may be quite unusual for the former state enterprise and will require a lot of considerations. For instance, if OKTYABR has certain plans to attract a "strategic" investor (foreign or domestic), it should be careful in selling the shares to outsiders during privatization because a certain amount of these shares may be bought by a competitor of the potential "strategic" investor. Financing through the bank may require using a part of the assets of the enterprise as collateral, which is permitted by the Law on Pledge, but so far did not become a widespread practice.

The relationship with customers and suppliers will be another challenge for OKTYABR in a new environment. Though privatized enterprise will have a right to choose to whom to sell its product and at what price (though here might be some antimonopoly restrictions), it is true that the suppliers may obtain the same freedom, and OKTYABR will have to establish relations with new companies or renegotiate the terms of the old contracts. It will require significant marketing skills which are now at great shortage in Russia.

2. Hard currency regulation

OKTYABR may face some restrictions on hard currency operations it may be engaged in while it is importing and probably will continue to import some raw materials (ingredients, substances) for its production; or, since it is planning to export part of its production, it will generate some hard currency revenues.

i) At the present time, all Russian resident companies, regardless of whether they are state or privately owned, with or without foreign investments, have to sell 50% of their gross hard currency revenues to the Central Bank at the market rate of exchange. There are rumors that next year this percentage will be increased up to 100%, which may affect incentives to export production while uncertainties on the domestic market (e.g., lack of demand if the prices on pharmaceuticals will not be subsidized any more) may create problems with the sale of products. Besides, the lack of hard currency will have negative impact on the ability of enterprise to import necessary materials.

ii) Because of the insolvency of many enterprises and delays in payment, many foreign exporters do not ship goods unless the Russian importer makes a deposit in an escrow account in the foreign bank. Meanwhile, the legal ability of Russian enterprises to open accounts abroad is restricted and may be realized only by specific permission of the Central Bank.

3. Import and Export Regulation

Import

i) Licensing. In 1993, medicines and chemicals for their production as well as medical equipment can be imported into Russia only by licenses which could be obtained at the Health Ministry. The law provides that the licenses are granted to the enterprises, regardless of their form of ownership. Still, in practice it was easier to the state enterprise, particularly in the case of an enterprise with price-controlled finished products, to obtain such license than for the private enterprise. It would be desirable to get an assurance that privatized OKTYABR will be able to get import approvals for all materials it needs for its production.

ii) Duties. In accordance with government resolution #553 of August 5, 1992, some food products and medicines specified in the resolution, as well as raw materials for their production, are exempt from import duties when imported to the territory of the Russian Federation. The list of exempt goods may be amended by the State Customs Committee upon joint application of Ministry of Economy, Ministry of Finance and "other ministries concerned". In the case of pharmaceutical products and related raw materials, the Medical Industry Committee will certainly be involved. So, if not all raw materials and ingredients that OKTYABR is importing for the purpose of production are in this list, it will be desirable to apply for further exemption.

Export

i) Licensing. All export of the medicines and chemicals for their production is approved by the Health Ministry in the same way as their import (see above). A special procedure is established for export as well as for the import of narcotic substances and poisons. Depending on what products OKTYABR is actually planning to export, it may be subject to one or another procedure.

ii) Duties. There is a vast list of products which are subject to export duties. The list is being changed on a regular basis and potentially any of the product OKTYABR is willing to export might be included in this list.

4. Intellectual property

The intellectual property protection is available under Soviet law (Statute on Discoveries, Inventions and Rationalization Proposals of 1973 and the Patent Law of the Russian Federation, 1 October 1992.) provided for two forms of protection: (1) an author's certificate, which was a mere recognition of the authorship, and (2) a patent which besides such recognition would give the exclusive right to use the patented invention or industrial design. There was a list of inventions which could be protected only by certificate: this list included, among others, the invention of medical substances. If the certificate was granted, it meant that the authorship is recognized but an unlimited right to use the invention is transferred to the state. This right included the right of the state to use this invention inside the country or to sell it abroad. All state, cooperative and public organizations had a right to use this invention without specific approval of the government agency or consent of the author, unless the use of

such invention was outside the scope of activity of such organization (enterprise). All other organizations had the right to use the invention for fifteen (15) years from the date the certificate was issued only with the permission of the State Committee of Discoveries and Inventions.

If a patent was issued, the patent holder would have the exclusive right to use patented invention, and could conclude a license agreement which was subject to compulsory registration of the Committee. Since no enterprise prior to 1989 could carry out foreign economic relations, i.e. enter into transactions directly, basically all license agreements were concluded through the Soviet foreign trade organizations.

In view of the above, OKTYABR may encounter some problems in the protection of its product. One may not exclude the possibility of manufacturing the same product (or part thereof) at other state pharmaceutical enterprises if it was included in their state plan. Some of these enterprises may be located on the territories of other than Russian republics of the former Soviet Union. In the case if OKTYABR would like to export its production, it may compete with these enterprises selling the product generated by OKTYABR. It may happen on domestic market as well but significantly later in time, since the demand for medicines in Russia is satisfied up to 60-70%.

Apparently, there will be no problem with the protection of new products since they will be covered by new Patent Law which is very close to the world practice and allows adequate protection of pharmaceutical products.

5. Antimonopoly laws

One of the major antimonopoly regulatory tools in Russia is price control. When the government subsidizes the industry, the

price control may be justified. However, when OKTYABR, as a newly privatized enterprise, will appear on the market, in order to survive on its own, it will have to make the production profitable and therefore will almost inevitably increase the prices. In order to avoid accusation of monopolistic position and corresponding incorporation into the Register of monopoly enterprises, OKTYABR will be forced to reduce the costs of production. In the circumstances when OKTYABR will have to bear a lot of new costs (e.g., installation of environmental safety controls), new management may be forced to undertake a large lay-off.

Though OKTYABR owns about 35% of the market share up to date, one should not disregard a role of growing import competition, i.e., competition with imported goods as well as products of subsidiaries and joint ventures of foreign firms developing their activities on the Russian market. Unless the government adopts protectionist trade policy (which is not desirable since in such a highly monopolized market the entry of a new participants is a major alternative to the forced break-up of Russian monopolies or government control of prices), OKTYABR may find itself in a very unusual and challenging environment.

One of the easiest ways for OKTYABR to survive on the first phase will be, like for other Soviet monopolies, to use its independence from central planning system to shift its output mix in favour of higher-priced products, to cut production targets, to impose conditions on buyers such as requirements for barter exchange, etc. This will certainly have negative impact on the local consumers, which may trigger the regulatory measures by the Antimonopoly Committee.

6. Environmental Liabilities

Environmental considerations will be one of the major challenges for OKTYABR during its conversion into private

enterprise and corresponding efforts to bring into the process serious (possibly, foreign) investors as well as for subsequent functioning of the enterprise in the framework of stricter environmental requirements.

OKTYABR, along with other state enterprises, did not have an excellent environmental record and sacrificed an environmental protection for the fulfilment of state production plans. Therefore, OKTYABR's efforts to attract foreign investments may encounter the concerns of investors or financial institutions lending money to such investors about the degree of environmental liability that will be imposed.

A normal business practice in developed countries includes an evaluation of environmental conditions before investing in companies being privatized. Therefore, potential investors in OKTYABR are likely to make a risk assessment before starting any large project. It will have direct economic implications for OKTYABR. The value of OKTYABR's business will be significantly less if one takes into account the cleanup costs for prior pollution as well as the need for installation of the modern pollution controls in order to comply with new environmental legislation and avoid liability in the future. OKTYABR will have to deal with the concerns of the investors about potential liabilities. It will have to provide all relevant data and to determine, through specific agreement, what will be the responsibility (if any) of investor: up to what amount and time frame. The uncertainty about these issues may damage the success of the investment process.

7. Tax Challenges

OKTYABR in particular is subject to all of the unfavourable tax laws currently in force in the Russian Federation.

Profits Tax Law Challenges

The Profits Tax Law does not distinguish between producers of pharmaceuticals and other manufacturing industries. It imposes a tax at the rate of 32% on the income of pharmaceutical manufacturers. The Profits Tax Law does not permit deductions for wages and provides only limited deductions for interest in the context of funds borrowed to improve plant and equipment or for working capital. To the extent deductions are permitted, they are furthermore limited to Russian normative interest rates as set from time to time by the Central Bank.

Depreciation is permitted on plant and equipment at slow rates when compared to foreign standards on most equipment. The full carry forward of start-up or other losses, permitted in the US, for example, to be carried forward for 15 years, is not available under the Profits Tax Law. Instead, Russia may permit a carry forward of up to five years, but this carry forward, together with all other tax "privileges", is limited cumulatively to reducing annual taxation by only 50%. Thus, profits may be viewed as existing in the Russian system in a year in which most other jurisdictions would consider as a loss year.

It is important to emphasize that the prior Russian tax law, the Enterprise Tax Law, recognized these faults in the Russian tax system and specifically corrected them in the case of Russian enterprises with more than 30% foreign ownership. Thus, for example, foundation documents could create a series of depreciation rates much closer to foreign norms, salaries of employees would be fully deductible, interest would be fully deductible, and start-up losses could be fully deducted and carried forward for five years. Thus, the tax system generally encouraged foreign capital investment.

Furthermore, and very importantly, under the prior Enterprise Tax Law, funds expended to increase production at an existing facility, including repayments of interest and principal on loans used for this purpose, were fully deductible and that, together with the five year carry forward of losses, generally would insure that most enterprises engaged in the production of pharmaceuticals (or other material production) that had a substantial injection of new funds to improve production facilities would likely not pay tax for a five or greater year period but apparently could not extend the total tax free period over five years. However, with the deduction for contributions to the production and development fund, rules for a seven to ten or greater tax free period existed.

A vestige of the deduction for contribution to the production and development fund is contained in the Profits Tax Law to the extent annual profits of an enterprise are reinvested in activities that will lead to increased production, but this together with other "special privileges" is limited to reducing tax due by 50% or less of those profits. In fact, all "special privileges" are cumulatively limited to 50% of profits in any one year. Thus, the rule does not take into account start-up funds or any funds invested except out of profit. For example, only an already profitable business operation could use a portion of its profits to increase its production, but the investment of funds in a currently unprofitable business would be given no tax benefit under the current Profits Tax Law. For the Russian pharmaceutical industry as distinct from production of gold, petroleum or other raw materials with a ready, unsubsidized market both in Russia and abroad, the current version of the deduction is virtually without value.

In contrast, foreign pharmaceutical enterprises whose sales compete with the Russian pharmaceutical industry through

manufacture within Russia would be granted certain important tax advantages. For example, in the case of foreign pharmaceutical manufacturers, subject to the 32% tax rate, the limitation on salaries and interest deductions is not present, these are fully deductible to foreign enterprises.

Foreign enterprises which manufacture outside of Russia and pass title to Russian middleman organizations or Russian consumers outside of Russia are in fact not normally subject to any Russian income taxes. Pharmaceutical industries such as those in France or the Netherlands, countries that have territorial tax systems, may be able to avoid tax both at home and in Russia on their pharmaceutical sales. Therefore, from the standpoint of taxation of foreign competition, the Russian tax system also discourages investment in the existing industry.

Import Tax Issues

In addition, Russia does not protect its domestic pharmaceutical industry by imposing tariff barriers on imports of pharmaceutical products and, indeed, the 15% import tax generally applicable to imported goods in Russia is specifically not applicable in the case of imported pharmaceuticals. However, it can apply to necessary raw materials coming from within or without the CIS and to the import of needed equipment, spare parts, etc.

Foreign Investment Tax Issues

In connection with foreign investment in the pharmaceutical industry in Russia, high Russian withholding taxes are also discouraging. Distributions of profits to foreign investors are subject to a 15% withholding tax in the absence of an income tax treaty with the country of the investor, and royalties paid on the licensing of products

to support Russian manufacture is subject to a 20% withholding tax, unless an income tax treaty with the licensing country reduces this rate.

Value Added Tax

One tax that Russia does eliminate in the case of the pharmaceutical industry is the Value Added Tax (VAT). This is, however, of no help to the pharmaceutical industry as this tax is imposed on the consumer, not on the producer who merely collects the tax. Indeed, as noted earlier, purchase of domestic equipment to manufacture pharmaceuticals could give rise to a VAT obligation of 20% (from January 1, 1993) which cannot be recovered from sales that do not give rise to VAT receipts (and in any event are not currently recoverable under Russian rules).

Property Tax

The recently enacted Property Tax that calls for an additional tax of 1% per annum on the gross asset value of a Russian enterprise will also discourage investment. For example, in connection with a new investment of $50 million in plant and equipment, an enterprise would pay $500,000 per year in property tax.

B. Financial Challenges

- operating capital
- financing receivables/payables
- construction financing for new plant and equipment
- social costs
- subsidization of products
- tax and customs' regime
- purchases

- profitability

C. Technical Challenges

To be provided:

- Training; TQM
- new plant and equipment
- new product production
- exports/imports
- quality control

SECTION V

THE PROCESS OF CONVERSION - CHALLENGES TO THE CONVERSION OF THE PHARMACEUTICAL INDUSTRY IN RUSSIA

A. Legal and Regulatory Challenges

1. Privatization issues

The privatization of the whole industry, though sharing all the problems one separate enterprise may encounter, will have a different scale and magnitude of problems and, therefore, will require a balanced government policy which must identify and accommodate the interests of all of the affected constituencies: state, business, labour and consumers.

The pharmaceutical industry as a whole cannot be transformed immediately into private sector: it may be a gradual process particularly because it is a very sensitive sector of the economy. However, it is possible and desirable to submit all enterprises of industry to some market control. Those of the enterprises that are not subject to immediate privatization may be transformed into joint stock companies, and though the stock may be owned for some time by the state, the enterprises may be subject to the discipline of the market and the cost of capital.

The privatization of even one part of the pharmaceutical sector may generate a number of challenges. First of all, one must not disregard high social costs to privatize large portion of the industry: the massive lay-offs are quite predictable and the government will be required to pay the welfare compensation to laid-offs workers and to pay for their retraining.

The management of every particular enterprise as well as of the industry as a whole are to resolve the issue of separating certain welfare or consumption aspects of enterprises from their

productive elements. Continued ownership of housing, day-care centres, shops and other non-operating business assets may threatens economic viability of enterprises and certainly distorts their economic efficiency. The industrial management has to resolve this issue in different ways, for example, to give part of these non-productive assets to the municipalities, to sell some of them, to privatize housing, to contract out certain services, etc.

The privatization laws provide for significant privileges of employees during the process of privatization. However, the subsequent restructuring of the enterprise in pursuit of economic efficiency (i.e., potential cut of the labour costs) may conflict with the interests of employees who will be the owner of the significant part of the stock. Since the majority of the stock will be given for free or at major discount, the industry will not receive as a result of privatization any injection of capital unless it will bring in outside investors, preferably foreign investors.

The relationships with consumers who are used to greatly subsidized pharmaceutical products will be another challenge for the industry and will require adequate government policy in terms of pricing, subsidizing hospitals and low-income consumers, etc.

2. Antimonopoly implications

Since pharmaceutical industry in Russia is highly monopolized sector, the privatization of this sector will necessarily have an antimonopoly implications. The Government will be protecting the public interests of abuses of private monopoly power. Price control, probably, will continue to be the major antimonopoly device, but gradually has to be reduced. More effective way to deal with monopolies may be the encouragement of the competition on the domestic market with imported goods and products of Joint Ventures and subsidiaries of the foreign

companies. The risk is that the government may adopt a protectionist trade policy.

Another way to deal with the issue is to break-up huge post-Soviet monopolies (conglomerates of enterprises) and allow different parts of them to compete with each other. Currently, these state monopolies are being transformed into all sorts of joint stock companies to Decree of President No. 721 from 1 July 1992.

3. Environmental regulations

Since pharmaceutical industry has been and in many cases continue to be one of the major polluters, the environmental considerations associated with the process of privatizing pharmaceutical enterprises in Russia should not be disregarded. Russian governmental agencies should adopt environmental policies that encourage investments so needed by the privatized enterprises.

Since Soviet government was both regulator and owner of industry, environmental requirements were very weak or non-existent. Now when state enterprises are being privatized and are seeking investments (preferably, foreign investments), the government should define the liabilities of all parties involved into the process (privatized enterprise, investors and government itself).

The major concern of every enterprise going through the privatization is the valuation of its assets and liabilities, particularly when the subscription for shares is pen to the public (which is the case with large enterprises including pharmaceutical enterprises). However, the cleanup costs for prior pollution and a need to install modern pollution control systems will reduce the value of business, unless somebody will share that liability.

Investment (foreign as well as domestic) is extremely important for pharmaceutical industry in Russia. However, all investors or financial institutions such as the World Bank, the European Bank for Reconstruction and Development, and other agencies lending money will require environmental assessments prior to the initiation of large projects, particularly those involving foreign investment.

Now a lot of developed nations, international organizations, international lending institutions and international trade agreements require introducing local environmental requirements similar to those in developed countries in order to avoid unfair trade advantages and the creation of "pollution havens". Therefore, the Russian government will have to introduce stricter environmental requirements which, in turn, will generate a need for enormous amount of additional investment into environmental safety systems.

All environmental concerns of potential investors into pharmaceutical industry of Russia should be addressed initially. An explicit environmental policy should be incorporated in investment and privatization statutes, any relevant data should be accessible. The environmental liabilities are to be reviewed during privatization or prior to signing an investment agreement. There should be no uncertainly about allocation of such liabilities. The options may include:

i) imposing on the newly privatized enterprise and investors no liability for past contamination;

ii) imposing full environmental liability on privatized enterprise; this option, however, may discourage investment and divert the scarce resources of newly privatized enterprise;

iii) the government will pay for a portion of cleanup; the allocation of the remaining liabilities should be known to the enterprise and investors;

iv) the government may allow a tax credit on new entities for a number of years in exchange for cleanup, etc.

B. Tax Challenges for the Russian Pharmaceutical Industry

The tax issues raised earlier in connection with the specific case of OKTYABR are similarly problematic for the Russian pharmaceutical industry in general. The various tax laws in force in the Russian Federation create a complex series of income and excise taxes which provide little incentive to investment in the pharmaceutical industry in Russia.

1. Profits Tax

As described earlier, the Profits Tax Law does not distinguish between producers of pharmaceuticals and other manufacturing industries. It imposes a tax at the rate of 32% on the income of pharmaceutical manufacturers. The Profits Tax Law does not permit deductions for wages and provides only limited deductions for interest in the context of funds borrowed to improve plant and equipment or for working capital. To the extent deductions are permitted, they are furthermore limited to Russian normative interest rates as set from time to time by the Central Bank.

Depreciation is permitted on plant and equipment at slow rates when compared to foreign standards on most equipment. The carry forward of start-up or other losses, permitted in the US, for example, to be carried forward for fifteen years, is not available under the Profits Tax Law. A five year rule is present which, together with other tax privileges, is limited to

deductions to only one-half (½) of the taxable profit for the year. Thus, taxable profits may be viewed as existing in the Russian system in a year in which most other jurisdictions would consider as a loss year.

It is important to emphasize that the prior Russian tax law, the Enterprise Tax Law, recognized these faults in the Russian tax system and specifically corrected them in the case of Russian enterprises with more than 30% foreign ownership. Thus, for example, foundation documents could create a series of depreciation rates much closer to foreign norms, salaries of employees would be fully deductible, interest would be fully deductible, and fully deductible start-up losses could be carried forward for five years. Thus, the tax system generally encouraged foreign capital investment.

Furthermore, and very importantly, under the prior Enterprise Tax Law, funds expended to increase production at an existing facility, including repayments of interest and principal on loans used for this purpose, were fully deductible and that, together with the five year carry forward of losses, generally would insure that most enterprises engaged in the production of pharmaceuticals (or other material production) that had a substantial injection of new funds to improve production facilities would likely not pay tax for a five year or longer period.

A vestige of the deduction for contribution to the production and development fund is contained in the Profits Tax Law to the extent annual profits of an enterprise are reinvested in activities that will lead to increased production, but this is limited to 50% or less of those profits. In fact, all "special privileges" are cumulatively limited to offsetting tax of 50% of profits in any one year. Thus, the rule does not take into account start-up funds or any funds invested except out of profit. For example, only an already profitable business operation could use a portion of its profits to increase its

production, but the investment of funds in a currently unprofitable business would be given no tax benefit under the current Profits Tax Law. For the Russian pharmaceutical industry as distinct from production of raw materials with a ready, unsubsidized market both in Russia and abroad, the current version of the deduction is virtually without value.

In contrast, foreign pharmaceutical enterprises whose sales of goods manufactured within Russia compete with the Russian pharmaceutical industry would be granted certain important tax advantages. The Russian pharmaceutical industry, including joint ventures between Russian pharmaceutical companies and Western companies, are subject to tax at the same 32% tax rate as foreign enterprises but are subject to the limitation on salary and interest deductions. In contrast, these items are fully deductible to foreign enterprises operating in Russia.

Foreign enterprises which manufacture outside of Russia and pass title to a Russian intermediary organization or to a Russian consumer outside of Russia, are in fact not normally subject to any Russian income taxes. Pharmaceutical industries such as those in France or the Netherlands, countries that have territorial tax systems, may be able to avoid tax both at home and in Russia on their pharmaceutical sales. Therefore, from the standpoint of taxation of foreign competition, the Russian tax system also discourages investment in the existing industry.

2. Import Tax

Russia does not protect its domestic pharmaceutical industry by imposing tariff barriers on imports of pharmaceutical products and, indeed, the 15% import tax generally applicable to imported goods in Russia is specifically not applicable in the case of imported pharmaceuticals.

3. Foreign Investors

In connection with foreign investment in the pharmaceutical industry in Russia, high Russian withholding taxes are also discouraging. Distributions of profits to foreign investors are subject to a 15% withholding tax in the absence of an income tax treaty with the country of the investor, and royalties paid on the licensing of products to support Russian manufacture is subject to a 20% withholding tax, unless an income tax treaty with the licensing country reduces this rate.

4. Value Added Tax

One tax that Russia does eliminate in the case of the pharmaceutical industry is the Value Added Tax (VAT). This is, however, of no help to the pharmaceutical industry as this tax is imposed on the consumer, not on the producer who merely collects the tax. Indeed, as noted earlier, purchase of domestic equipment to manufacture pharmaceuticals or of domestic raw materials could give rise to a VAT obligation of 20% (from January 1, 1993) which cannot be recovered from sales that do not give rise to VAT receipts (and in any event are not currently recoverable under Russian rules).

5. Property Tax

The recently enacted Property Tax that calls for an additional tax of 1% per annum on the gross asset value of a Russian enterprise will also discourage investment. For example, in connection with a new investment of $50 million in plant and equipment, an enterprise would pay $500,000 per year in property tax.

C. Proposed Solutions

1. Profits Tax

i) It is strongly recommended that, for a period of no less than five and possible as long as ten years, OKTYABR and/or any investment made by OKTYABR with a foreign investor should be free of enterprise level income tax.

In the context of a new investment between OKTYABR and a foreign investor, this is justified for a number of reasons. First, a combination of the five year net operating loss carry forward, the deduction for contribution to the fund for production and development and the two year tax holiday would in many cases have produced a seven to ten year tax free period under the prior tax law. This would have been true until as recently as 1 January 1992, regardless of the industry as long as it was manufacturing material goods. These benefits should clearly be maintained to attract investors in selective, key industries such as pharmaceuticals. The same policy considerations that caused these benefits to be available, until 1992, on a non-selective basis in the case of manufacture, continue to have force in industries such as the pharmaceutical industry. Competition from Hungary and other countries which provide for lengthy tax holidays in the case of critical industries such as pharmaceuticals make Russia an unlikely recipient of foreign investment in such industries in the absence of similar tax holidays.

ii) The tax exemption should, furthermore, be provided in such an absolute and binding fashion so as to be "bankable" in the case of investments that require

project finance from foreign banking or international lending institutions.

iii) Interest payments on funds lent in connection with the creation of such projects must be fully deductible to the payer company, as is typical in most countries, and regardless of the rate of interest provided it is a commercial, arm's length rate, and such intent should not be subject to withholding tax, regardless of whether the recipient bank is in a country covered by an income tax treaty.

iv) Payments of royalties in connection with the licensing of intellectual property to pharmaceutical concerns should be deductible to the payer company and should be free of withholding tax to the recipient, regardless of whether a tax treaty is applicable.

2. Import Tax

Products imported into Russia by pharmaceutical companies, whether items for resale or raw materials for processing into other forms or for plant and equipment, should not be subject to import duty or VAT. While current law (which could be changed and in the context of Russian import and export taxation is frequently changed) would not impose this 15% charge on imported pharmaceuticals, the charge could be imposed on key raw materials which go into the production of pharmaceuticals and on machinery and other items used in their fabrication.

3. Workers Tax Issues

Salaries of workers and other necessary business expenses must be fully deductible in order for such plants to compete with others in the CIS and in Eastern Europe in which such deductions

are uniformly available (as they are for foreign-owned Russian enterprises).

Salaries of foreign persons employed in pharmaceutical ventures as supervisory personnel, technical advisers, etc., should be exempt from Russian income taxation in the case of employees present for two or fewer years. The high (40%) individual tax rate, coupled with high social insurance costs (approximately 36%) are borne by the paying enterprise which must pay sufficiently high salaries in order to cover tax charges for its foreign employees and which are responsible for the social insurance payments. The Russian government will wish the pharmaceutical industry to encourage, at least initially, employing foreign persons with commercial pharmaceutical backgrounds and training and management expertise.

4. Value Added Tax

Full refunds of VAT on plant and equipment should be available.

5. Property Tax

Property tax should be specifically made inapplicable to key industries such as pharmaceuticals.

D. Financial Challenges

1. Operating Capital

Funds for operations must be tightly managed because of the general lack of liquidity in the Russian banking system. Working

capital loans from Russian banks are restrictive and carry high interest rates.

2. Financing Receivables/payables

Because of the aforementioned lack of liquidity, Russian suppliers now demand payment of advance of shipments to customers. Purchases of production material must now be closely tied to collections from customers.

3. Construction Financing for New Plant and Equipment

There is an immediate need for modern facilities and equipment. Much of this must be procured from western sources for hard currency. The timing and method of repayment for any loans will challenge businessmen to devise creative payback schemes and realistic business plans.

The commercial banking system is not well developed as yet in Russia. Russian banks need to adopt western-styled practices in the area of long-term construction and equipment financing to assist business investments. Without a functional commercial banking system in Russia, foreign businesses and western banks will be reluctant to risk their money on investments in Russia.

Russian banks need to establish correspondent banking relationships with western banks to facilitate business transactions. Hopefully, the World Bank, the International Bank for Reconstruction and Development (IBRD) as well as the United National industrial Development Organization (UNIDO) can help Russia develop its commercial banking system.

4. Special Costs

Russian workers are accustomed to a variety of social benefits, such as subsidized vacation, recreation, consumer loans, etc. The cost of these benefits must be incorporated into the financial planning for the Russian business.

5. Subsidization of Products

The Russian pharmaceutical consumer has been subsidized by the state in the form of "below cost" prices. Many non-critical medicines are now no longer subsidized or paid for by the state at pharmacies and at hospitals. Examples are non-prescription vitamins and pain relievers.

The state will likely continue to subsidize drugs deemed essential to public health. Non-essential medicines will be allowed to sell at market prices. Until Russian consumers have greater purchasing power, the price of these non-essential medicines must be kept low in order to sell them.

6. Tax and Customs Regime

The imposition of import and customs duties as well as heavy VAT taxes add greatly to the cost of bringing western technology into a Russian company. In addition, bureaucratic delays and paperwork must be considered in any project schedule. New joint venture companies should seek exemption from such duties and taxes.

7. Purchases

Sources of supply have been disrupted by the breakup of the former Soviet republics. A Russian Federation company must not

deal with the payment, delivery and other uncertainties when trading with companies in the Ukraine, Georgia and the Baltic states.

8. Profitability

The profitability of a Russian enterprise is challenged daily by supplier cost increases, inflation adjustments to salaries and wages, high interest cost of working capital loans, and many other inflation related problems.

E. Technical Challenges

1. Training, i.e., TQM

Russian managers and workers are unfamiliar with western policies, procedures, methods, accounting principles (GAAP), etc. Extensive orientation and training will be needed to bridge the gap.

2. New Plant and Equipment

Russian pharmaceutical workers must be educated in the vastly different standards and procedures demanded by western societies for the production of medicines.

3. New Product Production

The absence of many basic pharmaceuticals in Russia suggest the importance of producing many products new to the Russian market. Also many current medicines produced in Russia should be reformulated, repackaged, and/or re-engineered into different methods of application.

4. Exports/Imports

The Russian government requires Russian pharmaceutical producers to met domestic needs before it will issue export licenses. However, to earn hard currency and to take advantage of low production costs in Russia, companies must be allowed to do some exporting. Lobbying the Russian health ministry is needed to open their minds to this strategy which is critical to attract western investment capital.

5. Quality Control

The emphasis in Russian companies has been on meeting production quotas, not adhering to strict standards of quality. Clearly, the focus must change to move the industry closer to western practices. Several steps must be taken to improve the quality of Russian medicines:

* Worker training on the importance of quality
* Clearly written product specifications/formulations
* Better testing equipment
* More modern production equipment
* Move away from worker bonuses based only on production quantities.

ANNEX 1

SITUATION OF THE CHEMICAL-PHARMACEUTICAL SCIENCE IN RUSSIA

by Mr. M. Polievkov

Chemical-pharmaceutical science in Russia is mainly progressing in the following fields:

1. **Research and development of new drugs**

This area covers the chemical, physico-chemical, analytical and biological studies of newly synthesized compounds. There are two general approaches to synthesize new, effective medicinal substances.

One approach is to synthesize chemicals with a pre-planned chemical structure with desired biological activity. Usually there are substances having similar structures as indigenous compounds like CNS mediators or already known drugs. This type of work is probably done to modify the chemical structure of compounds to detain receptor systems, as well as strengthen certain properties and prevent specific functional groups for inactivation in the human body. The other approach is to synthesize a whole range of completely new chemicals. Both the approaches have their advantages and disadvantages and are discussed in the following section.

Research work which is directed to obtain biologically active compounds, is carried out in a number of research institutes all over Russia. But the main centres of such work are concentrated in Moscow, where there are quite a few establishments, in which both chemical and biological departments exist, providing an opportunity to maintain reasonably close contact between chemists and biologists and for that enabling fast study of biological and toxicological properties of newly synthesized compounds. Among such main institutes, the Institute of Pharmacology belonging to Russian Medical Academy of Sciences

and Russian Research Chemical-Pharmaceutical Institute can be mentioned.

Certainly, research work of this type (directed or oriented synthesis) does not always result in new drugs, but in many cases opens opportunities for better understanding of numerous ambiguous and complex interactions of bioactive substances in a human body system. Thus, it stimulates new researches in the development of new drugs as well as creating new ideas to obtain new groups of compounds with distinct therapeutic effect.

As an example, research of Captopril, an antihypertensive preparation, published in the Chemical-Pharmaceutical Journal, (issued in Russia) can be mentioned. The concept is based on the fact that Captopril and similar drugs, usually amino acid derivatives, can be inactivated in human body by means of decarboxylation under appropriate decarboxylases conditions. To prevent this undesirable phenomenon, it is proposed to use Captopril together with inhibitors of peripheric decarboxylation. The pharmacological research, based on this idea, has shown significant strengthening and prolongation of the Captopril antihypertensive action. It is therefore clear that the extension of this specific approach to other drugs can result in the development of new ways of increasing their efficiency.

Another example, reasonably indicating the benefits of the designed changes of drug properties as a result of structural modification is the antidepressant Pirlindole, first synthesized and at present widely used in Russia.

Essential increase of lipophility by the replacement of the methyl group by a cyclohexyl one has led to another effective antidepressive drug, possessing features that Pirlindole is missing and hence giving it certain advantages over Pirlindole, especially in its fast-acting properties. On the contrary, the introduction of a nitrogen without infringement of a main skeleton of the molecule has resulted in obtaining an

antidepressive drug of some other type. All these three drugs, created in Russia, have received the official permission to be applied medically and are used in clinical practice.

It should be noted, that relatively large number of original, new and effective medicaments has been created first in research institutions and then in clinics of Russia, but unfortunately, they are little known in the Western world. The main problem in this area seems to be the differences in various requirement levels of preclinical and clinical studies and introduction and marketing regulations of new drugs in medical practice.

Nevertheless, anyone seriously studying scientific and practical aspects of an opportunity to integrate Russia in a global system of public health service should bear in mind the rather high scientific level of chemical and biological research and a large number of drugs developed in Russia and suitable for adaptation by foreign pharmaceutical companies.

Registered drugs and potential new products in the pipeline at various stages are as follows:

Carbidine — It has neurolytic and antipsychotic activity, renders moderate antidepressive and central adrenolytic action. It is used for the treatment of different kinds of schizophrenia and alcoholic psychosis.

Oxylidine — It is a tranquilizer, rendering moderate antihypertensive action.

Mebicar — It is a tranquilizer, strengthening action of soporific properties and improving sleeping conditions.

Azaphene	It is an antidepressant with a wide area of application in the treatment of various depressions.
Sydnophene	It is a CNS stimulator also possessing expressed antidepressive activity making it a valuable preparation for treatment of astheno-depressive conditions.
Sydnocarb	It is mainly a psychostimulator used in medical practice in Russia. Its stimulating action is not accompanied by euphoria and locomotor exciting activity. In the period of post action there is no phenomenon of common weakness or sleepiness.
Pantogam	It has nootropic activity, increases resistance to hypoxia, renders anticonvulsive activity.
Picamilon	A nootropic and cardiovascular drug, used to treat the various forms of insufficiency of cerebral blood circulation and alcoholic intoxication. It is useful to increase stability towards physical and psychological overloads.
Benzofurocaine	It has central analgetic and local anaesthetic activities.
Quifenadine	It is an H1-blocker having high antihistamine activity. It is effective for the treatment of allergic diseases.

Sequifenadine Hydrochloride	It is effective in various allergic diseases, unlike antihistamine drugs, H1-blocker possesses antiserotonine activity and is effective for diseases that are accompanied by itching of skin.
Dimebon	It renders expressed antihistamine and partial antiserotonine activity, has sedative effect.
Phenicaberane	It is a spasmolytic
Methiopril	It is a new antihypertensive drug
Moracizin Hydrochloride	It is an effective antiarrhythmic of group I, rendering moderate coronarodilator, spasmolytic and M-cholinoblocking effects.
Aethacizine	It is also an antiarrhythmic of group I.
Chinoxydine	It is an antibacterial drug with a wide spectrum of action, used in the treatment of severe forms of purulent inflammatory processes caused by Gram-negative bacteria.
Dioxydine	Another antibacterial drug with a wide spectrum of action used in the treatment of severe purulent inflammatory processes of various localization.

Arbidole — An antiviral drug with a wide spectrum of action, having immunomodulate and interferon-producing properties. It is used to treat influenza A and B.

Prospidine — An active antitumor drug with main application in cancers of larynx and malignant tumors of esophagus.

It was not the purpose of this short survey to give the comprehensive list of new drugs, and certainly, the medicinal preparations created in Russia are not limited to the ones listed above. It is rather an illustration (though reasonably detailed and representative) of those areas of medicine, pharmacology and medical chemistry, in which Russian scientists have achieved progress.

At present, despite the significant difficulties and severe economic conditions prevailing in Russia, drug research is going on at its own pace. Quite recently a new (β and α) adrenoblocker, Proxodolole, has been created. It renders antihypertensive and antianginal activity and effectively lowers intra-ocular pressure at glaucoma. As another example, the clinical trials of an endogastric ulcer drug, Quiditene, are approaching the final stage.

A number of new and interesting substances are at the final stage of pre-clinic research. Among them, a new nootropic drug, developed on the basis of an original transport system making bioactive compounds capable to penetrate through lipophilic membranes.

The pharmacological and toxicological studies of a potential activator of cognitive functions have already been completed. However, one possible application of this new compound requires additional clinical trials for the treatment of Alzheimer disease.

Finally, new anticonvulsive compound with a wide spectrum of action, is planned for clinical study as an antiepileptic.

Finally, a few words about an essentially new field of drug research should be given special attention. This is the discovery of a new class of substances (not containing C-NO, S-NO, O-NO, $O-NO_2$ and other NO containing groups) capable of oxidation with formation of nitrogen oxide, and thus, causing activation of soluble guanylate cyclase of human platelet and administering distinct antihypertensive and spasmolytic action.

Taking into account of the recently discovered fact that nitrogen oxide plays a vitally important physiological role, one can say that the development of compounds such as the first representatives of a new class of neuromediators (EDRF - endothelium derived relaxing factor), can become of large scientific achievement and result in the creation of new, highly effective antihypertensive drugs.

Synthetic chemical and biological investigations, going on in Russia, consistently reveal new interesting bioactive compounds. It should be noted, however, that at present there are a number of complexities hindering the realization of such work. Among the sharpest problems, absence of reagents, extreme wear of the equipment and absence of new editions of the foreign scientific periodicals and books in the main libraries of the country are worth mentioning. The last circumstance can turn down the Russian science for many years. The Russian scientists need the urgent assistance to have major chemical and medical journals readily available.

So, the first approach of research is in planned synthesis. Nevertheless, at present our knowledge about the human body, the bases of drugs and biotargets interactions and the factors determining biological action, are in no doubt insufficient for the envisaged designing of drugs necessary for medicine. Therefore, alongside with biologically justified approach to

synthesize bioactive substances, the traditional, empirical investigation has not lost its significance yet. The modern chemistry, including the Russian one, permits to synthesize practically unlimited quantity of new substances including those not possessing structural analogues with known indigenous substances or already existing medicines. Therefore, new chemical compounds which do not have analogues, should be subjected to the widest biological testing.

2. R & D in the field of pharmaceutical technology in Russia

Another field of development of chemical-pharmaceutical science is directly connected to the technology of the synthesis of pharmaceutical chemicals and the manufacture of new formulations and dosage forms.

For a long time, scientists in the USSR, now Russia, have participated in the applied research to organize the industrial manufacture of known, most effective drugs. These works are not exclusively technological in nature and frequently include a wide spectrum of scientific investigations in other disciplines. In a number of cases, they have resulted in the introduction of new applications or indications of existing medicines.

An example of the latter approach is Pyridinol carbamate. The ointment form was developed as a new formulation which proved to be an effective preventive and curative means to administer in radiation injuries of skin, neurodermatitis and scleroatrophic lichenoid eruptions of children's skin. This original development of new formulation of the known drug has found wide application in medical practice.

Similar studies cover a wide field of research. Their introduction in the Russian Public Health Services in addition to the essential drugs maximizes the application of the most important and effective remedies, known in the pharmaceutical industry. It is necessary to note that this applied development

work is not limited to simple reproduction of those steps of synthesis described in the literature earlier. Significant efforts are made to improve technological processes for production of essential drugs, analytical techniques for quality control and technologies for new formulations and dosage forms.

A large part of medicaments in Russia are so-called "reproduced" drugs. The manufacture of the majority of these drugs, assimilated by industries established long ago or quite recently at multi tonnage level as well as small scale is based on advanced methods of synthesis and other scientific achievements developed in research institutes.

Excluding the drugs developed and produced in Russia for a long time, we shall discuss some achievements of the last two decades as examples of recent technological developments.

The industrial manufacture of Pirazetam, one of the most known nootropic drugs, started in Russia at the end of the 1970s. It was based on the evolution of a new, non-traditional approach to synthesize this preparation. Later on, a more economically advanced and environmentally sound method of synthesis was developed for this process.

It should also be noted that with the improvement of a chemical method of Pirazetam synthesis, intensive biological studies of its medical properties were parallely carried out. Thus, pharmacologists and clinicians received a number of new data developing of more accurate methods of testing and determining of the limits of possible application of this drug.

Other examples of new advanced methods of synthesis adopted by industry are already mentioned e.g. Pyridinol carbamate, Allopurinol to treat gout, Clonidine to use in hypertension and all the drugs belonging to the group of benzodiazepines.

At present, development of advanced methods of synthesis of analgetic Diclofenac Sodium and antiemetic drug Metholopramide have been completed at pilot scale and their industrial production will start very soon.

It is worth mentioning that the introduction of new methods of synthesis of known remedies goes parallel with the development in the relevant pharmaceutical and allied industrial subsectors as well.

As described in the above, there are two major areas of the development of chemical and pharmaceutical science in Russia, namely the research for new compounds and the improvement of manufacturing processes and analytical analysis of techniques. However, progress has to be made in the following fields:

- More effective formulations and dosage forms.
- Pharmacokinetics and metabolic studies of drugs.
- Toxicological studies and safety of medicines.
- The economic evaluation of new synthetic methods.

3. Research in disciplines, connected with directed drug research

In the course of studies directed towards the synthesis of bioactive compounds (including the development of new ways for the production of known drugs), theoretical approach has a rather important role since it can be the basis of promotion of new ideas and aspects in research work. Here, it is necessary to mention novel synthetic achievements in the field of organic chemistry such as study of new reactions, development of modern synthetic methods for obtaining basic structures containing various pharmacotropic groups.

These studies are accompanied by establishing of a structure and investigating of spectral and other physico-chemical properties of the newly synthesized systems.

There is no doubt that biochemical study, research of receptor binding of bioactive substances, work in the field of theoretical pharmacology, efforts directed to understand the mechanism of biological action of drugs and their analogues, are necessary conditions of effective directed research of drugs. Significant attention in research work, conducted in Russia is traditionally given to all these fields.

Recently a relatively new approach of investigation has been developed. Mathematical modeling of interactions between bioactive substances and appropriate receptor systems and problem of correlation between a structure and biological activity have developed in Russia. The analysis of correlations through comprehension of experimental data gives the best understanding of those structural features which are responsible for the biological activity.

This approach appears to have a reasonable perspective, especially because the development of mathematical methods permits to increase the number of correlation parameters and thus enables the quantitative consideration of such factors as ability to penetrate through lipophilic membranes, facility of metabolic processes, linkage with specific sites of receptors, pharmacokinetics parameters, electronic and stereochemical characteristics and many others including data on toxicity.

4. Prospect of development of a chemical and pharmaceutical science in Russia

It is well-known that in the USSR all research establishments belonged to the state. A little has changed in this aspect in modern Russia. At present, the state is not in

a position to finance research work in sufficient volume even in such priority areas as the pharmaceutical science. Therefore, it is extremely important and urgent to find new approaches to improve the conditions for research in this sector, or at least, preserve the existing scientific potential.

One of the possible ways could be the integration of the Russian science into the international scientific life through contract research and development work assigned by the Western pharmaceutical companies. This approach seems to be economically viable for both parties, taking into account the inexpensive but experienced labor in modern Russia at reasonably high scientific level of qualification. But the realization of this is unfortunately not so simple.

The old management of Russian Research Institutes is not yet ready for such changes. Also there is an obvious lack of information on Russian Research Institutes and their potential capabilities in Western pharmaceutical enterprises.

The Russian Pharmaceutical Industry is rather weak at present. The production of the most economically feasible dosage forms (in a large degree from imported raw materials) or even the packaging of dosage forms, made by foreign companies are priorities. However, in the process of privatization, the most farseeing manufacturers of pharmaceutical production aim not only at saving manufacture of pharmaceutical chemicals, but also at the development of research departments involving qualified experts from research institutes in their activities.

Summarizing this brief survey on the development of the chemical and pharmaceutical science in Russia, it should be pointed out that despite of the difficult economic situation in the country in general and science in particular, the pharmaceutical science is developing intensively enough. It has significant potential with respect to quantity and quality of new ideas, as well as the qualification and experience of the

scientific employees. It is also quite able to compete at a level of the scientific importance with the pharmaceutical science in the leading countries of the world.

OKTYABR'S POWER RESOURCES

ANNEX II

Power Plant and Cost Article Names	Characteristics of Power-Consuming Equipment and its Parameters					
	At the Association on 1.07.92	At the head Production	At vitamin Production	At "Pharmacon" Plant Prod. N 1	Prod. N 2	Prod. N 3
1	2	3	4	5	6	7
1. Power transformers						
1.1 Total installed capacity of power transformers,	14.08	1.89	1.43	8.7	1.26	0.8
1.2 Number of power transformers	21	3	3	11	2	2
2. Maximal power, consumed by the enterprise, for characteristic:						
- summer day	5285	1200	830	2300	430	525
- winter day	5860	1300	900	2700	430	530
3. Where power enterprise supply is performed from Lenenergo system						
4. Annual power consumption, thous. kW/h	30254	4912	3318	17308	2428	2190
including: percentage of annual consumption:						
4.1. for technical needs,%	49	43	45	51	55	53

1	2	3	4	5	6	7
4.2. for water supply,%	8	2	2	12	12	10
4.3. for compressed air generation,%	10	25	23	50.5	0.5	
4.4. for cold generation,%	8	-	-	7	8	9
4.5. for illumination	6	6	6	5	5	5
4.6. for heating and general ventilation by dilution	13	10	11	15	14	18
4.7. for purification works	-	-	-	-	-	-
4.8. for auxiliary plants	8	14	13	5	3	2
5. Enterprise capacity coefficient	0.9	0.93	0.90	0.90	0.90	0.90
PRODUCTION HEATING BOILING HOUSES						
1. Number of boiling houses	4	1	1	1	-	1
2. Number of steam boilers	11	3	2		-	2
3. Type of boiler and operation start	-	DKVR-6,5/13	DKVR-4,0/13 3 pl.-1973	DKVR-20/13 2 pl.-1963	- 3 pl.-1969 DE-25/13 1 pl.-1986	DKV-6.5/13 2 pl.-1959
4. Boiling house capacity, t/h	125.5	19.5	8.0	85.0	-	13.0
5. Boiling house efficiency	87.63	90.3	90.2	90	-	80

1	2	3	4	5	6	7
6. Fuel type: principal	gas reserve	gas fuel oil	gas fuel oil	gas fuel oil	- fuel oil	gas -
7. Annual fuel consumption, thous.	25.3	4.2	3.0	15.8	2.3	
8. Presence of reservoirs for liquid fuel and their volume	5x2400 m^3	2x100 m^3	1x100 m^3	2x1000 m^3	-	-
HEAT ENERGY						
1. Annual heat energy consumption with an account of external receipt,	157848	24800	16528	77750	24580	12608
including annual consumption percentage:						
1.1. for technological needs,	58	60	61	54	53	52
1.2. for heating,	12	14	13	15	14	12
1.3. for ventilation	10	9	8	14	12	13
1.4. for everyday necessities (hot water supply)	20	17	7	30	28	26
2. Enterprise heading	water	water	water	water	water	water
3. Percentage of condensate return to the boiling house	80	85	80	70	-	70
4. Released condensate amount	20	15	20	30	100	30
5. Reason for incomplete condensate return	technological contamination					

1	2	3	4	5	6	7
FUEL FOR TECHNOLOGICAL NEEDS						
1. Fuel type	gas	gas	gas	-	-	
2. Names of technological processes	-ampoule producing	-	-	-		
3. Annual fuel consumption for technology		924	496	428	-	
SECONDARY POWER RESOURCE APPLICATION						
1. Source of secondary power resources						
2. Type of secondary power resources	-	Condensate 100	C	Condensate		90° C
			cooling water 35-45° C			
3. Annual output of secondary power resources		10018	4800	3200	2018	
4. Percentage of secondary power resource application of the general presence	57%	72	70	45	-45	
COMPRESSOR STATIONS						
1. Total number of compressors and capacity of stations, m/min	29	13	12	22-		
	332.0	154	132	40	6-	
REFRIGERATING STATIONS						
1. Total number of refrigerating stations	15	-	-	564		

1	2	3	4	5	6	7
2. Capacity of refrigerating plants, kcal/h	-	-	-	1100000	4800000	3200000
WATER SUPPLY						
1. Total annual amount of water, consumed by the enterprise, m^3/year	3258.3 thous.m^3	246.0 thous.m^3	117.7 thous.m^3	2083 thous.m^3	431.7 thous.m^3	378.8 thous.m^3
a) from municipal water supply	100%	100%	100%	100%	100%	100%
b) from artesian wells	-	-	-	-	-	-
CIRCULATION OF WATER SUPPLY						
1. Processes of circulating water supply application		a) cooling of power equipment hot water supply				
2. Amount of water in circulating water supply	4613.0 thous.m^3	303.0 thous.m^3	202 thous.m^3	2815 thous.m^3	1237 thous.m^3	56.0 thous.m^3
3. Circulating water application percentage of the total enterprise water consumption,%	142%	123%	173%	135%	207%	15%
PURIFICATION WORKS						
1. Sewage water amount, thous.m^3/year	3136.0	236.0	113.0	2015.0	398.0	373.0

Permit distribution of pharmaceuticals on a market basis.