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**STUDY ON THE TRANSFORMATION OF THE RUSSIAN PHARMACEUTICAL
INDUSTRY TO A MARKET-ORIENTED SYSTEM**

TF/GLO/92/010

Executive summary and recommendations

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EXECUTIVE SUMMARY

The Russian pharmaceutical industry, as with other state-controlled production and distribution sectors, has undergone dramatic changes. Previous to the economic reform program of President Yeltsin, the control and direction of this industry was centrally planned, by the Minister of Health. State orders and accompanying financial support determined all pharmaceutical production and distribution in the USSR, as well as the CMEA countries. It was not unusual for large volumes of pharmaceutical production to be distributed beyond the region wherein the production complex was located, such as the City of St. Petersburg, formerly Leningrad. One such example was the Leningrad Chemical, Pharmaceutical and Industrial Association "OKTYABR".

OKTYABR was a standard state-controlled production association. Its raw and semi-finished materials were supplied through the state orders system; its production was distributed by a similar state-controlled association and its products were made available to the public at state prices in the state-controlled Apotekar. This system of state orders for all inputs and outputs, with companion state-decision making with respect to operating costs, sourcing, pricing, product lists, and distribution was closely monitored by several levels of bureaucracies in the Ministry. The Ministry set the priorities of output, both volume and distribution, often exchanging such output among other Ministries in the USSR for their respective output, i.e. pharmaceuticals for consumer goods, or to other pharmaceutical Ministries throughout the CMEA network in exchange for raw, semi or finished materials. As long as the system was closely monitored, and market sources were not introduced which could effect its more inefficient or over-producing parts, a significant volume of pharmaceutical production and distribution was achieved. The absence of market forces and prioritization of state orders without regard to local need, however, negated the marginal efficiencies of the system. The

result was the inconsistency of significant industry output often characterized by the local shortages.

OKTYABR, for example, produced significant levels of quality pharmaceutical products. Leningrad City, however, experienced significant shortages of even the most basic pharmaceutical products; a serious result among a population with large numbers of elderly and children.

The Gorbachev/Yeltsin economic reforms seriously disrupted the CMEA-control system of pharmaceutical production and distribution. Where previously, all output distribution decisions were made in Moscow in the Ministry of Health, accompanied by the resources essential to such production, these economic reforms began to shift their decision making to the local level while reducing or failing to increase resources necessary to maintain production. As with other industrial sectors, production associations attempted to maintain output levels as a means of avoiding employee layoffs. Hyperinflation, and over production soon resulted, effecting the ability of the average citizen to purchase those pharmaceutical products essential to even a minimum standard of health care. Generally, the association continued to over-produce, and the Ministries no longer monitored output levels and product types. As the Ministry of Health began to fall behind in financial support for the association, the more entrepreneurial general directors of product plants, began to produce products unrelated to pharmaceuticals, such as confectionery, or food products.

OKTYABR, for example, shifted some production in 1992 from vitamins to lemonade, chocolate, and olive oil. OKTYABR did not produce as a retailer, but as a supplier to other enterprises or associations. The result was a vicious cycle of increased costs for raw and semi-finished materials, diverting production from primary pharmaceutical products to obtain additional resources to pay salaries and bonuses for workers to avoid layoffs. Salaries,

however, could not keep pace with hyperinflation. Short-term production could not produce sufficient amounts of pharmaceuticals and related products. Thus, fewer pharmaceuticals were being produced and distributed and that which was produced was at prices that the average citizen could not pay.

With the transition of decision making from the Ministry to the local level, each component of the production and distribution began to set its own priorities. As state orders were reduced, and in 1992 all but eliminated, the incentive to maintain an integrated system of production collapsed, and general directors at each stage of production began to pursue different pricing, sourcing, product, and distribution strategies more often to maintain full employment than for efficiency.

Finally, despite the prospect of hyperinflation, falling production, over employment, and limited state resources, the mass privatization program began. Under the law of privatization, each Russian citizen would receive a voucher nominally valued at 10,000 rubles by which he could invest by several means in either his own enterprise or any other enterprise offering shares.

OKTYABR for example, through a vote of its worker collective, decided to enter the process of privatization. By doing so in 1992, the worker's plan of privatization would be based on OKTYABR's overall value set at 1982 levels. In 1993, these value levels would increase by a co-efficient established by the State Committee on Privatization to adjust for hyperinflation. Therefore, an enterprise could privatize itself at a lower price if it filed its plan in 1992.

Contemporaneous to the economic reforms in Russia, was an aggressive promotional effort by the government to attract foreign investment. In principle, foreign investment was viewed as the best means, at least in the early days of the policy, to offset the

destabilization of the economic reform program. Foreign capital could be used to finance the transition from state-control to a market-driven economy. Foreign investment in new plants, equipment, training of employees, distribution and even export could replace, in some industrial sectors, the resource demands on the state, foreign managers/investors could replace the role of the state in decision making. Finally, a foreign investor/manager would have the incentive to inject market discipline at all levels of production and distribution, making the difficult decisions with regard to source, pricing, products, distribution, salaries, and employment levels, relieving the state from making tough political and social decisions. Consequently, a legal framework of Presidential Decrees and Laws of the Supreme Soviet were enacted to encourage, promote and facilitate such investment. Unfortunately, other laws and regulations were enacted which established an equal number of disincentives to such investment, i.e. new forms of taxation, customs duties, and property ownership.

The Russian pharmaceutical industry, therefore, has been under serious stress in the last few years. Structural changes have not stabilized the economic situation; on the contrary, circumstances within the industry are much worse than expected. Unfortunately, the Russian people are those who suffer the consequences of the changing conditions.

International organizations, such as the World Bank, EBRD, United Nations (UNIDO, UNESCO and WHO) have offered resources and assistance to the Russian Federation to stabilize and improve the Russian pharmaceutical sector. A substantial amount of this assistance is in the form of finished pharmaceutical production, e.g. humanitarian aid, which more often than not misses its intended target, the average Russian, and instead competes with Russian-origin pharmaceutical production in the black and grey markets. A portion of this assistance would be better used to resolve the structural problems of the Russian pharmaceutical

industry.

International technical and financial assistance could make a dramatic difference in stabilizing the best elements of the Russian pharmaceutical industry. The system of integrated sourcing, pricing, production, and distribution could be re-established; the Ministry of Health could re-assert its oversight and management. Enterprises, such as OKTYABR, could be encouraged to resume meeting state orders in return for realistic support from the Ministry of Health in the form of operating capital. The most immediate impact of this policy would be to respond more effectively to the health needs of the Russian people.

One does not suggest that the Russian Federation abandon its economic reform program, as such pertains to the pharmaceutical industry. On the contrary, President Yeltsin's economic reforms have been the difficult process of transitioning the Russian pharmaceutical industry from sole reliance on state support to market-oriented producers and distributors.

It is the pace of the transition and its near-term impact on the health conditions of the populace which should be of concern. In addition, there should be some well-defined, specific design or model of a more market-oriented pharmaceutical industry which the Russian Federation is seeking to achieve from the transition. Unfortunately, it is difficult to identify from the policies and rules of the Russian Federation or Ministry of Health what the design might be. Further, without a specific design or model to follow, each producer and distributor is free to adopt its own form. The new forms of production and distribution do not generally take into consideration the same policy concerns of priority to either the Ministry of Health or the Russian people. These new forms are the most expedient model to the local producer and distributors; these models are often developed as short-term solutions, a quick fix to address the immediate problem of hyper-

inflation, low wages, increased taxation, uncertainty among raw material suppliers, and a concerned labor collective. Often, a General Director responds to these pressures by transitioning the enterprise away from its primary purpose to a more profitable line of production. Such a transition results in a loss of production of needed pharmaceuticals, an unfortunate result, in that it will be more expensive to re-constitute this production than to maintain it in its present form.

Foreign investment has been suggested by many as the catalyst which will facilitate the transition of the Russian pharmaceutical industry. Foreign investors seek a realistic pace of economic transition, economic focus and a well-defined design or model promoted by the Ministry of Health. Also, foreign producers of pharmaceuticals are generally reluctant to invest large amounts of capital in the industry, are in large measure to the uncertainty of Russia's economic political reform program, but also, due to the emerging independence of individual producers and distributors. Unlike other terms of manufacture, pharmaceutical production and distribution is subject to some level of state regulation e.g. Ministry of Health, Food and Drug Administration (USA).

The quality and availability of pharmaceuticals are public policy issues in most countries not just economic. Russia is at risk of losing its basic production and distribution system, with the related political and economic consequences, if it continues to permit the diversification and dissolution of its suppliers, plants, and distributors. The Ministry of Health must re-assert its oversight so as to stabilize conditions of the plant level, to stem the shift in production away from basic drug production. Otherwise, the sole interest by foreign investors will be in the network of product distributors for the purpose of supplying foreign production as Russian production. Such a result would be a disincentive to produce pharmaceuticals in Russia, further stressing an already over-stressed industry.

The Ministry of Health and regional authorities should review carefully any foreign investment proposal to determine if the project will actually result, in the near-term, in direct improvement, technical and financial, of an existing Russian producer of pharmaceuticals. If the proposal merely substitutes foreign for local production, if the Russian partner merely distributes and has not prospect of new improved means of local production, then the project fails to achieve the overall goal. The Ministry should promote only those projects which will result, at some point in the relationship, in an improved modern means of production employing local workers while preserving, if possible, the current Russian producer. This form of investment benefits all the partners, will also serve the goals of the Ministry of Health, enhancing the production and distribution of pharmaceuticals in Russia. If the foreign investor could be assured that the government would promote the investment through realistic investment incentives which could further contribute to stabilizing the needs of pharmaceutical production and distribution, the risk of a foreign firm entering the Russian market becomes more manageable. Finally, if the foreign manager has the support of the state in making the hard choices any market-driven enterprise must make, such as maximizing profit, reducing cost, developing new products, methods and means of production, then the goal of the Russian government, and in particular the Ministry of Health, to modernize Russian pharmaceutical production and distribution is possible.

Each of these goals must be evaluated in the context of an actual, active producing enterprise, such as OKTYABR. The problems and solutions arising from such project will frame a design or model of a production and distribution system unique to the challenges and needs of Russia. Also, from this experience at the local level, the Ministry of Health can project the feasibility of such a model as a design for the entire industry.

The UNIDO team has evaluated the conditions of Russian pharmaceutical industry as it currently exists. The team of international and Russian experts have reviewed the regulatory, technical and financial conditions of the industry. The UNIDO team has attempted to compare and contrast conditions, policies and problems in Russia with pharmaceutical operations in Spain, Yugoslavia, and the United States. The team has attempted to concentrate its analysis at two levels-national and local. OKTYABR has served as a focal point of study at the local, enterprise level. The UNIDO team offers its recommendations on the same basis.

RECOMMENDATIONS

1. STABILIZE THE RUSSIAN PHARMACEUTICAL SECTOR

- 1.1 The Russian Federation should take into consideration the human resource costs and instability arising from Russia's inability to produce and distribute pharmaceuticals and related products at minimal levels to meet the basic health needs of the populace.
- 1.2 The Russian Federation needs to take into consideration the serious strain on the Russian pharmaceutical sector imposed by the current economic reform program.
- 1.3 The Russian Federation needs to develop and adopt policies particularly targeting the Russian pharmaceutical sector the purpose of which would be to stabilize that industry sector by exempting it where appropriate, it from elements of the economic reform program which have caused its deterioration. Technical advice and assistance from international organization and experts should be focused (e.g. World Bank, EBRD, UNIDO) to assist in the development of these policies.
- 1.4 The Russian Federation needs to develop on an emergency basis a near-term program to improve the production and distribution of pharmaceuticals in Russia which has as its long-term goal a gradual transition of the Russian pharmaceutical sector into a market-oriented industry taking into consideration the impact of such a transition on the public health.

2. DETERMINE THE MOST EFFICIENT FORM OF PRODUCTION AND DISTRIBUTION OF PHARMACEUTICALS AND RELATED PRODUCTS FOR RUSSIA THROUGH MODEL PROJECTS

2.1 The Russian Federation should encourage the Ministry of Health to identify, promote and develop model projects in the production and distribution of pharmaceuticals in Russia.

2.2 The Ministry of Health should identify those Russian pharmaceutical associations which would be serious partners in a model project with a realistic foreign producer and distributor. The criteria of such associations should include actual experience in the sourcing, production, and distribution of pharmaceuticals and related products in Russia as well as previous experience in the CMEA system; ongoing local production and distribution; close proximity to foreign markets; and production in immediate demand by the Russian people.

2.3 The Ministry of Health should promote these model projects by inviting international health organizations, and private foreign pharmaceutical firms to participate. The form of participation should be technical and financial assistance, on a public or private basis. The goal of participation would be to develop and demonstrate at the enterprise level, the methods and means required to transition a Russian pharmaceutical complex from a state-oriented association to a more market-oriented enterprise.

2.4 The Ministry of Health should develop model projects which have the potential to be self-sustaining, technically and financially as soon as possible. These projects should also have some export capability. The

Russian enterprise must be willing to integrate its management, production and distribution with that of the foreign partner and permit the foreign partner to restructure the enterprise accordingly. As the foreign partner moves the Russian enterprise closer to a more market-oriented form, the support of the Russian Federation allocated to that specific enterprise should be decreased. In short, the Russian enterprise should undergo a "phased conversion" from a state entity into a private venture.

- 2.5 The Ministry of Health should monitor the progress of the project and should ensure that throughout the project the production and distribution of pharmaceuticals meets the needs of the market.

3. ESTABLISH A MECHANISM TO SUPPORT PROJECTS

- 3.1 The Russian Federation is eligible for a variety of forms of assistance. The Ministry of Health should be granted a priority allocation of international technical and financial assistance for the exclusive purpose of supporting and overseeing a limited number of model projects in the pharmaceutical sector. Qualifying model projects should be realistic in scale; focused on specific types of production and distribution; of a direct relationship between an existing Russian producer and foreign firm; and integrated locally.
- 3.2 The Russian Federation should establish a Russian Pharmaceutical Development Fund, the sole purpose of which shall be to identify, promote and develop a limited number of model projects. The Ministry of Health should be responsible for the work of the Fund. International

organizations, such as the World Bank, European Bank for Reconstruction and Development, UNIDO, and regional assistance programs should be invited to participate in these model projects as well as to participate in developing the criteria by which qualifying foreign pharmaceutical firms will be identified.

3.3 Each model project must involve three partners - the qualifying foreign pharmaceutical firm, a Russian enterprise, privatized or not; and the local government to ensure that local needs for drugs will be considered as a priority over the pressures to distribute local production in other regions of Russia or exclusively for export.

4. ANALYZE THE METHODS AND MEANS RECOMMENDED BY THE UNIDO TEAM TO TRANSITION THE LENINGRAD CHEMICAL, INDUSTRIAL AND PHARMACEUTICAL ASSOCIATION, OKTYABR FROM A STATE ENTERPRISE TO AN INTEGRATED PRIVATE MANUFACTURER

It is most expedient to apply these policies and goals to a concrete example. OKTYABR is such an example. If it is possible to propose recommendations which can be implemented by the Russian government and local authorities in the City of St. Petersburg without the need for significant political or economic action on behalf of either, then it may be possible to develop and investment program for other production complexes in Russia. Therefore, the following recommendations are made with regard to OKTYABR as a pilot project. If successful, these recommendations could lead to more general policies, legislation or decrees by the government which could accomplish its overall goals of improving the production and distribution of

pharmaceuticals throughout Russia's other markets.

Russian state enterprise, OKTYABR, must stabilize its management, labor relations, means of production and distribution if it is anticipated to continue as a viable producer of pharmaceuticals. The UNIDO team recommends the best method of stabilization for OKTYABR is integration with a foreign partner. The foreign partner, however, will be reluctant to invest significant amounts of capital without adequate assurances by the Ministry of Health and the Russian Federation that certain conditions favorable to the investor will be provided, e.g. regulatory, financial, technical. Consequently, the UNIDO team recommends an investment strategy for OKTYABR which "phases in" the foreign investors risk as the state's responsibility to sustain this enterprise is "phased out".

The "phased" or transitional investment model, as recommended by the UNIDO team is as follows and pertains solely to the conditions found in OKTYABR.

4.1 PRIVATIZE OKTYABR AS A JOINT STOCK COMPANY, OPEN TYPE, WITH THE MAJORITY OWNERSHIP AND CONTROL OF THE ENTERPRISE BELONGING TO THE WORKERS' COLLECTIVE AND CURRENT MANAGEMENT:

- a. Stabilizes the legal form of the enterprise
- Legal entity with rights
 - Specific ownership by shares
 - Specific management (for at least one year)
 - Workers' collective has vested interest in success of enterprise
 - Specific rights in plant and equipment

- b. **Compels enterprise to operate on a market basis**
 - Means of production become key management concerns, e.g. sourcing, wages, operating capital
 - Production shifts to respond to market needs away from state orders
 - Training (management and worker) seen as investment

- c. **Management and labor relations becomes more reciprocal**
 - Workers' collective demands more accountability from management as to profits and investment
 - Basis exists for introduction of modern management, quality assurance, program techniques
 - Work force reductions more effectively managed
 - Management decisions more likely oriented toward improving working conditions, training, productivity and new plant/equipment

- d. **Appears more attractive to foreign investor than state enterprise**
 - Stable ownership, management, labor force
 - Certain ownership rights to plant and equipment
 - Market orientation

4.2 CONTINUE STATE SUPPORT OF OKTYABR FOR "PHASED" OR TRANSITIONAL PERIOD:

- a. **Incentive to attract foreign investment**
- b. **Permits enterprise to treat State as a guaranteed customer, thereby ensuring near-term operating capital**
- c. **Ensures that a specific volume of production will be available to the public, e.g. State should not permit shortages of crucial pharmaceuticals**
- d. **Involves State in some planning decisions, labor**

- relations, and joint venture negotiations thereby adding additional stability to the development of the enterprise
- e. Permits State and enterprise to balance mutual needs (State orders for operating capital)
 - f. Ensures potential investor of minimal State regulatory interference

4.3 PROMOTE AND FACILITATE FOREIGN INVESTMENT IN "OKTYABR":

- a. Publicize OKTYABR as a potential partner with a foreign producer of pharmaceuticals
- b. Offer clear criteria as to the type of foreign investor sought for OKTYABR, and publish that criteria among international organizations and enterprises
- c. Offer investment incentives, regulatory, technical and financial, to any qualified investor equal to a commitment to invest directly in plant and equipment in Russia
- d. Permit reinvestment of tax revenues, federal and local, into the joint project
- e. Permit special licenses to import/export means of production without tariffs or duty in order to source the most cost-effective raw, semi-finished materials thereby reducing production costs
- f. Permit importation of plant and equipment essentials to the operation of the joint enterprise without delay or custom duties
- g. Require integrated management between the foreign partner

and the Russian enterprise, thereby ensuring modern techniques of production and distribution will be introduced into the Russian pharmaceutical industry

- h. Require a minimum volume of production be exported to adjacent markets
- i. Ensure local/regional support for the joint enterprise by permitting municipal participation
- j. Review structure of joint enterprise for fairness and the protection of all parties
- k. Establish with the Russian and foreign partners a schedule of gradual elimination of special conditions (regulatory, technical and financial) in favor of assumption of greater risk by the joint enterprise
- l. Review periodically the progress of the joint enterprise, its level of production, types of pharmaceuticals produced, ownership changes, and results of shared research, e.g. new compounds

4.4 INTEGRATE THE JOINT ENTERPRISE OF OKTYABR AND A FOREIGN PARTNER INTO THE REGIONAL AND INTERNATIONAL MARKETS FOR THE PRODUCTION AND DISTRIBUTION OF PHARMACEUTICALS:

- a. Introduce international standards for the production of pharmaceuticals in Russia, including the requirement that all new plant and equipment must be GMP certified to international standards
- b. Introduction of international accounting standards to govern the joint enterprise

- c. Facilitate the introduction of generic pharmaceuticals through the joint enterprise
- d. Ensure the protection of intellectual property rights of authorized, license distributors or investors of pharmaceutical on the territory of Russia
- e. Permit distribution of pharmaceuticals on a market basis