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# MASTER PLAN FOR THE DEVELOPMENT OF NATIONAL RESEARCH INSTITUTIONS AND THEIR CONTRIBUTION TO THE DEVELOPMENT OF THE INDUSTRY

UC/IRA/93/032

ISLAMIC REPUBLIC OF IRAN

# <u>Technical report: Research and development and</u> production in the fine chemical and pharmaceutical industry\*</u>

Prepared for the Government of the Islamic Republic of Iran by the United Nations Industrial Development Organization

# Based on the work of F. Kovats, expert in fine chemical and pharmaceutical industry

Backstopping Officer: M. Sanchez Chemical Industries Branch

\* This document has not been edited.

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# EXPLANATORY NOTES/ABBREVIATIONS

Currency: Rial (IK), or (Rls) IR10= 1 toman

On March 21, 1993, the Government abolished the old official rate (IR 70-\$1) and the competitive rate (IR 600=\$1). At the time of the present mission (April-June 1994) the Government managed exchange rate was: IR 1750=\$1, while on the free market (available for private persons and also for private enterprises) IR 2400-2700=\$1.

\$: US Dollar tons: metric tons

finished or formulated products are pharmaceutical products or pesticides ready for use, made from active substances and additives

raw materials are used to produce intermediates to prepare active substances which have the desirable effect

additives auxiliary materials added finally to the active substance by the formulation in order to modify/enhance the effects (diluents, carriers, surface active agents, etc.)

# Abbreviations:

ECO	Economic Cooperation Organization
FDPPC	Fertilizer Distribution and Pesticide Production Company
IBB	Institute of Biochemistry and Biophysics
IROST	Iranian Research Organization for Science and Technology
ISIRI	Institute of Standards and Industrial Research of Iran
MO	Ministry of Oil
MOA	Ministry of Agriculture
MOE	Ministry of Education
Moh	Ministry of Health Treatment and Medical Education
MOI	Ministry of Industry
MOJ	Ministry of Jihad Sazandegi = Ministry of Construction
	Crusade
NIIO	National Iranian Industrial Organization
NPC	National Petrochemical Company
NPD	National Project Director = Dr. A. Torigh Deputy Minister of Industry
PPDR	Plant Pests and Diseases Research Institute
PPO	Plant Protection & Quarantine Organization
PRCI	Polymer Research Center of Iran
R&D	Research and Development
GMP	Good Manufacturing Practice
GLP	Good Laboratory Practice
GCP	Good Clinical Practice
	Reference to expert reports

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## ABSTRACT

<u>Title and number of project</u>: Master Plan for the Development of National Research Institutions and their contribution to development of the industry, UC/IRA/93/032.

**<u>Objectives</u>**: The project intends to upgrade the technological base of the country by the research institutes to important sectors.

<u>Purpose of the mission</u>: To provide advice and assistance to the Government of the Islamic Republic of Iran in assessing the present R&D institutions working in the chemical and pharmaceutical related activities of these institutions to contribute to the improvement of the related industrial sectors.

<u>Duration of the mission</u>: 4 April - 3 July, 1994 (the expert being also the team leader).

<u>Activities</u>: The mission has been accomplished by a team of eight experts. The expert after having visited 31 institutions (R&D institutes, private research centres, factories, governmental and international organizations) has prepared this technical report.

On his activity as team leader separate report is being prepared.

#### Summary of findings and recommendations:

The Islamic Republic of Iran is a country rich in natural resources and has a quickly developing petrochemical industry. The fine chemical and pharmaceutical industrial sectors provide for the country with finished products (90-95% of consumed drugs or pesticides are being formulated locally), however practically all of them are based on imported active substances. Contact/interaction between R&D institutions and industry is poor, similarly the flow of (or even the possibility of acquiring) information. A number of highly qualified experts -graduated at renowned foreign universities -are available. Certain isolation from world market and global scientific results (due mainly to limitations in foreign currency and constraints of possibility to acquire foreign capital investment) have resulted in a "green house" effect: artificially low prices (due to subsidies) make economical justification of R&D results (esp. those of saving material or energy) difficult, factories (with the exception of pharmaceutical companies) have limited interest for new developments.

- To prepare a national development plan, detailed also to coherent sectoral/subsectoral programmes,
- To consider to establish a ministry of R&D in order to enhance the utilization of results of research and improve interaction between central organizations and companies,
- To improve the reciprocal flow of information between R&D industry -market - government by specialized agency, to increase the self sufficiency in the production of active substances in the pharmaceutical and pesticide industries by selecting products manufactured from indigenous raw materials and intermediates from the petrochemical industry seem to be the most important tasks.

It has to be mentioned that the above conclusions and recommendations are related to the fine chemical-pharmaceutical sector of industry, however, during the mission observations have been discussed daily by the experts, and it can be said that findings concerning the Iranian situation in economy and industry have been shared by them.

It must not be left without mentioning that the Iranian counterpart did their best to help the expert.

## 1. INTRODUCTION

The Government of the Islamic Republic of Iran recognized the rehabilitation needs of the industrial sector and accorded high priority to upgrade the technological base and replace the ageing technology particularly in the industrial sector.

The first Five Year Plan set a growth target of 14 per cent per annum during the period 1989-1993 in the industrial output and a several fold increase in non oil exports.

In order to achieve these targets, technical assistance may be required to prepare a programme to update the technology of the industrial sector. For this it is envisaged that the activities of the Iranian research institutions should be geared to assess and update the technological needs of the Iranian industry.

The Ministry of Industry (MOI) intends to implement a national plan to establish a linkage between the programmes of the research institutions and the existing industries, to upgrade ageing technology, ensure improved production and commercialization of the research findings. This will also increase export and encourage the private sector entrepreneurs to invest in industries.

In 1992, during the last official mission of the Director-General of UNIDO to Teheran, UNIDO was requested to assist the MOI to provide highly qualified advisory assistance to develop a framework to facilitate to establishing of a linkage between the work programme of the research institutes and the requirements of industries.

Initiated by the above mentioned activities the implementation of the project: "Master Plan for the development of national research institutions and their contribution to the development of the industry" has been decided by UNIDO-UNDP and the Iranian Government.

The project is addressing the scope of the activities to a group of sectors selected by Iranian counterpart of vital importance for the improvement of the industrial production in the country.

The direct beneficiaries of the project will be the medium and small-scale industries needing urgently to upgrade their ageing technology. On the other hand, the research institutes will also develop a direct link with the need of the industries which will enable them to orient their programme to suit the development efforts of the country.

The programme will also attract the interest of the private entrepreneurs who are expected to invest in the industrial sector with the development of new technologies and product lines.

The immediate objective of the project is to facilitate the MOI to establish a mechanism to link the activities of the research institutes to the needs of the related industrial enterprises.

The execution of the project is being done by a team consisting of eight experts.

The consultancy for the fine chemical and pharmaceutical sector has been undertaken by Ferenc Kovats M.Sc.Chem.Eng.;M.Sc.Mech.Eng., licensed expert (retired technical director and head of R&D of CHINOIN Pharmaceutical and Chemical Works Ltd. Budapest, Hungary).

The present report, as a part of and contribution to the above mentioned project, is a summar, of the findings and recommendations related to the fine chemical and pharmaceutical sector.

As missions of the members of the team overlapped, several visits to companies and discussions with counterparts have been jointly executed. Cross references to the other experts' reports will be signed by [name of expert].

The structure of the report is complying with UNIDO requirements. However due to difficulties in acquiring of the envisaged data for the sectors/subsectors, some items of the job description have not been able to be discussed in details.

On the other hand the Iranian counterpart's first priority is to get useful and usable answers to the following questions formulated by the NPD:

To achieve the objectives of the project, the following questions are expected to be answered and necessary advices to be given:

- What mechanisms could be recommended to link the research and development centres with the Iranian industries and <u>vice versa</u>?
- 2. How can the findings and results of the research works be commercialized?
- 3. What are the present capabilities of research centres? What new researches can be performed?
- 4. How can MOI involve the national researchers in definition of the development strategy of the country (not just to do research)?

The expert has concentrated his efforts to give useful answers to the above questions in the chapters FINDINGS and RECOMMENDATIONS.

#### II. ACTIVITIES

Time frame of mission. The expert being also the team leader has spent the whole duration of the mission (three months) in Teheran.

Initial day of contract:	April	4,	1994
Briefing in Vienna:	April	5,	1994
Arrival to Teheran:	April	6,	1994
Departure from Teheran:	July	2,	1994
Last day of contract:	July	3,	1994
Debriefing in Vienna:	July	4,	1994

#### Starting-up activities

The mission has started with meetings with counterparts headed by the NPD. After the necessary briefing the time schedule of the mission has been set up. Appointments for visits for the first two weeks had been fixed. Regular weekly meetings of the team had been decided:

- for mutual information of team members,
- to evaluate and discuss performed visits and
- to prepare visits and activities of the next week.

Newly installed office equipped with telephone, fax and personal computer has beet put at the disposal of the expert. At the request of UNIDO the programme WORD PERFECT had been installed into computer.

Accommodation of all experts in the same building made daily discussions and evaluations possible which proved useful for the mission.

### Visits to companies

In order to get acquainted with the activity of research institutions and factories a number of visits had been organized. As seen in Annex 3, the visited companies, selected by Iranian counterparts, are representing a cross section of the fine chemical and pharmaceutical sector (large "homogenous" research institutes, medium size and small private research centres, industrial companies, factories of various sizes) and contributed to the orientation and acquisition of general and detailed information for the expert within short time.

#### Visits to central authorities

For basic information the relevant ministries had been also visited. Concerning the pharmaceutical sector various departments and sections of MOH and MOI have been asked for information/data. (Requested information is summarized in Annex 5). Data on the pesticide production/consumption and research (Annex 6) has been requested from PPO, PPDR, FDPPC (all reporting to MOA). For the same information concerning cosmetics/hygienic products no central source have been found.

# Visits to international organizations

Information on cooperations with international organizations had been collected from FAO, WHO and ECO.

# III. FINDINGS

# A. General observations

## Population

The average annual growth rate of the population of the Islamic Republic of Iran is 3.28 per cent. The importance of this figure may be interpreted and realized by some facts and projections:

Population in year	1960	1994	2000	1020
millions	20	60	80	110

Such an increase rate makes extremely difficult to fulfil the socio-economic plans of the country.

The following data have been picked out from the available sources of information and collected in Annex 4 (Basic Data) purposely because of their influence on the fine-chemical-pharmaceutical industry.

Origins of gross domestic products (1990/91):

	per cent
Hydrocarbons:	19.4
Agriculture	17.8
Industry&mines	15.8
Services	47.0
	100.0

Main imports by type (1988/89):

	ш\$	z
Total	8,177	100
Food&animals	1,374	16.8

Main imports by destination (1989/90):

Total raw materials	7,548	100
Food&animals	453	6
Total capital goods	2,915	100
Agriculture	119	4

Conclusions: Agriculture production represents 17.8 per cent of the gross domestic product of the country, and 16.8 per cent of imports, however its allotment from the imported raw materials and capital goods is only 6 per cent and 4 per cent respectively.

Data for the pharmaceutical and fine chemical (hygienics, pesticides) sectors are included in those of the chemical industry, no separate figures were available.

# B. Pesticides Demand - consumption

Demands: The main priorities among principal crops (Annex 4, Table 7) are the following:

vear

	million tons per
grain (corn)	11
fruits&nuts	11
sugar (beet&cane)	) 5.3
cotton	0.3

Consumption in 1993 ( data from FDPPC):

	tons
insecticides	31,500
acaricides	2,600
fungicides	3,200
herbicides	ŝ.000
rhodenticides	100
mullusicides	200
total	45.600

Conclusion: Agricultural production of such an order of magnitude using advanced agrotechnology including properly selected and dosed pesticides, needs significantly higher amounts of pesticides. The reason of the relatively small import is most probably the limitation in foreign currency.

#### Application

Based on information from research laboratories of MOA and from FAO

- improvement information of users (farmers) and
- introduction of forced (obligatory) control of
- application and distribution seems to be necessary.

Assistance of UNIDO has been asked for organizing training course(s) for field advisors and staff of control authorities.

#### Production

54 per cent of the 45.600 tons pesticides per year has been formulated locally, 46 per cent has been imported in finished form. Reportedly (FDPPC) more than 70 per cent of the locally formulated products used imported active substances, similarly to additives, surfactants, adjuvants. Diluents, solvents are available from local sources.

Conclusion: In terms of value 80 per cent of pesticides are based on imports, which is unacceptably high considering the petrochemical background of the country.

## Self-sufficiency import replacement

Based on the above detailed importance of the agriculture in the national economy (18 per cent of GDP, food production, cash crops for export) a moderate, but steady (10 per cent) growth in consumption of pesticides can be forecasted. The necessary foreign currency may be created by replacement of imported active substances by local production using indigenous raw /intermediate materials.

#### C. Pharmaceuticals

#### Demands - consumption

The rapid growth of population represents a challenge also to the pharmaceutical sector. For detailed assessment, data related to consumption, imports should be separated from those of the chemical industry.

# Production

Out of the drugs consumed in the country, reportedly 90-95 per cent have been locally formulated. The share of imported active substances is estimated to 80 per cent. There are 55 companies dealing with the production of pharmaceutical products. 25 companies out of them are belonging to the Pharmaceutical Industries Group accounting for about 63 per cent of the total production. Based on the operation of the units under the group, they are categorized into four divisions:

- pharmaceutical: 17 companies, producing 400 items,4.500 employees, representing 74 per cent in value of the Group's production,
- tubes, chemicals, tooth paste: 11 per cent of value, 500 employees,
- hygienics, cosmetics: two units, 100 employees,
- distribution and export: 67 offices in provinces, sales force: 1.600, covering 50 per cent of the market, exporting company (the only specialized to export in the Group), R&D efforts of the Group s.: next paragraph.

It is worth mentioning that the main quantities of detergents and cosmetics are produced by companies not belonging to the pharmaceutical group. The "flagship" of this sector is PAKSAN Co. (Annex 3.)

# R&D in the pharmaceutical sector

Being traditionally research oriented, pharmaceutical companies usually have their own R&D units. Iranian companies are not exceptional either.

The objectives of R&D units in the pharmaceutical factories are:

- to develop new products and/or
- better technologies: more economical, safer (working, environmental) processes

The output of them is however depending- among other factors -strongly on the magnitude of financial resources. All the visited companies have R&D units - as reportedly the others also do - with up to date instruments esp. laboratory size process equipments, enabling them to elaborate practically all traditional dosage forms. It must be emphasized that the elaboration of new products, even "only" in new delivery forms of existing active substances need high sophisticated methods (both analytical and biological) and no laboratory can tend to be self-sufficient in this respect. The size of the companies in Iran hardly allow at present to carry out integrated full research (starting from synthesizing of new chemical entities, followed by chemical/biological selection and the necessary preclinical and clinical investigations, finally

registration), so - with the exception of Darou Pakhsh Co. - they concentrate on the above mentioned product/process development.

The Research Centre of Darou Pakhsh is the only one in the country which is capable to carry out integrated full research. However to meet internationally accepted demands, operating procedures together with requirements on working conditions/infrastructure are to be improved in order to comply with GMP, GLP, GCP prescriptions, especially in case of export ambitions.

Background for basic pharmaceutical research (an "indigenous research institute") for the whole industry is badly needed. The Research Centre of Darou Pakhsh Co. (with certain extensions) may be an option. The profile and field of activity of such a new institute should carefully decided, not forgetting the possible, even necessary cooperation with specialized research institutions, clinics.

As far as cooperation is concerned, it for sure does not belong to the strong points of the Iranian industries. The pharmaceutical one is not again exception: existing (and by international contribution realized) multi-purpose pilot plant is going to be utilized as production facility (for which it was not envisaged, neither planned); while other companies can not realize scaling up technologies and are harbouring the plans to erect new pilot facilities of just the same character.

Cooperation, or coordination at least is also seem to be lacking in developing of new products.

Another problem is poor (if any) market considerations in new projects. Far reaching plans are prepared to produce active substances without own formulation facilities, without assured sales conditions, even without market considerations.

Cooperation in marketing, R&D; coordination of product development are of vital interest for both resp. companies and for the Iranian economy as well.

In order to avoid misunderstanding, the expert wishes to emphasize that all the above criticism is due to his appreciation of the development of the pharmaceutical industry of Iran and the high level of skill and professional expertise of the colleagues working in the field. The relative low (and slow) utilization of the possibilities is beyond their competence. The aim and objective of the present mission is just to find the means to eliminate the obstacles in the way of utilization of new results.

Positive feature in the picture is the activity of the private research centres. Flexibility, speed, market orientation, cooperation are their main weapons. More details see next paragraph. Another positive item is the effort of the Pharmaceutical Industries Group in R&D: Over the last ten years eight projects have been elaborated for the production of pharmaceuticals, veterinary products. Three of these projects already started production: Amin Chemical  $\ddot{a}$  Pharmaceutical Co., Shahid Ghazi Co., Zahravi Co. The implementation of a multi-purpose pilot plant in the Darou Pakhsh company (organized by UNIDO, with the financial assistance of UNDP) in 1992 is also a good example of target oriented concept.

During visits the extraction of essential oils from medicinal herbs has been

many times mentioned. In Iran there is long time broad experience available. The growing and extraction is concentrating to the traditional plants, marketable products. The brand new approaches of foreign scientists should also be taken into consideration: recent discoveries on new phytochemicals, or their effects, esp. in the field of prevention of cancer (sulforaphane, indole-3-carbinol, new flavonoids, p-coumaric acid, chlorogenic acid, etc.) may not prove to become only new fashion, but may yield market possibilities esp. for countries having favourable climatic and soil conditions of growing the respective plants.

# D. Research and Development Institutions

Organizations active in the R&D field in Iran can be classified in three groups:

- "homogenous" research institutes
- R&D units of factories
- private research centres

Homogenous Research Institutes (Engineering Services and Research Companies of Homogenous Industries)

There are 15 well staffed and equipped institutes under the supervision of MOI, directly or indirectly owned by the state, with the aim to satisfy the demands of a concrete industry (with the exception of the fine chemical-pharmaceutical sector, which has none). These institute differ from each other, due to the characteristics of the sector they "serve". Some of them do also basic research, some are oriented mainly toward applicable results. The contacts with factories could be more fruitful, in case:

- factories were more market oriented and asking for research resulting in new products requested by the market, or useful new processes, and if
- the institutes concentrated more on directly applicable results, than on research for itself.

In addition to those, a more open attitude towards other sectors, participating in interdisciplinary projects, even cooperation with end users from outside of the "homogenous" field, a better utilization of available expertise-instruments-personnel, may also be taken into consideration.

Constraints: Insufficient information on recent scientific results in the world (books, periodicals, on-line access to data banks). Poor (if any) background for maintenance/spare parts and reference material for high performance analytical instruments.

## **R&D** units of factories

Among the companies supervised by the MOI there are 172 having its own R&D unit. MOI makes efforts to urge to organize R&D units in companies having more than 250 employees.

The main fields of activities of these units are:

- global orientation in new results, products, processes (in close cooperation with the marketing department)
- development of new products, better processes
- technological development to comply to environmental prescriptions
- contribution to quality control, analytical support
- assistance in trouble shooting.

#### Private research centres

A chain consisting of medium/small size private enterprises taking the advantage of the expertise and financial resources of the private sector has been organised by MOI with the objective to realize the central concepts of the Iranian Government. Headed by a renowned scientist with good reputation, having also of broad industrial expertise and staffed by some 2-10 specialists, these "small but beautiful" units with their keen sense for market demands, can develop new products, elaborate, scale up and commercialize new processes within short time. With high working standards, flexibility, profit orientation and enthusiasm, this "brigades" serve as the "light cavalry" of the army of innovation. They can not (and do not want to) replace the big corps of the army, but used for reconnaissance, quick attack, surprise, they could complement the work of bigger units.

The number of these companies under the supervision of the MOI is 64 at present but 139 new licences are being issued in consequence of the privatization policy of the government and the incentives of MOI. They cover the following sectors of (except oil, - and heavy, -) industry:

- chemical
- electrical, electronical
- pharmaceutical
- metallic
- nonmetallic minerals
- food
- environmental protection
- medical engineering
- ligno-cellulose
- textile & clothing .

By creating these companies, the advantages of both governmental institutions (central concept for the country, central financial, better technical and personnel resources) and the those of the small private enterprises (described above) can be combined. Their output could be further enhanced:

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- use their skill and expertise for evaluation of
  - tenders, selection new equipments
- allocate financial support to projects having national priority
- better access to high performance instruments

This system of Iranian speciality proved to be the most agreeable surprise of the mission.

# E. Planning and Management of R&D, Flow of Information

During his three month stay, the expert could not encounter with centrally formulated research plan (concept) broken down to industrial sectors. The various ministries and/or organizations having national competence elaborate their own plans, set up their targets trying to realize the general decisions of the government. The lack of coherent R&D plan for the whole national economy, broken down to industrial sectors (taking into consideration of needs of other sectors as well) is badly needed. Management of R&D projects should be improved, using more advanced methods (inc. personal computers), but the most important factor would be the personal competency (authority, linked with responsibility product oriented salary). The delegation of authority (together with responsibility) to the proper (lower) level would liberate heads of departments from unnecessary details of daily administrative burdens and let them concentrate to their essential tasks. The distinction between order (used in the armed forces) and management (practised by disciplined, independent, responsible civilian individuals) should be born in mind. Competence of managers, programme officers must be clearly formulated and separated from higher and lower levels. Duplications, overlaps, ambiguities should be avoided.

# F. Patent Situation

A general experience during the mission has been that no proper attention is attributed to questions related to patents. Not going into details of the patent law and practice in Iran (being off the scope of the present mission) a general observation however cannot be avoided:

Cooperations concerning acquisition of processes of new products, buying licences, know-how, can be realized only in case the patent legislation of the country is complying with international practice.

On the other hand results of Iranian research cannot be commercialized with success without proper patent protection.

## IV RECOMMENDATIONS

Reasons and consequences of the findings detailed in the previous chapter may be summarized as follows:

The various branches of the Iranian industry have developed unevenly in the past, with many missing links in between. This means they are not capable of meeting requirements of other industrial branches. (Dependence on import: 56.7 per cent; chemical sector: 71.1 per cent; food: 29.1 per cent.) The absence of a model of industrial development in the post-revolution years has impeded the framing of a clear-cut industrial policy. On various fields of the economy efforts have been made to transfer the national targets (mainly those of the Five Year Plans) to sectoral levels, seemingly ignoring the fact that the desired changes would only be enduring and really useful in an institutionalized economic system.

The results could be felt in all sectors on all levels:

- lack of contact/information between R&D and industry between industrial sectors
- lack of personal/institutional financial interest in outputs
- conflict of interest between sectors, state and institutions, employees and company consumers and producers

The solution may have structural, organizational, and economical components. The following recommendations try to offer some:

1. Coherent development plan for the whole economy broken down to industrial sectors should be prepared. Coherent means, the plan has to take into consideration the reciprocal needs/supplies/services between the various sectors. The plan should have two parts:

- strategic national concepts and
- sectoral elements

The plan should be prepared by iterations i.e. the first draft of concept summarizing the strategic tasks/long term targets of the Iranian economy should be given to the sectors to set up their targets in their sectoral plans; these sectoral plans should be fed back to modify parts the original concept. Then as a second iteration the plan should be given for public discussion and criticism, especially to private companies and experts of high reputation. After collecting the remarks and proposals the final plan should be prepared and permanently adjusted to actual demands.

#### 2. Bridge organizations

R&D activities by its nature are going on in various fields of the science and also divided among the sectors of the economy. Direction or guidance of R&D by government is realized by so called "bridge organizations" in many countries. Even countries having separate Ministry of R&D utilize this practice. The main task is to link various sectors of the economy/industry, and also realise a closer contact between R&D and production. Especially the activity of the German "Fraunhofer Society", the Japan KTC (Top Technological Centre), or the French: ANVAR (International Agency for Utilization of Research) could be recommended for closer study. The best way would be personal visit and exchange of experiences on the spot by Iranian top officials.

## 3. Agency for development information is badly needed.

"Development" in two senses: Conveying information on recent developments to industry, and also developing (improving) the present flow of information. The direction of their activity should be "horizontal" (connecting various sectors) and also "vertical" (linking research, development, production, sales, marketing). As a first step the agency could be the joint verture of the private research centres, doing service for them, such as information/list of available/needed materials, equipments(new and/or second hand), instruments, new results of finished projects, requests of new processes /projects offers of free capacities for production or research, etc. They can be in contact with foreign companies of similar profile. As a second step the agency could extend its activity to the whole R&D field, including that of the homogenous research institutes and universities. Finally they can also become the conveyor of governmental plans, requests, tenders etc. From the very beginning they must have contact with companies in the industry and the agriculture. The financial support should be started by direct governmental fund, but gradually the agency should earn its operating costs by its services, so it should be self supporting on the long run.

# 4. Public tender for support of projects

R&D projects are and will always fully or partly be sponsored by the state. (Even private companies are not exceptions, using various means of support). The system of allocation of funds is always a target of criticism, however the following may be useful for consideration: Projects having first priority in the national plan should be sponsored by the state. But even the initiation of such projects should be made publicly, through tenders. The competitors should make their proposals and the evaluation should be made by independent (if necessary foreign) experts. In addition to these projects, all companies, small or big, private or state-owned, should have the possibility to submit their projects asking for financial support. The evaluation should be done by the same way as mentioned before. The tender could be managed by a unit independent from related sectors.

#### 5. Flexible ways of support

The financial support of R&D projects may have several forms:

- full support without obligation of repayment
  - full support with repayment
    - in equal parts in time, starting after the project have been finished
    - only from profit of the project
    - repayment may have been performed as royalty on revenues
- part-support, without or with repayment according to the above variations.

## 6. Ministry of Research and Development

All the above recommendations raise the question of a separated ministry. The discussion in detail is exceeding the frames of the present mission.

7. Agency for the support of analytical instruments especially for the high performance, sophisticated and expensive ones seems to be necessary. It is usual practice of major suppliers to have local representatives with the necessary support. Until this situation will be reached, a central, state owned agency should be organized with the task of supplying spare parts. accessories, standard samples, special reagents, repair works to customers. With a reasonable stock of permanently needed materials and spare parts significant (even if not directly demonstrable) losses and damages could be avoided. By collecting demands and orders of several users his position towards suppliers would be much stronger than that of individual customers.

8. Separate funds for information, i.e. for purchasing books, periodicals, using on-line information of data banks are needed in all type of institutions. The present proposal is addressed especially to factories where a part of the revenue should be obligatory to separate and put at the exclusive disposal of the head of R&D.

9. Economical assessment of the pricing/subsidizing system. The issue, by its nature is out of the scope of the present study. The necessity has been provoked by the need of financial support of the R&D activity and as an incentive of developments:

- companies should have adequate financial resources for R&D. These resources are related to their income, moreover to their profit before tax. In case of "too low" prices no margin between sales prices and costs remains to cover R&D expenditures.
- the incentives for reducing costs by decreasing the demand for raw materials and especially to decrease wastes is significantly impeded by low prices making the result of such developments hardly justifiable.

Prices should cover the costs of production, distribution and should assure a proper margin for resources of R&D as well. So artificially low prices though agreeable, may be necessary on the short run - are obstacle of development for future. Enstead of being given to producers, the same amount of subsidy should be distributed among those families who really deserve it (social status, income per capita, etc.). The expert is fully aware of the fact that all such changes have socio-political consequences. It is by far not the objective of the present mission to deal with such issues, but a supervision and a carefully executed change of the system of subsidizing is strongly recommended.

10. Support of new products, replacement of imports. Commercialization of R&D results may be enhanced if:

- the end point of the research should not be the final report, but the industrial application, new product or technology;
- the institute should get recompensation (royalty for a certain period) from the revenue;
- staff members, who contributed to the implementation of the project both in the factory and in the institute should also participate.

Protective tax-duty policy for home-made products, tax exemption for raw materials used for replacement of imported goods should also considered.

11. Supervision of patent system. In order to meet the demands of the development of certain industries (first of all those of the pharmaceutical and chemical ones) revision of the present patent legislation serms to be inevitable. No new achievements of science and technology could be hoped to acquire unless complying with internationally accepted practice.

12. Development plan for the pharmaceutical industry seems to be essential in order to make a frame for cooperation. The plan should (among others) consider:

- national priorities (social/health care, export potentials)
- existing production facilities
- export possibilities (esp. to newly established neighbouring countries)
- cooperation possibilities between factories, in marketing, in production, in R&D.

The plan may be based on a comprehensive study, collecting all starting information and data as inputs for the development plan. This study could be a sectoral study.

13. Sectoral study: Possibilities to introduce environment-friendly technologies to produce pharmaceutical active substances utilizing indigenous raw materials and intermediates from the petrochemical industry and from the agriculture in order to increase self-sufficiency. In the preparation of the study the expertise of UNIDO may be useful.

14. Research institute for the pharmaceutical industry. The sector has no "homogenous institute" of its own. The fields of activity of the recommended institute:

- basic research for the sector
- background for R&D units in factories and private research centres
- link to international institutions

The Research Centre of Darou Pakhsh may be used as a basis.

15. Subsectoral study: Utilization possibilities of medicinal herbs of Iran. The extremely good conditions and traditions of the country should be assessed especially in the light new inventions and trends of the phytochemicals and phytopharmacology.

16. Sectoral study: Possibilities to introduce environment-friendly technologies to produce active substances for pesticides utilizing indigenous raw materials and intermediates from the petrochemical industry and from the agriculture in order to increase self-sufficiency." In the preparation of the study the expertise of UNIDO may be useful.

17. New research targets. Economical research for pricing/subsidizing system. Phytochemistry/phytopharmacology

- 18. Training courses, seminars, consultations requested from UNIDO
- Production of anti malaria vaccines. (Request mentioned in Pasteur Institute)
- Training course for field advisors and staff of control authorities on the proper use and handling of pesticides. (Requested in MOA)
- Training course/seminar on R&D management. (Requested in MOJ)

#### V. ACTIVITIES NOT CLOSELY RELATED TO PRESENT MISSION

1. Shahid Modarres Drug Industries Co. ANTECEDENTS

As phase I of the UNIDO project SF/IRA/90/901 a "Detailed Study for the Establishment of the Industrial Pharmaceutical Complex" has been prepared and submitted to SMDI in June 1993. In July 1992 UNIDO requested UNDP to obtain SMDI's advice related to the continuation of the project using the remaining funds.

# ACTIVITIES

After visits to SMDI's office in Teheran on April 30, May 12 and to the site of production and its Research Centre in Esfahan on May 23 a memo has been prepared (Annex 3) with the conclusion of the expert: As a continuation of the project it is suggested to:

- select one product (based on market and technological considerations)
- acquire (or elaborate, with necessary assistance) the technology with
- demonstration in the laboratory and pilot plant of SMDI.

At the final visit to SMDI's office in Teheran on June 21 Dr. Ejeian unfolded the standpoint of SMDI as follows:

- SMDI has made the selection for one product: methyldopa
- remaining funds at UNIDO should be used to
  - to collect offers for know-how acquisition and to
  - cover the expenses (price) of the know-how (to be completed with necessary additional funds by SMDI) and in order to save foreign currency
  - all steps of implementation (including preparation of basic and detailed engineering; planning the facilities. designing and manufacturing of equipments [with the exception of some special ones only available from import], commissioning and starting-up will be carried out by Iranian partners.

Formal request to start this phase will be requested from UNIDO by SMDI soon.

2. Veterinary products (RAZI Institute)

During discussion in MOJ and RAZI Institute (Annex 3) it became obvious that the need for assistance of UNIDO concerning the project proposal "Cooperation efforts with UNIDO in the production of veterinary pharmaceutical materials" prepared by RAZI Institute in 1992 is still a living request, however not initiated yet formally by the Iranian counterpart. For decisions on the practical activities concerning the implementation of the project the preparation of a feasibility study seems to be the best basis. The main issues (titles of chapters) of such a study requested by counterparts has been prepared and submitted to them by the expert (Annex 3). Attention has been drawn to the necessity of a formal initiation of the project by Iranian counterpart.

# 3. Placenta project (Darou Pakhsh)

No continuation of the project had been mentioned during the visit to the company .

4. Cooperation with African countries and the newly established neighbouring republics.

The issue (enhancing the export of pharmaceutical products, first of all to former CIS republics) has been initiated by H.E. Dr. Velayati, Minister of Foreign Affairs in February 1992, continued by Dr. H. Nakajima, Director-General of WHO and Mr. D.L. Siazon Director-General of UNIDO, followed by the activity of the Managing Director of the Industrial Sectors and Environment Division (UNIDO), resulting in a Preliminary Project Document prepared by Senior Interregional Adviser (UNIDO) and Dr. P. Sizaret (WHO) in Recently H.E. A.Jamshidi, Deputy Minister of Industry also October 1992. emphasised the importance of the project. The programme, if approved, would fit to the strategy of UN system, since it would be implemented by two UN agencies (UNIDO, WHO). The WHO office in Teheran has been informed on the project by the expert. During the discussion the possible involvement of ECO has also been mentioned. However the project hardly can start without the active initiation of the future beneficiary i.e. the Iranian pharmaceutical industry.