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ASSISTANCE IN THE INTRODUCTION OF HIGH TECHNOLOGY IN THE PRODUCTION OF ENZYME OINTMENT

AND

DEVELOPMENT OF THE PHARMACEUTICAL INDUSTRY IN MONGOLIA AND REVIEW OF OTHER PROJECT PROPOSALS

SI/MON/89/801

THE MONGOLIAN PEOPLE'S REPUBLIC

Technical report: Findings and recommendations*

Prepared for the Government of The Mongolian People's Republic
by the United Nations Industrial Development Organization

Based upon the assignment of Mr. G. Dumont,
consultant in pharmaceutical technology

Backstopping Officer: Mr. Arnaud Atger
Chemical Industries Branch

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* This document has not been edited.

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ABSTRACT

As part of the project "Assistance in the introduction of high technology in the production of enzyme ointment and development of the pharmaceutical industry in Mongolia and review of other project proposals" (SI/MOM/89/801/11-53), the Chief Technical Advisor organized as a first step a study tour for three Mongolian participants to Denmark and France. As a second step, he visited the Mongolian People's Republic from 2 to 8 December 1992 to assess the current status of the pharmaceutical and related sector, the veterinarian sector, the agro-food sector and the telecommunications sector.

Recommendations included the implementation of a regulatory system for quality assurance; the modernization of factory premises, including the purchase of equipment; and improvements in the quality Control Laboratory.

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INTRODUCTION

The present report was prepared by the Chief Technical Advisor as part of the project "Assistance in the introduction of high technology in the production of enzyme ointment and development of the pharmaceutical industry in Mongolia and a review of other project proposals" (SI/MON/89/801/11-53). The job description appears in Annex I.

The purpose of the mission was: to prepare and organize a training programme, consisting of study tours to Denmark and France; to meet with the Resident Representative of the United Nations Developement Programme as well as national authorities in Mongolia to discuss new elements of the project proposal; and to make recommendations on the development of national standards, research on and development of indigenous natural products and quality control, assistance in environmental control, scientific and technological applications and serums and vaccines programmes.

The study tour in France, from 22 to 29 November 1992, at Sterling-Sanofi (Herouville) and Sanofi-Winthrop (Notre-Dame-de-Bondeville) gave participants the opportunity to see and discuss in-depth analytical procedures to be applied on Chymotrypsin and Pancypsin. Mr Espejo and Mrs Canuet, former experts for the local training of national counterparts at Monenzym, received the study tour participants and gave very valuable answers to the technical problems raised. An analysis of Pancypsin done by Mr. Espejo on specially sophisticated equipment revealed that Pancypsin is rich in Trypsin indeed but also in Chymotrypsinogen (which may be activated in Chymotrypsin). Monenzym study tour members were given valuable reagents and equipment.

The study tour at Radiometer Denmark took place on 30 November 1992. Participants toured the premises of a factory manufacturing laboratory equipment, where discussions and demonstrations took place, and participants were given disposable spare parts. A summary of the visit is contained in Annex II.

The mission to Mongolia, from 2 to 8 december 1992, included discussions with the Resident Representative and an intensive programme of visits to:

- Ministry of Foreign Affairs
- Ministry of Health
- Ministry of Agriculture
- Mongolian Telecommunications Company
- Ministry for Trade and Industry
- National Development Board

A list of persons contacted appears in Annex III and a schedule of appointments in Annex IV.

UNIDO projects are now submitted by the various ministries jointly to National Development Board (which makes the priorities choice, according to the

economic policy decided at the level of Prime Minister) and to Ministry of Trade and Industry (which has the experience for formulating the project and approaching UN Organizations for funding). Final decisions are up to the Prime Minister Cabinet.

As a very positive result of the mission, Mr. Dumont obtained an official letter sent on 8th December to Mr. Swietering, UNDP Resident Representative, by Mr. Yondon, First Deputy Minister for Trade and Industry. The Ministry for Trade and Industry has selected, from the various proposals, six to be implemented as soon as possible under UNIDO funding, namely:

- cheese an yoghurt preparation for small or medium scale enterprises
- Purification of antitetanic serum at Biocombine Songino facilities and experience
- Serums and vaccines for human use, utilizing Biocombine Songino facilities and experience
- Special project for introduction of purified gonadotropin technology
- Institution of a regulatory system for new pharmaceutical drugs, with bilateral assistance of the French Ministry of Health
- Modernization of equipment Central Drug Control Laboratory and of Biodiagnostics Laboratory at Central Hospital Ulan Baator.

Finally, a one-hour meeting was held on Tuesday, 8 December with Mr. Jasrai, Prime Minister of the Mongolian People's Republic, and Mr. Swietering, UNDP Resident Representative. Mr. Jasrai clearly expressed the present Mongolian priorities, which are food and exports, and the infrastructure to help improvements in these two priorities. At the end, Mr. Jasrai said that he will give instructions to all organizations concerned to work on the proposals and to keep close contact with UNDP/UNIDO.

DISCUSSIONS WITH GOVERNMENT AUTHORITIES AND ACTION RECOMMENDED

A. MINISTRY OF FOREIGN AFFAIRS

Meeting Friday December 4th, 1992 with Mr. Kh. Bekhbat, Vice Minister Foreign Affairs.

* Mr. Kh. Bekhbat will be soon promoted as Mongolian Ambassador in France.
* We learnt that:
  1. WHO sent recently a consultant to help Ministry of Health in selecting the drugs essential for Mongolia - a list of 220 drugs[1], more restricted than the WHO essential list has been established.

  2. Mr. Bekhbat intend, on his arrival in France, to renew with the French Health authorities, in order to establish a Franco-Mongolian cooperation in the health sector and to learn more about health problems or institutions in France.

  3. As French politician Mr. Vivien visited 2 years ago Mongolia and offered equipments and medicinal drugs, Mr. Ekhbat advised Mr. Dumont that it would be of great interest to obtain from Mongolian Ministry of Health, the list of the surgical equipments and drugs received.
     It would be very useful to learn from Ministry of Health, the list of the surgical equipments and drugs received.
     It would be very useful to learn from Ministry of Health what are the most useful for Mongolia in view to import them again from France or to produce them in Mongolia with French cooperation.

Action

- Mr. Dumont will inform French Ministry of Health of the intention of Mongolian Government to develop bilateral/multilateral cooperation in Health Sector.
- Mongolian Ministry of Health will establish a report to Mr. Bekhbat listing what are the most useful for the country by the equipments and drugs received as a grant from France.

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[1] See Annex V, appendix I.

B. MINISTRY OF HEALTH (Telex (0800) 7922 Medic MH)

Mr. Nymadawa - Minister of Health was abroad
(He received Mr. Dumont in 1988).
Dr. Dahszeveg - First Deputy Minister
(He received Mr Atger in 1990).
Dr. Bayarsaihan - Vice Minister, responsible for Health, Economics and Cooperations.

1. **First meeting Friday December 4th**
with Dr. Dahszeveg - First Deputy Minister
Miss Buyandelger - External Relations Officer
(Biochimist, graduated in Germany, specialized in enzyme field)

During one hour, the memorandum[2] submitted to Mr. Nymadava has been extensively discussed with great interest for the various proposals.

* installation of a regulatory system for homologation of drugs, with possible assistance of the French Ministry of Health
* modernization of the Central Drug Laboratory, with possible assistance of DANIDA funds;
* modernization of the pharmaceutical factory, with view to produce WHO essential drugs:
For Mongolian government, priority today is to produce soon 25-30 of the 220 selected WHO essential drugs with view to satisfy 50 to 60% of the total list by the year 2000[3].

* blood transfusion, blood fractionation and tissue banking;

* installation of a modern biodiagnostics laboratory at the Ulan Baator Central Hospital as pole of excellence, with possible assistance of Danish funds ;

* implementation of UNIDO project, with Chinese funds, for assistance in the field of industrial extraction of indogenous medicinal plants[4] : it has to be clarified why there are 3 centers for traditional medicine, two related to Ministry of Health, one related to veterinarian sector ;

* domestic production of antitetanic vaccines and various serums for human use, taking opportunity of th veterinary production facilities existing at Biocombine Songino - and applying the technologies developed through UNIDO in Africa (Cameroon).

Some of these projects, expressed by G. Dumont to the Ministry through

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[2] See Annex V.

[3] See Annex V, appendix I.

[4] See Annex VI.

former letters, have been already taken into consideration in the Programmes handed over by Mr. Nymadawa to all participants, of the 2nd Donor Aid Consultation held in Ulan Baator 14-15 October 1992, including UN Organizations, particularly in the document said "National Drug Policy and Essential Drugs Programme 1992-1995"[3].

Mr. G. Dumont handed to Mr. Dahszeveg some drafts of UNIDO projects proposals pending for Mongolian official request. As a consequence, Mr. Dahszeveg declared himself prepared to express his opinion about it before the end of the mission, asking an in-depth meeting with all relevant directors on Monday December 7th.

2. Second meeting with Departments Directors - Monday December 7th

with Dr. Zorig, Director Central Control Laboratory for remedies
Dr. Dagvatseren, Director - Research Institute for Traditional Medicines
Mr. Magsar, Research Institute of Traditional Medicine
Dr. Samdantsoodol, Director - Ministry of Health company producing traditional medicines.
Dr. (Mrs) Shurentsetseg, Director Blood Transfusion Center

* Central Control Laboratory for Remedies

Review of the draft project document for preparatory assistance and implementation of a modernized Central Control Laboratory for remedies - as one of the items included in the document "National Drug Policy and Essential Drugs Programme 1992-1995" remitted to the participants of the 2nd Donor Aid Consultation held in Ulan Baator 14-15 October 1992, including UN Organizations (as written pages 5, 10, 12, and 18).
(Draft project proposal reviewed annexed[5]).

This project has been considered to be one by the first to be implemented under UNIDO resources, as expressed in the letter n° 2 - 3719 dated December 8th 1992 adressed to UNDP Resident Representative under signing of Mr. Yondon, First Deputy Minister for Trade and Industry.

* Biodiagnostics Control Laboratory in Central Hospital Ulaan Baator as a reference Centre.

This project, considered with great attention by Ministry of Health, has been equally retained to be one by the first to be implemented under UNIDO resources, as expressed in the letter n° 2 - 3719 dated December 8th 1992 adressed to UNDP Resident Representative under signing of Mr. Yondon, First Deputy Minister for Trade and Industry.

* Research Institute for Traditional Medicine

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[3] See Annex V, appendix I.

[5] See Annex V, appendix II.

This Institute, belonging to Ministry of Health, is not involved in the similar project funded by Chinese Government, as this one is intending to cooperate with a similar institute but belonging to the Veterinarian Administration.

This Institute has initiated a scientific work on immuno-depressive activity of aconitum alkaloids. The idea of this study came from a long experience of this formula in traditional medicine.

Preliminary report has been sent early 1991 to G. Dumont in order to interest a foreign company for a joint in-depth study : unhappily the document was not sufficiently detailed for self-explanation and it has been recommended to Dr. Dagvatseren to establish a report detailing the experiments, as to provide evidence to foreign companies and to interest them with precise detailed results for a further possible cooperation.

. Blood Transfusion Center

Assistance of foreign UNIDO consultants would be appreciated for establishing a pilot-scale line for blood fluid packaging and storage.

Same for improving platelets separation and storage, as the presently old-fashion Russian method used through plasmapheresis is not fully satisfactory.

Red cells concentrate would be considered equally as an interesting development project.

. Pharmaceutical Factory

As soon as funds would be available, total renovation of the existing pharmaceutical factory will have to be considered urgently. At present time, as a very modern tabletting unit has been implemented through UN funds and as recent WHO mission established with Mongolian authorities the list of the most important WHO essential drugs for Mongolia, a small TSSI project for providing the specific know-hows and formulations would allow to start in a near future the production of the WHO essential drugs tablets-formulated.

As this would provide more pharmaceutical medicines to the health sector and particularly to hospitals and to the poors, this project endeavour to be prepared and presented soon to UNDP/UNIDO.

3. Final debriefing meeting - Monday December 7th 1992

with Dr. DAHSZEVEG - First Deputy Minister
and Dr. BAYARSAIHAN - Vice Minister of Health ; responsible for Health, Economics and Cooperation.

. The projects proposals are indeed considered as useful and urgent for Ministry of Health : draft project documents will be very soon sent.

. At the occasion of former visits to Mongolia of French Parliament people Mr. VIVIEN and French Minister of Health Mr. KOUCHNER, France has offered surgical equipments and pharmaceuticals :
Following a demand of Mr. Bekhbat (soon Mongolian Ambassador in France), Ministry of Health will establish a survey of the list and will precise those items considered as the more useful for Mongolia.

. Due to the established relationship, Mongolian Ministry of Health want to develop cooperation specially with France in the pharmaceutical field and to establish a special understanding with for the renovation of the governmental pharmaceutical factory :
G. Dumont promised to convey these intentions to the French Minister of Health .

4. Action

. Formal presentation of the proposals and official requests to be transmitted for the proposals listed by Mr. YONDON in his December 8th letter :

- Institution of a regulatory system for homologation of new drugs
  (with possible bilateral cooperation with French Ministry of Health) ;

- Modernization of equipments at Central Control Laboratory for drugs and institution of a systematic control system for drugs
  (with possible funding of Danida) ;

- Modernization of equipments at Biodiagnostics Laboratory of Central Hospital Ulan Baator
  (with possible funding of Danida).

. Letter to be addressed to French Ministry of Health listing the most interesting equipments and drugs by those offered by French Government - with information to Mr. BEKHBAT, as soon Ambassador of Mongolia in France.

. Information of the French Minister of Health through Mr. Dumont, about the Mongolian Ministry of Health desire to cooperate with France for the up-grading of its pharmaceutical industry and renovation of the factory.

C. MINISTRY OF ROADS, TRANSPORT and COMMUNICATIONS

Mr. SANDALKHAN - Minister
Mr. BOLDBAATAR - Mongolian Telecommunications Company
Mr. JARGALSAIHAN - International relations Officer

Meeting Saturday December 5th 1992
with Mr. Tserenpuntsagiin BOLDBAATAR, General Director Mongolian Telecommunications Company

Address : Sq. Sukhbaatar 9 - Ulan Baatar 210 611
Telephone : 24855
Telex : 79237

During 1 hour, the memorandum submitted to His Excellence Mr. SANDALKHAN and transmitted to Mr. BOLDBAATAR has been explained and discussed in-depth :

A/ Turn of the Mongolian Telecom institution to semi-public system

Mongolia intending to turn to a semi-public institution, as France did the same change along the recent years, it appears wise to G. Dumont to inform Mr. Boldbaatar about the possible interest for Mongolia to appoint a French consultant specialized in strategic consulting in this field.
It would save time and avoid errors to be assisted by someone knowing in-depth the difficulties faced in France and the ways used to solve them : evidently such big change from governmental to semi-public institution is risky, but the experience of privatization finally successful in France (where Government is also under a socialist majority) would be certainly a valuable contribution for helping Mongolia to reach in a short time the semi-public institution they want.

By a rare opportunity, G. Dumont was knowing directly one of the consultants to French Telecom, specialized in strategic development and management support to Telecom Direction .
As very soon, the general study funded by Asian Development Bank will be remitted to Mongolian authorities, it is quite sure that such consultants would help Telecommunications management in their choices and advise them on the best ways to succeed.

In a further step, it is foreseen to select one or 2 consultants for a temporary assistance and a junior professional consultant to assist Mongolian authorities under a permanent 1 - 2 years contract.
Problem of funds necessary for such consultancy contracts would be probably solved when project will be decided.

B/ Satellite education for children

Mr. BOLDBAATAR, as a former member of the Mongolian Parliament, has a deep interest for his native region where education of young children is a problem :
as schools have management difficulties, parents stopped to send their children to school as more as they are interested to have them for farm work. A very big risk appear to have a decrease in the education level of the new generations.

Having heard of education programmes through satellite for the very primary children in isolated countries (in India for example) supported by international funds, Mr. Boldbaatar was particularly interested due to his parlementary social care for his homeland and due to the possible involvement of Mongolian Telecommunications Company in this duty.

He was willing that this project would be supported at the level of the Government and funded by UNICEF or other United Nations Organizations in the frame of a programme including equipments and educational TV programmes for the very youngs, allowing them to receive a basic education at their parents place when they are not in position to follow school courses.

C/ Development of local production for cheese and beer

In his homeland, farmers have difficulties to increase their earnings and also cannot use the excess milk produced during summer time.
Mr. Boldbaatar has been directly interested by the UNIDO Draft Project suggested, submitted to Ministry of Agriculture and wish to associate to it farmers of his region.

G. Dumont has informed that France being by the large producers of cheeses it would be easy to provide experts knowledgeable in cheese production adapted to isolated farmers unable to transport the milk on long distance : he gave to Mr. Boldbaatar reference of the voluntary association ECTI where he is acting and which is able to provide experts for direct assistance or preferably in the frame of the UNIDO proposed project.

Same interest for a local beer production as a way to add value to the wheat or barley crops of the farmers and to create a small local industry of brewery.

D/ Action

. As food is a priority for Mongolia, Mr. Dumont has exposed the concern of Mr. Boldbaatar about his homeland farmers and problem is now known at the level of Ministry of Agriculture and Prime Minister : Mr. Dumont will inform Mr. Boldbaatar.

D. MINISTRY OF AGRICULTURE AND FOOD INDUSTRY

Adress : Enkh Taivan Street 16 - Ulan Baatar 49
Telex : 800.242

Mr. Ould - Minister, has received part of the memorandums sent by G. Dumont but was on a trip to Europe
Mr. SUHREN JARGAL - Vice-Minsuter

1. VETERINARIAN SECTOR [6] - Meeting on Monday December 7th 1992

with Mr. DORJSAMBUU, Director of Veterinary Services
Mr. MAGSAR, Veterinary Department Officer
Mr. DORJGOTOV, Director at Biocombine Songino
Mr. BAATAR, Joint Director at Biocombine Songino
(already visited by G. Dumont in 1988)
Mr. BAYARSOGT, Foreign Relations Department - English translator

BIOCOMBINE Songino has been established with an Hungarian cooperation of PHYLAXIA about 20 years ago. Hungarian technical assistance has been provided on a regular basis through permanent Hungarian engineers.
It is now an important factory producing 70 different products with an annual turnover of 700 millions Tugriks.

A. OXYTETRACYCLINE

Large production of oxytetracycline (100 tons per year) has been produced under Hungarian agreement and exported regularly to Hungary till 1990 : production and corresponding exports stopped, as Phylaxia claimed that transportation costs through Russia are now uneconomical.

B. MODERNIZATION OF FACTORY

As soon as funding will be available, Biocombine Songino want to modernize the existing equipments with possible cooperation of a foreign company.

C. ANTITETANIC SERUM PURIFICATION

Mongolia is able to produce 10.000 liters per year of crude antitetanic serum : it has been regularly exported till 1991 to Hungary. Exports were stopped due to increased air-freight cost transportation. Purification of antitetanic serum would bring an added value to the product, would allow Biocombine to approach the various users of the international market (and not only the Hungarian buyer who was certainly purifying himself and re-exporting to many countries).

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[6] See also Annex VII. A.

As it is a specific and small project with good export possibilities - and as export is by the immediate priorities of the Government, this subject could be valuable for a TSS 1 project.

This project has been considered to be one by the first to be implemented under UNIDO resources, as expressed in the letter n° 2 - 3719 dated December 8th 1992 addressed to UNDP Resident Representative under signing of Mr. YONDON, First Deputy Minister for Trade and Industry.

Draft project proposals have been established and remitted to Ministry and UNDP.

D. PURIFICATION OF GONADOTROPINE SERUM AND EXPORTS OF IT

At Biocombine Songino place, 500 horses are bred for the needs of the factory : **100 of them are pregnant mare and such a large number at the same place is exceptional in the world.**
This provide a good opportunity to produce in Mongolia and to export pregnant mare blood derivatives (gonadotropin but also the residual by-products like immunoglobulins).
Potential of Mongolian collection for mare blood serum would reach 20 - 30.000 liters/year. Presently crude gonadotropin serum is used in Mongolia for veterinarian uses (cow sterility).

Exports initiated to Hungarian PHYLAXIA has been stopped due to the fall in activity during transportation of crude serum.

Technical cooperation was decided with DESSAU - DDR but stopped after Germany reunification.

Recently SANOFI FRANCE took a financial interest in PHYLAXIA : BIOCOMBINE SONGINO was inquiring near G. Dumont how to reestablish PHYLAXIA cooperation, through SANOFI and to obtain licence for their purification technology.

As G. DUMONT was personally General Manager of one of the Chemical Sanofi Companies, he offers to introduce the subject at the Sanofi top level management :
He will argue on the long understanding between Biocombine and Phylaxia, as the mutual interest represented by the rare large possibilities of collection for mare serum in Mongolia and by the perfect handling of the international market by Phylaxia.

2. DAIRY PRODUCTS

2.A. R and D Laboratory acting as a reference center

As the chief of the Blood and Dairy Products Department (Food Industries Division), Mr. ALZAKHGU, was not available on the same day, the special memorandum addressed to Mr. OULD on October 28th will be remitted personnaly to him by Mr. GANKUYAG, UNDP/UNIDO Programme Officer. [7]

A special letter will be sent also to him by G. Dumont with special emphasis on the high priority expressed for food projects by the Prime Minister Mr. JASRAI during the meeting held with him on Tuesday December 8th.
With the memorandum, Mr. ALZAKHGU will be also remitted a copy of an ancient UNIDO project, requested by letter signed by Mr. BAVUU Deputy Minister of External Economic Relations and Supplies on August 11th, 1988 for an R and D dairy product laboratory.

The project has not been finalized till now but the project document could be very useful for reintroducing this project in a near future with view to establish such an R and D Laboratory as a reference center able to provide informations and technologies to the various parts of the countries.

Main subjects of interest for the R and D Laboratory would be

- **Cheese and yogburts improved technologies,**
- **Mare milk (spray-dried or concentrated under vacuum) for newborn children use**

2.B. Assistance to isolated farmers in cheese production

A second type of intervention could be useful at the level of small isolated or nomadic farmers :
As they have big problems to avoid losses of milk in summer time, it would be profitable for Mongolian food availability to educate these farmers (at their level, through possibly voluntary experts acting in the homeland) for producing long-storage cheeses - as it is usually done in Europe in the mountains in the summer season when the farmers are not able to descend the milk in the valleys as they are with their cows on the upper part of the mountains for grass-feeding availability.

During the meeting held with the Prime Minister on Tuesday December 8th, Mr. JASRAI emphasizes on the top priority given to any project improving food supply.

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[7] See Annex VII B.

This explains why this project - mainly implementation of improved technology for cheese and yoghurt production at level of small or middle-sized enterprises - has been considered to be one of the first to be implemented under UNIDO resources, as expressed in the letter n° 2 - 3719 dated December 8th 1992 addressed to UNDP Representative under signing of Mr. YONDON - First Deputy Minister for Trade and Industry.

Such a small project of direct assistance in the field to farmers could be realized quickly with assistance of voluntary ECTI Association experts, in the frame of a TSS 1 project.

3. BLOOD AND MEAT PROCESSED PRODUCTS

3.A. R and D Laboratory as a reference center

As the chief for Dairy Products, Mr. ALZAKHGU, is also in charge of Blood products, similar documents for improving hygienic blood recovery and for providing improved quality meat products recipes (at the same time than for Dairy products memorandum) will be remitted to him. *

Same high priority is given by Government for this project able to provide better availability for food products.

As equally an ancient UNIDO project has been written and requested by letter signed by Mr. BAVUU Deputy Minister for External Relations on August 11th, 1988, a copy of the document will be provided to Mr. Alzakhgu as it can be useful for reintroducing the project in a near future with view to establish such an R and D Laboratory as a reference center able to provide informations and technologies to the various parts of the country.

Main subjects of interest for this R & D Laboratory are

- Hygienic blood recovery
- Use of clean blood for food (black sausages, etc ...) or for protein rich isolates
- Improved quality of meat processed products and applied technologies for producing them

Draft for a first step small project proposal for hygienic blood collection has been established and remitted to UNDP and Ministry.

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* See Annex VII C.

3.B. Immediate improvement of the quality of some meat processed products - through small project - using eventually voluntary French ECTI experts in the frame of a TSS 1 project funded by UN Organizations.

Quality of beef tripe dry sausage can be improved through adapted experience of a foreign meat-processing professional expert to the Mongolian conditions - as in some countries as France there is an extensive use of tripes dry sausages and also fresh tripes sausages using other tripes as veal or porc.

For blood, adaptation will have to be studied for beef blood from the classic use in Europe of porc blood for producing very palatable and appreciated black sausages.

Advises for hygienic blood collection through needle would also contribute efficiently to reduce the pollution at the slaughter-houses place.

4. ACTION

A. Veterinary sector

- Ministry of Agriculture will soon establish formal project draft for official request about the purification of antitetanic serum - as indicated by the priorities listed by Mr. YONDON in his letter to UNDP dated December 8th 1992.

- Mr. Dumont will approach Sanofi Group due to personal introduction and will try to reestablish the former existing relations between Biocombine and Phylaxia - as Phylaxia is now belonging to Sanofi and as Mr. Dumont was formerly a General Manager of this Company.

B. Dairy Products

- Ministry of Agriculture will soon establish formal project draft for official request about cheese and yoghurt production for small or middle-sized enterprises as indicated by the priorities of Mr. YONDON in his letter to UNDP dated December 8th 1992.

- Mr. Dumont is prepared to provide cheese experts to assist Mongolia at the level of the isolated farmers or villages, through the French voluntary experts association ECTI where he is acting as a manager - this voluntary assistance can be included in UNIDO projects.
This Association, and the help it can provide to Mongolia at small cost, has been presented to the Prime Minister.

C. Blood and meat processed products

As food is an urgency, French voluntary ECTI experts knowledgeable in this field can assist Mongolian slaughter-houses or meat industries, preferably with assistance of UNIDO.

E. MINISTRY OF GEOLOGY

Mr. TSOGBAATAR - Minister

As Mining industry is relatively new in Mongolia, it has been confirmed to G. Dumont by Ministry for Trade and Industry that valuable assistance in this field would be greatly appreciated.

During his stay, Mr. Dumont was not able to meet Mr. Tsogbaatar but Ministry for Trade and Industry recommended a letter to be sent by UNIDO to Mr. Tsogbaatar on behalf of Mr. BATTSENGEL and Mrs TUNGALAG ANDOYUNUMEG of Ministry for Trade and Industry.

As the main priorities of Government are presently "food and exports" it is not sure that funding of proposals would be easily obtained presently from UN Organizations.

It would be possible wise to introduce the subject and to propose the contribution of French voluntary ECTI experts, knowledgeable in this field of the mining industries - as a mean to obtain TSS 1 projects at low cost of funding.

Action

- Mr. Dumont will ask ECTI to inform UNIDO Mr. Beinhoff about the ECTI experts available and their competences (particularly in gold mining and gold recovery).

- Letter to be sent by UNIDO Vienna to the attention of Mr. TSOGBAATAR.

F. NATIONAL DEVELOPMENT BOARD (Belonging to Prime Minister)

(One of the governmental administrations directly involved in the choice of priorities for UN projects)

Meeting on Tuesday December 8th, 1992

with Mr. GANZORIG - Director General of Economic Cooperation Department
Address : 210646 Negdsen/ Undestnii Street - Ulan Baatar
Telex : 236

Mr. Ganzorig as Director General of this Economic Cooperation Department has been recently appointed as responsible for establishing the priorities between the different ministry proposals - according to the policy economics development (under direct control of the Prime Minister Cabinet).
This duty is done in close cooperation with Minsitry of Trade and Industry which is in charge to formulate the final projects and to finalize them with UN Organization.

As this meeting was at the end of the mission and after Mr. JASRAI meeting, G. Dumont has been able to summarize to Mr. GANZORIG the various proposals discussed and to remit him for consideration a complete set of the memorandums remitted to the different Ministries.

NB - It has been heard from Mr. Ganzorig that the former Minister for National Development Board was Mr. BATSUURI who is now a Member of Parliament.
Mr. Batsuuri had a special interest in the Veterinary Traditional Medicine Company named "SHINE EKHLEL" for which a draft project with Chinese funding is waiting for official request.
Mr. GANZORIG will inquire after Mr. Batsuuri and will return to UNIDO about the eventual interest for an official request in a near future.

G. MINISTRY FOR TRADE AND INDUSTRY

(One of the governmental administrations directly involved in the choice of priorities for UN projects).

Address : Sambu Street n° 11 - Ulan Baatar
Telex : 221 GEZN MH

Mr. YONDON - First Deputy Minister (who signed official letter dated 8/12/92)
Mr. GANBAATAR - Vice Minister

1. First meeting Friday December 4th, 1992

with Mr. Gunchingiin BATTSENGEL - Chief Department of UN Organizations and Western Countries

Mrs TUNGALAG - Deputy Chief Department of UN Organizations and Western Countries, responsible for projects with UN and USA mainly

For UN projects, proposals established by Ministries are now submitted jointly
to National Board Development - which is recently also in charge to do the choice of priorities between the projects in accordance with policy economics development (under control of Prime Minister),
and to Ministry for Trade and Industry, which was formerly alone to do this choice and which have a long experience for the relations with UN Organizations, as for the formulation and discussion of these cooperation projects.
Final decision is taken at the level of Prime Minister Cabinet.

Among the different subjects involved through the various memorandums established by G. Dumont, every small project able to improve food quality and ability (cheese and dairy products, baby foods, meat processed industries, spray-dried or semi-concentrated mare milk for newborn children) will be certainly considered as a Mongolian top priority.

Also every proposal able to increase exports is a priority for the country.

2. Second meeting Monday December 7th, 1992

Direction of Investments

Mr. NARANHCUU - Director, was unavailable on the 7th

Mrs OYUNCIMEG - Responsible for every project involving bilateral financing with France or Belgium.
Responsible also for every project involving agricultural or food industries sector.

This Direction of Investments is in charge of every Mongolian project for funding : they will contribute to the choice of the best funding possibilities for each project.

As Mrs. OYUNCIMEG is in charge of bilateral projects with France, G. Dumont informed her about the draft proposals which would possibly involve French cooperation or French experts :

- Regulatory system for homologation of new pharmaceutical drugs - with French Ministry of Health ;
- Audit and modernization of the Pharmaceutical Factory under French cooperation, as a wish of Mongolian Ministry of Health ;
- Telecommunications strategic consulting to help the turn to semi-public institution ;
- Cheese production : implementation of an R and D laboratory acting as a reference center - and also assistance to the small sized nomadic farmers with French voluntary consultants of the ECTI association (where G. Dumont is one of the managing directors) ;
- Blood hygienic recovery and meat processed products, also under possible assistance of ECTI voluntary experts preferably in the frame of a TSS 1 UNIDO project - and implementation of an R and D Laboratory acting as a reference center.

3. Final debriefing meeting Tuesday December 8th, 1992

with Mr. BATTSENGEL and Mrs. TUNGALAG

By the various proposals, the following are considered by Ministry for Trade and Industry as a real urgency and they merit to be submitted in a near future as official request to UNIDO financing :

. Cheese and yoghurt production for small and medium scale enterprises ;

. Antitetanic serum purification and concentration at Biocombine Songino ;

. Serums and vaccines for human use, utilizing veterinarian facilities and experience at Songino Biocombine ;

. Special project for introduction of purified gonadotropine technology and the exports of the finished product ;

. Institution of a regulatory system for new pharmaceutical drugs with bilateral assistance of French Ministry of Health ;

. Modernization of analytical equipments of Central Drug Control Laboratory and of Biodiagnostics Laboratory at Ulan Baatar Central Hospital.

With the friendly and efficient contribution of Mr. Battsengel and Mrs. Tungalag, **an official letter (copy included page 4 bis) has been established resuming these priorities and addressed to UNDP Resident Representative on December 8th under signing of Mr. YONDON, First Deputy Minister for Trade and Industry**.

It is also precised in the aforesaid letter that other proposals will be transmitted to UNDP in a near future.

H. GOVERNMENT OF MONGOLIA - PRIME MINISTER

Meeting held on Tuesday December 8th, 1992

with Mr. JASRAI - Prime Minister

Mr. BAGBAATAR - Senior Advisor to the Prime Minister (met by G. Dumont in Paris in February 1992, when Minister of Trade and Industry)

Mr. SWIETERING - UNDP Resident Representative in Mongolia

Mr. GANKUYAF - UNDP/UNIDO Programme Officer

Mr. JASRAI has already received Mr. DUMONT - with Minister of Health and Minister of Agriculture - in 1988 when he was acting as Chief of an UNDP auditing mission.

Mid 1992, Mr. Dumont having heard of Mr. JASRAI nomination as Prime Minister wrote to him with various proposals able to help Mongolian development and to be probably funded through UNIDO or bilateral cooperations.

Mr. JASRAI replied in a letter dated August 28th 1992, supporting the submitted suggestions.

When UNIDO asked Mr. Dumont to approach the various ministries and to hear their priorities, Mr. Dumont established and sent in advance memorandums to each of the relevant Ministers involved - these subjects have been extensively discussed with responsible persons at ministries from 2 to 8 December 1992.

As a final debriefing meeting, Mr. JASRAI, assisted by Mr. BAGBAATAR, accepted to receive Mr. SWIETERING and Mr. DUMONT on Tuesday December 8th, 1992.

During one hour, Mr. JASRAI was explained about all the subjects submitted and discussed and he summarized the Government policy about :

- . Present time is the most critical period for Mongolia
  . Transition time have to be short
  . Economic present system differs from 1988 situation totally
  . Mongolia being IMF member, has obligation to coordinate Mongolian economy with IMF

- Clearly expressed Government present priorities are food and exports - and infrastructures able to help improvements of these 2 priorities ;

- Projects proposals presented by G. Dumont are in accordance with Mongolian policy and priorities :

  In a first step, proposals will be studied in-depth.
  In a second step, proposals will be reviewed with assistance of UNDP.
  In a third step, Mongolian economic concept presently under working on for 1993 will have precised the policies level to coordinate with IMF and other financial institutions (including UNDP as a key role).

All the proposals established by G. Dumont will be carefully considered in this work - and every administration involved will have to work very hard for.

At the end, Mr. JASRAI said that he will give instructions to all organizations concerned to work on and to keep close contact - and thanked Mr. Dumont for his continuous efforts given to Mongolian development particularly in the health sector.

PJ Copy of the document presented to Mr. Jasrai as a guide-line for the meeting. (see page 28)

NB At the end of same day, Vice Minister for Trade and Industry, Mr. YONDON has been able to send to UNDP Resident Representative Mr. SWIETERING, a special letter dated December 8th, 1992 listing 6 of the proposals as valuable for immediate implementation, if possible, as small specific projects (TSS 1) through UNIDO funding. (Copy included at page 4 bis).

ANNEX I
JOB DESCRIPTION
SI/MON/89/801/11-53

Post Title : Consultant in Pharmaceutical Technology, Chief Technical Advisor

Duration : 10 days

Date required : 24 November 1992

Duty Station : Ulan Bator, Mongolia (9 days) ; Vienna (1 day debriefing)

Purpose of the Mission : To develop the Pharmaceutical Industry in Mongolia, to audit project site for the transfer of high level technology for the production of enzyme ointments as well as to develop project proposals which correspond to the upmost needs of Mongolia (programming mission). Objective of the mission should be to serve to contribute to national capacity-building, to develop scientific and technological know-hows, skills and practices through the strategies outlined hereafter, as to reach self-sufficiency for essential drugs in the country.

Duties : The expert is expected to carry out the following activities :

1. Prepare the training programme for the second group of the study tour

2. Organization of the study tours in France and Denmark including visiting the holder of technology for stable enzyme ointments, equipment manufacturer and scientific institutions engaged in research of pharmaceutical enzyme products and biotechnology.

4. To meet and discuss with Mr. Swietering, new Resident Representative of UNDP for Mongolia, new elements of project proposals taking into account:

- the medical needs of the country expressed in the development programs included in the national plans of the Mongolian Government.

- the need to contribute to national capacity building and self-sufficiency for medicinal drugs,

- the new guidelines and policy framework to be applied to the new UNDP programs to be funded by TSS1.
- the support given on 28th August 1992 to the CTA's proposals by His excellency Mr. P. Jasrai, new Prime Minister for Mongolia.
  Contact Adress: UNDP, P.O. Box 49/207 - 7, Erhuu Street Sukhbaatar Region, Ulaanbaatar
  Tel (800) 26-221, 21-539 (RR)
  Télex (800) 79-225 UNDEV MH

5. To meet and discuss with the counterpart, national authorities:
   Prime Minister, Ministry of Health, Ministry of Agriculture,
   Mr. Tseredendev (Director-General MONENZYM), etc...

6. Elements of program to be suggested:

A. Development of national standards, with appropriate reference to international ones and with application of excellence in sciences and Technologies.

a.1: Installation of a regulatory system for homologation of every pharmaceutical drug in Mongolia.

a.2: Central Laboratory for control of remedies

B. Introduction of programs which would assist both the private and the public sectors, including for instance research and developments of indigeneous natural products including also introduction of quality control systems.

b.1: Quality control system for medicinal drugs

b.2: Modernization of the governmental pharmaceutical factory in Ulan Bator

b.3: Scientific cooperative study with Institute of Traditional Medicine

C. Environmental Controls and impact assistance

D. Scientific and technological evaluations and applications (i.e.Central Biodiagnostic Laboratory for the City of Ulan Bator as excellence center).

E. Serums and vaccines programmes (veterinarian field)

Qualifications: Pharmacist with marketing experiences. Particular knowledge in production of bioactive substances of animal origin is necessary. Experience of technical-cooperation activities in developing countries would be an asset.

Language: English/French

Background information:
See detailed information enclosed.

ANNEX II

Visit to RADIOMETER DENMARK (30 November 1992)

Addresses

(1) RADIOMETER ANALYTICAL - Head Offices
Address : Krogshøjvej 49 - 2880 BAGSVAERD (10 kms north of Copenhagen)
Telephone : 39 69 63 11
Fax : 44 49 00 11

(2) RADIOMETER INTERNATIONAL - for international relations
Address : Tagensvej 135A - DK 2200 COPENHAGEN N. DENMARK
Telephone : 45.39 69 61 11
Fax : 45.35 82 15 11
Telex : 27195

Persons met

Mrs. Ritta LUUKKONEN - Product Manager (Training)
Miss Anne Margrethe GRAABAEK - Procuct Manager
Mr. Jens SORENSEN - Service Manager - Radiometer International (who visited Mongolia September 1992 for servicing medical equipment offered by Denmark Development Fund to the Ulan Baator hospital - blood gas analyzer unit).

Summary of the talks

- Meetings and demonstration allowed Mrs. Selenge and Urtnasan to obtain precise replies on the various uses of the equipment offered by UNIDO :
  - plastic beakers are better than glass ones, particularly for lipase determinations ;
  - for pH-Stat, microhead is required for 1 to 5 ml volume samples ;
  - determination unit 160 : the most flexible, to be used for ordinary determinations and pH-Stat till 70 minutes.
    270 : uniquely for pH-Stat, able to work till 2 hours.
    260 : for ordinary routine determinations.
  - lipase activity determination, with a practical training in laboratory working conditions.

- Training of Mongolian analysts has been conducted on the same equipment than the one offered to Mongolia by UN Organizations : the existing equipment is absolutely sufficient for all the present needs of Monenzym, Radiometer confirm that it is not at all necessary to buy the determination unit 270 for the work done at Monenzym.

- Extensive explanations have been provided by Radiometer scientists to solve some small difficulties.

Action

At the end of discussions with Mr. SORENSEN (Radiometer) it appear possible to interest very probably Denmark DANIDA Agency to offer laboratory equipment to Mongolia - as DANIDA has already provided medical equipment to Mongolian hospitals : it would be wise UNIDO to approach DANIDA and to ask their participation for financing the equipment refurbishing of the Central Drug Laboratory and of the Biodiagnostics Laboratory at the Central Hospital of Ulan Baator.

The address of the Danish Development Fund able to participate possibly to financing of equipments to be offered to Mongolia in the frame of UNDP/UNIDO projects is

DANIDA (DANISH DEVELOPMENT AGENCY)
Asiatik Plads 2
1448 COPENHAGEN K

Telephone : 33 92 00 00
Fax : 31 54 05 33

ANNEX III
LIST OF PERSONS CONTACTED

GOVERNMENT OF MONGOLIA

Mr. JASRAI - Prime Minister
Mr. BAGBAATAR - Senior Advisor to the Prime Minister (met by G. Dumont in Paris in February 1992)

UNDP - 7 Ehru Str. Sukhbaatar Region PO Box 49/207 Ulan Baatar Tlx 800.79225 Fax 873.150.7441

Mr. SWIETERING - Resident Representative
Mr. YASUAKI AIHARA - Junior Professional Officer
Miss AYUSH NARANTUYA - Programme Assistant UNFPA
Mr. GOMBOSUREN GANKUYAG - Programme Assistant UNIDO

MINISTRY OF FOREIGN AFFAIRS

Mr. BEKHBAT - Vice Minister, soon to be promoted as Mongolian Ambassador in France
Mr. PUTRAKSHAA - Former Commercial Counsellor at the Mongolian Embassy in France

NATIONAL DEVELOPMENT BOARD

Mr. GANZORIG - Director General of Economic Cooperation Department
Address 210646 Negdsen/Undestnii Street - Ulan Baatar
Telex 236

MINISTRY FOR TRADE AND INDUSTRY

Address : Sambu Street n° 11 - Ulan Baatar
Telex 221 GEZN MH

Mr. YONDON - First Deputy Minister
Mr. GANBAATAR - Vice Minister
Mr. BATTSENGEL - Chief Department UN Organizations and Western Countries
Mrs TUNGALAG - in charge of UNIDO projects, assisting Mr. Battsengel
Mrs OYUNCIMEG - in charge of all projects involving France, Belgium and Agricultural sector - Speaks French

MINISTRY OF HEALTH - Telex 0800 - 7922 Medic MH

Mr. NYMADAWA - Minister of Health, visited by G. Dumont in 1988, has received memorandum but was on a trip in Europe

Dr. DAHSZEVEG - First Deputy Minister, visited by Mr. Atger in 1990
Dr. BAYARSAIHAN - Vice Minister of Health - Responsible for health, economics and cooperations

Miss BUYANDELGER - External relations Officer - Biochemist, English interpreter of Ministry

Dr. ZORIG - Chief Central Control Laboratory for Drugs - Visited by G. Dumont in 1988, 1989, 1992

Dr. (Mrs) SHURENTSETSEG - Director Bloodtransfusion Center
Dr. DAGVATSEREN - Director Research Institute and Traditional Medicine
Dr. SAMDANTSOODOL - Director of Ministry of Health Company producing traditional medicines

Mr. MAGSAR - Institute of Traditional Medicine
Dr. DANDII - Director Blood fractionation Center, visited by G. Dumont in 1988, finally unable to join the meeting.

MINISTRY OF ROADS, TRANSPORT AND COMMUNICATIONS

Mr. SANDALKHAN - Minister
Has received memorandum established by G. Dumont but was not directly involved and transmitted to Mr. Boldbaatar

Mr. BOLDBAATAR - General Director Mongolian Telecommunications Company - Former Member of the Mongolian Parliament
Address Sq. Sukhbaatar 9 - Ulan Baatar 210611 - Telex 79237

Mr. JARGALSAIHAN - International Relations Officer

MINISTRY OF AGRICULTURE AND FOOD INDUSTRIES

Address : Enkh Taivan Street 16 - Ulan Baatar 49
Telex : 800.242

Mr. OULD - Minister
Has received the memorandum of G. Dumont but was on a trip in Europe

Mr. SURENJARGAL - Vice Minister
Mr. DORJSAMBUU - Director of Veterinary Services
Mr. MAGSAR - Veterinary Department Officer
Mr. DORJGOTOV - Director at Biocombine Songino
Mr. BAATAR - Joint Director at Biocombine Songino, already visited by G. Dumont in 1988

Mr. BAYARTSOGT - Foreign Relations Department - English translator
Mr. ALZAKHGU - Chief Blood and Dairy Products Department at Food Industries Division (formerly direct Chief of Mrs Selenge - Monenzym)

MINISTRY OF GEOLOGY

Mr. TSOGBAATAR - Minister - Was not met by G. Dumont

MONENZYM

Mr. TSERENDENDEV
Mrs ALIMAA
Mrs SELENGE
Mrs URTNASAN

ANNEX IV
APPOINTMENTS PROGRAMME

Wednesday 2 December
- UNDP Mr. SWIETERING

Thursday 3 December
- 9h00 UNDP
- 14h00 Mr. CONTARD - French Professor at University
- 16h00 MONENZYM - Mrs. ALIMAA, Joint Director

Friday 4 December
- 9h00 UNDP
- 10h00 MINISTRY FOR TRADE AND INDUSTRY
  Mr. BATTSENGEL and Mrs TONGALAG
- 12h00 MINISTRY OF FOREIGN AFFAIRS
  Mr. BEKHBAT - Vice Minister, soon to be Ambassador in France
- 15h00 MINISTRY OF HEALTH
  Mr. DAHSZEVEG - Vice Minister

Saturday 5 December
- 9h30 MONENZYM - Mrs. SELENGE
- 13h00 MONGOLIAN TELECOMMUNICATIONS COMPANY
  Mr. BOLDBAATAR - Director General
- 14h30 MONENZYM - Mrs. SELENGE and Mrs URTNASAN

Sunday 6 December
- 18h45 Mr. CONTARD - French Professor at University

Monday 7 December
- 9h00 MINISTRY OF HEALTH
  Dr. DAGVATSEREN, Institute Traditional Medicine
  Dr. SAMDANTSOODOL, Company of Traditional Medicine
  Dr.(Mrs) SHURENTSETSEG, Director Blood Transfusion Center
  Dr. ZORIG, Chief Central Control Laboratory for Remedies
- 11h30 MINISTRY FOR TRADE AND INDUSTRY
  Mrs. OYUNCIMEG in charge of cooperative projects with France and agriculture projects
- 12h40 MINISTRY FOR TRADE AND INDUSTRY
  Mr. GANBAATAR - Vice Minister
- 13h45 MINISTRY OF HEALTH
  "Final debriefing meeting" with Mr. DAHSZEVEG and Mr. BAYARSAIHAN - Vice Ministers
- 16h00 MINISTRY OF AGRICULTURE
  Mr. SUHRENJARGAL - Vice Minister and Directors Veterinarian sector
- 21h00 NARANBULAG COMPANY
  Mrs. TSENDEM, Pharmacist and Director General

Tuesday 8 December
- 9h00 UNDP - Mr. SWIETERING
- 10h00 GOVERNMENT OF MONGOLIA
  Mr. JASRAI - Prime Minister
  Mr. BAYARBAATAR - Senior Advisor to the Prime Minister
- 12h00 MONENZYM - Mrs SELENGE
- 14h30 MINISTRY FOR TRADE AND INDUSTRY
  Mr. BATTSENGEL and Mrs TONGALAG

Tuesday 8 December	- 16h00 NATIONAL DEVELOPMENT BOARD Mr. GANZERIG - Director General
	- 17h00 MINISTRY FOR TRADE AND INDUSTRY Mrs. TONGALAG
	- 17h30 MONENZYM Mr. TSERENDENDEV, Mrs. ALIMAA, Mr. PUTRAKSHAA
	- 19h00 MONGOLIMPEX Mr. BATBOLD, Director General

ANNEX V
ELEMENTS FOR A UNDP MEDICINAL DRUGS PROGRAM IN MONGOLIA

M E M O R A N D U M

to the attention of His Excellence
Dr. P. NYMADAVAA - Minister of Health

*

- Taking into account the medical needs of your country expressed in the development programs included in the national plans of the Mongolian Government ;
- Taking into account to contribute to national capacity-building and self-sufficiency for medicinal drugs ;
- Taking into account the new guide-lines and policy framework to be applied to the new UNDP programs to be funded by TSS 1,

we are submitting for consideration to Your Excellence and to UNDP Resident Representative, the elements of a program devoted to "the medicinal drugs in Mongolia", which is one of the priorities of your Government :
The final document will survey the different points - including policy, strategies and objectives for the coordination of the various activities.

Mention of the objectives should serve to contribute to national capacity-building, to develop scientific and technological know-hows, skills and practices through the following strategies, as to reach self-sufficiency for essential drugs in the country.
Some of them have been prepared so far that written UNIDO draft projects have already been sent to UNDP Resident Representative in Mongolia and are only waiting the "official request" of Mongolian Government to finalize them.

Through separate mail, your Prime Minister, Mr. P. JASRAI has been informed about most of them and replied on August 28th 1992 through a personal letter to Mr. G. DUMONT that he is supporting these suggestions.

1/ DEVELOPMENT OF NATIONAL STANDARDS, WITH APPROPRIATE REFERENCE TO INTERNATIONAL ONES AND WITH APPLICATION OF EXCELLENCE IN SCIENCES AND TECHNOLOGIES

1A) Installation of a regulatory system for homologation of every pharmaceutical drug in Mongolia.

It is wise to impose a minimum control on every pharmaceutical drug, either imported or produced domestically, before to allow a product to be sold in Mongolia - in order to prevent the introduction of medicines with adverse, uncontrolled or illusory effects.

Such a system exist in quite all countries and it would be an efficient way to create a tripartite commission including some experts from a foreign country acting exactly in this field in their own country.

Evidently such a project would have to be installed step by step : the important point is to establish in a near future a minimum of regulatory measures well applied and later on to consider a more sophisticated system.

An example of a simplified homologation file - as utilized by French Ministry of Health for exported drugs - has been transmitted to Mongolian Ministry of Health by Mr. G. DUMONT, as the French Laboratory LEURQUIN submitted such a file for homologation in Mongolia of its Injectable Sterile Chymotrypsin.

1B) Central Laboratory for control of remedies

It is important for Mongolia to have a control laboratory - at the Ministry level - well equipped for controlling medicinal drugs in Mongolia.
As long as each producer is not able and equipped to do himself the control of safety and quality, with all guarantees of reliability, it seems a necessity to have these controls performed at the Ministry level (on samples picked by Ministry officers during the processing and also from time to time in the stocks of the pharmacy-shops which are delivering them).

The Central Laboratory for Control of Remedies, managed by Doctor ZORIG, is well-adapted for this duty, but equipment has to be totally refurbished and modernized.
A corresponding UNIDO draft project has been established and is waiting for Mongolian official request.

2/ INTRODUCTION OF PROGRAMS WHICH WOULD ASSIST BOTH THE PUBLIC AND THE PRIVATE SECTORS, INCLUDING FOR INSTANCE RESEARCH AND DEVELOPMENTS OF INDIGENOUS NATURAL PRODUCTS INCLUDING ALSO INTRODUCTION OF QUALITY CONTROLS SYSTEMS

2A) Quality control system for medicinal drugs

It has to be a normal rule for pharmaceutical producers to control their raw materials before processing and to verify on the final processed forms that active ingredient content and stability are correct :
it is recommended to Ministry of Health to consider the possibility to impose a minimum of these controls in a near future as it is undesirable to let non-pharmaceutical persons producing and selling medicinal drugs in Mongolia without any evidence of activity and quality.

In order to protect Mongolian people health it would be efficient for Ministry of Health **to ask UNIDO for a special project in order to build rapidly** (1 to 2 years time) **a system able to bring a sufficient level of safety as long as each producer is not able and equipped** :
this project would ask experience of some international experts in quality control and would lead to perform at least the quality control on finished forms through the Central Laboratory for control of remedies.

The project would include, through a possible study tour and exchange of specialists, the survey of the methods applied in some different countries.
The main objective (and also the main difficulty) for the experts involved in the project will be to limit their ambitions in the beginning stage - in order to initiate a limited control quickly, where there is none today - and to envisage more complete analysis only in a second stage or on episodic sampling at the production place.

2B) Modernization of the governmental pharmaceutical factory in Ulan Bator

In a country as Mongolia, with a limited number of inhabitants and with a limited currencies availability for importing drugs, a central production unit for essential medicinal drugs is wisely the economical way : this will avoid duplication of costly equipments and will allow to cover at cheapest cost the domestic needs of essential drugs through local production.

First step : Before to decide any major transformation, it is recommended to ask UNIDO for an evaluation mission of the existing factory and future needs and to appoint a tripartite experts commission able to precise the WHO essential drugs formulations which are particularly a need for Mongolia.

Second step : As UN Organizations have already built up, in 1986 - 1987, a fully modernized tabletting unit with large capacity, a new UNIDO small project would allow optimization of its use and introduction of new know-hows for enlarging the variety of the formulations to be produced in accordance with the priorities of domestic needs in WHO essential drugs.

Third step : A good view would be to consider the liquid formulations department renovation - in order to produce in Mongolia these products and to avoid to pay high cost for transportation of the liquid excipients from abroad : this would include - among others - antiseptic solutions, cough syrups and possibly shampoos.

Fourth step : Renovation of the sterile injectable forms department can also be considered as important, to insure domestically the production of emergency and essential drugs.

The auditing mission will have to consider, in this scope, the optimization of the use of the big ROTA-line automated vial-filling machine, offered previously by UN Organizations and presently located in RPAEM facilities at Ulan-Bator : such a valuable equipment has to be utilized full-time and the RPAEM programs and the Pancypsin RPAEM programs were far below the potential of the machine.

Government will have to impose a decision - as RPAEM is not related to the Ministry of Health - either for RPAEM filling antibiotics as a sub-contractor for Ministry of Health needs or for displacing the Rota-line from RPAEM to pharmaceutical factory where its capacity would be utilized and managed under control of pharmacists.

Fifth step : Setting up of a **multipurpose ointment production line**.

A project for such an equipment has been precised and evaluated by a former UNIDO mission, when RPAEM was intending to develop and produce a stable Pancypsin ointment : it would be more logical to set up the ointment production line inside the pharmaceutical factory, as this equipment would, by others, produce the Pancysin ointment needs of the country.

2C) Scientific cooperative study with Institute of Traditional Medicine (Dr. KHAIDAV)

2Ca/ Thermopsis as anti-tussive

Finally professors of PARIS Pharmacy University are not really interested to invest in further research work on thermopsis :
Reason is that a quite large bibliography has been collected, mainly from Russian origin and such a complementary research would not be a genuine work, except if you know that the Mongolian variety is different from the Russian one in its composition and activity.

2Cb/ Anti-immuno depressant drugs

This is a very promising sector, where large international companies are investing presently.

Dr. KHAIDAV sent us, early 1991, a preliminary note on the interest of Manchin (aconitum) :
the details summarized in the note were not sufficient for approaching possible partners and **we ask Your Excellence to let establish an up-to-date report on the recent works, with all details on the botanical variety utilized and on the exact conditions applied to each test**.

This subject is promising and as soon as we receive Dr. KHAIDAV report we will act for interesting one of the European leaders of this type of research with view to obtain a secrecy agreement and a cooperation with your Institute.

An alternative possibility would be to include this objective in a UNIDO project with view to establish a committee of scientists (foreigners and Mongols) in order to precise the framework of the further research program and to organize an international approach - through study-tours out of Mongolia and scientific lectures in Mongolia.

3/ ENVIRONMENTAL CONTROLS AND IMPACT ASSISTANCE

This point deserve further in-depth thought, as needs are increasing year after year :
certainly, in a near future, attention has to be paid - through **a small UNIDO project - to elimination of the hospital scraps** (with essential objective to avoid bacterial contamination).

4/ SCIENTIFIC AND TECHNOLOGICAL EVALUATIONS AND APPLICATIONS

4.1. Central Biodiagnostic Laboratory for the city of Ulan-Bator and as an excellence center

Mr. G. DUMONT ask His Excellence to look at the subject with special consideration, because he is convinced that it is a real necessity to dispose of modern methods and equipments for biomedical analysis **at one place at least in the city of Ulan-Bator - as it is a must for specialists and surgeons to have certain analysis done in order to precise their diagnostics or to limit the surgery risks**.

Use of modernized methods and semi-automated equipments located in a unique centralized laboratory will provide an enlarged capacity of tests per day in the existing building facilities : it will cover the various departments needs of the hospital, but also those of other medical centers in the city.

After visiting the Laboratory existing in the main hospital at Ulan-Bator, Mr. G. DUMONT, in his report of 1988 mission, recommended to UNDP and UNIDO to consider as important **to sustain a project for a bigger and modernized laboratory acting as a Central Laboratory for the city of Ulan-Bator**.

At the time, this project has not been considered as a priority : **it seems now due time to initiate this project with enlargement of the objectives to the use of this laboratory as an excellence center for the country** : this would provide the possibility to train in its facilities the biologists working in other Mongolian laboratories and to let them learn the new biological tests in a place where they are well applied routinely.

Mr. G. DUMONT - as a biochemist and as the former general manager of a reagents biodiagnostics company for years - is prepared to advise and to contribute to the evaluation of the needs and to propose a program for refurbishing the existing laboratory.

5/ DEVELOPMENT OF SCIENTIFIC AND TECHNOLOGICAL EDUCATION AND RESEARCH

This point will include study-tours and trainings under **UNIDO projects for improving the competence of the various pharmacists working in the pharmaceutical factory and of the biologists working at the Ulan-Bator main hospital central laboratory** - in order to provide them experience in the new technologies to be applied after refurbishing of their facilities.

*

Excellence, it would be my honour and my pleasure to know later on that this memorandum has been useful for improving the Health Sector in Mongolia, through new UNDP or UNIDO projects.

With this hope, I Remain, Your Excellence,

Sincerely yours,

G. DUMONT

APPENDIX I
LIST OF ESSENTIAL DRUGS, MONGOLIA (1991-1993)

15 June. 1992.

No	Drugs	Package	Requirement for a year	
			Packages	Total
	1	2	3	4
	1. Anaesthetics			
1.1.	General anaesthetics and oxygen			
	- Ether anaesthetic, inhal.	100 ml x 10 bt.	1 000	100 000 ml
	- Halothane, inhal.	250 ml x 10 bt.	2 000	5 000 000 ml
	- Ketamine, inj. 50 mg/ml	10 ml x 100 vials	50	50 000 ml
	- Nitrous oxide, inhal. 50 atm	10 cubic m x gas.cont.	800	8 000 cubic m
	- Oxygen, inhal. 50 atm	1 cubic m x gas.cont.	8 000	8 000 cubic m
	- Thiopental sodium, powder for inj.	0,5 g x 1000 amp.	5	2 500 g
1.2.	Local anaesthetics			
	- Lidocaine, inj. 2%	2 ml x 1000 amp.	10	20 000 ml
	- Ethylchloride, spray	30 ml x 10 vials	500	150 000 ml
	- Procaine, powder	1 kg/box	400	400 kg
1.3.	Preoperative medication			
	- Atropine, inj. 1 mg/ml	1 ml x 1000 amp.	75	75 000 ml
	- Chloral hydrate, powder	0,1 kg/box	100	10 kg
	- Diazepam, inj. 5 mg/ml	2 ml x 100 amp.	750	150 000 ml
	- Morphine, inj. 10 mg/ml	1 ml x 100 amp.	600	60 000 ml
	- Promethazine, inj. 5 mg/ml	1 ml x 100 amp.	350	35 000 ml
	2. Analgesics, Antipyretics Nonsteroidal Anti-inflammatory drugs			
2.1.	Non-opioids			
	- Acetylsalicylic acid, tab.	500 mg x 1000 tab.	15 000	15 000 000 tab.
	- Indometacin, cap. or tab.	25 mg x 1000 tab.	300	300 000 tab.
	- Paracetamol, tab.	500 mg x 1000 tab.	200	200 000 tab.
	- Noramydipyrin methylsulfonat., tab.	500 mg x 1000 tab.	15 000	15 000 000 tab.
2.2.	Opoid analgesics			
	- Morphine, inj. 10 mg/ml	+	+	+
	- Pentazocine, inj. 30 mg/ml	1 ml x 100 amp.	10	1 000 ml

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	3. Antiallergics and drugs used in Anaphylaxis			
	- Chlorphenamine, tab.	4 mg x 1000 tab.	10	10 000 tab.
	- Dexamethasone, inj. 4 mg/ml	1 ml x 100 amp.	10	1 000 ml
	- Diphenhydramine, inj. 1 mg/ml	1 ml x 100 amp.	2 700	270 000 ml
	- Epinephrine, inj. 1 mg/ml	1 ml x 1000 amp.	40	40 000 ml
	- Prednisolone, tab.	5 mg x 1000 tab.	3 000	3 000 000 tab.
	4. Antidotes and other substances used in Poisonings			
4.1.	General			
	- Charcoal activated, tab.	250 mg x 1000 tab.	500	500 000 tab.
4.2.	Specific			
	- Atropine, inj, 1 mg/ml	+	+	+
	- Methylene blue, inj. 10 mg/ml	1 ml x 100 amp.	10	1 000 ml
	5. Antiepileptics			
	- Carbamazepine, tab.	200 mg x 1000 tab.	350	350 000 tab.
	- Phenobarbital, tab.	100 mg x 1000 tab.	6	6 000 tab.
	6. Anti-infective drugs			
6.1.	Anthelminthic drugs			
	- Piperazine, tab.	500 mg x 1000 tab.	10	10 000 tab.
	- Mebendazole, tab.	100 mg x 1000 tab.	180	180 000 tab.
	- Niclosamide, tab.	500 mg x 1000 tab.	10	10 000 tab.
6.2.	Antibacterials			
6.2.1.	Penicillins			
	- Ampicillin, inj.	250 mg x 100 vials	700	17 500 000 mg
	- Ampicillin, tab.	250 mg x 1000 tab.	1 440	1 440 000 tab.
	- Benzylpenicillin, inj.	600 mg x 100 vials	28 000	1 680 000 000 mg
	- Cloxacillin, tab.	500 mg x 1000 tab.	10	10 000 tab.
6.2.2.	Other antibacterials			
	- Cefalexin, tab.	250 mg x 1000 tab.	100	100 000 tab.
	- Cephaloridine, inj.	500 000 IU x 100 vials	1 000	50 000 mill. IU
	- Chloramphenicol, tab.	250 mg x 1000 tab.	1 800	1 800 000 tab.
	- Erythromycin, tab.or cap.	250 mg x 1000 tab.	5 500	5 500 000 tab.
	- Gentamycin, inj. 40 mg/ml	1 ml x 100 amp.	2 200	220 000 ml
	- Metronidazole, tab.	500 mg x 1000 tab.	2 400	2 400 000 tab.
	- Metronidazole, tab.	250 mg x 1000 tab.	900	900 000 tab.
	- Nitrofurantoin, tab.	100 mg x 1000 tab.	10	10 000 tab.
	- Sulfadimidine, tab.	500 mg x 1000 tab.	600	600 000 tab.
	- Sulfamethazole + trimethoprin, tab.	400 mg+80 mg x 1000 tab.	1 000	1 000 000 tab.
6.2.3.	Antituberculoses drugs			
	- Ethambutol, tab.	400 mg x 1000 tab.	500	500 000 tab.

	1	2	3	4
	- Isoniazid, tab.	300 mg x 1000 tab.	10 000	10 000 000 tab.
	- Pyrazinamide, tab.	500 mg x 1000 tab.	50	50 000 tab.
	- Rifampicin cap.or tab.	300 mg x 1000 tab.	500	500 000 tab.
	- Streptomycin, inj.	500 000 IU x 100 vials	8 000	400 000 mill. IU
	- Streptomycin, inj.	1 000 000 IU x 100 vials	3 000	300 000 mill. IU
	- INH+thiocetazone,tab.	100 mg+300 mg x 1000 tab.	1	1 000 tab.
6.3.	Antifungal drugs			
	- Griseofulvin, cap.or tab.	500 mg x 1000 tab.	20	20 000 tab.
	- Nystatin, tab.	500 000 IU x 1000 tab.	200	200 000 tab.
6.4.	Antiprotozoal drugs			
6.4.1.	Antiamoebic and antigiardiasis drugs			
	- Metronidazole, tab. 500 mg	+	+	+
6.4.2.	Antimalarial drugs			
	a) For curative treatment;			
	- Chloroquine, tab.	150 mg x 100 tab.	10	1 000 tab.
	b) Prophylaxis;			
	- Chloroquine tab. 150 mg	+	+	+
	7. Antimigraine drugs			
7.1.	For treatment of acute attack			
	- Acetylsalicylic acid, tab.	+	+	+
	- Paracetamol, tab.	+	+	+
7.2.	Prophylaxic			
	- Propranolol, tab.	10 mg x 1000 tab.	80	80 000 tab.
	8. Antineoplastic and immunosuppressive drugs			
8.1.	Immunisuppressive drugs			
	- Azathioprine, tab.	50 mg x 1000 tab.	3	3 000 tab.
	- Azathioprine,unj. 100 mg/ml	1 ml x 100 amp	10	1 000 ml
8.2.	Cytotoxic drugs			
	- Bleomycin, powder for inj.	15 mg x 100 vial	10	15 000 mg
	- Cyclophosphamide, powder for inj.	500 mg x 100 vial	100	5 000 000 mg
	- Doxorubicin, powder for inj.	20 mg x 100 vial	10	20 000 mg
	- Fluorouracil, inj. 50 mg/ml	5 ml x 100 amp.	50	25 000 ml
	- Mercaptopurine, tab.	50 mg x 1000 tab.	18	18 000 tab.
	- Methotrexate, tab.	2,5 mg x 1000 tab.	1	1 000 tab.
	- Methotrexate, inj.	50 mg x 100 vials	30	150 000 mg
	- Vinblastine,powder for inj.	10 mg x 100 amp	10	10 000 mg
	- Vincristine,powder for inj.	5 mg x 100 vials	10	5 000 mg

1	2	3	4
8.3. Hormones and antihormones			
- Dexamethazone, tab.	4 mg x 1000 tab.	60	60 000 tab.
- Dexamethazone, inj. 4 mg/ml	1 ml x 100 amp	30	3 000 ml
- Ethinylestradiol, tab.	50 µg x 1000 tab.	1	1 000 tab.
- Prednisolone, tab. 5 mg	+	+	+
- Prednisolone, inj.20 mg/ml	1 ml x 100 amp.	1 500	150 000 ml
- Tamoxifen, tab.	10 mg x 1000 tab.	1	1 000 tab.
9. Antiparkinsonism drugs			
- Benzhexol, tab.	2 mg x 1000 tab.	100	100 000 tab.
- Levodopa+carbidopa, tab.	250 mg+25 mg x 1000 tab.	35	35 000 tab.
10. Blood, drugs affecting the			
10.1. Antianaemia drugs			
- Ferrous salt, tab.	60 mg x 1000 tab.	160	160 000 tab.
- Iron and folic acid, tab.	60 mg+250 µg x 1000 tab.	100	100 000 tab.
- Folic acid, tab.	1 mg x 1000 tab.	250	250 000 tab.
- Hydroxocobalamin, inj.1 mg/ml	1 ml x 100 amp.	17 000	1 700 000 ml
- Iron+dextran, inj. 50 mg/ml	2 ml x 100 vials	10	2 000 ml
10.2. Anticoagulants and antagonists			
- Heparin, inj.	2 500 IU x 100 amp.	160	40 000 000 IU
- Phytomenadione, inj.10 mg/ml	1 ml x 100 amp.	110	110 000 ml
- Protamine sulfate, inj.10 mg/ml	5 ml x 100 amp.	10	5 000 ml
- Warfarin, tab.	1 mg x 1000 tab.	1	1 000 tab.
11. Blood products and Plasma substitutes			
11.1. Plasma substitutes			
- Polygeline, inj, 3,5% sol.	500 ml/bt	20 000	20 000 000 ml
11.2. Plasma fractions for specific uses			
- Albumin human, inj. 5% sol.	0,5 l/bt	2 500	1 250 l
12. Cardiovascular drugs			
12.1. Antianginal drugs			
- Glyceryl trinitrate, tab.	500 µg x 1000 tab.	1 000	1 000 000 tab.
- Isosorbide dinitrate, tab.	10 mg x 1000 tab.	70	70 000 tab.
- Nifedipine, cap.or tab.	10 mg x 1000 tab.	10	10 000 tab.
- Propranalol, tab.40 mg	+	+	+
12.2. Antidysrhythmic drugs			
- Lidocaine, tab.	40 mg x 1000 tab.	1	1 000 tab.
- Lidocaine, inj. 20 mg/ml	5 ml x 100 amp.	10	5 000 ml
- Procainamide, tab.	250 mg x 1000 tab.	10	1 000 tab.
- Procainamide, inj.100 mg/ml	10 ml x 100 amp.	20	20 000 ml

	1	2	3	4
12.3.	Antihypertensive drugs			
	- Reserpine, tab.	250 µg x 1000 tab.	15 000	15 000 000 tab.
	- Hydrochlorothiazide, tab.	25 mg x 1000 tab.	900	900 000 tab.
	- Methyldopa, tab.	250 mg x 1000 tab.	500	500 000 tab.
	- Nifedipine, cap or tab, 10 mg	+	+	+
	- Propranolol, tab. 40 mg	+	+	+
12.4.	Cardiac glycosides			
	- Digoxin, tab.	250 µg x 1000 tab.	125	125 000 tab.
	- Digoxin, inj. 250 ug/ml	1 ml x 100 amp.	10	1 000 ml
	- Strophanthinum K, inj.0,05%	1 ml x 100 amp.	500	50 000 ml
	- Corglyconum, inj.0,06%	1 ml x 100 amp.	1 000	100 000 ml
12.5.	Drugs used in vascular shock			
	- Dopamine, inj.40 mg/ml	5 ml x 100 vials	10	5 000 ml
	- Isoprenaline, inj.2 mg/ml	2 ml x 100 amp.	10	2 000 ml
12.6.	Antithrombotic drugs			
	- Acetylsalicylic acid, tab 500 mg	+	+	+
	- Dipyridamole,inj.150 mg/ml	2 ml x 100 amp.	40	8 000 ml
	13. Dermatological drugs			
13.1.	Antifungal drugs			
	- Benzoic acid + salicylic acid, 6% + 3% oint or cream	10 g x 10 tubes	100	10 000 g
	- Miconozole (or cotrimazole), 2% oint or cream	10 g x 10 tubes	10	1 000 g
13.2.	Anti-infective drugs			
	- Methylrosanilinium chloride (Gentian violet) 1% sol	1 l	10	10 l
	- Neomycin,oint or cream 5 mg/g	10 g x 100 tubes	300	300 000 g
13.3.	Anti-inflammatory and anti-pruritic drugs			
	- Bethamethasone, 0,1% oint or cream	10 g x 100 tubes	20	20 000 g
	- Hydrocortisone, 1% oint or cream	10 g x 100 tubes	500	500 000 g
13.4.	Astringent drugs			
	- Potassium permanganate, powder	0,2 kg/box	2 000	200 kg
13.5.	Keratoplastic and keratolytic agents			
	- Salicylic acid, solution 5%	10 l/bt	10	100 l

	1	2	3	4
13.6.	Scabicides and pediculicides			
	- Benzyl benzoate, 25% lotion	1 l/bt	2 000	2 000 l
13.7.	Miscellaneous			
	- Lidocain. 5% gel	10 g x 100 tubes	10	10 000 g
	14. Diagnostic Agents			
14.1.	Radiocontrast media			
	- Barium sulfate, powder	100 g/box	25 000	2 500 000 g
	- Iopanoic acid, tab	500 mg x 1000 tab.	300	300 000 tab.
	- Propyliodone, susp. 500-600 mg/ml	20 ml x 100 amp.	10	20 000 ml
	15. Disinfectants and Antiseptics			
	- Chloramine	1 kg/box	60 000	60 000 kg
	- Hydrogen peroxide. sol 33%	10 kg/bottle	5 000	50 000 kg
	- Iodine, cryst.	10 kg/bottle	100	1 000 kg
	- Phenol, powder	10 kg/bottle	2 500	25 000 kg
	- Surgical spirit, sol	10 kg/bottle	1 500	15 000 kg
	16. Diuretics			
	- Furosemide, tab.	40 mg x 1000 tab.	1 000	1 000 000 tab.
	- Furosemide, inj, 10 mg/ml	2 ml x 100 amp.	1 000	200 000 ml
	- Hydrochlorothiazide, tab. 25 mg	+	+	+
	- Mannitol, inj. 10%	500 mg x 100 bt	65	3 250 000 ml
	- Spirinolactone, tab	25 mg x 1000 tab.	140	140 000 tab.
	17. Gastrointestinal drugs			
17.1.	Aluminium hydroxide, susp.	170 ml bottle	140 000	23 800 000 ml
	- Aluminium hydroxide, gel.	20 ml x 100 packs	500	1 000 000 ml
	- Cimetidine or ranitidine, tab.	200 mg x 1000 tab	20	20 000 tab
17.2.	Drugs for replacement of gastric and pancreatic juice			
	- Pancreatin, powder	50 kg/box	60	3 000 kg
	- Pepsin, powder	50 kg/box	60	3 000 kg
17.3.	Anti-emetic drugs			
	- Promethazine, tab.	25 mg x 1000 tab.	440	440 000 tab
	- Promethazine, inj. 25 mg/ml	+	+	+
17.4.	Anti-haemorrhoidal drugs			
	- Local anaesthetic, astringent and anti-inflammatory drugs oint	10 g x 100 tubes	10	10 000 g

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17.5.	Antispasmodic drugs			
	- Atropine, 1 mg/ml	+	+	+
	- Drotaverinum, tab.	40 mg x 1000 tab.	3 000	3 000 000 tab.
17.6.	Cathartic drugs			
	- Magnesium sulfate, powder	35 kg	20	700 kg
	- Phenolphtaleinum, tab	100 mg x 1000 tab.	840	840 000 tab.
17.7.	Drug used in diarrhoea			
	- ORS - for glucose electrolyte solution	100 g x 10 packs	46 300	46 300 000 g
17.8.	Drugs for improvement of liver and bile function			
	- Silimarin, tab.	35 mg x 1000 tab.	80	80 000 tab.
	- Dihydrochiolic acid, tab.	200 mg x 100 tab.	200	20 000 tab.
18.	Hormones and, other Endocrine Drugs and Contraceptives			
18.1.	Adrenal hormones and synthetic substitutes			
	- Dexamethasone tab.4 mg	+	+	+
	- Hydrocortizone acetate, inj. 100 mg/ml	1 ml x 100 amp.	100	10 000 ml
	- Prednisolone, tab. 5 mg	+	+	+
18.2.	Androgens			
	- Methyltestosterone, tab.	200 mg x 1000 tab.	60	60 000 tab.
18.3.	Contraceptives			
18.3.1.	Hormonal contraceptives			
	- Ethinylestradiol + Levonorgestrel, tab.	30ug+150ug x 21 tab.	120 000	2 520 000 tab.
18.3.2.	Intrauterine devices			
	- Copper-containing device	100 pieces/box	200	20 000 pieces
18.3.3.	Barrier methods			
	- Condoms	10 pieces/box	150 000	1 500 000 pieces
18.3.4.	Estrogens			
	- Ethi-Hilestradiol, tab.	50 mg x 1000 tab.	5	5 000 tab.

1	2	3	4
18.5. Insulins and other anti-diabetic agents			
- Insulin, inj. 40 IU/ml	5 ml x 100 vials	10	5 000 ml
- Insulin-intermediate 80 IU/ml	5 ml x 100 vials	20	10 000 ml
- Tolbutamide, tab.	500 mg x 1000 tab.	300	300 000 tab.
18.6. Progestogens			
- Progestron, inj.10 mg/ml	1 ml x 100 amp.	520	52 000 ml
18.7. Thyroid hormones and antothyroid drugs			
- Levothyroxine, tab.	100 µg x 100 tab.	10	1 000 tab.
- Potassium iodode, tab.	60 mg x 1000 tab.	5	5 000 tab.
- Propylthiouracil, tab.	50 mg x 1000 tab.	15	15 000 tab.
19. Immunologicals			
19.1. Diagnostic agents			
- Tuberculin, inj.	3 doses x 10 amp.	30 000	900 000 doses
19.2. Vaccines			
- BCG vaccine, inj.	10 doses x 10 amp	6 800	680 000 doses
- Brucellosis vaccine, inj.	6 doses x 5 amp.	700	21 000 doses
- Diphtheria-pertussis-tetanus vaccine, inj.	20 doses/vial	20 000	400 000 doses
- Diphtheria-tetanus vaccine, inj.	20 doses/vial	6 000	120 000 doses
- Hepatitis B vaccine,inj.	2 doses/vial	117 000	234 000 doses
- Measles vaccine, inj.	10 doses/vial	20 000	200 000 doses
- Meningococcal vaccine, inj.	5 doses/vial	1 000	5 000 doses
- Poliomyelitis vaccine,oral	20 doses/vial	28 500	570 000 doses
- Typhoid vaccine, inj.	20 doses/vial	1 925	38 500 doses
20. Muscle relaxants			
- Gallamine, inj. 40 mg/ml	2 ml x 100 amp.	50	10 000 ml
- Pipecuroni bromide, inj. 500 mg/ml	2 ml x 100 amp.	100	20 000 ml
- Neostigmine, inj. 2,5 mg/ml	1 ml x 100 amp	800	80 000 ml
- Suxamethonium, inj. 90 mg/ml	1 ml x 100 vial	450	45 000 ml
21. Ophthalmological Preparation			
21.1. Antiinfective agents			
- Gentamycin,0,5% eye drops	10 ml x 10 vials	100	10 000 ml
- Idoxuridine,0,1%, eye drops	10 ml x 10 vials	100	10 000 ml
- Silver nitrate,1%, eye oint	10 / tube	1 000	10 000 g
- Tetracycline, 1%, eye oint	5 / tube	1 000	5 000 g

	1	2	3	4
21.2.	Local anaesthetic			
	- Tetracaine, powder	0,1 kg/box	30	3 kg
21.3.	Miotics and anti-glaucoma drugs			
	- Acetazolamide, tab.	250 mg x 1000 tab.	150	150 000 tab.
	- Pilocarpine, powder	1 kg/box	4	4 kg
	- Timolol, 0,25% solution	1 ml x 100 vials	10	10 000 ml
21.4.	Mydriatics			
	- Atropine,0,1% drops	+	+	+
	- Epinephrine,2% drops	+	+	+
	- Homatropine,powder	0,1 kg/box	50	5 kg
	22. Oxytocics and Antioxytocics			
22.1.	Oxytocics			
	- Methylergometrine, inj. 0,2 mg/ml	2 ml x 100 amp.	1 000	200 000 ml
	- Oxytocin, inj. 5IU/ml	1 ml x 100 amp.	800	80 000 ml
	- Salbutamol, tab.	4 mg x 1 000 tab.	20	200 000 tab.
	23. Peritoneal dialysis solution			
	- Intraperitonial dialysis solution, powder	1 kg/box	5	5 kg
	24. Psychotherapeutic drugs			
	- Amitriphyline, tab.	25 mg x 1000 tab.	315	315 000 tab.
	- Chlorpromazine, tab.	25 mg x 1000 tab.	600	600 000 tab.
	- Chlorpromazine, inj.25 mg/ml	1 ml x 100 amp.	2 500	250 000 ml
	- Diazepam. tab.	5 mg x 1000 tab.	1 750	1 750 000 tab.
	- Diazepam inj. 5 mg/ml	+	+	+
	- Haloperidol, tab.	2 mg x 1000 tab.	100	100 000 tab.
	- Haloperidol, inj. 5 mg/ml	1 ml x 100 amp.	250	25 000 ml
	- Lithium carbonats, tab.	300 mg x 1000 tab.	20	20 000 tab.
	25. Respiratory Tract, drugs acting on the			
25.1.	Antiasthmatic drugs			
	- Aminophylline, inj 25 mg/ml	10 ml x 100 amp	3 000	3 000 000 ml
	- Beclometasone, inhal, 50 mg/dose	200 doses x 100 vials	50	1 000 000 doses
	- Epinephrine, inj 1 mg/ml	+	+	+
	- Salbutamol, tab 4 mg	+	+	+
	- Salbutamol, inhal, 100 mg/dose	100 doses x 100 vials	25	250 000 doses

	1	2	3	4
25.2.	Antitussives			
	- Codeine, tab.	10 mg x 1000 tab.	120	120 000 tab.
	26. Solution correcting water, Electrolyte and acid base balance			
26.1.	For oral rehydration			
	- ORS	+	+	+
	- Potassium chloride, powder	0,1 kg/box	4 000	400 kg
26.2.	Parenteral			
	- Glucose, powder	50 kg	10 000	50 000 kg
	- Glucose, inj.40%	20 ml x 100 amp	25 000	50 000 000 ml
	- Glucose + sodium chloride 5% + 4,5%	500 ml bt	50 000	25 000 000 ml
	- Potassium chloride, inj.sol.	+	+	+
	- Sodium chloride, 0,9%	500 ml bt	50 000	25 000 000 ml
	- Sodium bicarbonate, powder	0,1 kg/box	550 000	55 000 kg
	- Water for injection			
	27. Vitamins and Minerals			
	- Ascorbic acid, tab.	50 mg x 1 000 tab.	24 000	24 000 000 tab.
	- Ergocalciferol, 50000 IU/drog.	1 kg/box	15 000	15 000 kg
	- Ergocalciferol, 200000 IU/ spirit.sol.	20 ml/ bt	10 000	200 000 ml
	- Pyridoxine, tab.	25 mg x 1 000 tab	200	200 000 tab.
	- Retinol, 200000 IU/cap	50 kg/box	6	300 kg
	- Vitamin A + D cap.	100 cap. x 100 vials	1 000	10 000 000 cap.
	- Sodium fluoride, tab.	500 mg x 1000 tab.	100	100 000 tab.
	- Thiamine, powder	5 kg/box	2	100 kg
	- Calcium gluconate, inj. 100 mg/ml	10 ml x 100 amp.	5 800	5 800 000 ml
	- Vit B compound, tab.	1 000 tab./bottle	10	10 000 tab.
	- Multivitamin, tab. or drug.	1 000 tab./bottle	3 000	3 000 000 tab.

APPENDIX II
OUTLINE OF A PROJECT "NATIONAL DRUG POLICY AND ESSENTIAL DRUG PROGRAMME"

PROJECT TITLE: NATIONAL DRUG POLICY AND ESSENTIAL DRUGS PROGRAMME

DURATION: FOUR YEARS - 1992-1995

EXECUTING AGENCY: MINISTRY OF HEALTH

GOVERNMENT INPUTS: 8,088,160 MNT

DONORS' INPUTS:

without drugs: 1,378,000 US$
with drugs : 11,878,000 US$

The changes in the political and economic situation that have overtaken the country have resulted in the drying up of the traditional sources of drug supply, with the attendant need to obtain the badly-needed drugs from hard currency areas, formulating an Essential List of Drugs and a National Drug Policy and training of physicians in the rational use of drugs.

Immediate assistance is needed for importing $ 10.5 mln worth of drugs for the three year period ending 1994. In the medium-term, technical and financial support is needed for a variety of other subsidiary objectives such as formulation of a National Drug Policy, drawing up of an Essential Drug List, registration, setting up a mechanism for selection, procurement, storage and distribution of drugs, training in the methodology for quantification of drugs based on standard treatment, the rational use of drugs, standardization of traditional medicines procured in the country and quality assurance of imported drugs, upgrading the existing pharmaceutical factory by reequipping the sections for ampouling, production of solutions, tableting and capsuling and preparation of dressing materials. In the long-term perspective, assistance will also be needed for local manufacture of drugs and biological product preparations in order to make the country self-sufficient. Proper utilization of the existing natural resources will be also a priority area to reduce drug consumption.

INTRODUCTION

Due to change in political and economic system in 1990, the country is facing acute shortage of essential drugs as now they are forced to buy drugs with hard currency. Until 1990, Mongolia was heavily dependent on USSR for supply of drugs, medical equipment and vaccines. The physicians and pharmacists are used to a large number of drugs mostly under brand names coming from USSR and other East European countries. Many of these drugs purchased (from out of a list of 730 drugs) are irrational and non essential.

The country has now adopted an Essential Drug List of 220 drugs some are not included in the WHO Essential Drugs list. MONGOLEMIMPEX, the sole Government agency for import and distribution of drugs, has been directed by an order of the Ministry of Health, to purchase these drugs on priority. This will result in the procurement of many drugs, the names of which are hitherto not known to the prescribers and pharmacists. It will therefore be necessary to provide adequate information and training to the Health personnel in the proper use of these drugs. During the past one year, the country's currency(tughriks) has undergone repeated devaluation and the rate has changed from 5.6 tughriks per dollar to 7.14 tughriks in early 1991 to 40 tughriks per dollar in July 1991. This has resulted in the decrease of availability of hard currency equivalent to the budget allocation in local currency to purchase drugs from other countries.

1. EXECUTIVE SUMMARY AND RECOMMENDATIONS

The programme shall be titled the Mongolian National Drug Policy and Essential Drugs Programme, the overall objectives of which shall be to implement a National Drug Policy to provide essential drugs of proven safety, efficacy and quality, at affordable cost to the whole country, and the knowledge and training required for rational use of drugs. It will be a WHO/Ministry of Health collaborative programme for which funding will be sought. It will be for an initial period of 3 years starting from 1992. Preparatory activities could be initiated in 1991 provided funds will be available.

1.1 Policy and Management

The Government has not yet finalized its National Drug Policy. In June 1991, a Drugs and Biopreparations Council consisting of 30 members was formally constituted by a decree of the Minister of Health. The Council, amongst its other functions, is also required to elaborate the nation's Drug Policy. Selection of essential drugs is however, not mentioned among the functions. Neither are criteria for selection of essential drugs officially laid down anywhere. Even in the government's Activity Guidelines adopted by the MPR's State Little Hural 1991, there is no special mention of the commitment of the Government to provide essential drugs to the population.

The country does not have a separate legislation to regulate the import, manufacture, sale and distribution of drugs. At present, limited control is

exercised under the existing health law which has 3 sections and 9 elements on drug regulation.

Recommendations

(1) The Drug Council should prepare a draft Drug Policy document to be discussed and finalized in a National Drug Policy Meeting attended by representatives(physicians,pharmacists,administrators etc.) of Departments involved in the Drug Supply System. the proposed time for this meeting is March 1992.

(2) For selection and review of essential drugs, a Committee of experts should be formed as a sub group of the Drug council. This Committee will be responsible to lay down criteria for selection of the essential drugs and for regular review of the list.

(3) The essential drug list should be translated into Mongolian and should be distributed to all health workers with a foreward by the Minister of Health, on essential drug concept and rational use of drugs, by January 1992.

(4) A working group on the operational level consisting of about six persons with representatives from the Ministry of Health(Pharmacist,Physician), MONGOLEMIMPEX, Medical College, Medical University, Central Laboratory for Drug Control and Biopreparations should be formed to coordinate and monitor activities concerned with quantification of needs, procurement, supply and quality, rational use and training. This working group should meet every two weeks.

(5) A separate drug legislation to regulate the import, manufacture, sale and distribution of drugs should be drafted by the end of 1992. The definition of "drug" should be included in the Act. All other basic elements of a Drug Legislation should also be included.

(6) It is recommended that imports of essential drugs should be exempted from levy of customs duty.

1.2 Supply and Logistics

The procurement and supply of drugs is made by MONGOLEMIMPEX, a pharmaceutical company under the Ministry of Health, solely responsible for import, storage and distribution. The procurement of drugs is based on the requirement received from doctors in hospitals and pharmacy shops of various aimaks(provinces) and somons(districts). The supply is made every month to 18 aimaks and 3 cities which have their own storage warehouses and administration. Each aimak further supplies drugs to somons, each of which has a pharmacy shop. The procurement by Mongolemimpex depends on the availability of funds in hard currency. no systematic procedures exist at present to check the quality of imported drugs. The number and quantity of drugs purchased depends on the demand indicated by the doctors and their familiarity with these drugs under Russian system and not on quantification procedure based on needs, morbidity and standard treatment schedules.

Recommendations

(1) The methodology for quantification based on morbidity data, drug usage and standard treatments should be introduced. Training in this methodology should be provided to the health workers at different levels of care.

(2) Procurement methods should be revamped and new standard operating procedures introduced. For this purpose external expertise and advice will be needed.

(3) WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce should be requested for all imports.

(4) For drugs donated and received from external sources, data on usage and indications should be collected and analyzed to monitor rational drug therapy.

(5) For drugs currently used in medical practice, a cross index on generic and trade names should be prepared and presented under the same therapeutic class as the Mongolian essential drug list. This index should also be presented alphabetically.

(6) Drugs in the entire Mongolian pharmaceutical supply system should be stored either alphabetically or under the above-mentioned therapeutic classification.

1.3 Rational Use

The physicians, pharmacists and other health personnel do not have ready access to modern literature on drugs and therapeutics because of the language barrier. Massive training and education in Mongolian language would be necessary to familiarize the prescribers and pharmacists with the generic names of drugs now proposed to be procured under the Essential Drug List. Physicians will also need to be made aware of the concept of essential drugs, rational prescribing and standard treatment schedules especially for the high Mongolian morbidity and mortality diseases such as Acute Respiratory Infections, Children's Diarrhoeal Diseases and Urinary Tract Infections etc.

Recommendations

(1) The drug information sheets received from WHO and other sources for commonly used drugs should be translated into Mongolian, printed and distributed to all health workers as a priority. This process should be completed in phases as a part of a Mongolian National Drug Formulary cum Therapeutic Guidelines.

(2) The Concept of Essential Drugs and rational therapeutics with emphasis on generic names should be urgently introduced into curricula of the Medical University and the Medical College.

(3) Standard treatment schedules for commonly occurring diseases must be prepared and introduced through workshops and seminars and their application monitored.

(4) Workshops, seminars and other training activities on rational drug therapy shouldbe carried out for different levels of health personnel and material to be used for this purpose should be prepared in Mongolian language.

(5) University teachers teaching pharmacology and therapeutics should be exposed to current concepts of clinical pharmacology and therapeutics by way of fellowships and study tours to other countries. Experts from abroad should also be invited to give lectures on these topics.

(6) Prescription auditing in selected institutions should be introduced and analyzed with a view to improve prescribing and cost effectiveness and Hospital Therapeutic Committees introduced at least in major hospitals.

1.4 Regulatory Control and Quality Assurance

As stated earlier, a Drugs and Biopreparations Council constituted in June 1991 has been entrusted the responsibility of regulatory control, and quality assurance but the procedures, functions and status of various functionaries have not been laid down.

About 10-20% of the drugs required in the country are manufactured at the Medical Factory of the Ministry of Health, and the production depends on the availability of raw materials. The facilities in the factory need to be augmented with modern equipment and the premises revamped under the concept of Good Manufacturing Practices(GMP) in order to manufacture about 25-30 mostly used items, from which the raw materials should be made available.

The country also uses drugs of traditional system. The use of these drugs has gained special importance since the last 2 years as the modern drugs are becoming less available. An institution of traditional medicine has started functioning since 1990 and about 40 drugs derived from plant sources which are mostly imported from India and China are manufactured for use in pharmacies and hospitals. These drugs however need to be standardized and their quality tested and controlled.

Recommendations

(1) Following the proposed Drug Legislation mentioned under 1.1., rules, regulations and procedures for registration need to be more clearly laid down

(2) A full time Drug Controller with appropriate qualifications should be appointed as Licensing Authority for manufacture and sale of drugs, supported by inspectors and other supervisory personnel. The procedures for inspection, licensing and sampling need to be laid down.

(3) The duties, powers and responsibilities of the licensing authority, Inspectors, Quality Control Laboratory and the institutions authorized to import drugs, should be defined.

(4) The Quality Control Laboratory needs to be equipped with modern instruments of analysis and the staff trained for this purpose in a laboratory identified by WHO for the purpose of testing and controlling the quality of drugs imported and produced in the country.

(5) Traditional medicines need to be standardized and procedures to regulate the quality should be specified.

2.1. Structure and Health Economics of the National Health Services

The comprehensive health system of Mongolia has an efficient administrative system and a well established infrastucture. There is no shortage of health units or manpower and hospitals and pharmacies are present in every aimak, somon and sometimes intersomon health units.

The number of health facilities are:

Specialist Hospitals	20
Aimak Hospitals	36
Somon Hospitals	294
Intersomon hospitals	32
Physician Post4	35
Feldsher Points	1.381
Pharmacies	483
Dispensaries	254

Number of Health Personnel:

Physicians	5.875
Pharmacists	452
Pharmacy Assistants	1.288
Nurses	11.296
Feldshers	4.217

The number of trained health personnel and hospital bed per 10.000 population is therefore higher than most countries.

Health Economics

The total Government budget for 1991 is 6,700 million tughriks.

The health budget is 11% of the total government budget, and is about 737 million tughriks.

Allotment for drugs is about 109 million tughriks.

The Gross National Product(GNP) per capita for 1990 is US$ 840.

2.2 Epidemiological Indicators

It has been reported that the health situation in Mongolia has improved within the last few years but many problems and disease conditions still exist. A survey questionnaire revealed that the leading causes of morbidity are:

- Acute Respiratory Infections
- Gastrointestinal diseases
- Neurological diseases
- Diseases of Urinary System
- Pregnancy and child birth
- Heart diseases
- Infectious diseases: TB and Meningococcal infection
- Cancer

The leading causes of mortality as shown by the survey are:

- Acute Respiratory Infections
- Gastrointestinal diseases
- Heart disease: Ischemic Heart Disease and hypertension
- Perinatal infections
- Trauma/Accidents
- Infectious diseases - TB and Meningococcal Infections

Regarding infants and children, acute respiratory infection, diarrhoea diseases, and diseases due to malnutrition were the main causes of morbidity and mortality. Short birth spacing also contributes to the high infant mortality rates.

Hepatitis B prevalence is about 14.000 cases per year, the large incidence of home injections greatly contributing to the number.

The survey also reports that the health coverage in Mongolia is 90% although the coverage of the country by essential drugs has been drastically reduced.

3. SPECIFIC BACKGROUND TO THE PROJECT

The Ministry of Health, Mongolia has requested assistance of WHO for supply of drugs. A list of about 15 items to be supplied urgently, was received. The essential drug list consisting of 220 drugs has been recently adopted by the Government. The Mission reviewed the essential drugs list and observed that some drugs included therein are not included in the WHO essential drugs list.

3.1. Pharmaceutical profile of the country

The country was using about 1,000 drugs mostly imported from USSR and other East European countries. The doctors were used to Russian system and the drugs

which were mostly in brand names. About 90% of the drugs required were imported and only 10% were manufactures in the single, government run factory. the recent political changes have forced the country to import drugs from countries which require hard currency. They do not have the expertise with global market knowledge to purchase drugs under generic names by tender system at the competitive prices. The doctors will have to be made aware of the generic names of drugs, so purchased, and the information on their use etc. will have to be given in the local language.

3.2. Policy and Management

3.2.1. National Drug Policy

Health is a fundamental human right and it is the responsibility of every government to develop a national drug policy for the country which would ensure abundant availability of safe and effective drugs and good quality to those who need them. The Government of Mongolia has not yet formulated its National Drug Policy although some efforts have been made in this direction. A Drugs and Biopreparations Council has been constituted to carry out amongst others the function of formulating the National Drug Policy. It is recommended that the council should prepare a draft Drug Policy document which should be discussed in meeting to be attended by representatives of all departments and institutions involved in the Drug Supply System in the country. Physicians, Pharmacists, administrators and other health personnel should also participate in the discussions before the Policy document is formally adopted by the Government.

3.2.2. Legislation

There is no separate drug legislation to regulate the import, manufacture, sale and distribution of drugs. The Drugs and Biopreparations Council constituted by the Government in June 1991, has been entrusted the responsibility of issuing licenses for manufacture of drugs and vaccines, introduction of new drugs, removal of less effective and substandard drugs, permitting pre- clinical and clinical testing of drugs, registration and review of standards.

However, the procedure of issuing licenses, the duties and powers of licensing authority, the procedure of inspection and sampling by inspectors, the authority to take action in case of non conformance, the penalties to be applied, the authority for regulation of labelling, information and advertising, the rule-making powers, mechanism of appeals and exemptions to be given, have not yet been laid down.

It is recommended that a separate legislation should be drafted and enacted by the Government which would include a definition of "drug" and all the above mentioned procedures, duties and responsibilities of the functionaries.

3.2.3. Selection of Drugs

It is estimated that about 1,000 drugs have been in use in the medical practice in the country. Physicians are mostly used to Soviet medical system and the drugs so far used were coming from the Soviet and east European markets under brand names. Many of these drugs can be considered irrational and non essential. A list of 220 essential drugs some of which are not included in WHO essential drug list, has now been accepted by the Government. The prescribers and users will need education and training to get acquainted with the generic names under the essential drugs list and their proper use.

3.2.4. Traditional medicines

With the less availability of allopathic drugs in the country, there has been increasing emphasis on the use of traditional medicines since 1990. The system has the support of the Government and interest of the people. An institute for manufacture of traditional medicines from herbs, in the form of powders, tablets and aqueous/alcoholic extracts, has been set up under the Ministry of Health. It would however be necessary to evaluate the safety and efficacy of these drugs and also to standardize the preparations in order to exercise control on their quality. Most of the herbs used in the manufacture of traditional medicines are imported from India and China and only a few are grown locally.

3.3. Supply and Logistics

3.3.1. Estimating Drug Requirements

The quantities of drugs required at present is based on the demand sent by doctors and pharmacies from aimaks and somons, mostly based on the past consumption. These figures of drug use can be unreliable since quantities of some may be too large due to overprescribing or too small due to shortages in the past. It would be necessary to adopt the morbidity standard treatment methodology for quantifying drug requirements. This would require information on total number of treatment episodes of each health problem, data on morbidity and adoption of standard treatment schedules for the common health problems.

3.3.2. Procurement

About 90% of the drugs are imported and the balance 10% are manufactured in the country. The Medical Factory under the Ministry of Health, established in 1931, is the only factory to manufacture drugs. About 21 drug items in tablet form and 2 injectables were manufactured in 1991 and a few items were repacked. It was observed that the drugs manufactured include combination tablets of Calcium chloride and Hexamethylene tetramine, and tablets of Aspirin, Phenacetin and Caffeine(APC). These combinations are irrational and are not included in WHO essential drug list.

There should be proper coordination between what should be manufactured in the country and what should be imported. Policy makers should realize that it takes about one year to affect procurement of drugs. Procurement methods need to be revamped. A cross index of generic and trade names of the currently used

drugs requires to be prepared under the same therapeutic class as the Mongolian essential drug list. At present very few imported drugs are tested. The quality of imported drugs need to be tested in a manner that would bring about a better assurance of quality.

The factory needs to augment its manufacturing and testing facilities by providing modern equipment. The premises need revamping and the staff needs to be trained in the concept of good manufacturing practices. The factory should identify about 25-30 priority drugs which are required in large quantities and the active ingredients for these should be made available for production of dosage forms. The capacity of the factory can be slowly increased in phases to manufacture more number of drugs in the country.

3.3.3. Distribution and Storage

The storage facilities at Mongolemimpex and the warehouse at aimaks appear to be satisfactory. The country has a vast area and several somons and aimaks are located far away from Ulaanbaatar, with the result that it becomes difficult to send drugs at each place very frequently. The drugs are transported mostly by lorries and in emergency situations, by air planes.

3.3.4. Health Economics

The Ministry of Trade and Prevention had allocated a sum of 12 million dollars for purchase of drugs and medical supplies during 1991. Mongolemimpex had finalized contracts worth 9 million dollars for purchase of drugs and medical supplies but due to shortage of foreign exchange only 1.5 million dollars have so far been credited by the Government in the National Bank for purchase of drugs and medical supplies. The Ministry of Health thus needs urgent help for financing its drug supply. At present they do not have adequate system of quantifying their needs based on scientific methodology. Nevertheless, as a rough estimate it is felt that about 7-8 million dollars per year would be needed to meet the essential requirement of drugs until a realistic budget is made on the basis of standard treatment schedules and morbidity data. It was learnt that the Government has levied 25% customs duty on imported items. It is recommended that the customs duty should not be charged on the import of essential drugs.

3.4. Rational Use

Rational use of drugs means using the drugs only when necessary and in the right amount. Overprescribing, excessive self- medication when there is no need for drugs, leads to higher consumption of drugs. The physicians and pharmacists in Mongolia are not aware of the concept of essential drugs as they have been using a large number of Russian drugs under brand names. It would be necessary to introduce the concept of rational therapy with emphasis on generic names into the curricula of medical colleges/university. Information in Mongolia language on the commonly occurring diseases and the drugs (in generic names) required for their treatment would enable the prescribers to get acquainted with the short list of 220 essential drugs. So far, they have been using about 1.000 drugs in medical practice and it would

not be easy to adjust immediately to lesser number unless adequate information and proper training is given to them.

The programme of rational therapy on two programmes namely ARI and CDD is already under way. Training of doctors in the standard treatment of these diseases is being organized by way of seminars and workshops and the material for training has been translated into Mongolian.

It would be necessary to provide information on the usage of essential drugs in Mongolian. There is a need to prepare a National Formulary or Hospital Therapeutic Guides in Mongolian and distribute to all doctors and pharmacists. The material for educa tion and training, standard treatment schedules and information on drugs to public need to be prepared in Mongolian on priority, so that the time taken to change the prescribing habits of doctors to use lesser number of drugs, is not too long. It would be useful to undertake prescription audit at a few selected institutions with a view to improve prescribing and cost effectiveness.

3.5. Regulatory Control and Quality Assurance

Drug legislation and regulation are essential to ensure safety,efficacy and quality of drugs available to the public. The Mongolian Republic does not have a separate drug legislation at present. The control is exercised under Health Law which contains a limited provision for drug regulation. The Minister of Health has issued an order No.A/186 of 1990, dated 29th December 1990 under which a Drugs and Biopreparations Council has been constituted to carry out registration and other regulatory functions.

3.5.1. Registration

Annexure III of the above mentioned order of the Minister of Health, deals with the State Registration rules of Drugs and Biopreparations. It states that the State Registry of Drugs and Biopreparations is the authorization by the Ministry of Health on the basis of conclusions of the authorized organization of the National Health services. It further says that introduction into or removal from the medical practice of any drug or biopreparation for the prevention and treatment of disease is issued by an order of the Minister of Health based on the conclusions of the Drug and Biopreparations Council. According to this order, the production and use of drugs and biopreparations not registered in the State Registry are prohibited. Certain criteria have been laid down for registration. The drugs and biopreparations which can be registered and those which do not require registration have been mentioned. The applicants wishing to register their products have to furnish the required data to the Ministry of Health. The Central Laboratory for Control of Drugs and Biopreparations has to issue a conclusion to the Drugs and Biopreparations Council on the basis of materials received by the Ministry from the applicant. The order further specifies that the Central Laboratory is responsible for registration, control of standards and technical requirements.

From the above it is seen that although some rules have been made for registration of drugs, the procedure does not appear to be very specific. The

rules of the Central Laboratory and the council for Registration of drugs are not clearly described.

3.5.2. Licensing and Inspection

There is an urgent need to draft a drug legislation, giving the definition of "drug" and various functionaries such as Licensing Authority, Inspector and head of Quality Control Laboratory. the powers, duties and responsibilities of these authorities need to be clearly defined in the legislation. In order to ensure the quality of imported drugs, it would be necessary to define the role and functions of Mongolemimpex and the procedure to take imported consignments at the time of import.

Legislation must specify the authority empowered to make rules, regulations and guidelines, to enforce the provisions and also the penalties to be applied in case of non conformance to any provision. It must also specify the regulation of labeling, information and advertising, mechanisms of appeals against decisions and exemptions etc. Legislation must also specify the procedures for standardization and controlling the quality of traditional medicines manufactured in the country.

3.5.3. Quality Control Laboratory and Training

The Central Laboratory for Control of Drugs and Biopreparations is under the direct supervision of the Ministry of Health, and Dr.T.Zorig is the head of the institution. the laboratory was established in 1989 and performs the following functions:

(a) to analyze the samples of imported raw materials and finished formulations, sent by Mongolemimpex.(Very few samples are tested).

(b) to analyze the drugs manufactured in the country. Samples are taken randomly and occasionally by two inspectors of the laboratory.

(c) to analyze the drugs taken from Pharmacy shops. These samples are taken by inspectors selectively and rarely.

(d) to analyze samples (taken selectively by inspectors) of herbal preparation manufactured in the Institute of Traditional Medicine.

(e) to examine and analyse drugs for the purpose of registration and submit conclusions to the Drugs and Biopreparations Council.

The laboratory has a staff of 29, out of which 22 are trained analysts. It has three departments namely, Chemical, Biological and Pharmacopoeial Standards. The laboratory analyses about 1,400 drug samples per year. Random sampling of drugs manufactured in the country and from pharmacy shops in aimaks and somons is done by two inspectors working in the laboratory. Some selected samples of imported raw materials/finished fo rmulations are also sent for testing by Mongolemimpex. It was informed that about 5% of the tested samples are found substandard. These are mostly from aimak and somon pharmacies.

The laboratory needs modern equipment and the staff needs to be trained in Instrumental and Microbiological analysis. Dr.Zorig has the knowledge and expertise and with augmentation of equipment and training of analysts, the capacity of the laboratory to analyse various categories of drugs and biopreparations can be enhanced and it can function as an effective quality control laboratory and an important wing of the Regulatory Authority.

4. COORDINATION AND COLLABORATION WITH OTHER PROGRAMMES

The recent economic and political changes in the country have created acute shortage of drugs due to constraints in the availability of hard currency. the government has now adopted an essential drug list of 220 drugs and has directed Mongolesimpex to make these drugs available on priority. This means that unlike in the past when about 1,000 drugs were being used in the medical practice on priority, only 220 essential drugs will be procured and supplied. This would involve education and training of all health personnel in the rational use of lesser number of drugs available in generic names. For this purpose there is a need for close cooperation and coordination of all authorities concerned with the selection, procurement and supply of drugs and those responsible for dissemination of information on rational therapy, standard treatment and morbidity data. Coordination is also necessary with the teachers of medical institutions to ensure introduction of rational therapeutics and concept of essential drugs in the curricula for teaching. It is recommended that a working group consisting of representatives from the Ministry of Health, Mongolesimpex, medical colleges and the Quality Control Laboratory should be formed to coordinate and monitor activities concerned with quantification, procurement, supply and quality control, rational use and training.

It was informed that Programmes on ARI and CDD are already under way with the support of WHO and UNICEF. These programme officers should collaborate with the working group and other authorities to see that there is no duplication of the efforts and that the standard treatment schedules made for these diseases are circulated to all concerned. Coordination in drug supplies from all different channels is essential and Mongolesimpex must monitor supply and distribution.

5. OBJECTIVES

5.1. Development Objectives

Overall

To provide adequate essential drugs of proven safety,efficacy and quality at affordable cost to the whole country as well as knowledge and training required for rational use of drugs.

5.2. Specific Objectives

(1) To develop a National Drug Policy that would encompass the Essential Drugs Concept and Regulatory Mechanisms to include a drug registration relevant to the country's needs.

(2) To set up a mechanism for selection, procurement, distribution and storage of drugs that would ensure availability of essential drugs in the country.

(3) To train all levels of health workers in the country in the methods of estimation of drug needs in the health units and in the rational use of drugs.

6. PLAN OF ACTION/PROJECT STRATEGY

Political and economic changes in Mongolia resulting in acute shortage of hard currency and drugs has emphasized the urgency and need for WHO and other funding agencies to render assistance to the country. A situation analysis carried out by the WHO mission has revealed that together with the need for drugs, was an even greater need for training in the various aspects of drug supply management, particularly procurement, and in rational use of drugs. There is an urgent need to finalize the draft of the National Drug Policy and to have it adopted by the authorities in order that there be proper guidelines for procurement, regulatory control, and use of drugs.

A project proposal has been prepared which aims at developing a mechanism which will ensure adequate supply of good quality essential drugs to the community and provide the various levels of health workers with training in drug supply management, quality control and rational use of drugs.

6.1. Policy and Management

6.1.1. The National Drug Policy

The Government of Mongolia should frame a National Policy at the earliest. The Mission was informed that some attempts have been made to lay down certain principle directions and guidelines for Government's activity. The following two documents are annexed:

(a) Principle directions for improving people's health by the year 2000, approved by the 4th Congress of Health Workers, 1990.

(b) Guidelines for Government's activity adopted by the Mongolian State Little Hural, 1991.

In these documents there is no mention for giving priority to prepare a National Drug Policy, including all elements relevant to the country's need. A draft National Drug Policy should be prepared by the recently constituted Drugs and Biopreparations Council which should discuss and finalize by convening a National Drug Policy meeting to be attended by participants from all the departments involved in drug supply system. The meeting should be co-sponsored by the Ministry of Health/WHO and the finalized policy document should be approved by the authorities.

The objectives of the conference would be:

(a) to increase the awareness of the participants to the various components of a National Drug Policy concept

(b) to discuss in depth the various components of the Draft Policy and finalize a document relevant to the needs of the country.

As organization of such a meeting would require extensive preparation e.g. of background documents which may need to be translated into Mongolian, it may be necessary to recruit a short term consultant for 2-3 weeks to work with the national working group. A national short term consultant could also be recruited or contractual services given for translation of these documents.

6.1.2. Selection

Although a list of 220 essential drugs has been adopted by the Government, it would be necessary to lay down criteria for selection and review of this list from time to time. For this purpose, a small committee of experts should be constituted as a sub-group of the Drugs and Bioproparations Council. The essential drug list must be translated into Mongolian and distributed to all concerned along with a foreward from the Minister of Health on the concept of essential drugs and rational use. This work has to be taken up immediately and would require funds for printing and local contractual services.

6.1.3. Legislation

To ensure an adequate supply of safe and effective drugs of good quality, legislation and regulation must be included as an essential component of National Drug Policy. A separate drug legislation needs to be drafted by the end of 1992. For this purpose, a short term consultant would be needed to assist the local authorities to draft a proposed Drug Act, including definition of "drug" and all other basic elements of regulation, quality and procedure for registration etc.

6.2. Supply and Logistics

6.2.1. Procurement

Mongolexmimpex, a pharmaceutical company under the Ministry of Health is solely responsible for import and distribution of drugs in Mongolia. procurement is based on demand by the practicing doctors and although to a certain extent estimation is based on past consumption, rational therapy is not practiced, so that the estimated quantities do not reflect the actual need. Inadequate knowledge of drugs known mostly by brand names with no knowledge of generics make it difficult to make the best use of available hard currency.

Procurement procedures are not systematic due to lack of expertise with the global market, tender system and use of generic names. A short term consultant with expertise in the area of logistics and supply will be needed for about

2-3 months to work with the nationals to reorganize the whole procurement system.

In the same way, health workers will have to be trained in systematic quantification methodology and the use of morbidity- standard treatment method of estimating drug requirements, until such time as rational prescribing practice and consistent data on past consumption is available. In this area also, a short term consultant will be necessary for 2-3 weeks to conduct a workshop on quantification methods with nationals involved in training and supervision of the drug supply system as participants. Language would be a constraint in many of these activities and recruitment of nationals to act as interpreters may have to be considered. A second consultant may have to be recruited for a longer period at a later date (2-3mm) to help with the actual estimation of drug needs of the country.

6.2.2. Distribution

The distribution system in Mongolia seems to be efficient in spite of the varying distances between aimaks and somons, although there is room for improvement which could be worked out by the nationals.

6.2.3. Storage

There are facilities for storage in most of the hospitals and pharmacies visited. However, training in systematic store management is required which could possibly be done by the STC recruited for logistics. Renovation of premises may have to be done in certain places.

6.2.4. Local production

The premises of the Medical Factory of the Ministry of Health, the only unit manufacturing drugs in the country should be revamped; the principles of good manufacturing practices should be adopted and the facilities and equipment for manufacturing and testing should be augmented so that the factory can manufacture most of the common drugs used in large quantities in the country. The staff should be exposed to the modern manufacturing technology by visiting some drug manufacturing plants in other countries. A list of about 25-30 drugs for which the raw materials are easily available, should be identified and manufactured in the factory, keeping in mind the concept of GMP and testing of raw materials as well as finished products. A short term consultant would be needed to organize their production, quality control and GMPs.

6.3. Rational Use(RUS)

Appropriate use of drugs with sound prescribing habits and provision of adequate information to both the doctors and the public, are essential components of a country's drug policy.

6.3.1. Drug information

In order to acquaint the health personnel with the generic names given in the essential drug list which will now be purchased on priority, it would be necessary to prepare drug information sheets for distribution to all and to prepare a cross index between drugs currently available and those previously used. the information received from WHO and other sources should be translated into Mongolian and disseminated widely as a priority. A National Drug Formulary cum Therapeutic Guide should be prepared in Mongolian in a phased manner. Provision of adequate knowledge of the properties of the drugs, its adverse effects and its cost effectiveness would be a step towards promoting rational use of drugs. Therapeutic committees should be set up in hospitals to decide the number of drugs to be used at various levels.

6.3.2. Training

Training for rational prescribing would have to be done in a phased manner. For immediate impact, workshops,seminars and courses will have to be conducted countrywide so that all the doctors, pharmacists and health workers will become aware of the Essential Drugs Concept, the generic names of the drugs they are using and the principles of rational prescribing. At the same time information on drugs in the essential drugs list in Mongolian will have to be made available throughout the country. Mass media and public health education will promote patients' compliance in the use of essential drugs.

Doctors, pharmacists and persons concerned in the training of the various levels of health workers should be exposed to the concept of modern therapy and essential drugs programme through study tours and fellowships to countries with well developed essential drugs programmes and a good drug supply system.

6.3.3. Standard Treatment Regimens

These are useful both for estimation of drug needs as well as for rational therapy. These should be prepared for commonly occurring diseases by a group of experienced clinicians and clinical pharmacologists keeping in mind the rationale and cost effectiveness of the drugs. These should also be introduced through workshops and seminars and close monitoring of their use should be done.

Introduction of the Concept of Essential Drug and rational therapy should be introduced into the curriculum of health workers. The importance of clinical pharmacology and therapeutics for effective use of drugs should be emphasized and rational prescribing practice should be developed and reinforced throughout their career.

Prescription audit should be carried out in a few selected institutions and the data analyzed with a view to improve prescribing and cost effectiveness.

6.3.4. Self medication

Self medication appears to be rampant in Mongolia. Because of the non availability of doctors in remote areas and smaller places at all times, the

practice of taking home injections is quite prevalent. This seems to be the cause of several cases of Hepatitis B in the country. this practice of self injection, in principle, should be discouraged but its complete elimination may not be immediately possible. The public should however be made aware of the inherent risks involved in this practice because of the improperly sterilized needles. Whenever possible, disposable syringes/needles should be made available.

6.4. Quality Assurance(QUA)

6.4.1. Registration

The State Registration Rules have been issued by the Minister of Health on 29th December 1990. According to these rules, registration and introduction into or removal from medical service of any drug is to be done by an order of the Minister of Health based on the recommendations of the Drugs and Biopreparations Council. The applicant has to submit the required data(Annex 4), to the National Laboratory for the control of Drugs and Biological products (now called the Central Laboratory for Control of Drugs and Biopreparations) and the Council will register or not register the drug based on the evaluation and conclusions of the laboratory.

The rules and procedures outlined for registration do not appear to be clear and specific. Although the order was issued in December 1990, no systematic action has been taken to start registration of drugs. It is not clear whether the drugs which were so far being purchased will be treated as already registered or whether these will be subjected to fresh registration procedure. The order is also silent about registration of drugs which are now included in the essential drug list and which were not purchased earlier.

It is recommended that detailed procedure for registration should be laid down and the process of registration should be started immediately for old drugs as for those to be now purchased and which were not in the earlier list.

6.4.2. Inspection and licensing

A drug control administration with a full time Drug Controller (Licensing authority) supported by supervisory and inspecting staff should be established. This administration should have legal status in the proposed Drug Act and the duties and responsibilities of various functionaries and authorities including the one responsible for import and for quality control, should be clearly defined. This work can also be submitted to the short term consultant already recommended under drug legislation.

6.4.3. Quality Control Facilities

The central laboratory for control of drugs and biopreparations has the equipment and staff to test about 1.400 samples per year. It is recommended that the laboratory should be equipped with modern instruments and equipment and the analysts should be trained in the use of instrumental and microbiological analysis. Funds will be required for purchase of equipment and

for awarding fellowships for training of staff in a laboratory identified by WHO. This is necessary in order to increase the testing capacity and to test all categories of drugs imported as well as manufactured in the country. The laboratory also needs specially trained staff to standardize and test the quality of traditional medicines manufactured in the country.

7. WORKPLAN AND FINANCIAL ASPECTS

This workplan outlines the proposed activities to take place over a period of 4 years. Some of the activities require immediate actions and have been scheduled for 1992.

The drug component for 1992-95 is 10.5 million US$, the activities outlined in the workplan amount to 1,4 million US$.

8. PROGRAMME COORDINATOR

It is of crucial importance to manage and implement the programme effectively so as to achieve the established objectives and targets. For a programme that has been well formulated, successful implementation will accrue maximum benefits and will ensure its sustainability. If implementation is poor or follow-up is lacking, progress will be hindered and the programme itself will ultimately falter. Therefore, in the larger interest for the success of the Mongolia National Drug Policy and Essential Drugs Programme, there is a need and requirement for an external Programme Coordinator whose duties and responsibilities are defined as follows:

1. to plan and implement activities of the Mongolia Essential Drugs Programme according to the workplan for 1992-1995.

2. to assist the National Drug Council in coordinating and implementing activities under the national drug policy plan with all parties concerned.

3. to organize and assist in activities such as meetings/seminars/workshops, CSAs, LCSs and other related activities of the Mongolia Essential Drugs Programme.

4. to develop and monitor pharmaceutical supply system including procurement, storage, distribution and use of drug supplies in Mongolia.

5. to assist in the development of quality control and quality assurance of essential drugs in Mongolia.

6. to provide objective drug information and develop therapeutic guidelines to promote rational use of drugs.

7. to monitor and evaluate the Mongolia National Drug Policy and Essential Drugs Programme and prepare a 6-monthly progress report.

8. to assist the WR, Mongolia, in other activities relating to the drug programme, as may be needed from time to time.

Inputs

Government inputs

Project budget covering government contribution in kind

(local currency)

	Total		1992		1993		1994		1995	
	m/m	USD	m/m	USD	m/m	USD	m/m	USD	m/m	USD
PROJECT PERSONNEL										
Component total										
TRAINING										
-Maintenance of trainee's salaries -Subsistence for participants	45 840		20 000		7 100		8 520		10 220	
Component Total	31 840		6 000		7 100		8 520		10 220	
EQUIPMENT										
-Equipment -Premises	107 360		20 000		24 000		28 800		34 560	
Component total	107 360		20 000		24 000		28 800		34 560	
DRUG IMPORT										
Component total	63 000		15 000		16 000		16 000		16 000	

TOTAL GOVERNMENT INPUT 202 200

Computed at exchange rate 1 USD : 40 Tughriks

WORKPLAN FOR MONGOLIA ESSENTIAL DRUGS PROGRAMME
1992 - 1995

Activities	1992	1993	1994	1995
	US$	US$	US$	US$
CONSULTANCIES/NATIONAL CONSULTANCIES/TEMPORARY ADVISORS				
STC/Programme Coordinator: for establishment and implementation of MEDP	20,000	120,000	120,000	120,000
STC: Workshop on Quantification methodology (0,50 mm)4	10,000			
STC: Actual estimation of Drug requirements of MEDP (1.5 mm)4		15,000		
STC: Supply and Logistics - Procurement Procedures 2x1 mm4	10,000	10,000		
STC: National Drug Policy meeting (.75 mm)P		10,000		
RESOURCE PERSONS: 2 X 05 mm Procurement Rational use		15,000		
NSTC: for translation of background papers (3 mm)		3,000		
STC: Rational Drug Use - National Formularies - Standard Treatment Schedules(1mm)		10,000		
STC: To draft drug legislation and regulatory control (1.5 mm)			10,000	10,000
STC: Local Production GMP and Quality Control (0.75 mm)			10,000	10,000
CONTRACTUAL SERVICE AGREEMENT(CSA)				
CSA: Translation of Essential Drug List and forward into MongolianP	2,000			
CSA: Baseline -Morbidity Survey in all the health unitsh	4,000	4,000	4,000	

CSA: Preparation and translation of background documents for NDP meeting	2,000
CSA: Preparation for the National Formulary cum Therapeutic Guidelines and translation into Mongolian	5,000

CSA: Preparation of Standard Treatment Schedules		3,000		
CSA: Preparation of Drug Information sheets and translation into Mong.		3,000	3,000	3,000
CSA: Formulation of Drug Legislation and Regulatory Control			10,000	
CSA: Development of Health Education materials for patients			5,000	
<u>LOCAL COST SUBSIDIES(LCS)</u>				
Printing, distribution of National Essential Drug List in Mongolian		5,000		
Workshop on methodology of Quantification of drug requirements(trainers)	5,000	3,000		
Training courses on quantification for health workersh		4,000	3,000	3,000
National Drug Policy Meetingh		6,000		
Workshop for doctors on rational prescribing x 2		3,000	3,000	3,000
Workshop for health workers on rational prescribing x 24		3,000	2,000	2,000
National Formulary sub-committee meeting	1,000			
Printing and distribution of the National Formulary		10,000		
Meetings for discussing Standard treatments	1,000			
Finalization, Printing and Distribution of Standard Treatment Schedules		10,000		
Printing and Distribution of Health Education Materials			10,000	
Quantification of drug requirements per year				
Procurement/supply/distribution				

of Essential Drugsh	,500,000	4,000,000	4,000,000
FELLOWSHIPS To visit EDP in other countries in the SEAR		30,000 3x5mm	20,000 2x5mm

Regulatory Control & Registration		30,000 2x2mm	30,000 2x2mm	30,000 2x2mm
Production Technology & GMP		16,000 2x1mm	16,000 2x1mm	16,000 2x1mm
Quality Control Instrumental and Microbiological analysis		30,000 2x2mm	30,000 2x2mm	30,000 2x2mm
Procurement Procedures and store management		10,000 1x1mm	10,000 1x1mm	10,000 1x1mm
Clinical Pharmacology, Therapeutics(extra Regional)		60,000 2x3mm	30,000 1x3mm	
Supplies				
Stationary and office supplies		7,000	4,000	4,000
Equipment				
Quality Control Laboratory		50,000	100,000	
National Factory		50,000	100,000	
General Operating Expenses	5,000	5,000	5,000	5,000
TRAVEL				
Half-year Review October				
Joint Evaluation of MEDP Donor/WHO/National				17,000
TOTAL - with drugs*	2,558,000	4,532,000	4,525,000	263.000
1992-1995				11,878.000
without drugs	00	532,000	525,000	263.000
1992-1995				1,378.000

* drugs for 1991 = 2.5 million US$
1992 = 4 million US$
1993 = 4 million US$
1994 v

ANNEX VI

* On 17 November 1992, UNIDO sent to the Resident Representative in Ulaan Baator, Mongolia, a fax with the following text:

quote:
Re: Industrial extraction of indigenous medicinal plants and production of plant-derived pharmaceuticals
further to my telex dated 17/8 and 16/10 concerning the above project, pleased to inform you that the chinese authorities have agreed to finance the project from its special purpose contribution to IDF. The candidate of consultant has been evaluated and the mission could take place at any time considered apporpriate by the Mongolian authority. For the implementation of the project, we however need the govenment offficial request. Please confirm by return soonest, preferably this month.

* A draft project document and job description is attached.

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION

Project Document

Number: UF/MON/92/xxx Country: Mongolia

Title: Preparative Assistance for the Industrial Extraction of Indigenous Medicinal Plants and Production of Plant-Derived Pharmaceuticals

Total UNIDO Budget
(excl. support cost): US$ 12,500
Currency and amount

Estimated Starting Date: September 1992 Planned Duration: 1.0 m/m

Project Site: Mongolia

Government Implementing Agency: Ministry of National Development through the Research and Production Company "Shine Ekhlel"

Host Government/Agency

Brief description:

Plant based medicines are much used in the health care delivery system of the country. These preparations have to be improved in terms of both quality and standardization. Some can be converted into modern dosage forms. For this purpose technology transfer and manpower training are required.

This project enables a preparatory mission to identify Mongolia's needs in this respect and prepare a draft project document for such technical cooperation on industrial utilization of indigenous medicinal plants.

I. Background and Justification

There are more than 500 varieties of herbs growing in Mongolia. Many of them are indigenous and are rich resources of medicinal plants, e.g. Glycyrrhiza uralensis Fisch. Sophora alopecuroides L., Piplantus mongolicus M., Acoritum baicalense T., Hyocyamus riger L., Artemisia anua L., Ephedra equisetina, E. monosperma, E. prezevalski St. Some of these wild growing herbs can be cultivated on a large scale in various parts of the country.

Giving due concern to the importance of the utilization of medicinal plants, was set up a plant-derived pharmaceutical experimental stationin 1978 within the Veterinary Research Institute in Ulaanbaatar. This was reorganized in 1988 as the Research and Production Company "Shine Ekhlel". Since 1978 the organization acquired more than 10 technologies in the field of plant derived pharmaceutical products. Among those introduced into the production process are the preparation "TARGA" - cell stimulating small molecular weight peptides from plants, new types of diagnostics and vaccine therapy preparations against plant poisons of cattle.

Pharmaceutical manufacturing based on efficient use of plant derived materials is useful for the country. The finished products will be used not only within Mongolia but also for export. The cultivation of medicinal plants will ensure a steady supply of raw materials and create employment opportunities in rural areas. The technologies developed and introduced could be transferred to private and public sector industries.

This question has been given consideration in the Programme of the Mongolian government in connection with transition from centralized planning economy to a market one. Experienced personnel and a scientific approach are required to solve organizational and technological aspects with regard to conservation of an ecological balance.

In this respect, the Mongolian authorities stands in need of immediate advice on industrial extraction of indigenous medicinal plants and production of plant-derived pharmaceuticals. The advice will be used as a starting point for soliciting bilateral and multilateral cooperation with governmental and

non-governmental organizations of other countries as well as international organizations such as UNIDO and UNDP.

It was suggested by the Resident Representative in Mongolia that UNIDO look into the possibility of a TCDC arrangement with China which is advanced in this field. The Chinese authority, the State Pharmaceutical Administration of China (SPAC), subsequently agreed to send an expert to Mongolia, who will be financed under China's special purpose contribution to IDF, agreed by the China International Centre for Economic and Technical Exchanges (CICETE).

The outputs of of the project will assist to promote the implementation of the Governmental Programme on rational utilization of local resources of vegetable and animal origin, in particular:

- transfer of technology for industrial extraction of plant's active substance as the alkaloids, flavonoids, ethereal oils and so on.
- transfer of technology of production of pharmaceuticals in the form of tablets, pills, pastes, powders, and their standardization and quality control;
- national personnel training.

II. The Project

(a) Project Objectives

A preliminary assessment of the feasibility of industrial extraction of indigenous medicinal plants and production of plant-derived pharmaceuticals in Mongolia as the basis of a technical co-operation programme for the development of plant-based pharmaceuticals.

(b) Outputs

(1) A preliminary report on the feasibility of industrial utilization of medicinal plants assessing the:

(i) availability of raw materials for industrial utilization

(ii) prospects for improving production of plant based pharmaceuticals

(iii) available infrastructure for the production of plant based pharmaceuticals including a laboratory for standardization and quality control

(iv) market potential for plant derived pharmaceuticals both internal and external

(v) available trained manpower resources

(2) A draft project document for the consideration of the government and UNIDO based on expert's findings including:

(i) nature of the products that could be produced and the scale of operations,

(ii) the requirements in terms of equipment, training, expertise and facilities,

(iii) the technologies that should be transferred for the development of plant derived pharmaceuticals industry,

(c) Activities:

The consultant, with assistance from local counterparts will:

- i) collect the available data on plant species that could be utilized,
- ii) assess the physical and human resources available in terms of trained personnel, equipment, facilities for production and quality control and the current technologies used
- iii) investigate the market potential for plant based pharmaceuticals
- iv) prepare a report on his findings and recommendations and
- iv) prepare a draft project document for technical assistance for the development of industrial utilization of medicinal plants and plant derived pharmaceuticals and discuss it with government and UNIDO Headquarters.

(d) Inputs

i. Government Inputs:

The government will provide qualified counterpart personnel, office facilities, local transportation and administration assistance.

ii. UNIDO Inputs

International experts

11-51	1 short-term Consultant	- 1 w/m	US$12,000
42-00	Catalogues and publications		US$ 300
51-00	Miscellaneous -		US$ 200
Total	Budget		US$12,500

III. Reporting, Evaluation of requirements and expected follow up

The terminal evaluation exercise will be conducted for this project in accordance with the requirements of UNIDO's international evaluation system, at the completion of project operations.

Job Description

Project in Mongolia
UF/MON/91/105

Post Title: Expert in the Production of plant-derived pharmaceuticals

Duration: 1 w/m

Date required: ASAP

Duty station: Mongolia

Purpose of project:

To initiate technical assistance programme for the "Industrial Extraction of Indigenous Medicinal Plants and Production of Plant-Derived Pharmaceuticals."

Duties:

The expert is expected to carry out the following duties:

-Evaluate the present situation in Mongolia particularly the Research and Production Company "Shine Ekhlel" with respect to the possibility of producing plant-derived pharmaceuticals from indigenous plant species growing abundantly in the country.

-Assess available infrastructure facility for the production of plant based pharmaceuticals including a laboratory for standardization and quality control.

-Assess the market potential for the plant derived pharmaceuticals both internal and external.

-Recommend requirements for training of personnel, facilities, equipment and activities to be undertaken for the development of plant derived pharmaceuticals.

-Prepare a report covering his findings and recommendations and a draft project document for technical assistance for the development of plant based pharmaceuticals in Mongolia.

Qualifications: A fully qualified Pharmacognosist/pharmacologist with considerable experience in the operations leading to the processing of plant-derived pharmaceuticals.

Language: English

Background Information:

In Mongolia there are more than 500 varieties of herbs grown in Alpine steppes and deserts. Many of them are indigenous and resources of wild plants are rich. Natural thickets of Glycyrrhiza Uralensis Fisch, Sophora alopecuroides L., Piplantus Mongolicus M., Acoritum Baicalense T., Hyoscyamus Riger L., Artemisia Anua L., Ephedra Equisetina, E. Monosperma, E. Prezewalski St., and others here and there seem like artificial plantations. Some of these wild growing herbs can be cultivated on a large scale in various parts of the country.

Giving due concern to the importance of these plantations, in 1978 within the Veterinary Research Institute in Ulaanbaatar was set up plant-derived pharmaceutical experimental station which was reorganized in 1988 into the Research and Production Company "Shine Ekhlel". Since 1978 this organization acquired more than 10 Technologies of plant derived pharmaceutical products and introduced some of them into the production process. Among these production the preparation "TARGA" - cell stimulating small molecular - weight petides from plants, new types of diagnostics and vaccine therapy preparations against plant poisons of cattle occupy a leading place.

Pharmaceutical manufacturing based on efficient use of plant derived materials is possible and preferable for the country. The finished products will be used not only within the country but also for export. The cultivation of medicinal plants will ensure a steady supply of raw materials. This will result in creating employment opportunities in rural areas.

This question has been given consideration in the Programme of the Mongolian government in connection with transition from centralized planning economy to a market one. Careful experienced personnel and the scientific method of approach are required for solving organizational. technological aspects of this complicated problem with regard for conservation of ecological balance.

In this respect, the Mongolian authorities stands in need of immediate advice for the Industrial Extraction of Indige[illegible]cinal Plants and Production of Plant-Derived Pharmaceuticals. [illegible] be based on the experience will be used as a starting point f[illegible]ing bilateral and multilateral cooperation with governmental and non-governmental organizations of other countries such as SIDA, NORD, DANIDA as well as international organizations such as UNIDO, UNDP. That is why the Mongolian government in its request for SIS assistance from UNIDO refers to Prof. Sandberg from Sweden. We acknowledge his experience of many years in realization of such projects in some countries of Asia, Africa and Latin America, and also we take into account that he is informed about the situation in Mongolia more or less owing to previous contacts and cooperation. His services therefore are considered to be of prime urgency and importance.

Development objective of the project is to promote the implementation of the Governmental Programme on rational utilization of local resources of vegetable and animal origin, in particular:

- transfer of technology of industrial extraction of plant's active substance as the alkaloids, flavonoids, ethereal oils and so on.
- transfer of technology of production of pharmaceuticals in the form of tablets, pills, pastes, powders with application of different moulds, and their standardization and certifications;
- national personnel training.

ANNEX VII
SUGGESTIONS TO THE MINISTRY OF AGRICULTURE

A. SERUMS AND VACCINES PROGRAM IN MONGOLIA, TO BE IMPLEMENTED AT BIOCOMBINE SONGINO

*

MEMORANDUM
To the attention of His Excellence
Mr. Ould - Minister of Agriculture and Food Industry

- Taking into account the veterinarian needs of serums and vaccines of your country (due to the large number of animals bred in) expressed in national plans of the Mongolian Government ;
- Taking into account that the expertise of Biocombine Songino in this specialty can be extended to the human needs of serums and vaccines, for the best of Mongolian health and for the improvement of diseases prevention - justifying a close cooperation with Ministry of Health ;
- Taking into account the new guide-lines and policy framework to be funded by TSS 1,

we are submitting, for consideration, to Your Excellence and to UNDP Resident Representative the elements of a program devoted to "Serums and Vaccines, for veterinarian and human uses, to be implemented at Biocombine Songino", as improvement of health is one of the priorities of your Government.
The final document will survey the different points - including policy, strategies and objectives for the coordination of the various activities.

Mention of the objectives should serve to contribute to national capacity-building, to develop scientific and technological know-hows, skills and practices through the following strategies, as to reach self-sufficiency for serums and vaccines in the country.
Some of them have been prepared so far that written UNIDO draft projects have already been sent to UNDP Resident Representative in Mongolia and are only waiting for "official request" of Mongolian Government to finalize them.

Through separate mail, your Prime Minister, Mr. P. JASRAI, has been informed about most of them and replied on August 28th 1992 through a personal letter to Mr. G. DUMONT that he is supporting these suggestions.

*

1/ SERUMS AND VACCINES PROJECT FOR VETERINARIAN USE

1A) Modernization and extension of the present activity

The wide variety of serums and vaccines already produced, the quality of the Biocombine Songino scientists and the large demand due to the important live-stock and breeding of cattle in Mongolia, all are arguments for endeavouring and sustaining a technical and assistance UNDP/UNIDO project at Biocombine Songino.

A second argument in favour of an extension for the present activities is the exceptionally good possibilities for an easy collection of animal serums and the immunologic quality of it due to the severe climatic conditions.

A UNIDO project would include

in a first step an auditing review of the existing facilities and of the needs,

in a second step a plan for modernization of some sectors and extension of capacity in order to reach self-sufficiency - and possibly to envisage exportation for a part of the production as soon it will be possible to reach international standards,

in a third step introduction of new technologies where it is necessary, to be able to produce new required products or to reach a higher standard of quality.

As France is reknown world-over for its specialty in this field through "Institut Pasteur" and "Institut Merieux" graduation courses, Mr. G. DUMONT would specially recommend UNIDO to consider to appoint French consultants graduated from "Institut Pasteur" or formerly specialists at "Institut Merieux" for these projects.
They will be able to advise efficiently as most of them are also veterinarian doctors and as they will be able to organize in France for Mongolian veterinarian specialists the necessary study-tours or fellowships which will bring them an in-depth training on the new technologies to be transferred at Biocombine Songino.

1B) Purification and concentration of antitetanic serum

This precise project has been identified as urgent at the occasion of the former missions of Mr. ATGER - UNIDO and Mr. G. DUMONT.

Biocombine Songino is producing antitetanic serum, which is exported in significant quantities (15 million international units per year), in its unpurified and unconcentrated form, to Hungary (Phylaxia or Human Institute).

Mr. SODNOMDORJ, Director at Biocombine Songino, is willing to obtain purification and concentration technology - as it would permit to Mongolia to export at a better price and as availability of both qualities is enlarging the market possibilities.

Purified and concentrated antitetanic serum would also be useful for covering Mongolian domestic requirements.

Mr. G. DUMONT has indicated to UNIDO that he knows 2 valuable specialists, knowledgeable in serum purifications and prepared to fly to Mongolia as UNIDO consultants in order to cooperate with Biocombine Songino all along this development work.

A UNIDO draft project has been established and is ready for bringing assistance and technology for this purification :
would it be possible for Your Excellence to issue the official request from Mongolian Authorities and to remit it in a near future to the UNDP/UNIDO Resident Representative, as the subject is really of a deep interest for Mongolian economy and as Mongolia is one by the rare countries to have plenty of animals and to be able to provide large quantities of serums to the international market.

2/ SERUMS AND VACCINES FOR HUMAN USE

In a small country as Mongolia, it is already good luck to have such a specialized activity as serums and vaccines production.
As this production is handled at Biocombine Songino in good conditions of safety and quality, it is logical to envisage Biocombine Songino to be in charge equally to produce serums and vaccines for the human needs of the country (and eventually for exportation).

Such an enlargement of the scope in the present activities justify an attentive preliminary study in the UNDP/UNIDO program, with a special tripartite commission associating to the UN experts several members of the Ministry of Agriculture (for the Veterinarian sector) and of the Ministry of Health (for the human sector) :
this Commission will evaluate the total needs in terms of products and quantities - but also will have to invent the ways of cooperation between Biocombine Songino (related to Ministry of Agriculture and acting as a sub-contractor producer) and the Ministry of Health (acting as the customer for human needs products).

This can be an enthusiastic objective to allow Mongolia to be self-sufficient for human prevention and treatments utilizing vaccines and serums - through such a cooperation which is certainly easy to build, even it oblige 2 independent state administrations to establish a bridge between them.

3/ SPECIAL PROJECT FOR INTRODUCTION OF PURIFIED GONADOTROPIN TECHNOLOGY

At Biocombine Songino place, 500 horses are bred for the needs of the factory : 100 of them are pregnant mares and such a large number at the same place is exceptional in the world :
this provide a good opportunity to produce in Mongolia and to export pregnant mare blood derivatives (gonadotropin but also the residual by-products like immunoglobulins).

Crude serum gonadotropin has been previously exported, but during the transportation a large part of the gonadotropin activity was destroyed. In order to preserve a high percentage of the activity content, it is a must to purify it as soon as possible after collection from the mares, i.e. to treat the serum at Songino and to export it in the purified and stabilized form.

As horses are unfrequent now in many countries of the world, it would be wise to initiate a new UNIDO draft project including in a first step a market survey of the world needs and of the potential productions in different countries.
A second step of the project would be - if former discussions with DDR, Hungary and Behring-Hoechst group have not been finally positive - to propose the visit of a group of experts able to advise and assist Biocombine Songino in further negotiations with one of the recognized world producers of gonadotropin.

Indeed, such a delicate purification request a deal with a specialized company and it would be mutual interest as Mongolia can secure the foreign partner for its pregnant mare blood requirements or for the derivates from.

Excellence, it would be my honour and pleasure to know later on that this memorandum has been useful for improving the Health Sector in Mongolia, through new UNDP and UNIDO projects.

With this hope, I remain, Your Excellence,

Sincerely yours,

UNDP

B. ELEMENTS FOR A UNDP DAIRY PRODUCTS PROGRAM adapted to middle-size and small enterprises in Mongolia

**

MEMORANDUM
To the attention of His Excellence
Mr. Ould - Minister of Agriculture and Food Industry

**

- Taking into account the difficulties of milk storage in nomadic conditions, as they are in Mongolia ;
- Taking into account the needs of modernization expressed in the development programs of your country and included in the national plans of the Mongolian Government particularly in favour of middle-size and small enterprises ;
- Taking into account to contribute to national production capacity-building and self-sufficiency of good standard food, particularly in the field of dairy products - as processed cheeses and yoghurt fermented milks ;
- Taking into account the new guide-lines and policy framework to be applied to the new UNDP programs to be funded by TSS 1,

we are submitting, for consideration, to Your Excellence and to UNDP Resident Representative the elements of a program devoted to *"Dairy products production adapted to middle-size and small enterprises in Mongolia"*, as improvement of healthy food and development of small private enterprises are some of the priorities of your Government.
The final document will survey the different points - including policy, strategies and objectives for the coordination of the various activities.

Mention of the objectives should serve to contribute to national capacity-building, to develop scientific and technological know-how, skills and practices through the following strategies, as to reach self-sufficiency for healthy dairy products in the country and to solve the problem of extra-availability of milk in areas located far away from the big cities.

1/ DEVELOPMENT OF NATIONAL STANDARDS, WITH APPROPRIATE REFERENCE TO INTERNATIONAL ONES AND WITH APPLICATION OF EXCELLENCE IN SCIENCE AND TECHNOLOGIES

1A) Installation of a central laboratory acting as a reference center for providing the good strains for fermented cheese or for yoghurt production

This can be implemented as a subsidiary department to a universitary center with expertise in microbiology or to a dairy laboratory.

2/ INTRODUCTION OF PROGRAMS WHICH WOULD ASSIST BOTH THE PUBLIC AND THE PRIVATE SECTORS, INCLUDING FOR INSTANCE RESEARCH AND DEVELOPMENTS OF INDIGENOUS NATURAL PRODUCTS INCLUDING ALSO INTRODUCTION OF QUALITY CONTROL SYSTEMS

2A) Installation of a pilot equipment line for initiating Mongolian scientists to the different steps of the production for processed cheeses or for fermented milks as yoghurts.

It would be a wise decision to establish this project of pilot laboratory with view to use it as a training place for the middle-size entrepreneurs interested to build production capacities in different places of the country.

2B) **Institution of a tripartite scientists committee** with dairy specialists of the Ministry of Agriculture, with UNIDO or foreign experts and with universitary microbiologists interested to apply their competences to a specific project of industrial microbiology.

2C) **Implementation of small or middle-size enterprises** for cheese or yoghurt production - with assistance of foreign experts (for the design of the plant, for the choice of equipments, for the training of the technicians).

3/ ENVIRONMENT CONTROLS AND IMPACT ASSISTANCE

This point deserves further in-depth thought, with survey of the by-products and their innocuousness.
In every country producing cheese in industrial quantities, large amounts of whey are produced and frequently lost : as whey is protein-rich, it is important to valorize this by-product and to foresee from the beginning a regular total use (it is classic and economic in Europe to join a pig breeding farm to a cheese producing plant).

4/ SCIENTIFIC AND TECHNOLOGICAL EVALUATIONS AND APPLICATIONS

Training locally performed by foreign experts will be wisely completed through study-tours of Mongolian specialists :
it would allow them to visit similar dairy products production plants in Europe and to understand the management of such productions.

Excellence, it would be my honour and my pleasure to know later on that this memorandum has been useful for improving the Food Industry Sector in Mongolia, through UNDP or UNIDO projects - I am convinced that in France I would be easily able to discover valuable experts prepared to provide their experience to your country, as you probably know that France has a large variety of cheeses and a particular knowledge in this field.

With this hope, I remain, Your Excellence,

Sincerely yours,

G. DUMONT

C. ELEMENTS FOR A UNDP PROGRAM FOR MODERNIZATION OF BLOOD COLLECTION AND VALORISATION OF SOME BY-PRODUCTS - TO BE USED IN A SLAUGHTER-HOUSE USED AS A REFERENCE CENTRE

**

MEMORANDUM
To the attention of His Excellence
Mr. Ould - Minister of Agriculture and Food Industry

**

- Taking into account the needs of modernization expressed in the development programs of your country and included in the national plans of the Mongolian Government ;
- Taking into account to contribute to national capacity-building of good standard slaughter-houses and self-sufficiency for good meat products ;
- Taking into account the new guide-lines and policy framework to be applied to the new UNDP programs to be funded by TSS 1,

we are submitting for consideration to Your Excellence and to UNDP Resident Representative, the elements of a program devoted to "**modernization of blood collection and valorization of some by-products, in a Mongolian slaughter-house to be used as a reference center for the country**".
In order to express a not too ambitious program, **we will limit voluntarily the objectives to some points of special interest and able to be improved in a near future at reasonable cost**.

Final documents for the UNDP program will detail the different aspects - including policy, strategies and objectives for the coordination of the various activities.
Mention of the objectives should serve to develop scientifical and technological know-hows, skills and practices and Mr. G. DUMONT hopes that it will contribute significantly to improve sanitation and conditions of work in all the slaughter-houses - as to provide a complement of healthy food to Mongolian people.

*

1/ Development of a modernized blood collection at Ulan Bator slaughter-house - to be used as a reference center for the country

Blood in slaughter-houses is a permanent concern for ecological and pollution reasons.
As blood has a potential value as food industry material, now - in all the world - tendancy will be to collect safely the blood in the veins by needle at the moment the animals are killed :
blood has to be centrifuged and serum is usually dried by spray-drying.
It is used directly as food additive or processed in various proteic derivatives, used mainly as protein enhancers or as emulsifiers in sausage industry.

A tripartite survey of this important subject would allow to precise the existing difficulties and to list the various activities to be developed in order to improve this problem during the next years.

A UNIDO project for a pilot-unit in Mongolia (preferably at Ulan Bator) in order to learn people how to collect blood safely would be one of the first steps :
it would allow Mongolia to practice this new technique and to establish at this place a reference center with expertise to be applied elsewhere in future.

Such a safe collection system will provide economic value to the blood presently thrown-out or simply used after drying as soil fertilizer ; it will also contribute to reduce the pollution due to the blood presently spread on slaughter-houses grounds.

2/ Production of blood hydrolysates and peptones

This project has to be developed at BIOCOMBINE SONGINO where the subject has been studied till the pilot-scale :

BIOCOMBINE SONGINO has already initiated a project related to blood hydrolysates and the so-called "Heterolysine" (animal blood source material), with a pilot-scale production of 3.000 litres.

Today some difficulties are encountered with the final preparation : precipitates form in the solution, need of an improvement of the technology.

As need of this protein preparation is big in the country as there is a large number of healthy animals bred in Mongolia, production of heterolysine can be great :
this justify a small UNIDO project for auditing the difficulties, as a preliminary step for a new UNIDO draft project devoted to develop in Mongolia a larger size and modernized production of Heterolysine in order to satisfy the Mongolian domestic needs.

3/ Valorisation in food industry of intestines and blood

Beef intestines are processed in Mongolia in view to produce a special sort of sausage which is highly appreciated.
In other countries, as France, it exists a similar use of veal and porc intestines and it would be easy to select good meat-processing specialists able to cooperate locally for improving the quality (taste, palatability, appearance, spicing) and for enhancing the productivity of Mongolian productions presently offered to the consumers.

Blood - as itself - is used in some countries as a basis for some special sorts of sausages (frequently named "black-pudding").
These formulas have to be presented for testing to a panel of Mongolian persons :
if the taste is appreciated, it would be a real interest for Mongolia to develop a local production as it is a healthy food, cheap to produce and able to absorb a part of the slaughter-houses collected blood.

For these 2 subjects (intestine and blood processed products) it would be recommended to appoint for 2 weeks 1 or 2 meat-processing specialists in the frame of a UNIDO small project and to limit their intervention - in a first approach - to the Ulan Bator slaughter-house and to establish a working group with Mongolian specialists.

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Excellence, it would be my honour and my pleasure to know later on that this memorandum has been useful for improving sanitation and valorisation of by-products of your slaughter-houses, through UNDP or UNIDO projects.

With this hope, I remain, Your Excellence,

Sincerely yours,

G DUMONT

Backstopping Officer's Technical Comments
based on the work of Mr. G. Dumont
SI/MON/89/801

The report describes the excellent work done by the Chief Technical Advisor during his assignment, as a first step in France and Denmark (for the organisation of the study tour with three participants), and as a second step in Ulan Bator.

Mr G. Dumont has assessed the current status of several industrial sectors:

- the pharmaceutical sector and related industries,
- the veterinarian sector (serums and vaccines),
- the agro-food sector (dairy products, meat processed industries, etc...),
- the telecommunications sector.

and he has introduced and suggested a number of project proposals to all relevant ministers and to the Prime Minister of Mongolia as well as to the UNDP Resident Representative. Draft project documents were submitted by the CTA which are being processed.

At the end of his mission, Mr. Dumont has discussed several recommendations with both the UNDP and Government authorities who have expressed the willingness to initiate actions through several UNDP/UNIDO projects.

For the pharmaceutical sector one of the important recommendation relates to the effective implementation of a reliable regulatory system for quality assurance. Facilities in the factories visited need to be augmented with modern equipment and the premises revamped under the concept of Good Manufacturing Practices (GMP) in order to facilitate the role of the Licencing Authority for manufacturing and sale of drugs, supported by inspectors and other supervisory personnel.

Furthermore, the Quality Control Laboratory needs to be equipped with modern instruments of analysis and the staff trained for this purpose in a laboratory already identified by WHO for the purpose of testing and controlling the quality of drugs imported and produced in the country. At present very few imported drugs are tested owing to the lack of equipment ; the quality of imported drugs need to be tested in a manner that would bring about a better assurance of quality.

BSO hopes that a technical assistance project to follow up these recommendations would be a reality soon.