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ASSISTANCE TO GHANA INDUSTRIAL HOLDING CORPORATION, PHARMACEUTICAL DIVISION, PHASE I

DP/GHA/72/006

GHANA

TERMINAL REPORT

Prepared for the Government of Ghana by the
United Nations Industrial Development Organization,
executing agency for the
United Nations Development Programme

United Nations Industrial Development Organization

United Nations Development Programme

ASSISTANCE TO GHANA INDUSTRIAL HOLDING CORPORATION, PHARMACEUTICAL DIVISION, PHASE I

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GHANA

Project findings and recommendations

Prepared for the Government of Ghana
by the United Nations Industrial Development Organisation,
executing agency for the United Nations Development Programme

Based on the work of J. Surowiecki, production engineer; W. Grzegorzewicz, quality control adviser; and H. A. Abdel-Kader, maintenance engineer

United Nations Industrial Development Organisation

Vienna, 1976

Explanatory notes

References to dollars ($) are to United States dollars.

The monetry unit of Ghana is the new cedi (N¢). During the period covered by this report, the value of the new cedi in relation to the United States dollar was $1 = N¢ 1.15.

A full stop (.) is used to indicate decimals.

A comma (,) is used to distinguish thousands and millions.

GIHOC refers to the Ghana Industrial Holding Corporation.

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SUMMARY

In 1969, phase I of a plan of operation to upgrade the Pharmaceutical Division of the Ghana Industrial Holding Corporation (GIHOC) was initiated by the Government of Ghana, the United Nations Development Programme (UNDP) and the United Nations Industrial Development Organization (UNIDO), which was designated as the executing agency for the project. This programme was extended in 1972.

Three experts were assigned to the project: a production engineer, a quality control adviser and a maintenance engineer. With the co-operation of their local counterparts, management and the Government of Ghana, notable progress was achieved. While the GIHOC factory, which had been completed in 1967, had been designed to produce 1 million injections and 100 million tablets and capsules annually, by the end of 1974 production had risen to 5.9 million injections and to 645 million tablets and capsules, the line of products had risen from 14 to 57 items, and GIHOC's Pharmaceutical Division had become one of its most profitable.

As production was thus greatly expanded to meet the requirements of the country, the Quality Control Department of the Division found it necessary to put its Analytical Chemical Section on double-shift operation. Also, while there were but a dozen maintenance personnel in 1971, this staff had nearly tripled by the end of 1975 and included persons trained to cope with very advanced equipment. A programme to maintain all equipment and machinery mechanically and electrically had been established. Since the beginning of 1975, a master preventative maintenance chart covering all machines and equipment has been in use.

Recommendations for further improvements are presented. Phase II of the project is tentatively scheduled to begin in September 1976.

INTRODUCTION

The Pharmaceutical Division is one of 16 that operate under the aegis of the Ghana Industrial Holding Corporation (GIHOC). Its pharmaceutical plant and machinery installations were completed in 1966, and trial runs were conducted in 1967. Owing to management problems and abortive negotiations to have an internationally oriented pharmaceutical house take over production, the factory never attained its goal of producing a significant proportion of the medicaments needed in the country. Three years later, the factory lay virtually idle.

The Government of Ghana therefore decided that the factory should be operated as an entirely Ghanaian-owned industry under GIHOC, with technical assistance from the United Nations Industrial Development Organization (UNIDO). In August 1969, a Plan of Operation was signed by the Government of Ghana, the United Nations Development Programme (UNDP) and UNIDO, which was to be the executing agency. The job description of the production engineer was included and provided the framework of the assignment. More-detailed plans based on the project document and the needs of the factory were elaborated each year and submitted to UNIDO, together with progress reports.

Project activities began in 1971 under the terms of Project DP/GHA/69/528 (Assistance to GIHOC - Phase I), and since 1972 were under Project DP/GHA/72/006 (Assistance to the GIHOC Pharmaceutical Division - Phase I). The team of experts assigned to the project are listed in annex I. The project was financed by UNDP fund allocations totalling $270,500.

The project was completed in June 1975, and the UNIDO experts left the division after four and one-half years, turning over their responsibilities to Ghanaian technicians whom they had trained. By that time, the factory, which had been designed with a capacity of 100 million tablets and 1 million ampoules yearly, had attained an output of 645 million tablets, 10 million ampoules and 28 million capsules, which represent from six to ten times the original targets. The gross product of the factory in 1974 was N¢ 7.2 million, and the net profit was N¢ 2.3 million. The data for the five-year period 1970-1974 are presented in the accompanying table.

The findings and recommendations of this report, which covers the activities of the three UNIDO experts from February 1971 to June 1975, are presented in three sections, corresponding to the activities of the experts.

Development of the GIHOC Pharmaceutical Division, 1970–1974

Year	Production a/ (million units)		Number of formulations		People employed	Gross product (million N¢)	Net profit (million N¢)
	Injections	Tablets	Injections	Tablets			
1970	0.5	36	2	12	81	0.3	(0.004)
1971	0.9	145	3	21	115	1.0	0.1
1972	1.5	201	7	30	182	2.0	0.5
1973	4.5	553	10	39	346	4.0	1.0
1974	5.9	645	14	43	404	7.2	2.3

a/ The plant was designed to produce 1 million injections and 100 million tablets and capsules yearly.

The Government of Ghana has decided to devote further attention to the GIHOC Pharmaceutical Division, so a second-phase programme has been planned to expand the existing product line with such items as syrups, creams, lotions, vaccines and sera. UNIDO is to be the executing agency in this second phase, which is to start upon the completion of the warehouse building, which is tentatively scheduled for September 1976.

I. FINDINGS

A. Production

Status of the Production Department before the arrival of the production engineer

As it was built, the factory was intended to produce 100 million tablets and 1 million ampoules annually. The production building had three floors. There were stores on the ground floor for raw materials, auxiliary substances, packaging materials and finished goods. The area of the stores was about 550 m^2. On the first floor was the Tabletting Section, which occupied 550 m^2 and on the second floor was the Injection Section of about the same area. In May 1971 the factory employed 108 people and was found to be well organized. There were, however the following problems that affected the Production Department and the factory as a whole:

There was no planned production programme
Marketing and distribution of finished goods were not organized
Only a few drugs were being manufactured
Outmoded and inefficient production equipment was in use
Machine maintenance was unsatisfactory

Activities connected with increasing production

The major customers of the GIHOC Pharmaceutical Division are the Ministry of Health, the armed forces, hospitals and private drug stores. The co-operation that the factory was receiving from these major customers was highly unsatisfactory: their purchases were so irregular that any planned production programme was impossible. However, much effort was made by the management of the factory to obtain the Government's guarantee to purchase its finished products.

The most important alteration was the introduction, in December 1971, of a restricted list for certain drugs previously imported (annex II). This action gave the Pharmaceutical Division of GIHOC the heavy responsibility of supplying the country with these restricted drugs. Annex III lists the drugs being currently manufactured. In these circumstances, the main efforts of the Production Department were:

To work out new technologies for dosage forms suitable for tropical climates and to bring them into production

To increase production efficiency

To acquire new machinery and equipment

To train local staff

The Tabletting Section

The Tabletting Section was found to be operating, but its machinery and equipment were inadequate; the machines lacked some working parts. The central air-conditioning system had broken down, and the section was producing only 12 kinds of compressed tablets. It appeared that the principal reason that so few items were manufactured was the lack of formulae for the production of the desired medicaments.

These shortcomings were the main reason for the inability to satisfy increasing demands for locally made drugs. New equipment and spare parts were ordered and arrived after some time, and additional orders were included in the budget every year. The plans connected with refurnishing and equipping the section have been realized in order of importance but, owing to the financial position of the country this has taken considerable time. Nevertheless, the section now appears to be adequately equipped (see section C. Maintenance) for the work that is being currently carried out. Its air-conditioned rooms now provide improved conditions for work.

As mentioned previously, the need to produce drugs whose importation had been restricted imposed a large volume of work on the factory. In effect, this meant that these drugs should be provided by the Pharmaceutical Division for the country, so it was found necessary to work out new technologies for dosage forms, including some restricted ones that had not been manufactured previously. Experience had proved that the importation of certain granules for compression is inadvisable in the climate of Ghana. The stability of drugs manufactured from such semi-finished products is incommensurately short as compared with the period of distribution and consumption. The technologies that had been worked out in the factory were adequate, and the stability of the products in the prevailing climatic conditions has been found to be satisfactory.

The list of formulations in tablet and capsule form has been lengthened from 12 to 43 items, as shown in the table on page 6. They are listed in annex III.

The programme for the production of antibiotics in capsules was implemented at the demand of the Ministry of Health as well as to enhance the prestige of the Pharmaceutical Division. In this connexion, the following have been accomplished:

Two basic capsule-producing machines were set up

Technologies for the production of tetracycline hydrochloride and chloramphenicol have been developed and put into production

Local staff have been trained in the production of capsules

Another basic activity of the section was the theoretical and practical training of the local staff involved in film coating. (Tablets are film coated for several reasons, among them to disguise a bitter taste, to protect the active ingredients from the adverse effects of humidity and sunlight, and to prevent destruction of the active ingredients by enteric acids.) In the course of training, a method for producing film-coated tablets that was suitable to existing conditions was evolved, so the section should now be able to manufacture them.

The Injection Section

The Injection Section was also found to be operative, but its machinery and equipment were insufficient and underproductive; it was producing only two formulations. The primary reason for this situation appeared to be insufficient orders from the Ministry of Health.

As noted, the factory had been designed to produce only 1 million ampoules yearly. The main objective, therefore, was to increase the productivity of the section while maintaining high standards (those of the British Pharmacopoeia). Inquiries for new equipment were submitted to various suppliers and, after studying the answers, selections were made and orders placed. The same procedures have been followed during the four following years.

The section now appears to be adequately equipped, as discussed in section C. Maintenance. The list of formulations that it produces has been extended to 14 items, and output has been increased approximately twelvefold, which is nearly six times the designed capacity as shown in the table on page 6. (Activities for the control of environmental pollution are carried out in the Injection Section.)

The Packaging Section

The Packaging Section was found to be operating, but not efficiently enough to cope with ever-increasing production. To improve the situation, a double-shift system was introduced and additional machines were ordered. It now appears that this section is equipped with a sufficient number of counting and packing machines (see section C. Maintenance). The only remaining problem is with the quality of packaging materials, including containers and closures suitable for tropical climates with high relative humidities.

Related activities

Apart from daily matters of practice and administration, the Production Department also bears a heavy weight of other responsibilities. Close co-operation with the Procurement, Sales, Maintenance and Transport and Accounts Departments has been established. The production of drugs in the factory was based on imported raw materials. The Production Department and Quality Control Department were charged with selecting the best sources of supply by performing physical and chemical analyses. Calculations of the annual consumption of raw materials, additives and some packaging materials were performed by the Production Department, based upon sales forecasts and buffer stock. Special forms for evaluation of the real costs of manufactured drugs were designed by the Production Department and the Accounts Department. Daily reports about each batch of manufactured drugs were sent to the Accounts Department for further processing. The Pharmaceutical Division can now be said to have its own costing system.

The factory still lacks a Research and Development Department. This is due mainly to lack of staff adequately qualified in applied pharmacy. All everyday technological and analytical problems had to be solved by members of the Production Department and Quality Control Laboratory staffs. Selected people with the requisite experience from both departments, together with the experts, were charged with developing new drugs. This system appeared to be the best solution until the Pharmaceutical Division is able to have trained personnel take over this function. Arrangements were therefore being made to send at least one pharmacist abroad for appropriate training.

In order to broaden the theoretical knowledge of the staff, some professional books were ordered (with financial help from UNIDO) and subscriptions to some selected periodicals were entered.

For the future expansion of the Pharmaceutical Division of GIHOC, a seven-year development plan had been worked out and approved by the GIHOC Head Office. This project comprises a new main warehouse, a new production unit and conversion of the existing production block to the manufacture injections and syrups. The reasons for this project are as follows:

The increasing consumption of drugs in the country

The fact that existing plant is capable of providing only about 35 per cent of the drugs consumed

The fact that the GIHOC Pharmaceutical Division is very profitable makes its further expansion worth while

Analysis of this project has revealed that, after its completion, the division will be able to manufacture about 65 per cent of the total amount of drugs consumed in the country and will, in addition, provide work for 500 people. The present staff numbers about 404.

Another activity connected with future expansion of the Division (Phase II of project) was the elaboration of chloroquine phosphate syrup. (Present consumption is about 100,000 litres annually.) The formula for this syrup was perfected by the Production Department in collaboration with the Quality Control Department.

Premises

The Production Department now occupies the second, first and part of the ground floors, an area of about 1,300 square metres. The administration building also houses the Quality Control Department and the library. The factory premises also include the animal house, the workshop, stores, changing house that also houses the laundry, a canteen, a power house and accomodation for some senior staff. Enough space remains for further expansion.

Staff

The following categories of staff are employed in the Production Department: senior officers with university degrees and junior officers with primary school or secondary school O level certificates. On the arrival in the field of the

production engineer, the staff included 4 senior officers (pharmacists) and 62 junior officers. The senior officers with university degrees had adequate experience in production of both tablets and injections. The junior staff, especially new entrants, had to be given training in production and in the basic principles of the technology of dosage forms, hazards, cleanliness and personal hygiene. This training was carried out with excellent support from the senior staff.

The staff of the Production Department now consists of 210 persons: 9 pharmacists (2 of whom are on one-year National Service), 1 packing superintendent and 200 junior officers.

During the past four years one pharmacist, who had been rather well trained, left the Production Department to join a foreign pharmaceutical company.

Training was mainly done on the job and was continued for the whole period in connexion with new equipment and new drugs technologies, which were introduced into production. Some senior staff members were sent to attend local and overseas courses. Two persons completed a one-month course, organized locally by the Management, Development and Productivity Institute. One pharmacist attended the course in pharmaceutical technology organized by UNIDO in Ghent, Belgium. Apart from the training of the factory staff, extra-curricular training for students from the Pharmaceutical Faculty of the University of Science and Technology at Kumasi was carried out every year. The local staff now appears to be adequately prepared to carry out the production programme planned for the factory.

Over-all status and assessment of the project

Thanks to the joint efforts and understanding of local counterparts and experts, the factory achieved really substantial results. The Pharmaceutical Division of GIHOC became one of its most profitable; it received the Best Division Award for 1972. With existing facilities, the factory approached its ultimate goal of production. The progress of the Pharmaceutical Division during the period under review is shown in tabular form on page 6.

B. Quality control

The activities of the Quality Control Department are intimately connected with those of the Production Department. At the entry on duty of the expert, the department had functioning Analytical Chemical and Microbiological Sections; the Pyrogen Section was set up later. The activities connected with the reorganizing, upgrading and creation of the various sections are considered below.

Analytical Chemical Section

This section was found to be operative but to be using mainly conventional methods of analysis, since its equipment was inadequate and obsolete. However, new equipment had been ordered and arrived after some delay. During the past three years, supplementary orders have been placed, and plans have been made to refurnish and re-equip the laboratory. These plans are gradually being realized, in order of their importance, but this has been taking considerable time, owing to foreign exchange problems. The Analytical Chemical Section now appears to be adequately equipped for the work that it now performs. Its equipment is listed in annex IV.

In addition to its day-to-day operative and administrative responsibilities, the section has heavy responsibilities in certain other areas. For example, it staff helped in the proper organization of the main depot for chemical reagents in the factory. The reorganization has necessitated the construction, as quickly as possible, of a special facility for the storage of inflammable and explosive materials.

Close co-operation with the Procurement Office of the Pharmaceutical Division has been established. This was necessary because the production of all drugs in the factory is based on imported raw materials. The section analyses samples submitted by various producers. The findings make it possible to select the best sources of supply.

Samples of the drugs produced in the factory are drawn from the sample-keeping room and observed and analysed when necessary. These studies permit valid conclusions to be drawn about drug stability. It was found that the packaging materials used are inadequate for local (tropical) climatic conditions.

Because the factory does not as yet possess a Development Section, all every-day teohnological and analytical problems must be solved by the Production Department staff and that of the Analytical Chemical Section. Laboratory staff also participate in investigations connected with the improvement of existing drug formulations and the elaboration of new ones. For example, positive test results for quality, quantity and stability were obtained for a chloroquine phosphate syrup that had been elaborated by the Production Department. The formula for this product had been developed with the future expansion of the project under phase II in mind.

Microbiological Section

At first, the Microbiological Section of the Quality Control Department did not possess adequate equipment and facilities to perform sterility tests, so samples of injections produced were sent to an outside hospital laboratory far from the factory. As soon as the necessary equipment was received (September 1972), the Microbiological Section began to operate. The staff was trained in the task of sterility testing of injections containing bacteriostatic and fungistatic agents.

The factory has begun to produce capsules containing antibiotics. On receipt of the ordered standards, test organisms and media, the activities of this section were expanded by the introduction of microbial assays of the antibiotic activity of the produced capsules.

Pyrogen Section

The Pyrogen Section did not exist at the beginning of 1972. When a sufficient number of rabbits had been obtained from a rearing project organized on the factory premises, the needed equipment had arrived and practical training of the staff had been completed (April 1972), the section began to function. It should be emphasized that it was then the only industrial laboratory in Ghana that performed this test.

Supplies and equipment

While most of the laboratory equipment oan be operated by people who have been trained on the job, the more oomplioated ones are maintained by a technician who was trained at the University of Ghana at Legon.

The actual consumption and usage of instruments, glassware and chemical reagents in each section of the Quality Control Department was studied and documented to permit adequate planning of purchases. It was found necessary to maintain a stock of spare parts for laboratory equipment because of the long delivery time (about one year) after the placement of an order.

Premises

The Analytical Chemical Section and the Microbiological Section of the Quality Control Department occupy the ground floor of the main administration block, an area of about 500 square metres. While the air-conditioned rooms provide adequate space for working and the orderly placement of the equipment and reagents presently in the Analytical Chemical Section, it appears to be inadequate for the Microbiological Section. There is also an animal house on the factory premises with rooms for the Division's colony of experimental animals as well as for pyrogen testing.

Staff

The following categories of staff are employed in the Quality Control Department: senior officers with university degrees, and junior officers with primary school (O level) or secondary school (A level) certificates.

At the time of the arrival of the expert, the staff was as follows: 2 pharmacists, 1 biochemist, 1 biologist and 3 junior officers employed as laboratory technicians.

The senior officers represented a fairly good professional standard. Technically trained personnel were not available. O and A level entrants to the laboratory had to be given training in the basic principles of a wide range of analytical techniques.

The staff of Quality Control Department now consists of 26 persons: 6 senior officers (an additional microbiologist has been employed, and one pharmacist is performing his year of National Service at the factory), 14 technicians, 2 operators, 2 labourers and the animal-house keeper and his assistant.

During the past three years, five junior officers, already fairly well trained, left the laboratory to continue their studies within Ghana or travelled abroad on scholarships.

Training was mainly done on the job and was continued for the whole period of the project in connexion with new equipment and new methods of analysis of drugs, which were introduced into production.

Members of the senior staff were sent to attend local and overseas courses. Two persons finished a one-month refresher course, organized locally by the Management, Development and Productivity Institute. One pharmacist completed the half-year course in management of quality control organized by UNIDO in the Netherlands. Another pharmacist attended the course in pharmaceutical technology organized also by UNIDO in Belgium.

Staff has been instructed in work safety and hygiene and in first aid.

To control the problem of environmental pollution, which is increasing in Ghana, instructions for the disposal of chemicals used in the laboratory have been issued. The recovery of organic solvents used in the laboratory has been introduced.

To broaden the professional theoretical knowledge of the staff, suitable books and periodicals were ordered and partially acquired with financial assistance from UNDP.

It should be pointed out that the staff of the Quality Control Department are now adequately trained to manage and operate the laboratory themselves.

In addition to training for their own staffs, the Production Department and Quality Control Department have introduced training for students from the Pharmaceutical Faculty of the University of Science and Technology at Kumasi and for secondary-school leavers. This training is offered every year.

Activities related to upgrading quality control

As the production programme of the factory was expanded to meet the pharmaceutical requirements of the country, the Quality Control Department found it necessary to introduce a double-shift system in its Analytical Chemical Section to cope with the increased work-load.

C. Maintenance

Maintenance procedures at the arrival of the expert

The machines that were originally installed in the factory were few and mainly Hungarian, but there were also a few Italian and Danish ones. They were of old types and operated at very slow speeds.

It was very difficult to obtain spare parts, as the manufacturers no longer produced these machines or parts for them. As a result of the slow speeds of the machines, their rates of production were low. It was therefore necessary to order new and faster machines with available spare parts.

In 1971 there were only twelve people in the Maintenance Department. Their designations were as follows:

1 Foreman	2 Automobile mechanics
2 Electricians	1 Welder
1 Plumber	1 Painter
2 Carpenters	2 Boiler mechanics

There were no qualified or properly trained technicians to maintain the production machines. The two automobile mechanics, who had been long associated with the production machines, were trying to maintain them. There was no plan for the purchase of spare parts, of which there were just a few in stock. This situation was attributable to the fact that no one was qualified to select the needed items. Also, there was no record of what work had been done on any of the production machines.

Training and staff

Trained plant maintenance technicians and electricians were employed and given further on-the-job training. This was necessary because technicians trained in the repair and maintenance of pharmaceutical machinery were not available. The training programme that was carried out under this new system has raised the standards and skills of the various workers and improved their efficiency. The maintenance staff have now gained the confidence and respect of management, and their importance and contribution in the industry are

accepted and appreciated by all concerned. In order to get the best possible technicians for the factory, only applicants with at least two years of training in a technical institution are selected for the Maintenance Department.

In 1975, the staff of the Maintenance Department consisted of 34 technicians as follows:

2 Supervisors	1 Machinist
2 Injection technicians	1 Welder
4 Distillation operatives	3 Automobile mechanics
3 Tabletting technicians	1 Automobile electrician
3 Boiler mechanics	4 Carpenters
2 Plumbers	2 Painters
3 Electricians and 2 Apprentices	1 Mason

The staff of the Maintenance Department are adequately trained to manage and operate all of the present machines and to manage and operate the new ones that will arrive in the near future. Maintenance staff have also been instructed on industrial safety and fire-fighting.

Operation and maintenance of machinery and equipment

Under the guidance of the maintenance engineer, a system has been established to record information on the maintenance of the machines and on the performance of the maintenance staff. Plant cards, consisting of plant-registry history cards, have been prepared for each machine. When new machines are installed, operatives are trained on them. With some of the more complicated ones, operating and maintenance instructions are clearly written on the machines themselves. Report books have also been provided for the technicians in which to record all work carried out during their shifts on any of the production machines. Extracts from these report books are entered on the plant history card. The kind of preventive maintenance required, covering inspection, as adjustments and replacements, are written on the plant card. While this system did not operate smoothly at first, it now functions well and systematically.

A programme for the mechanical and electrical maintenance of all equipment has been established and has been operating successfully over the last three years. Since the beginning of 1975, a master preventive maintenance chart has been introduced, covering the maintenance of all production machines and their

auxiliary equipment as well as the machines in the workshops. The schedule embraces all types of maintenance: daily, weekly, monthly, quarterly, semi-annual and annual, including overhauls of the machines. This schedule is followed in the identical manner for each machine every year, except in cases of overutilization or underutilization. In such cases, the schedule is amended in a suitable manner.

Machines and equipment presently in use

The power house of the Pharmaceutical Division has two stand-by generator sets, each with a capacity of 250 kilovolt amperes. They had stood idle since 1967 because they were in a state of disrepair. In December 1974, they were restored to working condition and are now used whenever there is a power failure at the mains.

In the Production Department, mainly the Tabletting Section, all six of the air-conditioning compressors had been burnt out. In the Injection Section, two of the four compressors were also burnt out. New compressors have since been ordered and installed. The cause of the burning-out of these compressors was investigated, and it was found that the existing capacity of the cooling tower was insufficient for the air-conditioning system in the factory. It has been suggested that another cooling tower be built and coupled to the existing one. This plan has been approved and will be implemented.

A part of the ground floor that originally had been used for stores has been converted into the Packaging Section, and, with the increase in the cooling load caused by packaging machinery and its staff, two new air-conditioning units have been installed. This increase has also contributed to the need to build the new cooling tower. So that the state of the air-conditioning units can be known at all times, a maintenance record sheet has been designed for the proper maintenance of all the air-conditioning units in the factory.

There are two fully automatic Henschel rapid steam boilers (types HK 650 and 750), a feed-water tank and two hot-water tanks in the boiler house. The latter supply hot water to the factory, canteen and laundry. This equipment has been functioning satisfactorily, since it is well maintained.

The kitchen equipment, which includes electric cookers, mixing equipment etc., also functions properly since it is well maintained. There is one cold

room and one deep-freezer room; their condensing units, which had not been functioning, have been replaced and the new ones are working very well.

The factory has a laundry equipped with the following machines: a washing machine, a hydro-squeezer, a drier and a sterilizer. All of them have been used successfully, but the washing machine must be operated manually in the absence of the automatic programmer that controls its operation automatically. A new one is on order, but it took a long time to identify its manufacturer (it is of an old type), and delivery was still awaited as this report was being written. The sterilizer is not really required in the laundry, and a recommendation has been made to management to consider its removal to the Injection Section, where it would be more useful.

The division has its own sewage-disposal plant, which had not functioned well for a long time. The pumping system has been changed and it now operates efficiently.

Some of the machines have been modified either to adapt them to production requirements and improve their performance or because of the lack of spare parts for machines of old design. For example:

A new Bonapace autoclave originally imported for the line of intravenous infusions has been modified to suit the production of ampoules

Three compressing machines manufactured by DIAF (Denmark) have been modified to carry on production since neither these machines nor parts for them are any longer being manufactured

Transport

The division has a fleet of 20 vehicles, comprising the following:

- 3 Peugeot 404 automobiles
- 1 Peugeot 504 automobile
- 2 Volkswagen automobiles (one Beetle and one Variant)
- 2 Datsun pick-ups
- 1 VW van
- 1 Mercedes-Benz van
- 1 Audi 80 automobile
- 4 Buses, (2 Commer, 1 Bedford and 1 Mercedes-Benz)
- 3 Trucks (1 Morris, 1 Austin, 1 Bedford)
- 1 Tractor
- 1 Fork-lift

In order to simplify the spare parts problem, it was decided to reduce the different makes of the vehicles to a few standard ones but, owing to the unavailability of some models, this decision could not be implemented.

A preventive maintenance programme for these vehicles has been drawn up in the workshop of the division. For major overhauls, however, the vehicles are sent to the representatives of their manufacturers. A separate workshop for vehicle maintenance is under construction. A chart has been designed to record the fuel and oil consumption of each vehicle so as to provide reliable information on its performance.

II. RECOMMENDATIONS

A. Production

Construction of the new main warehouse should start as soon as possible. The preparatory work on this building has been done; the drawings are ready and the ground has been tested.

Co-operation with foreign construction companies that specialize in the pharmaceutical field should be established so as to expedite the building programme for the new production unit.

Adaptation of air-conditioned parts of the new main warehouse for expansion of the Tabletting Section should be considered only if funds for the construction and for equipment and machinery for a new production unit should not be available.

Advantage should be taken during the time required to complete these two buildings to send young pharmacists for overseas training to gain on-the-job experience in the production and analysis of a new dosage form of drugs which will be manufactured in the future.

A separate Research and Development Section should be organised to work on formulae for new products and on improving the stability of drugs in tropical climates with high relative humidities.

Constant co-operation with the Faculty of Pharmacy of the University of Science and Technology in Kumasi and with Korle Bu Teaching Hospital in Accra should be organized to help the division in research and development and in collecting clinical data on the drugs that it manufactures.

Refresher courses for senior pharmacists should be offered at least every two years.

Increased attention should be paid to the quality of packaging materials for use in tropical climates. There is general agreement that there should be a continuing programme to solve this problem.

The Tabletting Section should be gradually equipped with fluid-bed spray granulators to avoid the need to import granules ready for compression.

The Injection Section should be additionally equipped with a complete new production line to process reduced-vacuum closed ampoules. Such a line would permit further increase in the productivity of this section and reduce the proportion of rejects. The sterilizer now installed in the laundry is not really needed there and should be removed to the Injection Section.

In order to earn some foreign exchange, the Pharmaceutical Division should try to develop export programmes for drugs already manufactured or that will be produced in the near future. More sophisticated drugs should be chosen for the beginning, for example, some plain and film-coated tablets, capsules and vials.

In order to avoid the further migration of trained pharmacists from the division to private pharmaceutical companies, the management of GIHOC should create some incentives and revise the salary system to minimize differences in wages between comparable posts in the GIHOC Pharmaceutical Division and similar pharmaceutical enterprises in Ghana.

B. Quality control

Advantage should be taken of the time needed for the completion of the new production unit to send members of its staff for overseas training to acquire on-the-job experience in the production and analysis of new drug formulations.

A Development Department should be organized as soon as possible to work on further improvement of existing product formulae and development of new ones. Preferably, this department should be situated not far from the Quality Control Department so as to enable their staffs to share the use of costly analytical equipment.

The seven-year development plan does not provide for any enlargement of the laboratory. Consequently, two small investments should be considered:

(a) A separate store (situated at a safe distance from the factory buildings) should be built as soon as possible for bulk quantities of inflammable and explosive chemicals;

(b) The Microbiological Section should be expanded by at least two rooms:

(i) A special room for the membrane filtration method, supplied with filtered air at a pressure higher than in adjacent areas;

(ii) A specially designed room for autoclaves with surrounding solid walls that would provide complete protection for the operator.

Increased attention should be paid to packaging materials, which at present are inadequate for tropical climates. Improvements would improve the stability of the drugs produced.

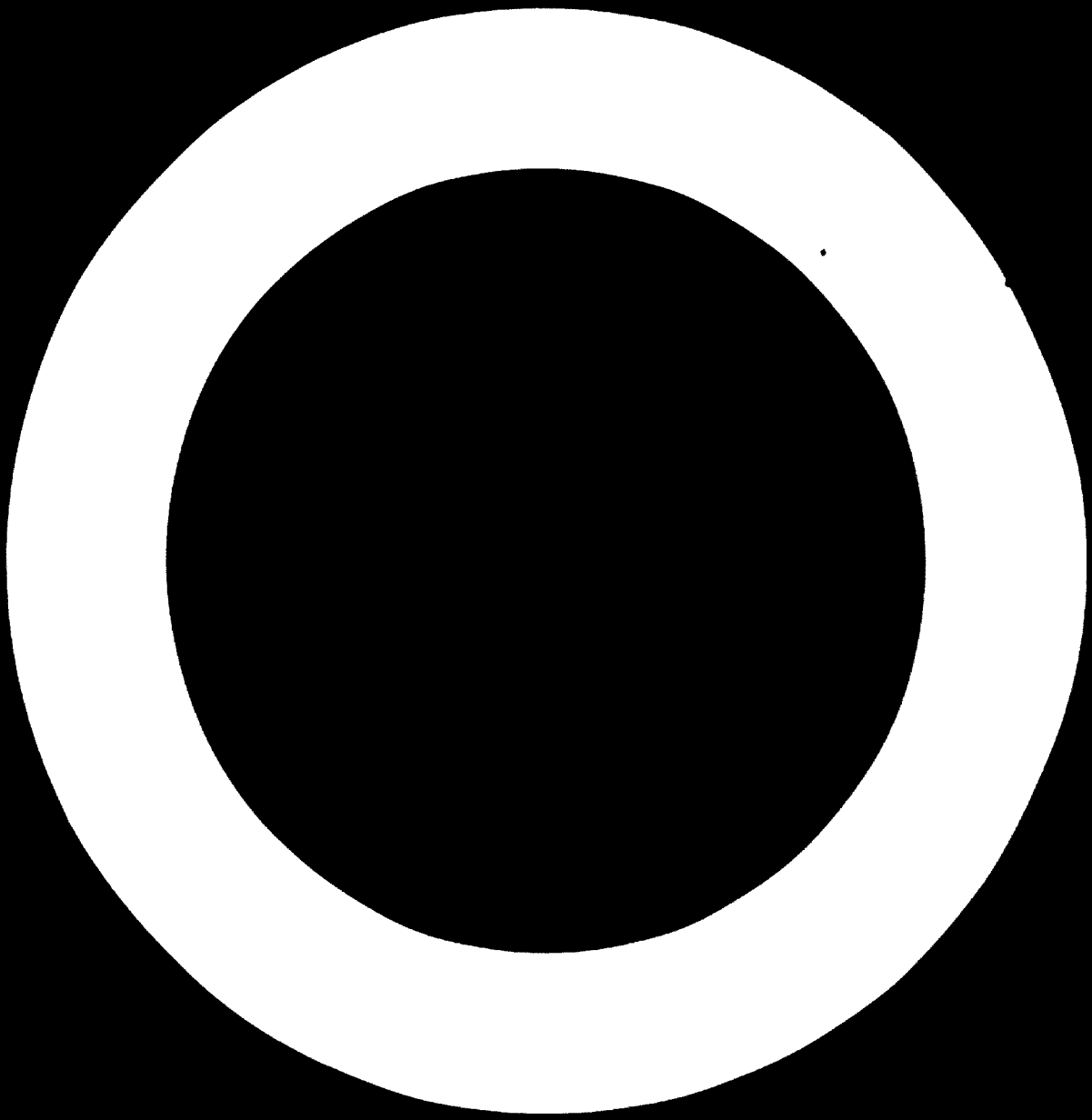
It would be advisable to organize, in co-operation with the Faculty of Pharmacy of the University of Science and Technology in Kumasi, periodical consultations concerning more complicated problems.

C. Maintenance

Advantage should be taken of the time needed to complete the new production unit to send staff members for overseas training to gain on-the-job experience in the operation and maintenance of the new machines, especially in planned new fields such as syrups and ointments.

The volume of the maintenance work has increased so much that there is a need to employ another engineer to take over the Maintenance Department when the present engineer is away.

In order to produce as many spare parts as possible in the factory's workshop, it is necessary to equip the existing machines fully with the appropriate accessories. For example, the universal milling machine should be equipped with all the milling cutters, and mills and gear cutters. The ventilation in the Tabletting Section should be modified, but since a new Tabletting Department is to be put up soon, and since modification would be rather more expensive, it has been recommended to incorporate this modification in the design of the new installation. The sewage disposal plant is very old and has been breaking down very often. It is therefore recommended that a new one be installed as a stand-by.



Annex I

INTERNATIONAL STAFF OF THE PROJECT

Name	Job title	Dates of service
J. Surowiecki	Production Manager	May 1971 to June 1975
W. Grzegorzewicz	Quality Control Adviser	January 1972 to January 1975
H. Abdel-Kader	Maintenance Engineer	May 1972 to May 1975

Annex II

NOTICE TO IMPORTERS NO. 574 - IMPORTATION OF DRUGS - RESTRICTION OF

Tablets

Acetylsalicylic acid (300 mg)
Acetylsalicylic acid compound (APC)
Ascorbic acid (100 mg)
Aluminium hydroxide (500 mg)
Bisacodyl 10 mg
Butobarbitone (100 mg)
Chloroquine phosphate (250 mg)
Chloroquine sulphate (200 mg)
Codeine compound
Calcium with vitamin D
Diazepam (3 mg)
Diazepam (5 mg)
Diethylcarbamazine citrate (50 mg)
Ephedrine hydrochloride (30 mg)
Ephedrine hydrochloride (60 mg)
Ergometrine maleate (0.5 mg)
Folic acid (5 mg)
Furomide (40 mg)
Griseofulvin (microsize) (125 mg)
Metronidazole (200 mg)
Paracetamol(500 mg)
Phenobarbitone (30 mg)
Phenobarbitone (60 mg)
Phthalylsulphathiazole (500 mg)
Prednisolone (5 mg)
Reserpine (0.25 mg)
Sulphadimidine (500 mg)
Sulphamethoxypyridazine (500 mg)
Triple sulpha
Tolbutamide (500 mg)
Thiacetazone and isoniazid
Vitamin B complex (Aneurin Compound) plain

Injections

Atropine sulphate (0.6 mg/ml)
Adrenalin hydrochloride (1 mg/ml)
Aminophylline (25 mg/ml)
Chloroquine diphosphate (50 mg/ml)
Ergometrine maleate (0.5 mg/ml)
Mihethamide (250 mg)
Vitamin B_1 (5 mg)
Vitamin B_1 (25 mg)
Vitamin B_1 (50 mg)
Water for injection (5 cc)
Water for injection (10 cc)

Annex III

DRUGS PRODUCED BY THE PHARMACEUTICAL DIVISION OF GIHOC

Tablets

Aluminium hydroxide
Ampicillin
APC (aspirin, phenacetin, caffeine)
Ascorbic acid (50 mg, 100 mg)
Aspirin (acetylsalicyclic acid)
Bisacodyl
Butobarbitone
Codeine compound
Calcium with vitamin D
Chloroquine phosphate
Chloroquine sulphate
Diehthylcarbamazine citrate
Diazepam (2 mg, 5 mg)
Ephedrine (30 mg, 60 mg)
Ergometrine maleate
Ferrous fumarate
folic acid
Furesemide
Griseofulvin
Guanethidine
Isonianid
Metronidazole
Nalidixic acid
Nitrofurantoin
Paracetamol
Phenobarbitone (30 mg, 60 mg)
Phenoxymethyl penioillin (125 mg, 250 mg)
Phthalysulphathiazole
Prednisolone
Sulphadimidine
Sulphaguanidine
Sulphamethoxypyridazine
Thiacetazone and isoniazid
Tolbutamide
Trisulphonamide
Vitamin D complex

Capsules

Chloramphenicol
Tetracycline hydrochloride

Ampoules

Adrenalin hydrochloride
Aminophylline
Atropine sulphate
Chloroquine diphosphate
Ergometrine maleate
Morphine sulphate
Nikethamide
Pethidine (50 mg, 100 mg)
Vitamin B_1 (5 mg, 25 mg, 50 mg)
Water for injection (5 cc, 10 cc)

Annex IV

LABORATORY EQUIPMENT IN THE QUALITY CONTROL DEPARTMENT

Analytical-Chemical Section

1 Spectrophotometer (Unicam SP-500)
2 pH-Meters
1 Refractometer
1 Polarimeter
1 Fluorimeter
2 Drying ovens
1 Vacuum-drying oven
1 Vacuum pump
3 Technical balances (Student)
5 Analytical balances (Mettler)
1 Melting-point apparatus
1 Centrifuge (2 tubes - 10 cc)
3 Disintegration testers
2 Friabilators
1 Refrigerator
1 Kjeldahl apparatus (distillation stand)
1 Shaker
1 Dissolution tester
2 Water-baths (six places)
2 Magnetic stirrers
Equipment for thin-layer chromatography
1 Automatic pipette-washer
1 Titrator (Karl Fischer) - on order
Equipment for column and paper chromatography - on order

Microbiological Section

1 Incubator (1H-100)
1 Cooled incubator (1H-270)
2 Water-baths (Unitemp)
1 Refrigerator
2 Drying ovens
1 Dry-heat sterilizer
1 Colony counter
1 Autoclave (a second one is on order)
1 Microscope
1 Vacuum pump
1 Centrifuge - on order
1 Weigh balance - on order
Equipment for membrane filtration - on order

Pyrogen Section

1 Automatic temperature recorder
1 Pyrogen-testing thermometer
Metal cages for rabbits (made locally)

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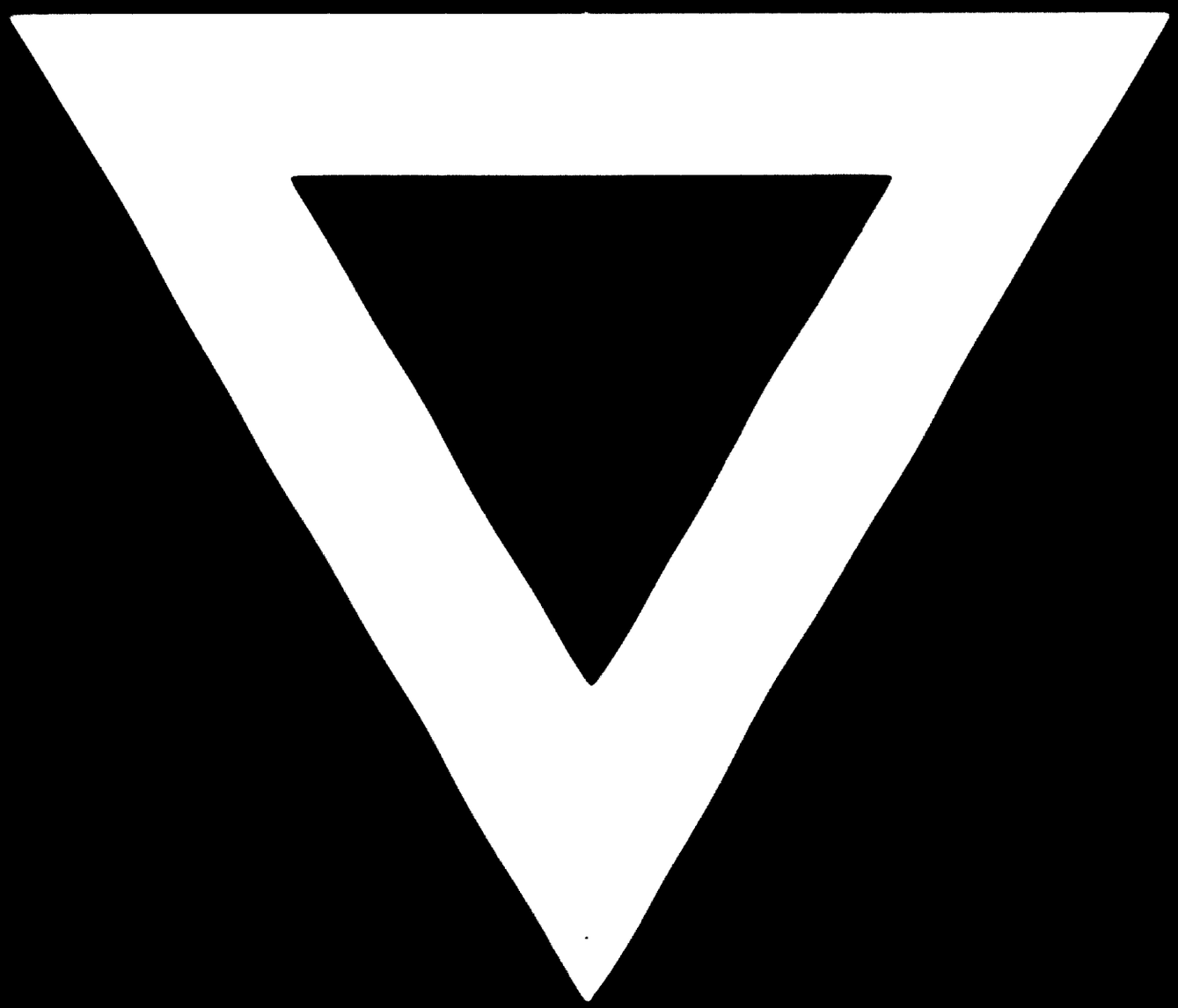

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