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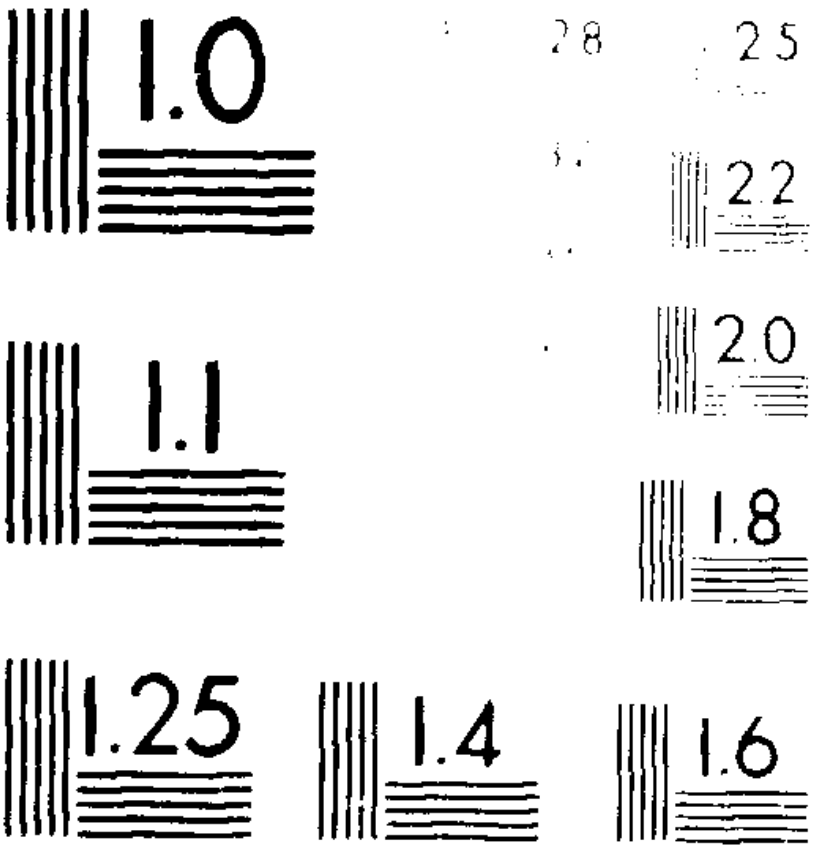

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REPORT OF A MISSION TO

TRINIDAD, BARBADOS AND THE USA

6-21 FEBRUARY 1985

(Pharmaceutical Industry).

by

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TRINIDAD AND TOBAGO

Background

At present, the only pharmaceutical company producing in Trinidad is Sterling Winthrop. Pharmaceutical imports in 1984 amounted to a value of US$ 37.5 million, of which antibiotics accounted for US$ 5.6 million. The main countries from which pharmaceutical products are imported are the United Kingdom, United States of America, Canada, Federal Republic of Germany and Switzerland, as well as Barbados, Jamaica and Puerto Rico.

The Plant

The inactive pharmaceutical plant that the consultant inspected (see Terms of Reference at Annex III) is situated about 20 km from the capital Port of Spain, in an industrial zone. The site had been rented from the Government by a private entrepreneur. Production started in 1982, but was discontinued as installed capacities were too large for the local market and there were no prospects for exports. Price Waterhouse, Port of Spain was appointed receiver.

The consultant visited the plant together with a representative of Price Waterhouse, Mr. Herde, and the Senior Industrial Development Field Adviser, Mr. Ryan. It is a flat-roofed, one-storey building, without windows or a basement. It is in good shape, having been under guard and kept up since the shutdown. The interior space is about 2,000 square meters; the whole area is about 10,000 square meters.

The production machines are located in separate rooms; the location of the specific production areas allows for efficient material flows. Walls and floors are even and easy to clean.

The following are the functional areas of the plant:

- Drug formulation
  - plain and film-coated tablets
  - liquids and ointments
  - capsules
- Packing
- Quality control
- Warehouse and quarantine
- Offices and canteen.

The entire building is equipped with air conditioning and humidity control systems. Exhaust systems have been installed in the cabins of the production machines.

Utilities available are: electricity from the public grid; steam from the plant's boiler; compressed air from the plant's compressor; and demineralized and distilled water from the plant's own production.

Annex I lists machinery meeting advanced standards as regards function and capacity. Annex II lists the machines that are somewhat sub-standard. The age of the machinery is 5 to 10 years; it is in good condition, equipped with all the necessary utilities, and ready for operation.

The laboratory's size and equipment are appropriate for all the operations normally carried out on raw materials, bulk drugs and finished products.

Technical Aspects

The plant's most advanced equipment as well as its main capacity are geared for the production of solid dosage forms - plain and film-coated tablets and hard gelatin capsules. The products of this type will be of high quality. Production capacity for liquids and ointments is more limited, and the equipment standards for these products is mediocre.

Packaging conforms with standard U.S.A. practices (the drugs are filled in bottles, which are sealed and labelled). If export to Europe is envisaged, equipment will have to be upgraded and the following investments should be earmarked:

	Estimated cost
1 generator (power breakdown)	US$ 30,000
1 high speed tabletting machine	US$ 70,000
1 high speed capsule filling machine	US$ 100,000
2 blister packing machines (for European exports)	US$ 200,000
	US$ 400,000

With the above level of investment in mind, the following annual capacities of products that comply with standards prevalent in Europe and the United States of America should be anticipated:

Plain and/or film-coated tablets:	500 million
Hard gelatin capsules:	150 million

Packing capacity should reach 5 to 10 million units annually. Annual gross sales are expected to be in the range of US$ 10 to 20 million.

FDA approval of the technical requirements for such a production can be expected. Additionally, it stipulates:

- qualified production and control managers
- trained staff
- production know-how and R+D results (e.g. bio-availability studies, stability data, etc.)
- material flow organization
- production documentation
- quality control system

Commercial Aspects

The consultant met with Mr. Richardson Andrews, General Manager of the Industrial Development Corporation (IDC) to discuss the framework of the project. The IDC is interested in either a joint venture operation, management contract, sale or leasing of the plant. For an existing plant such as this, no definite legislation has yet been formulated with regard to financial incentives. Therefore, aspects such as ownership, tax holidays, duty-free imports of raw materials and profit repatriation have still to be worked out in negotiations.

The plant (building and machinery) is valued at about US$ 3 to 4 million, whereas its commercial value depends to a large extent on the financial framework to be approved by the Trinidad Government.

Export to the European Economic Community (EEC)

The Caribbean is associated to the EEC by the Lomé Convention. In principle, therefore, duty-free imports from the Caribbean are possible.

Export to the United States of America

The Caribbean Basin Initiative (CBI), supported by the United States of America, has been in operation since 1984, with a mandate for at least 12 years. The preconditions for duty-free imports into the United States of America are that:

1. An article must be imported directly from a beneficiary country;
2. The cost or value of the article must consist of at least 35 per cent direct cost of processing in one or more beneficiary countries (components made in the United States of America may comprise 15 per cent of this percentage, leaving 20 per cent value-added in beneficiary countries); and
3. A product including foreign components must be substantially transformed into a "new and different article of commerce" in one or more beneficiary countries.

See page 7 for more details on the CBI.

BARBADOS

Barbados' pharmaceutical market is smaller than that of Trinidad and Tobago. Due to the limited size of the market, no transnational pharmaceutical company has set up operations in the country.

Collins Ltd.

The sole pharmaceutical producing company in the country is a private enterprise, Collins Ltd., owned by Mr. P.H. Bourne. The consultant visited the enterprise, accompanied by the SIDFA, Mr. Ryan. The plant appeared to be run efficiently and meets local standards and requirements as far as the building and technical equipment are concerned. On the other hand, production does not meet FDA standards; there is no quality control of the raw materials or in-process control, with control of the finished products done in the United Kingdom.

The plant produces plain and coated tablets, hard gelatin capsules, ointments and liquids. The most efficient equipment, with considerable excess capacity, is for the production of liquids (about 1.5 million units annually). This excess production could be exported to the European Economic Community or to other Caribbean countries. In principle, Mr. Bourne would be interested in a joint venture or similar arrangement.

Industrial Development Corporation

The consultant met with the Deputy General Manager of IDC, Mr. Harding. The proposal for the creation of a joint venture based on the excess capacity from Collins Ltd. was discussed. Mr. Harding explained that a joint venture may enjoy 10 years' tax holiday if the following conditions were met:

- A new firm must be founded to rent the excess capacity.
- Products not produced by Collins Ltd. should be introduced.
- Production should be for export only (in this case there would also be a 10 per cent refund of import taxes)
- Investments in new equipment should be made.

IMPORT AND DISTRIBUTION OF CARIBBEAN-PRODUCED PHARMACEUTICALS IN THE UNITED STATES OF AMERICA

The enactment of the Waxman legislation simplified considerably the registration of safe and efficacious pharmaceuticals in the United States of America. The procedure can be compared to the German practice of "bezugnehmende Zulassung". The regulation resulted in a boom in the generic drugs market (with sales of US$ 800 million that year) and contributed to rises in the costs of the public health system. This development was compounded by the relatively low social security benefits in the country, leading to increased consumer interest in high quality generics at lower prices than brand name equivalents.

The marketing of generic products is the almost exclusive domain of the distributors. A few distributors also manufacture part of their product range. Normally, a distributor offers a product range that includes the whole spectrum of generics, based on contracts with drug manufacturers (several or one). Every one to two months the distributor mails his catalogue to an average of 50,000 customers (private drugstores or drugstore chains). Customers are contacted by telephone about once a month for their orders (known as "telemarketing"). Customer lists are computerized, and information such as amount and time of sales, amount and type of products ordered, etc. is recorded. This retailing system is cheaper than its European equivalent.

The consultant was able to meet with two distributors:

- Mason Distributors Inc. (President: Carlos J. Rodriguez)
- Gulf Coast Drug Supply Inc. (President: Robert M. Pollack).

Caribbean Basin Initiative (CBI)

In Washington D.C., the consultant met with the following persons involved with the CBI:

P. Unruh, Deputy Assistant Secretary, Department of Commerce
L.H. Theriot, Director of the CBI, Department of Commerce
Mr. Food, Customs Administration

The Government of the United States of America strongly supports the CBI programme, aimed at the economic strengthening of the Caribbean region. Since the programme took effect, considerable trade increases have been achieved, and it seems likely that the CBI will be extended beyond its original term of 12 years.

The three essential conditions for qualifying for duty-free imports into the United States under the CBI are:

1. Direct import from a beneficiary country;
2. Substantial transformation of a product into a "new and different article of commerce"; and
3. The cost or value of the article must consist of at least 35 per cent direct cost of processing in one or more beneficiary countries; imports from the United States of America can comprise up to 15 per cent, leaving 20 per cent value added from beneficiary countries.

Based on their detailed examination of every individual product (and not an entire product range), Customs authorities decide whether the intended import qualifies under the CBI. Their decision is binding for the duration of the programme as far as 2. above is concerned. Value added aspects may, however, be re-examined, as wages, costs of raw materials and prices of the final product can change. The Customs authorities usually take great care to ensure that the CBI is not used as a pretext for more or less direct exports from Europe or Japan.

A pharmaceutical production in the Caribbean which would conform to the requirements of the CBI would be one in which:

- Active ingredients, auxiliaries and packaging materials are imported into the Caribbean from the United States of America or another country. Only the following materials and products are available locally in Caribbean countries: sugar, alcohol, glass and plastic containers, labels, leaflets and cartons.

- Raw materials are processed into tablets (plain and coated), capsules, liquids or ointments, and exported as packaged medicaments.

A pharmaceutical project in line with the above would conform with the requirement for substantial transformation as well as for new and different articles of commerce.

The value added aspect of CBI's requirements could present some difficulties, as active compounds cannot be bought in the Caribbean. In some cases, the active compound can be expensive and therefore take up too high a proportion of the finished product's value. The consultant discussed the kind of costs contributing to value added with Mr. Food of the Customs Administration. These comprise:

- Imported materials from the United States of America, where these represent 15 per cent of the product's value. In this case, value added could be reduced from 35 per cent to 20 per cent;
- Direct production costs (wages);
- Auxiliaries from the Caribbean;
- Normal material losses during production, even if these materials do not originate in the Caribbean;
- Production overheads (production manager, supervisors, etc.) (proportional share of each product);
- Chemicals for quality control;
- Wages for quality control;
- Overheads for quality control (proportional);
- Maintenance overheads (proportional); and
- Utilities (proportional).

The following costs do not contribute to value added:

- Storage costs;
- Administration and marketing costs;
- Provisions;
- Shipping costs; and
- Insurance.

It will be easier to distinguish between proportional costs and value added if the plant's administration and marketing operations are kept separate from production. Further, the plant should produce only for export to the United States of America and total costs should be reduced proportionately for products sold on the local market or for export to Europe.

Food and Drug Administration (FDA)

All foods and medicines manufactured in or imported into the United States of America are subject to approval by the FDA, which inspects manufacturers' facilities, tests products, establishes standards, approves licences of manufacturers under its jurisdiction and establishes labelling policies. Because of its high standards, it is respected by the United States consumer, and therefore generic medicines - which undergo the same rigourous examination as brand name drugs - have found wide acceptance by the population.

Foreign companies must meet the same requirements for product registration as United States companies. Two additional requirements for imported pharmaceuticals are (1) customs quarantine and a quality statement by an independent laboratory approved by the FDA and (2) examination of three batches per year under stress stability conditions.

CBI Meeting at Stuttgart, Federal Republic of Germany

The United States Department of Commerce, GTZ and the UNIDO Investment Promotion Service in Cologne organized a one-day meeting on 21 March 1985 in Stuttgart to promote investments in the Caribbean. Although competent representatives from the United States of America and the Federal Republic of Germany presented the advantages to be gained from partnerships in the Caribbean, little interest was shown by German and Swiss industrialists attending the meeting. Discussions with panel members and other persons attending revealed that there is no information available beyond that reported above.

CONCLUSIONS

1. On the basis of the Lomé Convention and the Caribbean Basin Initiative, a pharmaceutical plant in the Caribbean could produce for duty-free export to the European Economic Community and to the United States of America, as well as for the local and regional markets, thereby reaching essential segments of the world market.

2. Collins Ltd. in Barbados would be a viable partner for a joint venture for the production of liquid medicines for export to the European Economic Community and other Caribbean countries only. The firm is well organized and fully operational.

3. The reactivation of the pharmaceutical plant in Trinidad is attractive, especially for European pharmaceutical manufacturers seeking to export generic medicines to the quickly expanding United States market. The plant can go into operation at any time and can be rented without a risk of investment. However, prior to a final decision by the foreign partner, favourable conditions have to be negotiated with the Government of Trinidad.

ANNEX I

PHARMACEUTICAL PLANT IN TRINIDAD: MACHINERY MEETING ADVANCED STANDARDS

Quantitiy	Equipment Name	Manufacturer	Model
1	Fluid Bed Spray Granulator	Glatt	WSG-60
1	Fluid Bed Spray Granulator	Glatt	WSG-5
1	Film Coating Unit	Glatt	Wurster 18''
1	Film Coating Unit	Glatt	Wurster 6''
1	Tabletting Machine	Fette	Perfecta 2000
2	Dust Extractors	Torit	64
1	Twin Shell High Speed Blender	Patterson-Kelly	20 cu.ft.
1	Twin Shell High Speed Blender	Patterson-Kelly	10 cu.ft.
2	Automatic Dedusting & Polishing Machine	Erweka	KEA
1	Tablet Counter	King	TB-4
2	Tamper Proof Sealer	Fasson	Roll:P.S.
1	Capper	Resina	S
1	Scale 250 Kg.	Toledo	#2181
2	Scales 100 Kg.	Toledo	#2081
1	Scale 20 Kg.	Toledo	#3180
1 set	Tablet Tooling	Fette	

ANNEX II

PHARMACEUTICAL PLANT IN TRINIDAD: MACHINERY NOT MEETING ADVANCED STANDARDS

Quantity	Equipment Name	Manufacturer	Model
1	Tabletting Machine	Stokes	BB2-27
1	Tabletting Machine	Stokes	511
2	Capsule Filling Machine	Elanco	#85
1	Liquid Filling Machine	National	Filmatic DAB 16-2
1	Tablet Counter	Fairchild	27A
1	Strip Packaging Machine	Seibler	90/10
2	Labeller, Sealer	Auto Labe	Roll:P.S.
1	Filter Press	Ertel	EPS-B 6DV
1	Fitz Mill	Fitzpatrick	DASO-6
1	310 Gal S.S. Tank	Ertel	Jacketted 40 PSI
1	310 Gal S.S. Tank	Ertel	Plain
1	Agitator	Ertel	3BG-3/4 HP
1	Turbine Homogenzer	Ross	50 Gal.
1	50 Ga. Jacketted Kettle	Lee	Style D
1	Capper	Resina	RU 120
1	Capper	Newman	BS5000/11
2	Conveyor Plate/ Variable Speeds	Tri-Corp	18'
1	Unscrambler	Andora	-
1	Fork Life	Hyster	SA200
4	Stock Pots	Ertel	5x10 Gal.
1	Envelope Catch Covers	Seibler	Type 13
1	Cottoner	Lasko	#52
1 set	Tablet Tooling	Elizabeth Carbide	-
1 set	Capsule Change Parts		0,1,3&4
1 set	Stainless Steel Processing Sinks		-

ANNEX III

TERMS OF REFERENCE

The consultant will visit Port-of-Spain from 6 - 8 February 1985 on behalf of the Investment Co-operative Programme to assist the Trinidad and Tobago Development Finance Company in the establishment of a potential large joint venture for pharmaceutical and chemical products in Trinidad, as a follow-up on the Barbados Investment Promotion Meeting held last autumn, and for consideration for IFC financing. The consultant will

1. a) assess an existing plant in Trinidad. The plant has never been operational;

   b) determine the value of the existing equipment; determine the generic products which could be produced with the equipment available;

   c) identify groups of generic products which could be produced for export to other Caribbean countries and the USA; determine the additional equipment needed and give a cost estimate of such additional equipment;

2. assess the possibilities of expanding an existing small pharmaceutical company in Barbados by means of a joint venture for large-scale production of pharmaceutical generic products for export to other Caribbean countries and the USA;

3. Determine practical ways to commericalize future production of pharmaceuticals in either of the two plants for export mainly to the USA; he will discuss this issue with the International Trade Centre, Washingon;

4. Discuss the project with specialized companies in the USA such as Generics in Fort Lauderdale, as a potential partner in the joint venture.

5. Inform about the rules and regulations governing imports of pharmaceutical products produced in the Caribbean into the USA under the Caribbean Basin Initiative. To this end he will contact the Caribbean Basin Initiative in Washington and the Food and Drug Administration, also in Washington.

6. Write a comprehensive report on items 1 - 5 above and make recommendations regarding the production of generic products at either of the two plants visited.