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ANALYSIS OF MEDICAL DEVICES AND DISPOSABLES MANUFACTURING AND EXPORT POTENTIAL IN THE DOMINICAN REPUBLIC

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ARONYMS

AAGR	Average Annual Growth Rate
ABT	Administrative Barriers to Trade
ADOZONA	Asociación Dominicana de Zonas Francas, Inc.
BID	Banco Interamericano de Desarrollo
Business devel.	Program to develop Foreign Direct Investment
CEI- RD	Centro de Exportación e Inversión- República Dominicana
CBI	Caribbean Basin Initiative
CITD	Center for International Trade Development
CMS	Center for Medicare and Medicaid
CNC	Consejo Nacional de Competitividad
CNZFE	Consejo Nacional de Zonas Francas de Exportación
CPI	Center for the Promotion of Imports from Developing Countries
EU	European Union
FDA	Food & Drug Administration- Regulatory body for the MD and MS Industry
FDI	Foreign Direct Investment
FTZ	Free Trade Zone
GNI	Global National Income
GPO	Group Purchasing Organization; Hospital buying group; Buying Cooperative
HS	Harmonized System
IDB	Inter American Development Bank
IFC	International Finance Corporation
INFOTEC	Instituto Nacional de Formación Técnico Profesional
IPP	Intellectual Property Protection
IV	Intra Venous
LCC	Local (Dominican Republic) capital company
MD	Medical devices; devices; medical apparatus, equipment, machines
MNC	Multinational Corporation
MS	Medical supplies; medical disposables; disposables
Operadora	Company which owns and operates a Free Zone Park
PIISA	Parque Industrial Itabo, S.A.
R&D	Research and Development
SOW	Scope of Work
SWOT	Strengths, Weaknesses, Opportunities, Threats
UNCTAD	United Nations Conference on Trade and Development
US	United States
USAID	United States Agency for International Development Agencia de los Estados Unidos para el Desarrollo Internacional
USD	United States dollar
WTO	World Trade Organization

Executive Summary

Executive Summary

This study provides strategies on the medical device and disposables sector in the Dominican Republic, in the form of a S.W.O.T. analysis (strengths, weaknesses, opportunities, and threats). It presents to public sector and industry leaders a clear picture of where the Dominican Republic (DR) is positioned at this time to compete in the global market place. It outlines steps required to enhance this competitiveness at a macro level. It provides concrete steps that can be taken over the short run. Recommendations include strategies with specific initiatives to resolve near-term barriers to growth and set the stage for accelerating industry export development.

The Harmonized System (HS) Code 90 consists of seventeen pages with a listing in small print of products, raw materials and components covering many industries, including the medical devices, medical disposables, optical and photo industries. This study conducted research to isolate the industry and market segments that have the large size and growth potential that best fit the establishment of manufacturing plants in the DR.

The medical devices and disposables industry is massively large and has very good growth potential. The industry has large additional potential for manufacturing and exports from the DR.

Recommendation. The Dominican Republic should focus on attracting manufacturing companies in the medical devices/disposables industry. The program needs to also include the large segment of the devices/disposables industry which is classified in HS Codes beyond Code 90. The recommendation is that the focus of the country's efforts and programs not be diluted by attempting to simultaneously attract manufacturing companies in other industries covered in HS Code 90 Products.

Due to the nature of the other industries in HS Code 90, these industries have reduced potential compared to device/disposables. A focus on HS Code 90 industries beyond the large, higher growth devices and disposables industry potential may well hurt the Dominican Republic's competitiveness in drawing new manufacturing plants to the country, in that limited resources for industry attraction will be less focused and more fragmented.

The industry

The global, as well as individual country medical devices/disposables industry is highly segmented. It provides an estimated US\$80 billion manufacturing potential in the form of Cost of Goods Sold, the key line item of the products Profit & Loss Statements, which is what is generated by the plants in the Free Trade Zone Parks. (FTZs).

The industry is one of the higher technology industries globally. Investment in research and development (R&D) as a percentage of net sales is almost 7%. This contrasts with

R&D investments in most other global industries which have R&D investments that are closer to 1%. R&D is driven by the large need and potential for innovation.

The industry is highly regulated by public health agencies globally, as medical safety and efficacy are critical components of the industry. Device/disposables come into contact with the human body, and in many instances are inserted in the body. In order to ensure all products are free of contamination, manufacturing plants of these products generally involve high tech manufacturing processes which require higher capital investments.

Due to their nature, these plants need specialized skills, which translate to higher salaries and wages. Once high tech plants are established, the exit barriers are high and therefore most of the plants will have a long life in the country.

The market

The global market is estimated at US\$190 billion in 2004. The market is expected to grow at an estimated 7% per year. The market has some 6,000 competitors, just in the U.S. alone. It consists of multiple thousand products, many of which keep changing as innovations yield improvements. A specific company can make as many as 25,000 products. The product groups have different yearly growth rates, from 25% annual growth rate to almost flat.

The nature of the devices and disposables segments is quite different. Accordingly, most device competitors do not compete in the disposables segment, and most disposables competitors do not compete in the devices segment. The disposables segment generally accounts for over half the total market in currency terms in each country.

The market is primarily a hospital products market. This is followed by a physician specialties market and then a smaller consumer products market segment. The largest market segments as measured by the industry itself include areas such as cardiovascular devices, orthopedic devices, wadding, gauze, and bandages. The percentage breakdown of the global markets by countries is: USA 45%; Europe 27%, Japan 14%; Rest of World 14%. Two percent of the companies have an estimated 50% of the total global market.

Recommendation. A business development program to attract new manufacturing plants should be focused by company, not by product or product group. The reason is the vast diversity of products makes it challenging to talk the language of specific products. The country has an opportunity to show case global plants in the country, such as Baxter, Cardinal Health, Tyco International, and Johnson & Johnson.

Dominican Republic industry

The industry description and analysis covers the FTZs, and covers the 15 device/disposables companies in the FTZ. This includes dental medical products. In the future it may include the smaller veterinary products segment. The findings stem from meetings with selected companies, plant tours, and meetings with “Operadoras”- the Park owners, the Association of Free Trade Zones (ADOZONA), and appropriate public sector agencies.

Consistent with the outline in the subheading Harmonized System 90 Products, the description that follows does not include products in Code 90 that pertain to industries such as optical, photo, certain photocopiers, navigation compasses, drawing instruments, certain apparatus and instruments used in the education field. This description and analysis does not include the Dominican Republic’s local country market demand covering device/disposables for its 9.1 million citizens.

Overview of all Parks

The FTZ program commenced in 1969 and has grown successfully over the years with the influence of trade competitiveness programs such as the Caribbean Basin Initiative. The Dominican Republic currently has 57 Parks. Of these, 56% are privately owned. The Parks have 590 companies and 185,000 employees.

Principal areas of business are Textiles (51%). Medical devices and disposables, including a small volume of pharmaceuticals businesses account for 3%. The FTZs manage over 20 product and service industries. Country national and FTZ exports amount to US\$5.44 billion. FTZ exports amount to US\$4.4 billion, 81% of the country’s total exports. Key investors include the U.S. (61%), Dominican Republic (26%) and South Korea (5%).

Overview of the 15 Device and Disposables plants in the FTZ Parks

The companies by country of origin of capital are: U.S. 11 companies, Canada 2 companies, and Italy and Germany 1 company each. Cumulative investments are US\$163 million. Whereas U.S. investments account for 94% of the total, the other three countries have investments of less than 2% each. This investment figure represents 13% of the total FTZ investment of US\$1.3 billion.

Five of the 15 companies make up almost 90% of the cumulative sector investment. Their individual capital investments range between US\$8 and US\$62 million. They employ almost two thirds of the total headcount of the 15 companies. Their headcount is in the 736 to 1,504 range. The companies are Baxter, D&G (Tyco Int’l), Cardinal Health, Abbott, and Edwards Life Sciences.

Products manufactured, assembled, and packaged

The 15 plants mainly manufacture, assemble and package disposables. Key disposables and the number of companies that make them are: catheters (5

companies), surgical sutures (2 companies), and needles for biopsy (2 companies). Other key products made by single companies include blood and intra venous (IV) tubes, filters and related products (about 100 different individual products), clothing for operating rooms (about 120 individual products), dental floss, disposable dialysis apparatus, plastic bags, surgery sponges, and bandages for cold dressings. Non disposable devices produced and assembled in the FTZs include electrodes for pacemakers, electrodes for neonatal patients, and suture needle usage control cases.

Manufacturing capabilities and processes include several degrees of sophistication. The capabilities have regulatory approvals for export to countries that have the most stringent and demanding global standards. The countries with the highest regulatory standards in efficacy and safety are Japan, European Union (EU), and the US. Manufacturing capabilities and processes include Class 10,000 to 100,000 clean rooms; processing of thermoplastics; extrusion of wire, tubing; injection and insertion molding; balloon blowing; thermoforming; welding of different types; die cutting; stamping; sterilization; silk screen and flexography printing; UV bonding; and production tooling.

Primary export destinations of the above products are in North America. Thirteen companies export to the U.S.; four to Canada; three to Holland; and two to Puerto Rico. Single companies export to Italy, Spain, Saudi Arabia, Australia, Japan, and other FTZs.

Whereas there are 57 Parks in the country, the 15 plants operate out of just 6 Parks, as follows:

Free Trade Zone Park Locations of the 15 Companies.

Free Trade Zone Park	Year Created	Companies/FTZ
Itabo	1986	5
Las Américas	1989	4
San Isidro	1986	3
PISANO	1993	1
La Romana II	1987	1
San Fr Macorís	1990	1

The top three parks account for 85% of the 1.2 million square feet in buildings usage in this sector.

The concentration of companies in just a few Parks is due to their ability to meet the needs of high tech manufacturers. This includes a cleaner environment both outside and inside the Parks which meet the sterility needs of this sector, array of services provided by the Park owners, access to a worker pool, and the competitive advantage of prior successful experience with sector plants.

Cumulative investment of the device and disposables companies account for an estimated 12% of the total cumulative investments in the FTZs. This contrasts with the

number of actual device/disposable companies which account for less than 3% of the total companies in the FTZs.

The table that follows provides the development of the device/disposables plants from 1999 to 2003.

Medical Device and Disposables Companies, Employment, Exports and Value Added

Year	Number of Companies	Total Employment	US\$ Million		
			Exports	Value Added	Total FTZ Exports
1999	12	6,904	285.50	n.a.	4,331
2000	13	7,206	339.60	28.20	4,770
2001	13	8,677	315.90	44.20	4,482
2002	13	8,701	317.90	31.10	4,317
2003	14	9,084	330.60	39.70	4,399
AAGR '03 vs. '99 %	4%	7%	4%	n.a.	3½%

Source: CNZFE, 2004. Note: depending on the source, there are some differences in how the figures are assembled. For the purpose of consistency in this study the figures used in the above table are those published by CNZFE.

AAGR= Average Annual Growth Rate.

DeRoyal in 1994 became the 15th sector company in the FTZs.

The average annual growth rate (AAGR) of device/disposable exports in recent years has been close to 4%, lower than the 7% AAGR increase in the global device/disposables market.

In the sector in 2003 laborers accounted for 82% of sector headcount. Technical personnel accounted for 10% of total headcount, and administrative personnel for the remaining 8%. Technical personnel average weekly salary in Dominican Pesos was over twice the salary of laborers in each of the years from 1999 to 2003. The high tech nature of these manufacturing operations translates to higher value added with higher technical personnel compensation and increased technical capacity in the country.

The percentage breakout of key manufacturing and assembly non-compensation costs and expenses for the 14 companies that operated in 2003 was: 73% electricity, 12% IDSS - Social Security, 10% communication, 3% INFOTEC, and water 2%.

Electricity represents nearly three quarters of the expenses of the five non-compensation cost and expense items above. The electricity costs are over double the cost of electricity in many competitor countries, such as North American countries. Were these costs competitive with other countries, the total of these non-compensation conversion costs would be cut by almost half.

“Operadoras” (Companies that own and operate each Free Trade Zone Park). Itabo, Las Américas, and San Isidro have 80% of the 15 device/disposables plants in the

FTZs. All three “operadoras” appear to be well managed companies. The perception based on the meetings and review of facilities is that in general they run dynamic, productive, tightly managed firms. The companies have programs of effective communication with each of their client plants, and with all companies via periodic meetings and other forms of communication.

Each of the three “operadoras” covers a range of 5 and more industries in their Park. Their strategy is generally to keep diversifying industries as a path to stable growth and to ameliorate industry downturns. They also wish to attract more plants in the same industry, to position themselves as specialists in the perception of potential new plants. Devices/disposables are generally a sector of high interest because of the high tech manufacturing benefits.

Nearly all 15 companies are multinational corporations (MNCs). Surgex is an exception. As a contract manufacturer, it provides services to plants overseas as well as companies within the FTZ.

The 15 companies appear to be in a current growth mode which should be reflected in higher growth rates of manufacturing value added. DeRoyal, a 25,000 products company, commenced operations in 2004 at PISANO. Johnson & Johnson (J&J) is adding another building to handle increases in unit volume. Baxter has recently added and is adding new product lines. The “operadoras” claim that there are increases in production volumes in many of the 15 companies. This may reflect an increase in exports at a rate beyond the moderate increase in exports between 1999 and 2003.

No Park owner or device/disposables client recalls any established industry plant exiting the FTZ. Due to the substance of the combination of investment in machinery, equipment, manufacturing learning curve, and specialized trained personnel, once a device/disposables plant is established, a decision to close a plant in most lower overall Cost of Goods Sold countries, such as the Dominican Republic, faces a higher exit barrier compared to higher COGS countries.

Device/Disposables manufacturing in the FTZ goes back 33 years at company Surgex, a pioneer in the FTZs. Baxter has been in the FTZ for 16 years. Other companies have been in the FTZ for about 10 years. A conclusion is that the FTZs have a positive story of well established device/disposables manufacturing for over a decade.

Park owners indicate that there are perhaps less than 10 FTZs which would be qualified by devices/disposables companies as having a profile that meets the needs of sector plants. The rest would be excluded by potential clients based on inadequate environmental cleanliness, lack of Park profile and experience that generally meets the needs of high tech manufacturing plants.

As the Park owners manage a large number of industries, their collective business development efforts in the device/disposables sector overseas has been moderate to small to non existent.

Despite the above finding, the “operadoras” perceive that they do nearly all of the country’s limited business development efforts in devices/disposables overseas, and will rely on CEI-RD and CNZFE for the balance of the efforts. The recommended strategies outlined in this report capitalize on some of the above findings.

The “operadoras” were consistent in their views of what they consider to be significant country benefits of competitive lower labor costs, fiscal exemptions, very productive workers, and relative closeness to markets.

Areas of full concurrence included the very high cost of electricity, and lingering perceptions of economic stability. Other issues raised included concern with potential client perception of how the WTO requirements on prohibited subsidies are going to be resolved without destabilizing FTZ benefits. There was repeated mention of a shortage of technical personnel who have appropriate experience and expertise for high tech companies. One “operadora” volunteered that sea port red tape and turnaround time is an issue as is broken ocean shipping schedule commitments, on a frequent basis, to non highest-volume destination ports.

Product Manufacturing Analysis

Currently product manufacturing meets the following requirements in the Dominican Republic:

- Labor intensive processes. Labor includes a fair degree of technical expertise. This includes process engineering, machine shop tooling and maintenance, physical testing, chemical testing, quality assurance, and quality control processes. Some of the plants have engineering personnel that exceed 5% of total headcount, a reasonable degree of technical manufacturing sophistication.
- Labor represents a material piece of the overall total Cost of Goods Sold.
- Machinery, equipment, apparatus, and technology processes for all but the highest technology products in the industry. (The highest technology processes may include highly automated, high speed, high precision, robotics driven processes. Examples include implantable cardiovascular devices, selected imaging devices, laser technologies).
- Large, heavy machinery for which local machine shop process and maintenance know-how is available or can be developed on a sustainable basis, that is, without creating material production downtime.
- Overall size of capital investment that does not represent a dominant share of the overall unit Cost of Goods Sold. The capital investment will take the form of buildings (amortization or lease), machinery, manufacturing equipment, laboratory facilities, machine and equipment maintenance facilities, air conditioning facilities, sterilization rooms and capabilities, transportation vehicles. Most of the capital investments above are generally sourced globally from industrialized countries. As a result there is no competitive advantage to be gained in transferring most capital investment segments of a plant to an

emerging nation, if the variable unit cost of wages, salaries and fringe benefits do not represent a material piece of the overall Cost of Goods Sold.

As mentioned in the internal weakness segment of this report, this creates an opportunity to ensure supply of appropriate technically qualified personnel rise to meet the needed demand levels for the existing 15 companies as well as for incoming plants. When technically qualified skills capacity is developed to meet current and future demand, the FTZs will attract to increasingly high tech plants, with higher value Cost of Goods Sold non-labor components and processes. Ireland and Singapore are examples of successful countries in escalating the manufacturing technology learning curve.

Technically qualified capacity will itself help meet the objective of attracting increasingly more sophisticated high technology product manufacturing plants.

A list of sample products and product group that are candidates for production in the Dominican Republic are those mentioned in Appendix E. The production of the products in this Appendix generally fit with the requirements outlined in the prior five bullet points. A larger segment of the total global device/disposables products can be produced using the current level of production capabilities of the 15 companies in the FTZs.

In order to make a decision on where to produce a product or product line a device/disposables company undertakes a very detailed cost analysis of comparative locations: within its existing plants, a new owned plant, or outsourcing. The company first estimates unit sales (and resulting production spread sheets) for time periods such as each of the first ten years, going out in some cases to a generation. It will then calculate details of all fixed product costs, variable unit product costs, and semi variable costs. It will breakout each line item of all costs involved, by spreading the costs over each unit of product to be made. It will then conduct a comparative qualitative analysis of the alternative plants under evaluation. Existing plants, such as the ones installed in the FTZ have an edge in being awarded new or more existing product volume on the basis that they have already successfully demonstrated going through the learning curve in product manufacturing. These plants also have some fixed or overhead fixed costs of manufacturing that would grow minimally with the addition of more production volume in the plant.

Competitor countries

Key countries in competition for manufacturing plants of devices and disposables include U.S.A., Canada, Mexico, Puerto Rico and Costa Rica. Other countries include Ireland, Switzerland, Germany and France. In Asia key competitors include Japan, China, Korea, Taiwan, Malaysia. Target competitor countries are all countries in the Western Hemisphere.

The body of the report provides a table entitled “Estimated Relative Strengths of the Dominican Republic and selected key competitor countries to attract devices and disposables manufacturing plants.” This table provides an overview of strategic factors

in each country. This table furnishes in an easily visible matrix, the Dominican Republic's favorable position versus its key competitors.

The body of the report also includes a table under the title "Order of Magnitude Estimates of Wages per Hour for Selected Countries". This table shows for example, that hourly wages in the FTZs are about one tenth the hourly wages in Canada, U.S., Ireland, and Singapore. If 30% of the total manufacturing cost of a product in an industrialized country is made up of salaries and wages, the FTZ could provide roughly more than 20% lower total manufacturing cost product for those countries, if all other manufacturing variables are equal.

S.W.O.T. Analysis

Internal Strengths of the Dominican Republic include:

- Competence in device/disposables manufacturing for over 10 years.
- High tech plants, most with FDA approval; some with approvals from the most demanding global health agencies: FDA, European Union and Japanese Governments.
- Competitively low hourly labor rates in the Western Hemisphere.
- Close to zero impact of taxes, fees, and import duties in Europe and North America.
- Comparatively close to world's major markets.
- Competitive, flexible work ethic.
- Sector capabilities already account for 10% of all FTZ exports.

Internal Weaknesses include:

- Lingering perception of macroeconomic and political instability.
- Shortage of appropriate technically trained personnel for current and future plants hampers plant attraction programs.
- Historical discontinuity in government programs hurts progress.
- Electricity costs.
- Limited capabilities of local packaging and labeling industries.
- Inadequate local capabilities in laboratory and other testing services industries.

External Opportunities include:

- Emphasize investments on a limited set of product and service industries. Choose device/disposables industry as a very large, long term higher growth, and high tech manufacturing sector opportunity.
- Due to entry and exit barriers, each device/disposables plant addition means a stream of country benefits for decades.
- Create and implement an effective business development program, which includes the recommended strategies and other recommended programs outlined in this report.
- Implement a visibly strong public-private partnership which integrates the country's business development programs.

- Market the story of well established core competence in high tech world class quality devices/disposables, approved by the most demanding global healthcare agencies.
- Relative geographical closeness to key western hemisphere industry markets.
- Capitalize on CAFTA-DR approvals when they occur. The agreement provides an image of long term stability and growth.
- Improve environmental image near selected FTZs.

External and Internal Threats include:

- Lack of an effectively implemented business development program may result in moderate to flat sector plant yearly volume growth.
- Uncertainty regarding the impact of WTO direction to remove prohibited FTZ subsidies by 2009.
- Environments in and near some FTZs do not fit with the needs of sterile plants.
- New country competitor entrants for very large plants, such as China and India.

Vision. The Dominican Republic has excellent potential to become a leading country in the manufacture of competitively low cost, high quality medical devices and disposables for the Western Hemisphere.

The above vision statement is based on most of the significant internal strengths and external opportunities outlined above, and described in more detail in the body of the report.

Recommended Strategies

The following strategies are based on findings in the Dominican Republic; the profile, large size and large yearly growth rates of the global device/disposables market; a S.W.O.T analysis; and the Dominican Republic's competitive position compared with its country competitors.

Industry Focus. It is recommended the Dominican Republic focus its business development and promotion programs on the very large, high growth medical device/disposables industry.

The country should focus its efforts on the total industry just mentioned, not only the piece of that industry that is classified within Harmonized System Code 90. It is recommended the country maintain focus on the industry and not attempt to expand its programs and resources on the other industries included in HS 90, such as Optical and Photo industries.

Products. The country should pursue attracting manufacturers of all products that meet the following requirements, a) include labor intensive processes; b) where labor represents a material piece of the total Cost of Goods Sold; c) which involve machinery, equipment, and technology processes for all but the highest technology products. Appendix E provides a sample list of products and product areas with potential.

Appendix F lists product areas which have limited or no potential. The body of this report includes a subheading with a description and analysis of device/disposables manufacturing in the Dominican Republic.

Target. (Companies)

First priority companies. The country should pursue business development with the 15 device/disposables companies currently manufacturing in the Free Zones. The potential includes doubling or tripling the volume of products at some of these plants.

Second priority companies. Target companies should include the top 2% of the companies in the industry which account for roughly one half of global sales and COGS. A list of many of the largest companies is provided in Appendix D.

Third priority companies. These include medium size companies globally. Although there are many companies in this vast segment that hold potential for manufacturing, there are factors that need to be considered in approaching these companies. The body of the report provides explanations.

Promotion. High level Invitation Letter. A high level letter should be sent to Chief Executive Officers (CEO) of selected target companies. The letter may be signed by the President of the country, inviting the company to visit the Dominican Republic to evaluate its well established core competencies in device/disposables manufacturing for global markets. The letter will mention a local organizing committee for the visitor to the country.

Promotion. Campaign for Visit Programs. Create an effective long term Public and Private Sector program to persuade target companies to come to a Visit Program in the country. Details of the suggested Visit Program are contained in the body of this report.

Promotion. Trade Fairs. A Public Sector program involving the Export and Investment Center of the Dominican Republic (CEI-RD) and or the National Council on Free Trade Zones (CNZFE), with the partnership of the Dominican Association of Free Zones (ADOZONA), should be developed to invest and participate in only the key global device/disposables trade fairs that involve manufacturing.

Geographical Target Markets. The target markets should include the entire Western Hemisphere. This target includes three quarters of the world market, large manufacturing bases of the industry competitors and their third party outsourcing manufacturing companies.

Other Recommended Programs

Appropriate Technical Education Capacity. It is recommended INFOTEC focus substantial resources on developing and achieving technically specialized capabilities in

the country so that supply levels rise to meet current and future demand levels of these personnel.

Electricity. A long term program should address the country's globally uncompetitive, high cost of electricity. After the line item compensation, this line item within the overall conversion costs of raw materials and components is the largest one to impact total conversion costs, a significant cost variable.

Local Services Industry. It is recommended a study be conducted to determine the magnitude of needs not being met by the local industry. Currently many plants have to go overseas to have their needs met. This is costly and not timely. The study should include laboratory testing, and industrial air conditioning services in the FTZ for which there are limited capabilities in the country. An implementation program should be the result of the study.

Packaging and Labeling Industries. These industries do not provide a broad range of products and capabilities. Some packaging prices are not competitive. It is recommended a study be conducted and the findings be converted into an implementation program.

Communication. It is recommended that programs be put in place to develop web sites to market the Dominican Republic using the appropriate languages to attract Foreign Direct Investment and accelerate the attraction of more manufacturing companies in the high tech areas. Models to be followed include the excellent websites of Ireland, Canada and Singapore.

Areas Approaching Selected FTZs. It is recommended appropriate Government agencies plan and undertake a clean-up program of the roads and areas close to target Park entrances that contain and will contain plants which manufacture and assemble devices/disposables in sterile settings.

Multilateral Agency Funding. It is recommended a specific, time-bound funding program be sought and achieved from a multilateral agency such as the International Finance Corporation (IFC) of the World Bank or the Multilateral Investment Fund (FOMIN) of the Inter-American Development Bank (IDB). The funding program should be geared to develop and accomplish some of the strategies and other recommended programs contained in this report.

One-time Cash Grants for Larger Plants. Countries such as Ireland have provided cash incentives to assist companies with their decision to establish a plant in their country. These programs, contained in secrecy agreements, have contributed to the mix of factors that draw a device/disposables company to establish a plant in the country.

It is recommended the Dominican Republic assess providing such one-time incentives for larger new plants. This cash investment would be offset by the benefits of

employment for the country, and a flow of other benefits deriving from the plant for several decades.

SECTION I
INTRODUCTION

SECTION I

INTRODUCTION

The objective of this study is to prepare a strategic report on the Harmonized System Code 90 Products sector in the Dominican Republic. The report is carried out in the form of a S.W.O.T. analysis (strengths, weaknesses, opportunities, and threats) that will present to public sector and industry leaders a clear picture of where the Dominican Republic is positioned at this time to compete in the global market place.

The report outlines steps required to enhance competition at both a macro level but also concrete steps that can be taken over the short run. The report recommends strategies and specific initiatives to resolve near-term barriers to growth and to set the stage to accelerate industry export development.

HS Code 90 consists of seventeen pages with a listing in small print of products, raw materials and components covering several industries, including the medical device/disposables, optical and photo industries. Research was conducted to isolate the industry and market segments that have the large size and growth potential that best fit the establishment of manufacturing plants in the Dominican Republic.

A key recommendation of this report is that the Dominican Republic focuses on attracting manufacturing companies in the device/disposables industry. The program needs to also include the large segment of the device/disposables industry which is classified in HS Codes other than Code 90. This report recommends that the focus of the country's efforts and programs not be diluted by attempting to simultaneously attract manufacturing companies in other industries covered in the HS Code 90 Products.

The sequence of tasks in this assignment is:

1. Research on the extensive set of industries in HS Code 90.
2. Meetings with former industry leaders and people who negotiated and set up \$2 billion manufacturing plant investments in Ireland, a role model country for this study.
3. A trip to the Dominican Republic May 2 to May 14 to conduct meetings and interviews with all key stakeholders of this assignment.
4. Informal presentation to USAID and an informal presentation to the stakeholders, with the findings and key recommended programs.
5. A detailed report with an Executive Summary that includes the findings.
6. Second trip the Dominican Republic to make a formal presentation on all aspects of the assignment to all stakeholders.

Many of the findings from meetings held in the Dominican Republic are included in the chapter: Dominican Republic Industry.

SECTION II
THE INDUSTRY AND MARKET

SECTION II

THE INDUSTRY AND MARKET

A. Harmonized System 90 Products

The Harmonized System (HS) Code 90 products includes a list of products, raw materials and components involving mainly the larger segments of the Optical, Photo, Medical device/disposables including dental device industries. The products consist of items such as apparatus, machinery, equipment and supplies. HS Code 90 covers a variety of different industries which when combined, make up the finished products used in the global markets. In the case of medical device/disposables these are used by medical providers, their patients, and consumers.

The Harmonized System is a numerical global product classification program. It is used mainly to classify products in import and export trade, to establish nomenclature for duty rates, and to measure the performance of product trade internationally.

The global HS Code 90 of the Register is 17 pages in length (in small print). Code 90 lists products, component parts, raw materials, devices, apparatus, machinery, and equipment involved in these broad industries.

The overall strategic objective of the present study requires a strong customer orientation. This is needed to be successful in rapidly accelerating Dominican Republic's manufacturing and export program in these product areas.

The Harmonized System is generally used only by global public sectors, multilateral agencies, and a few specialists within the product manufacturing businesses. The HS is not generally used by people within the target customer companies of this study who will be approached by the Dominican Republic. Instead, the target customer companies segment their products by a) types of customers, b) customer specialty field (such as physician specialties in the case of device/disposables), by c) the technologies involved in manufacturing the products, by d) the materials used in the manufacturing of the product. In other words, the companies do not segment their business using the Harmonized System. In order to be closer to the customer and to speak the customer's language, this report will segment the opportunities as the competing companies do. It will not segment the markets and products using the Harmonized System.

Recommendation. In connection with Harmonized System Code 90 products, it is recommended the Dominican Republic as a key strategy focuses only on the medical device/disposables industry. This industry is made up of a) medical devices (machinery, equipment and apparatus), and b) medical supplies. This latter large industry segment is referred to as medical disposables in many countries in Europe and elsewhere. The medical device/disposables industry includes products used by the much smaller dental and veterinary industries and these products should be included in the strategic product focus of this study.

For simplicity purposes this report will use the words device/disposables jointly when describing products in the industry. The device and the disposables industry segments each account for roughly half of the combined industry.

The reason to focus only on this industry is it is a vast industry in terms of dollar size. The opportunities are estimated at about 80 billion U.S. dollars per year globally. This figure is measured in financial statement terms- Cost of Goods Sold, which represents the full cost of manufacturing all device/disposables for sale, a very large manufacturing opportunity.

The Dominican Republic should not focus on the Optical and Photo industries and their products, included in HS 90. The Dominican Republic does not have unlimited resources to simultaneously develop and implement effective business development programs for a broad set of high tech industries beyond medical devices/disposables. The country will be more successful in focusing its effort in attracting new companies and new plants in the device/disposables industry.

HS 90 does not include several segments of the medical disposables products. The products not included in HS 90 amount to an estimated one third of the total device/disposables industry globally. Many of the products included in this one third of the total industry represent material potentials in value added manufacturing processes in the Dominican Republic. They should be included in the overall potential market for the country.

Advantages include capitalizing on the very large potential to build the device/disposables industry; focusing limited resources to increase the success rate in attracting new companies to the FTZs; and not diluting efforts by trying to invest limited resources in too many industries.

Photo and Optics industries. As indicated, the recommended product focus strategy excludes these industries. Remarks on these industries are provided in Appendix H. The remarks highlight the fact that most of the manufacturing in both industries has moved to Asia during the past generation.

B. The Industry

The global medical device/disposables industry is large, intricate, complex, highly segmented, that is, it is an atomized industry.

The concept, medical device industry, is a convenient way to aggregate a large set of industries. The concept medical device industry usually tacitly encompasses both the device sector, and the larger disposables sector. These industries include products which are highly regulated by government healthcare bodies, such as the FDA, EU and Japanese governments. This is due to the nature of the products in the medical field as they relate to both patients and consumers. These industries include more moderately regulated products, such as many disposables.

B1. Industry from an R&D perspective. The high tech nature of the industry and its manufacturing plants, coupled with a very large market size and large yearly market growth rates, represent a certain opportunity to accelerate development of high tech, high value addition plants in the FTZs. The high tech nature of the industry is described in the paragraphs that follow.

The medical device/disposables industry by global standards is a high technology, a higher R&D investment-per-net-sales-dollar industry. R&D investments are concentrated primarily in the U.S., the European Union and Japan. The industry invests almost 7% of every net sales dollar in R&D. This can be contrasted with the investment in R&D of the following global industries: automobiles 4%; pharmaceuticals 16%; software 15%; hardware 10%. The U.S. industry is the largest investor in R&D in device/disposables. This investment is contributing to the country's industry sustaining the largest share of the world market for the foreseeable future. Investments in R&D in the device industry will continue to be higher than in the medical disposables industry. This is caused by the differing potential for innovation in each market. Also, as gross profit ratio margins are materially lower in the disposables market than in devices, the incentive for innovation is reduced.

R&D-based competitors drive most of the long term global demand and nearly all of the new products into the markets. Patents are important for a competitor to develop a successful market position with new products. These and other factors associated with high technology cause the industry to be driven, in rank size, by the U.S., the European Union, and Japan. Other countries are entering the R&D areas of the business including Singapore, Korea, China and Taiwan. Despite the importance of patents in driving new innovations, most of the global market consists of products for which patents have expired or which were never patent protected.

Companies establishing their own plants in the FTZs, as opposed to having a third party outsource company manufacture product for them in the FTZs, will do so not to protect patents, but to protect non patented know-how and technological processes, and control product quality within their own legal entities.

General differences between both industries are included in the following table:

General Differences between Medical Device and Supplies industries

Medical Device Industry	Medical Supplies Industry
High technology products	Low technology products
Multiple use products	Generally, disposable products (Disposables account for an estimated 95% of this industry).
More variability in yearly unit volume demand	More consistency in yearly unit volume demand

Medical Device Industry	Medical Supplies Industry
Device companies in the developed world essentially do not compete in the disposables industry	Disposables companies in the developed world essentially do not compete in the device industry
Comparatively higher priced products	Comparatively lower priced products
Higher gross profit ratios	Lower gross profit ratios
Products encounter less price pressure	Products encounter more price pressure
Reduced pressure to seek lower cost manufacturing alternatives. Labor a lower % of overall cost.	Increased pressure to seek lower cost manufacturing alternatives. Labor a higher % of overall cost.
A few key competitors dominate in the high technology markets segments. (Examples: cardiology and orthopedic segment)	Low technology products lowers new competitor entry barriers and drives up the number of competitors
More products have patent protection. Most products do not have patent protection	Fewer products have patent protection. Nearly all products do not have patent protection

For simplicity reasons, this report will refer to the device/disposables industry. When there is a need in this report to refer to only one of the two industries, this report will specify the industry.

The above table is provided to help explain in part why more disposables than devices are manufactured in the FTZs. There is potential for both industries as the country escalates the capacity of increasingly technically qualified personnel.

It is a challenging industry to understand due to the large number of sectors, hundreds of applications, products in the multiple thousands, with manufacturing and marketing competition from thousands of companies. Some companies have a portfolio of hundreds of products. A single company is known to own some 25,000 orthopedic and sports products.

The devices and disposables industries are not always well understood by peoples who are outside of the industries. This is in part due to the lack of media and other public information on the industries.

The device/disposables industries include sectors such as:

- Cardiovascular and peripheral vascular devices
- Musculoskeletal devices
- Electro medical devices. These include diagnostic and other imaging products, and patient monitoring products
- Wound management products
- General surgery and minimally invasive surgery
- Ophthalmic surgery
- Disposables

C. The Market

The following overview of the global market provides background information for all stakeholders involved in the decision to maintain the industry's position as a priority focus industry. It also helps stakeholders with the decisions to invest long-term in business development programs in order to take this industry to a leadership rank in the country's exports program.

The global devices/disposables market is estimated at \$190 billion in 2004. The figure stems from projections from several sources. It has been growing at an estimated 6% per year and is projected to grow at 7% per year.

The rate of growth is expected to be maintained over many years. This will be due to product innovations that fill previously unmet needs, and increasingly large older age populations which need the medical services provided by these products. The growth rate would be even larger, but the growth rate is partially offset by cost containment pressures, limits in reimbursement programs, and pressures on government budgets in the largest global countries which have socialized medical programs.

The estimated market by region and country is as follows:

Device/Disposables Market by Region and Country, 2003

Region or Country	Estimated Market Size US\$ Billions (1)	Estimated Market Share %
U.S.	85	45
European Union	51	27
Japan	27	14
Rest of World	27	14
World Total	190	100

(1) Projections from estimates from Advatec; CMS Dec. 2003.

The EU accounts for 90% of the total device/disposables European market. Germany, U.K., France and Italy account for an estimated 80% of the total EU market.

C1. Device and disposables sectors. The separate device and disposables sectors reflect the largest form of product segmentation in the overall industry, a construct referred to simplistically as the "medical device industry." Each of these sectors make up close to one half of the total market in currency terms globally. Whereas in the U.S. the disposables sector accounts for an estimated 58% of the total currency market (with the device sector accounting for 42% of the currency market) in the European Union the disposables sector accounts for an estimated 65% of the currency market of that region.

C2. Relative size of total medical device market by certain specialty segments.

Market data for the U.S. in the table that follows may be extrapolated for the other global regions and countries.

Estimates of the Total U.S. Market by Product Segment

Market Segment	U.S. dollar Share of Market (%)
Disposables	58
Devices	42
Total	100
Devices by sub segment	
Cardiovascular field	14
Orthopedic field	6
Ophthalmic field	6
Diagnostics field	3
Other fields	13
Devices Total	42

Source: industry competitors, 2001.

C3. Market size and segments using Harmonized System (HS) classification. The for-profit sector only uses the HS to classify products for export and import purposes and only for specialty work. It does not use the HS system to segment the market or conduct business development, manufacturing, marketing, sales and distribution functions. Regardless, following is a table of the European Union market using the Harmonized System. In order to capture the total device/disposables market, other Codes of the HS beyond Code 90 are needed.

European Union Devices and Disposables Market using the HS Classification (*)

Product Group- Using HS Chapters	Share of Total Monetary Value (%)
Electro-Diagnostic Apparatus	1
Surgical Instruments and Appliances	26
Dental Instruments	5
Materials X-Ray	3
Wadding, gauze, and bandages	26
Diapers and Similar Hygiene Products	22
Syringes, Needles and Catheters	15
Surgical Gloves	1
Wound Closure Products	1
TOTAL MARKET	100%

(*) Source: EU Market Survey, 2001. CPI.

C4. Market by use areas. Medical device/disposables are used primarily by the hospital industry in hospital settings. The second largest user segment consists of General Practice physicians, and specialty physician practices including dental practices. This segment is expanding as rapidly as the hospital market. The consumer

use segment is much smaller. In a region such as the European Union it accounts for 3% of the overall market.

Generally, product usage market segments in each of the countries and regions around the world maintain a rough pattern of consistency in unit volume.

C5. Structure of the industry by competitors. It is estimated that there are 6,000 device and disposables firms in this market in the U.S. alone. Some 2% (an estimated 200 of these companies) hold a sizeable 50% of the global market in currency terms. Some 80% of the companies are medium to small companies, with less than 50 employees in each company. Competing companies range in size from nearly 100,000 employees (Johnson & Johnson) to a 1-employee company.

The few large companies are financially stable, highly profitable, and have a solid financial future. Many of these companies also have sizeable businesses in other industries, such as pharmaceuticals, and electronic products. Examples of these companies are Siemens, General Electric, Johnson & Johnson, Abbott, Cardinal Health, and Tyco International.

Many of the medium and small size companies do not have financially stable businesses, or have product portfolios that guarantee staying independent or in business. Many companies are focused on R&D and do not generate a profit which enables sustainability. They work with third party investor capital as they pursue innovative technologies and products. As these companies lack marketing, sales, and distribution structures and do not have product demand creation structures outside of their home country, many companies eventually partner or divest their assets. The large and medium size companies generally are the key targets of those partnerships and divestitures. The RECOMMENDATIONS chapter addresses these companies.

D. Market Trends

The global medical device market is expected to grow at an estimated 7% per year. Based on the market drivers and constraints outlined below it is assumed that the global market will maintain this growth rate for many years.

The U.S. market, which accounts for nearly half the currency value of the world market, has grown at 9% annually from 1999 to 2004.

Market growth drivers include:

- (a) Continuing growth in unit volume due to increasing demand by increasing populations;
- (b) Replacement of used, older or obsolete products;
- (c) Long-term higher increases in aging populations;
- (d) Gradual increases in public sector medical reimbursement programs in the U.S., Europe, Japan and in many countries around the world;

- (e) Innovative products which provide longer and healthier lives. Some new technologies fill previously unmet needs. An example includes the recent introduction of cardiac rhythm management products. Other technologies provide better performance options for medical needs already being met;
- (f) Recent rapid growth in demand in several developing countries and regions. Examples include China and India- which jointly have 36% of the world's population, Latin America, South East Asia, and South Asia.

Market constraints that partially offset the above factors that drive market growth include:

- (a) Cutbacks in public sector reimbursement budgets.
- (b) Group purchasing organizations' (GPOs) pressure on bundling and other pricing strategies; and public sector price controls.
- (c) Tender bids that create downward pressure on prices.
- (d) Government delays in providing approvals for new technologies in the country market. This is prevalent in many countries beyond the U.S., in part to control costs and meet challenged healthcare budgets.
- (e) The European Union and Japan will slow the overall rate of increase of the global market over the foreseeable future. This is being driven by low population growth, budget pressures on reimbursement programs, and delayed approvals versus the U.S. in the adoption of new technologies. These technologies are generally launched at higher prices than the products and technologies which they replace, even though new technologies may provide medical cost benefits which include longer patient lives and higher quality of lives.

D1. Factors that shift the overall yearly size of the U.S. dollar denominated global market size. These include shifts in exchange rates of the major currencies such as the Euro and Yen, dramatic changes up and down in total country yearly purchases of product, and upswings in demand by large developing regions such as East Asia, South East Asia, and Latin America. Descriptions of large shifts in the overall yearly size of the U.S. dollar denominated global market size are provided in Appendix I.

D2. Annual growth rates of new technologies. Rapid increases in demand are being experienced in new technologies such as those in the cardiovascular and orthopedic fields. These technologies are filling previously unmet needs, particularly with rapid growth populations in the 55 and older age ranges. Sales of new defibrillator devices have been growing at about 25% a year, with units selling in the very high \$10,000 to \$30,000 price range. CMS projects the very large cardiac rhythm management segment will grow at 20% annually over the next several years. The orthopedic field, that is, the "joints" industry is projected by CMS to grow at an annual rate of 15% for the next several years. The large volume new drug-eluting stent segment has been tripling in size annually since 2002.

Other new technologies which will grow very rapidly include:

1. Non fusion technologies for the spine market.

2. Orthobiologics that stimulate bone growth.
3. Technologies for less invasive procedures- those which replace highly invasive surgeries. These involve, for example, interventions, from cardiac bypass surgery to angioplasty.
4. Subcutaneous heart valve repairs and replacements.

Country market currency growth rates and projections vary widely. For example, a 3% yearly growth rate is projected for Japan for the next few years. This is against a projected 13% yearly growth rate in Korea for the next few years.

D3. Pricing

The U.S. device market is in the highest range of unit prices globally. This is due in part to the U.S. market being driven by private supply and demand market dynamics. It contributes to more rapid uptake of improved products and technologies. This is contrasted generally with lower prices in the European Union, and to a lesser extent, Japan. Prices here are driven by lower-cost socialized public sector healthcare plans. Prices in the European Union are roughly 30% below U.S. prices.

Due to more limited resources, governments and non governmental healthcare programs in many countries of the developing world, generally cannot afford to pay for the newer very high priced technologies, such as cardiac pacemakers which may sell for \$5,000 to \$10,000 in the U.S.; or defibrillators which sell for prices in the \$10,000 to \$30,000 range; or a heart failure pacing device which is sold for \$25,000 to \$30,000. In general terms, prices of devices in the developing world may be as much as 70% below U.S. prices on a same-product basis.

As the industry involves thousands of products manufactured by thousands of competitors in over 50 countries, exact country price differential data is not generated for all products. The pricing remarks above explain why the U.S. market has a very large share of the world market, how the U.S. is able to capitalize on its higher prices with stronger investments in R&D, and why most new patents, new technologies, and new products originate in the U.S.

E. Manufacturing

Competitors globally manufacture products in their own plants and also make extensive use of third party manufacturers to make products for them.

In the U.S. the outsourcing manufacturing industry for device/disposables is large; it accounts for an estimated one third of all products manufactured. Outsourcing of manufacturing of products in this industry is a growing trend globally.

In countries such as Europe, Canada and the U.S. consumer products within the disposables segment are retailed by large retail pharmacy chains. These knock off, or house brand competitors generally outsource manufacturing of their products. The

house brands of the large retail chains are a significant piece of the overall market in North America and the European Union.

Product manufacturing has over recent decades been concentrated in the larger industrialized nations. Key countries in the western hemisphere included the U.S./Puerto Rico, Canada, Germany, France, U.K., Italy, and Switzerland.

Over the past three decades manufacturing has been moving gradually to other countries, both industrialized and emerging. Developed countries include Ireland, Singapore, and Spain. Emerging countries include China, Korea, Mexico, Costa Rica, Brazil, Thailand, Malaysia, and the Dominican Republic. The device and disposables competitors set up and own their own manufacturing plants in the new locations as well as set up manufacturing programs partnering with third party manufacturers.

In effect, the competitors conduct strategic manufacturing “make or buy” decisions. A “buy” decision offers the flexibility of a shorter term commitment to a manufacturing location and company. A “make” decision generally places the competitor in a position to have to commit to up front capital plant investments. Due to the specialized nature of device/disposables manufacturing, owning one’s own plant entails a long term commitment to that plant investment. The decision to operate using this strategy may involve the need to protect intellectual property rights, and/or the need to control the manufacturing processes more closely.

The alternative of moving sourcing out of one’s own plant to another location entails plant exit costs and other barriers. These may include areas such as, a) start-up investments and costs in the new location, b) significant breadth and depth of skill sets involving management, scientific and technical personnel, and c) challenges in divesting the prior plant at a market price that recovers the land, buildings, and certain equipment investment costs. In this latter area the marketability of the plant at the “right” price may be challenged by the design and layout of the buildings which fit the needs of the specialized nature of the device or disposables manufacture but not the needs of potential buyers of the property.

Manufacturing of the highest technology products, such as cardiac rhythm management products continues to be manufactured generally in developed countries. This is due in part to, a) the nature of the sophisticated computer technology of the products mentioned, b) the fact that some of these devices are implanted in the body with the attendant serious life threatening challenges of rejection and infection potential, and c) government regulatory bodies require more stringent scientific and technical discipline in certain manufacturing processes, such as Good Manufacturing Practices. Computer technology is improving markedly every 18 months so the owner of the product brand needs to control the manufacturing program for this brand in a more sophisticated manner.

The trend of manufacturing more medium and lower technology products in countries with lower labor rates continues and is expected to continue at a noteworthy pace. It is

projected that over the years the large MNCs will continue to move manufacturing of their products to low labor rate countries.

As mentioned in prior paragraphs, the device/disposables industry is primarily a high technology industry. High technology is reflected in the high levels of R&D invested per net sales dollar in creating innovative products that fill previously unmet needs, and that improve on the products that are currently on the market.

The industry is also high tech from a manufacturing standpoint. This is in part caused by the nature of the device/disposables with their contact with the human body or insertion in the body. As a result the industry is highly regulated from a product efficacy and safety viewpoint. Ministries of Health around the world regulate the introduction of new products and regulate what products can continue to be marketed in the country, and regulate manufacturing plants and processes.

Even the reduced tech device/disposables entail a degree of high tech manufacturing equipment and processes. In order to remove any potential for microbiological contamination of the products, many are manufactured in different types of sterile room or "clean room" environments. Many products undergo sterilization processes after manufacturing and after the products are placed in internal packaging. This in part explains higher investments in capital for buildings, machinery and equipment.

A degree of intricacy in manufacturing is seen in the ratios of the components of the overall Cost of Goods Sold of the product, or of the components of the total unit cost to make the specific product. The highest tech products will generally have higher content of capital and materials, and a low labor cost component within the overall cost of the product. If the labor cost, as an example, represents 20% or less of the overall cost of the product, a manufacturer will be less sensitive to manufacturing that product in a competitively low labor cost country.

As there are thousands of products in the industry there are no specialists in all products, certainly from a manufacturing viewpoint. Many device or disposables companies have a broad range of products in their portfolio. A company can easily have a range of 100 or 1000 products in its portfolio.

Appendix E provides a sample list of products and products areas which represent good potential for manufacture in the Dominican Republic. Appendix F furnishes a list of products which are viewed as not representing good potentials for manufacture in this country.

The bottom line is that the competitor conducts an exhaustive cost analysis, on a product by product basis to determine the best location for manufacturing of each product.

Recommendation In light of factors mentioned in prior paragraphs, the Dominican Republic should approach its business development program with a focus on selected

target companies. The Dominican Republic should not focus on specific products within a company's product portfolio. As stated, each company will make its assessment of what products or product lines are a good fit for manufacture in the Dominican Republic. Unless the business development person for the Dominican Republic is an expert in manufacturing in a relatively wide range of device or disposables technologies and processes, on the person should not engage in discussions of the manufacturing of specific products.

It is recommended, instead, that the business development person for the Dominican Republic have the understanding of why many products in this industry have good potential for value addition in the country. The person should display overview knowledge of the manufacturing, assembly and packaging technology capabilities in the FTZs.

Companies that are good candidates to showcase include Baxter, Johnson & Johnson, Tyco International, and Surgex.

In summary, a large segment of the industry represents a good potential for value addition via manufacturing, assembly and packaging processes in the FTZs.

As the Dominican Republic does not have the raw materials for most of the product components of the industry, it should focus on increasing its capabilities in technically qualified personnel so the companies may bring an increasing number of manufacturing processes to their plants in the FTZ.

SECTION III

THE DOMINICAN REPUBLIC INDUSTRY

SECTION III

THE DOMINICAN REPUBLIC INDUSTRY

A. Description and Analysis

The industry that will now be described and analyzed consists of the set companies that manufacture and assemble medical device/disposables in the FTZs. These include dental and medical products. In future it may include the smaller veterinary products segment.

As previously mentioned, the description that follows does not include products in Code 90 that pertain to industries such as optical, photo industries, and certain photocopiers, navigation compasses, drawing instruments, certain education field apparatus and instruments.

This outline does not include the Dominican Republic's relatively small local market demand for device/disposables. As with most countries the Dominican Republic demand for its 9.1 million citizens consists mainly of imported products, an estimated two thirds of which are imported from the U.S. There is limited manufacture of device/disposables beyond the FTZs. Manufacturing includes cotton gauze, surgical drapes, and orthopedic appliances.

B. Overview of all Parks

Following is an overview of device/disposables manufacturing in all FTZs in the country. This is followed by a more detailed overview and analysis of the companies that manufacture and assemble devices/disposables in the Parks.

The Dominican Republic currently has 57 Parks. Of these, 56% are privately owned, 39% are public sector owned and 5% are public- private enterprises. The Parks have 590 companies, with over 185,000 employees.

The FTZ program commenced in 1969 and has grown successfully over the years with the influence of trade competitiveness programs such as the Caribbean Basin Initiative starting in 1984.

Principal areas of business are Textiles (51%), Services- such as call centers and data entry firms (16%), Tobacco related firms (5%), Electrical and electronic component parts and products (5%), medical device/disposables (the number provided includes a small volume of pharmaceuticals business) (3%), and over 15 other areas of activity. If one breaks down the product and service areas, over 20 different areas are covered by the Parks.

Key capital investors include the U.S. (61%), Dominican Republic (26%), South Korea (5%), and less than 1% each Holland, Puerto Rico, Switzerland, Venezuela, Italy, France, and Germany.

Total country national exports and total Free Zone exports amount to 5.44 billion U.S. dollars. Free Zone exports amount to 4.4 billion U.S. dollars, or 81% of the country's total exports.

CNZFE, the Agency which regulates and manages the Free Zone program states the following factors as keys to the development of the program: closeness to markets; political stability, competitive low labor costs; excellent incentives for FDI such as an effective set of preferential and trade agreements, excellent tax and fees exemption program (15 years in duration which is renewable); modern port and airport infrastructures; modern telecommunication systems; and easy access to markets.

C. Overview of the 15 Device/Disposables Plants in the FTZs

Following are the number of companies by country of origin: U.S. 11 companies, Canada 2 companies, and Italy and Germany 1 company each. Cumulative investments amount to 163 million U.S. dollars. Whereas U.S. investments account for 94% of the total, the other three countries have investments of less than 2% each.

Total cumulative investments in the FTZs from companies in all industries amount to 1.3 billion U.S. dollars in 2003. The device/disposables industry cumulative investments represent 13% of investments in the FTZs by all industries. Device/disposables cumulative investments by country of origin: U.S. companies make up 94% of industry investments, and the remaining countries have less than 2% each of industry investments.

Five of the fifteen companies make up almost 90% of the cumulative industry investments, and employ almost two thirds of the total headcount of the 15 companies. This distribution of companies and share of investments and headcount is considered to be within normal range. The following table provides an overview of the size of the largest five companies in the industry.

Cumulative Investments and Headcount of the Top 5 Device and Disposable Companies

Companies	Cum. Investment U.S. dollars (millions)	Headcount
Baxter	61.5	1,504
D&G (Tyco Int'l)	41.5	736
Cardinal Health	24.0	1,282
Abbott	7.9	985
Edwards Life Sciences	8.9	890
Total top 5 Companies	143.8	5,397
Total all 15 Companies	162.6	9,084
% 5 vs. 15 Company Total	88%	59%

Source: CNZFE, 2004.

D. Products Manufactured, Assembled, and Packaged

The 15 plants mainly manufacture and assemble disposables. Key disposables and the number of companies that make them are: catheters (5 companies), surgical sutures (2 companies), and needles for biopsy (2 companies). Other key products are made by single companies: blood and IV tubes, filters and related products (about 100 different types of products known as product codes), clothing for operating rooms (about 120 product codes), dental floss, disposable dialysis apparatus, plastic bags, surgery sponges, and bandages for cold dressings. The following Non disposable devices are produced and assembled in the Free Zones: electrodes for pacemakers, electrodes for neonatal patients, and suture needle usage control cases.

Manufacturing capabilities and processes include:

- Class 10,000 to 100,000 clean rooms
- Processing of most thermoplastics
- Extrusion of wire, tubing
- Injection and insertion molding
- Balloon blowing
- Thermoforming
- Welding using laser and ultrasonic systems
- Die cutting
- Stamping
- Hot stamping
- Sterilization
- Silk screen and flexography printing
- UV bonding
- Production tooling

Primary export destinations of the above products are in North America. Thirteen companies export to the U.S.; four to Canada; three to Holland; two to Puerto Rico. Single companies export to Italy, Spain, Saudi Arabia, Australia, and Japan.

The 15 companies operate out of just 6 of the 57 FTZ Parks, as follows:

FTZ Park Locations of the 15 Companies

Free Zone Park	Created	Companies per FTZ
Itabo	1986	5
Las Américas	1989	4
San Isidro	1986	3
PISANO (Santiago)	1993	1
La Romana II	1987	1
San Fco de Macorís	1990	1

Source: CNZFE

The top three parks have 12 companies which account for 85% of the 1.2 million square feet in buildings usage.

The concentration of companies in just a few Parks is due to the profile of the few Parks that are geared to meet the needs of high tech manufacturers. The profile includes a cleaner environment both outside and inside the Parks; an array of services provided by the Park owners, access to laborers and technically skilled workers, favorable negotiation terms in the confidential service agreements between the Park owner company and the plant.

Cumulative investment of the device/disposables companies account for an estimated 13% of the total cumulative investments by companies of all industries in the FTZs. The number of device and disposables companies account for less than 3% of the total companies in the FTZs. On average each device/disposables plant cumulative investment is about 4 times larger than the average cumulative investment by each company in all industries in the FTZs. The preceding statement points to a device/disposables industry which needs higher relative capital investments for high tech manufacturing needs. This translates into an advantage for the Dominican Republic in that once established, the devices/disposables companies will encounter a higher plant reduction or closure exit barrier. Their investments in capital are “sunk costs” which are not easily removable. This, coupled with the collective expertise of technical personnel, makes an established device/disposables plant more committed to the Dominican Republic with its existing investments. This is more so than for less technical industry plants.

The table that follows provides the development of the device/disposables plants from 1999 to 2003:

Medical Device and Disposables Companies, Employment, Exports and Value Added

Year	Number of Companies	Total Employment	US\$ Million		
			Exports	Value Added	Total FTZ Exports
1999	12	6,904	285.50	n.a.	4,331
2000	13	7,206	339.60	28.20	4,770
2001	13	8,677	315.90	44.20	4,482
2002	13	8,701	317.90	31.10	4,317
2003	14	9,084	330.60	39.70	4,399
AAGR '03 vs. '99 %	4%	7%	4%	n.a.	3½%

Source: CNZFE, 2004. Note: depending on the source, there are some differences in how the figures are assembled. For the purpose of consistency in this study the figures used in the above table are those published by CNZFE. AAGR= Average Annual Growth Rate.

DeRoyal in 1994 became the 15th sector company in the FTZs.

The variations in U.S. dollars exports along with the value added by production conversion are caused by differences in the mix of products exported each year.

The currency value growth rate of device/disposable exports has been running in recent years at close to a 4% AAGR, a figure which is below the AAGR increase in the overall device/disposables sales and COGS globally, which is estimated at 7%.

Devices/disposables exports in 1999 amounted to US\$285.5 million, or 6.6% of the total exports from all FTZs that year. Industry exports in 2003 amounted to US\$330.6 million, 7.5% of total exports from the FTZs that year.

Value addition measures the value added in overall manufacturing, assembly and packaging costs and expenses in the country. It is measured by taking the value of the exports and subtracting the value of the imports of raw materials, and all components to make the end products for export. Device/disposables value added U.S. dollars increased at a significant AAGR of 15% between the years 2000 and 2003. The total FTZ value added in U.S. dollars for all industries during the same time period decreased at an average annual rate of 8%. This decrease was produced mainly by the downturn in the textile industry. The 39.7 million in device/disposables value added in 2003 represented 5% of the total Free Zone value addition of 810.8 million U.S. dollars.

Device/disposables laborers accounted for 82% of total industry headcount. Technical personnel accounted for 10% of total headcount, and Administrative personnel the remaining 8%. Technical personnel average weekly salary in Dominican Pesos was over twice the salary of laborers in each of the years 1999 to 2003. The high tech nature of these manufacturing operations means high value addition in high technical personnel compensation and benefits, in addition to increased technical capacity in the country. These are some of the advantages of pursuing a strategy of attracting high tech industries.

E. Key Device/Disposables Non-Compensation Costs and Expenses

The percentage breakout of non-compensation costs and expenses for the 14 companies that operated in 2003 were:

Key Non-Compensation Costs and Expenses All 14 Companies

Source of Cost or Expense	% of total of these Costs & Expenses
Electricity	73
IDSS- Social Security, incl. Medical	12
Communication	10
INFOTEC- Public Sector Training Fees	3
Water	2
Total	<u>100%</u>

Source: CNZFE data for year 2003.

Electricity represents nearly three quarters of the expenses of the five non compensation costs and expense items mentioned in the table. Electricity costs are over double the cost of electricity in many competitor countries, such as North American countries. Were these costs competitive with other countries, the total of these non-compensation conversion costs would be cut by almost half.

On the positive side, the hourly labor rates in the FTZs are so much lower than countries such as Canada, U.S., Puerto Rico and Ireland, that even if these countries provided electricity at zero cost to the device/disposables plant, the overall combined costs of labor and electricity in the FTZs, is materially lower than the combined costs of labor and electricity in the mentioned countries.

F. “Operadoras”

“Operadoras” are companies which own and operate each FTZ Park. Interviews were held with management of the companies that own Itabo, Las Américas, and San Isidro. The three FTZs have 12 of the 15 device and disposables plants in all FTZs.

All three “operadoras” appear to be well managed companies. The perception is of professional, productive, dynamic, modern, tightly-run service businesses. The companies focus on programs of effective communication with each of their client companies and with all companies via periodic collective plant meetings and other forms of communication.

The “operadoras” manage the businesses with a somewhat standardized set of contracts with each customer. This means each customer can negotiate different deals, but each of these is within narrow negotiating ranges. In most cases the “operadoras” own the buildings in the FTZ leased by the plants. Contracts have durations of approximately six years and have clauses on automatic renewal of contracts. Each Park owner provides a list of human resource, administrative, financial, customs and other services, all at pre-established fees.

The “operadoras” cover a range of 6 and more industries each. Their strategy is to keep diversifying industries as a path to stable success and to ameliorate industry downturns. They also wish to attract more companies in the same industry to build the image as specialists in order to attract new plants. Operadoras are interested in the device/disposables industry because of the high tech manufacturing benefits.

Nearly all 15 companies are MNCs. Surgex is a visible exception. As a contract manufacturer, it provides services to plants overseas as well as to a couple of companies within the FTZ.

The 15 companies appear to be in the start of a high growth mode which should be reflected in higher rates of value addition in manufacturing conversion costs. DeRoyal, a 25,000 products company, commenced operations in 2004 at PISANO. J&J is adding another building to handle increases in unit volume. Companies such as Baxter have

recently added and are adding new product lines. This may reflect an increase in exports at a rate beyond the slow increase in exports between 1999 and 2003.

No Park owner recalls a device/disposables plant leaving the FTZ. This finding confirms another favorable factor: due to the combination of investment in machinery, equipment, manufacturing learning curve, and specially trained personnel, there is a higher exit barrier once a device/disposables plant is established.

The only long term threat of plant closure appears to stem from Asia, and more specifically caused by “the China price”. These three words are being used at present to designate Chinese costs/prices, which are in many instances at a minimum 30% below existing costs/prices in the Dominican Republic. This is forcing some western hemisphere companies to seek the 30% lower cost/price manufacturing sources.

Device/disposables manufacturing in the FTZ started 33 years ago at company Surgex, a pioneer in the FTZs. Baxter has been manufacturing in the FTZ for 16 years. Other device/disposables plants have been in the FTZ for about 10 years. The FTZs have a positive story of well established device/disposables manufacturing for over a decade.

The Park owners believe that there are only 10 FTZs which are qualified to make devices/disposables. The rest would be excluded by potential clients based on inadequate environmental cleanliness, lack of “operadora” company profile, and industry experience that meets the needs of high tech manufacturing plants.

Device/disposables, alongside electronic parts manufacturing, constitute two of the high tech manufacturing areas, among 20 products and service industries being served by all FTZs.

The “operadora” strategy is to keep diversifying industries as a path to stable growth and to address downturns in individual industries. Operadoras mention the slippage in the textile sector as an example of the rationale for their strategy. Two of the “operadoras” claim that due to the device/disposable’s status as a high tech manufacturing industry, it is placed higher than other industries in business development efforts to attract and retain plants.

Business development. As explained “operadoras” manage a large number of industries. Their collective business development efforts in the device/disposables sector overseas has been moderate to very small.

One “operadora” indicates he has not conducted specific efforts to attract device/disposables companies. Instead, these companies have come to their Park by word of mouth communication among non competing MNCs. When companies interview the Park as a possible site for their plant, the Park owner then develops a competitive negotiating stance to win the plant contract, beating out the 10 other FTZs. Another “operadora” indicates he has conducted minimum business development efforts with device/disposables companies and that these have not provided rewards.

The effort included Internet research and writing letters to potential client headquarters personnel. Neither of these efforts were effective. The same Park owner hired a consultant to meet with these companies at their headquarters, but this approach was not successful either. At the present time, the operadoras are capitalizing on word of mouth communication. A third “operadora” states he has participated in some 5 design and manufacturing trade fairs over the past decade. They claim this program represents challenges in cost, know-how, and availability of people with the right profile to manage trade fair exhibits.

In general, the “operadoras” believe they do nearly all of the country’s limited business development efforts in devices/disposables, and rely on CEI-RD for the balance of the efforts.

Strengths. The “operadoras” were consistent in their views of the very significant country benefits of competitive lower labor costs, fiscal exemptions, trade agreements, very productive workers, and relative closeness to client markets.

Issues. Areas of full concurrence included the very high cost of electricity, economic instability, specifically in the area of recent large fluctuations in the exchange rate of the Dominican peso versus hard currencies. Other issues raised included concern with the uncertainty of how the WTO-subsidy requirement is going to be resolved without destabilizing FTZ benefits. There was repeated mention of the shortage of technical personnel with appropriate experience and expertise needed by specific high tech companies. One “operadora” volunteered that ocean port red tape and turnaround time is an issue as is broken ocean shipping schedule commitments on a frequent basis to non higher-volume destination ports.

G. Client Device/Disposables Companies with Plants

Following are the findings from interviews and plant tours at the three FTZs which have 12 of the 15 companies. The findings also include a phone interview with DeRoyal, a U.S.-based company which makes 25,000 medical accessories, mainly orthopedic and sports medicine products. The company has just started operations in PISANO-Santiago.

The plants came to the FTZs over the past decade to capitalize on very low labor rates, attractive fiscal exemptions, trade agreements and relative ease of client market access. This access includes geographical closeness to the market, ease of electronic communications, ease of relatively short flights, and relative faster speed and cost of shipping, particularly versus Asia. The managers also reviewed the very good productivity, flexibility, and loyalty of employees. This was contrasted with the nature of workers in some other countries who capitalize on the litigious nature of these countries, abusive collective bargaining, employees who are not loyal workers, and who provide resistance to work flexibility needs.

Following are findings from four plant tours.

G1. Baxter. This company has been in the FTZ for 16 years making some 200 different products within 5 product areas. The products are used mainly to extract, filter, and transfer blood; the plant also makes a large number of IV fluid and medicine soft tube lines. Manufacturing includes high speed thermoplastic tubes extrusion, running 24 hours a day. This plant is a global plant with FDA, EU, and Japanese Government approvals. This globally approved plant therefore makes global class products, competing in quality with plants in industrialized countries. This represents a significant story for Baxter and the country. The plant has approximately 1350 employees, which include some 200 professionals, and 90 engineers. This plant operates with clean rooms and post inner packaging sterilization capabilities. This plant has the ability to represent the Dominican Republic very well as an ambassador of the country's manufacturing capabilities in device/disposables.

G2. Cardinal Health. This plant makes an estimated 150 products, mainly disposables. The products consist of a wide array of disposable sheets and clothing used in surgical operations in operating rooms. Manufacturing consists of steps such as a wide variety of rolls stamping of synthetic thermoplastic materials. Class B rooms operate with approximately 1,500 employees, including a multi-layered organization with 73 quality specialists.

G3. Johnson & Johnson. The plant makes a broad range of dental floss product codes for all global countries except Africa and Latin America. This plant therefore has regulatory approvals that enable it to export globally. The global approval represents a strength that should be marketed by the country. J&J is adding another building to handle expansions in product volumes. An important point is that J&J does not manufacture, extrude strands. These are purchased globally from an industry that specializes in this type of commodity. This is mentioned as this is the norm in the device/disposables manufacturing industry. The industry does attempt to compete by making all of its product components, but instead purchases many of its product components.

G4. DeRoyal. This company chose PISANO Park in part because of the accessible labor pool, a cleaner environment both inside and outside the Park, and the negotiation of favorable terms in the service contract by the "operadora."

G5. Surgex. This is a Canadian capital company which is the pioneer in device/disposables manufacture in the FTZs. It provides services to large companies within the FTZs and to clients overseas. It has provided many plant tours over the years and meetings for companies which then established manufacturing operations in the FTZ. Surgex manufactures a range of products, from endovascular products, irrigation trays, to surgical sutures. Unlike management at the other companies in the FTZs, Surgex has the institutional history. The owners claim most companies came to the FTZs based on word of mouth communication among non competing MNCs.

Their anecdotal view, which was echoed by other companies in the FTZ, is that current and future competitive country manufacturing threats are coming from Asian countries, not western countries. Countries such as North America, including Puerto Rico and Mexico do not represent a threat. This is due to their higher hourly labor costs that have a material impact on overall product cost.

As most companies export to the U.S., they have FDA approvals to manufacture and distribute in that market. As the FDA is credited by the industry globally to have the most stringent standards for product approvals, the industry correctly views the products made by these companies in the FTZs as being world class products.

H. ADOZONA

This is the association that represents the interests of the “operadoras”. The association confirms the “operadoras” strategy of industry diversification.

ADOZONA confirmed that sector plants are adding volume with existing and new products. Some plants over time will need to add new buildings to meet their expansion needs. An example is J&J which is adding a building. New companies have entered the FTZ. The latest in 2004 is DeRoyal.

A review was conducted of the benefits of providing more focus on higher value industries such as the electronic components, pharmaceutical and device/disposables industries. There was concurrence on the benefits of investing in business development programs to attract high tech sectors for long term growth and stability.

ADOZONA’s believes the major competitive advantages of the Dominican Republic are competitively low labor rates, 100% fiscal exemptions, work ethic of plant workers, and closeness to markets. Major issues expressed are those described and analyzed in the report under S.W.O.T. analysis. ADOZONA specifically focused on the high cost of electricity. They also focused on the need to address the uncertainty associated with policy decisions surrounding the FTZ subsidies that are prohibited by the WTO, and the consequences of the uncertainty in attracting new plants. A shortage of supply versus demand of appropriately specialized workers is also a continuing issue in the high tech sectors.

Member companies have over the years conducted business development missions to markets such as the U.S. ADOZONA believes that the missions have not been very successful. The association concurs that overseas missions represent a challenging, costly program which requires specialized management over a long term period of time.

Why are the industry companies in the FTZs? Findings from meetings with the plant management, “operadoras” and the public sector agencies point to the companies coming to the FTZs for reasons discussed below.

A key reason is that the companies who came to the country determined that world class standard products can be produced at very favorable overall costs versus other nations, such as nations throughout most of the western hemisphere. However, there is increasing pressure to demonstrate materially lower overall production costs, particularly in the lower gross profit ratio, price sensitive disposables sector.

Primary factors for the companies being in the country are competitive low hourly labor rates. (Comparative information is provided under the subheading Order of Magnitude Estimates of Wages per Hour for Selected Countries). There is an overall tax and fees exemption program, in place since the FTZ Law 299 was enacted in 1968. Machinery, equipment and raw materials that are used in production enter the country duty free. Qualified devices/disposables made in the FTZs enter the U.S. duty free under the CBI initiative. Qualified products enter European countries with only 0 to 2% customs duty. There is free repatriation of hard currency.

Other factors include favorable experiences and stories shared by non competing companies operating in the FTZs, and reasonable FTZ import and export processes. There is relative closeness to the main markets, reasonable ocean and air shipment cost and lead times. There is also a good work ethic which includes productive, flexible, and loyal workers. State-of-the-art electronic communications are competitive. For management control purposes, there is relatively easy plane access to a plant in the FTZ.

The Dominican Republic's single largest competitive strength versus production in other countries is competitively lower labor rates, which coupled with nearly no cost impact of taxes, duties, and fees, provides a favorably low unit Cost of Goods Sold versus other low production cost nations.

The evolution of industry plants appears to have been influenced by the following events. First, the enactment of Law 299 in 1968 established the FTZ program. Next, Surgex established operations as the first device/disposables producer in the country in 1972. Word of mouth produced visits by manufacturers to the FTZ and Surgex facilities, as well as the addition of plants. The CBI initiative in 1984 strengthened the appeal of the Dominican Republic with the benefits of almost no import duties for qualified device/disposables entering the U.S. Law 890 in 1990 clarified and strengthened the rules of plants operating in the FTZs. Small marketing efforts plus word of mouth has continued to attract more plants, with 3 additional plants coming to the FTZ in the past five years.

From a public sector viewpoint, the FTZ programs were set up with the primary goal of creating employment opportunities and generating value addition from production conversion costs and export of finished products.

I. Dominican Center for Exports and Investments (CEI-RD)

Since the Government Administration came into power August 2004, CEI is initiating a government program to proactively invest in the following five areas: auto parts; electronic and electrical parts; devices/disposables; software (following the Irish, Indian and Israeli models), and call centers.

This plan seeks to develop higher value addition sectors. Benefits include higher yearly volume growth, more stability in yearly business, higher education level employees, higher added value exports, and increased generation of hard currency.

CEI will drive their overseas business development programs from a headquarters resource base of some 300 employees, which include some 20 staff focused on investments. CEI has 15 professional staff overseas, mainly in the U.S., Spain and Colombia. Their plan is to create programs whereby CEI participates in appropriate trade fairs, and conducts business missionary visits to headquarters offices of target companies in the five areas of focus. CEI has not had any business development program previously for the device/disposables sector.

The narrow sector focus areas will need to be reconciled with the “operadoras” strategy of diversification. The FTZs are working with a large number of over 20 industries.

Recommendation. The public sector’s 5 industries versus the 20 industry sectors be reconciled strategically by the “operadoras” allocating a larger sum of their resources on the 5 industries.

J. National Council for Free Trade Zones (CNZFE)

This Government Council regulates the FTZ program; it reviews and approves all new plant projects coming into the FTZs.

It has not conducted any business development programs for the device/disposables sector. Its focus has been on participation in textile fairs, and other development activities to grow and consolidate the textile sector in the FTZs. Textiles accounted for about one half of total FTZ exports.

The CNZFE plan is to develop a program to participate in device/disposables design and manufacturing fairs in large country markets. Concerns include limited resources and the profiles of the people charged with implementing the programs. This represents an area of opportunity which is covered in the Chapter OTHER RECOMMENDED PROGRAMS.

K. National Competitive Council (CNC)

The CNC is a high level public sector organization chartered to accelerate expansion of the economy by stimulating competitiveness.

Meeting discussion centered mainly around the large divergence in fiscal legislation involving the companies in the Dominican Republic which operate outside the FTZs, and pay approximately 32% in tax levies, with the companies in the FTZs which in effect are free of the same comparatively large tax burden. This is a large issue which will be addressed with fiscal reform. This issue is covered in the chapter RECOMMENDATIONS.

L. National Institute for Technical and Professional Training (INFOTEP)

This government agency manages a broad set of educational and more specific training and development programs for the country. The programs include employees in all FTZ companies.

The key issue reviewed was a shortage of technical personnel who have appropriate experience and expertise in specialized areas needed by the device/disposables plants. INFOTEP confirms that it can conduct focused surveys to determine the nature of the gaps for existing new plants, as well as conduct specific training programs. INFOTEP can do this if needed, with training consultants from overseas. This area is covered in the chapter OTHER RECOMMENDED PROGRAMS.

M. Product Manufacturing Analysis

Currently device/disposables products meet the following requirements in the Dominican Republic:

- Labor intensive processes. Labor includes degrees of technical expertise. This takes the form of process engineering, machine shop tooling and maintenance, physical testing, chemical testing, quality assurance, and quality control processes. Some of the plants have engineering personnel that exceed 5% of total headcount, a reasonable degree of technical manufacturing sophistication.
- Labor represents a material piece of the overall total Cost of Goods Sold.
- Machinery, equipment, apparatus, and technology processes for all but the very highest technology products. (The highest technology processes may include highly automated, high speed, high precision, robotics driven processes. Examples include implantable cardiovascular devices, selected imaging devices, laser, and nanotechnologies).
- Large, heavy machinery for which local machine shop process and maintenance know-how is available or can be developed on a sustainable basis, that is, without the potential consequence of material production downtime.
- Overall size of capital investment that does not represent a dominant share of the overall unit Cost of Goods Sold. The capital investment will take the form of buildings (amortization or lease), machinery, manufacturing equipment, laboratory facilities, and machine and equipment maintenance facilities, as appropriate air conditioning facilities, sterilization rooms and capabilities, transportation vehicles. Most of the capital investments above are sourced globally from industrialized countries. As a result, there is no competitive

advantage to be gained by transferring most capital investment segments of a plant to an emerging nation, if the variable unit cost of wages, salaries and fringe benefits, for both technical and non technical personnel, do not represent a material piece of the overall Cost of Goods Sold.

There is an opportunity to ensure that the supply of appropriate technically qualified personnel escalates and meets the demand levels for the existing 15 companies and incoming plants. When technically qualified capacity is developed to meet current and future demand, the companies will be interested in bringing in high tech plants, with higher value Cost of Goods Sold non-labor components.

Achievement of the appropriate level of technically qualified capacity will itself help meet the objective of attracting more sophisticated high technology product manufacturing plants.

A sample list of products and product groups which are currently potential candidates for production in the Dominican Republic are mentioned in Appendix E at the end of this report. The production of the products in this Appendix generally fit with the requirements outlined in the prior five bullet points. A large segment of the total global device/disposables global products can be produced using the current level of production sophistication of the 15 companies in the FTZs.

In order to make a decision on where to produce a product or a line of products, a device/disposables company will undertake a very detailed cost analysis of comparative locations. These may include its existing plants, a new owned plant, or outsource plants globally. The company will first estimate unit sales (and resulting production spread sheets) for time periods such as each of the first ten years, going out in some cases to a generation. It will then calculate details of all fixed product costs, variable unit product costs, and semi variable costs. It will break out each line item of all costs involved, by spreading the costs over each unit of product to be made. It will then conduct a comparative qualitative analysis of the alternative plants under evaluation.

The company will then conduct scenario analysis on the numbers. This analysis may include projecting total unit costs under a scenario where sales upsides are realized, where sales downsides materialize, and under a scenario with different rates of exchange in the foreign plant location. The analysis will be extended to consider a contingency plan for the event the plant alternative encounters a major event.

Existing plants, such as the ones installed in the FTZ have an edge in being awarded new or more existing product volume on the basis that they have already successfully demonstrated they can handle the learning curve in product manufacturing. These plants also have some fixed or overhead fixed costs of manufacturing that might not grow at all, or would grow minimally, with the addition of more production volume in the plant. An example includes the cost of the existing Plant Manager, the top Quality Assurance Manager, and other indirect high salary cost positions.

SECTION IV

BACKGROUND ON LEADING COMPETITORS

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A. Country Relative Strengths Matrix Analysis

The Dominican Republic has competed successfully for over a decade in developing and building a devices/disposables manufacturing, assembly and packaging base for export.

The country has a large number of country competitors which have a wide array of relative strengths versus the Dominican Republic.

Some of the information on the strengths and weaknesses analysis in the table that follows is not readily accessible due to the business nature of the manufacturing contracts. The related secrecy agreements involve the public sectors of the host manufacturing countries and the client companies which have set up manufacturing companies in the host country.

Most host country governments provide the framework and benefits of a manufacturing contract to a potential client, but as a matter of policy do not provide information of a certain substance and detail in general public media, such as websites and brochures.

The mentioned communication vehicles serve to build image. This helps attract the potential client to visit the host country to conduct a preliminary manufacturing viability evaluation. Secrecy agreements naturally also involve private companies in the host country and the client companies. For example, in the Dominican Republic, the “operadoras” and the client manufacturing companies sign business partnership agreements which include secrecy clauses. Several countries do not provide easily accessible information on the detailed benefits, laws and regulations involved in establishing manufacturing operations in their countries.

Despite the above, following is a broad gauge of key comparative strengths of the countries which compete (or will compete, as in the case of China and India) against the Dominican Republic.

Estimated Relative Strengths of the Dominican Republic and selected key Competitor Countries to attract Device/Disposables Manufacturing Plants

Factors that attract Establishment of Manufacturing Plants	D.R.	Mex	US	PR	Can	CR	Ire	Sin	Chi	Ind	Jap
Strategic Factors											
Competitively low hourly wages	2	1½	1	1¼	1	2	1	1	3	3	1

Factors that attract Establishment of Manufacturing Plants	D.R.	Mex	US	PR	Can	CR	Ire	Sin	Chi	Ind	Jap
Potential to maintain competitively low wages	2	1½	1	1¼	1	2	1	1	3	3	1
Low taxes, fees, duties in import countries	3	2	1	1	1	3	2	2	n.a.	n.a.	n.a.
Geographical and other access to key markets	2	3	3	2	3	2	2	1	1	1	2
Supply vs. demand of technical, specialized personnel for manufacturing plants	1	2	3	2	3	1	3	3	n.a.	n.a.	3
Other Factors											
Perceived long term political and macroeconomic stability	1	2	3	2	3	1	3	3	1	1	3
Public and Private Sector Business Development Program	1	n.a.	n.a.	n.a.	3	1	3	3	n.a.	n.a.	n.a.
Laboratory services; packaging and labeling industries capabilities	1	2	3	3	3	1	3	3	3	n.a.	3
Speed and cost of shipping capabilities	1	3	3	3	3	2	2	2	n.a.	n.a.	n.a.
Low cost, reliable energy	1	3	3	2	3	2	2	2	n.a.	n.a.	2
Quality of life services, such as schooling and security for expatriate plant families	2	2	3	2	3	2	3	3	1	1	n.a.

Estimated assessment score of relative strength of each factor in each country: 3= high; 2= medium; 1= low
n.a. designates not applicable, not accessible, or not available.

Summary country headings in the table, above: CR= Costa Rica; Mex= Mexico; US= USA; PR= Puerto Rico; Can= Canada; CR= Costa Rica; Ire= Ireland; Sin= Singapore; Chi= China; Jap=Japan

A conclusion is that the Dominican Republic is very well positioned to become a leading country in the manufacturing and assembly of device/disposables. The single factor is the FTZs ability to produce a high labor content product at a much lower cost compared to all industrialized countries. Industrialized countries have hourly wage rates that can be about ten times the FTZ hourly rates. If 30% of the total manufacturing cost of a product in an industrialized country is made up of salaries and wages, the FTZ could provide more than a 20% lower total manufacturing cost product for those countries, within a scenario of all other manufacturing variables being equal.

B. Order of Magnitude Estimates of Wages per Hour for Selected Countries

Access to information on wages paid per hour is limited despite an abundance of global and country websites and other sources of information.

The reasons for this are many. The wage scales vary over time and vary based on the exchange rate used to convert wages in local currency into the currency of the country making the assessment. Countries with the highest wages do not, for good reasons, freely publicize the data as they promote foreign direct investment. Instead these countries publicize their other competitive advantages. Wages vary by skill levels and industries. Wages vary depending on the variables included or excluded from the figures used. For example, many wage rates per hour are published without the significant impact of benefits associated with those wages, such as Social Security benefits. These benefits in many countries can add some 30% to the hourly wage rates. This may mean the reader does not know if the wage rate published includes or excludes all Social Security and other benefits associated with wages. Frequently the data on wages published does not provide the date of the wage data.

Despite the factors just mentioned, for the purposes of this study, order of magnitude estimates of current hourly wages are provided below for selected countries.

Order of Magnitude Estimates- Wages per Hour (*)

Country	Wages U.S. dollars/Hour
Dominican Republic	\$1.80
Mexico	>\$2.75
U.S.	\$22.00
Puerto Rico	\$12-\$15
Canada	\$17.00
Costa Rica	\$3.00
Ireland	\$ 19.00
Singapore	> \$20.00
China	< \$1.00
Japan	>\$26.00
Korea	\$10.00
Taiwan	\$ 6.00

Country	Wages U.S. dollars/Hour
Guatemala	<\$1.50
Honduras	<\$1.50
Nicaragua	<\$1.50

(*) Sources: Projections from U.S. Dept of Labor; DeRoyal International; For the Dominican Republic: CNZFE.

Guatemala, Honduras and Nicaragua have competitively low labor rates per hour. Despite this they do not represent a competitive threat to the Dominican Republic because all three countries lack a secure environment. There have been incidents of kidnappings of foreigners in all three countries. Establishment of device/disposables manufacturing plants sometimes entail use of specialized expatriate personnel. Companies generally will not expose its personnel to this level of risk.

C. Selected Remarks on Competitor Countries

C1. Dominican Republic. The Dominican Republic can be favorably positioned to take one of the leading manufacturing shares in this industry. To do this it must develop and implement a longer term business development program of substance to make it known as a strong manufacturing and assembly source of high global quality, lower cost device/disposables.

C2. Mexico. Mexico's key competitive advantages include demonstrated expertise in devices/disposables manufacturing and assembly plants, with an array of support industries. These include local industries that provide packaging, labeling, and services capabilities. Furthermore, trucking from and to major markets, Canada and U.S.A., represents an advantage. It is faster and cheaper to move products by truck than to ship them to and from the Dominican Republic via an ocean liner. Mexico also offers door-to-door shipments. Much transshipment is involved in the Dominican Republic.

Mexico has the benefit of having anchored its long term stability to NAFTA. On the other hand, its hourly labor rates have been climbing materially since the establishment of NAFTA in 1994. These higher rates are expected to continue to climb making the Dominican Republic an increasing attractive manufacturing location option.

C3. U.S. The U.S. controls innovative products with its own start-up manufacturing plants. It has full support-industry capabilities to aid in manufacturing products within the country. In order to stay competitive long-term, and to ensure it does not go out of business, the U.S. seeks competitive alternatives in other countries for an expanding set of sector products; the single largest cause is the U.S.'s higher hourly labor rates.

C4. Puerto Rico. Puerto Rico has been a device/disposables manufacturing competitor for over a generation, by capitalizing on U.S. Law 936 which provided fiscal incentives to establish high tech manufacturing plants on the island. The pharmaceuticals industry is a prime example. The location has the advantage of a capable support industry locally. Support capabilities include finishing, packaging, labeling, laboratory, quality

assurance operations. However, the benefits of Law 936 are winding down and labor rates in Puerto Rico are no longer competitive with Dominican Republic.

C5. Canada. Canada is competitive in its highly qualified labor forces, management and leadership skills. With NAFTA it has easy access to the comparatively large markets of U.S. and Mexico. Its closeness to these markets is enhanced by low cost and fast trucking of goods. Its high hourly labor rates compared to the Dominican Republic will continue to represent an issue for higher labor content products.

C6. Costa Rica. Costa Rica has made an entry into the manufacturing of device/disposables in recent years. The country's advantages include reasonable hourly labor rates, although these are somewhat higher than Dominican FTZ hourly rates. Assuming CAFTA-DR is enacted by all parties, Costa Rica's hourly labor rates may be higher than the Dominican rates for years to come. As with the Dominican Republic, Costa Rica does not have the breadth and depth of support industries capabilities. These support industries as stated, include packaging, labeling, laboratory, testing and other services. It is estimated that Costa Rica has similar challenges in achieving very frequent, fully reliable ocean shipping capabilities from and to ports of call beyond the high frequency routes to ports such as Miami. Costa Rica has a highly educated population, an offering greater than most countries in Latin America. The country is comparatively litigious in nature and workers are generally not as flexible as countries such as the Dominican Republic.

It is believed that with a successful business development plan coupled with its demonstrated competence in device/disposables manufacture (globally high quality product with low total manufacturing costs), the Dominican Republic will outperform Costa Rica in attracting new manufacturing plants.

C7. Ireland. Ireland has been extremely successful in attracting manufacturing plants in the high tech fields over the past generation. The plants include device/disposables, and significantly, very large pharmaceuticals plants. This competitor, as with other competitors, has attracted plants from overseas by providing funding toward capital investment in new plants. It has also paid for some of the more specialized education courses taken by technical employees at the plants. It is recommended the Dominican Republic follow the Irish model mentioned above. The segment of the model for which there is a particular need in the Dominican Republic is the subsidy of technical education costs. Candidate companies for new high tech plants in the Dominican Republic will hear from the existing high tech plants in the Free Zones that the country does not have an adequate supply of technically educated and trained personnel that meet the demand levels of existing companies in the FTZs.

Following essentially a generation of ramping up foreign direct investment, Ireland's excellent success has taken it to moving up the scale of technology, focusing on more sophisticated technologies. These include conducting R&D for foreign high tech industries. Hourly wages are comparable to the high wage rates in the European Union. The opportunity is for the Dominican Republic to now capitalize on new manufacturing

investments in the device/disposables fields that would traditionally have gone to Ireland.

C8. Singapore. Like Ireland, Singapore has established similar successful plant attraction programs. Some of the recommendations of this report include strategies which dovetail with those used by Singapore as well as Ireland in its foreign direct investment development programs. As with Ireland, Singapore's hourly labor rates are globally high. As a result, the country continues to move up to the highest technology industries.

Both countries very high hourly labor rates are a result of their outstanding success in foreign direct investment over the past generation.

C9. China. China's labor rates are in line with some of the world's lowest rates. The country represents a large long-term competitive threat to competing countries which manufacture device/disposables. In the intervening years, western competitors who own most of the technologies and patents in this industry will continue to seek lower cost manufacturing options in other western countries.

C10. Japan. Japan has substantial device/disposables manufacturing plants. It also continues to seek and access lower cost manufacturing alternatives as its labor rates are among the highest globally. Japan will continue to expand manufacturing sources to outsourcing plants, mainly in Asian countries such as China.

SECTION V
S.W.O.T. ANALYSIS

SECTION V

S.W.O.T. ANALYSIS

A. Internal Strengths

A1. Core competence. Device/disposables are an area of core competence in the FTZs for over a decade. The competence consists of the manufacturing of global high quality device/disposables at competitively low total unit manufacturing cost. This very significant area of strength has not been broadly marketed by the country to the large number of competitors in this atomized industry.

A2. Manufacturing expertise with high tech products. Examples of high tech manufacturing expertise include Baxter, Tyco International, Johnson & Johnson, and Surgex.

A3. Some DR plants have FDA, EU, and Japanese Government approvals. The Healthcare Agencies in these countries are known to have the most stringent device/disposables scientific and technical, review and approval standards globally. The high level global approvals include substantial Clean Room and sterilization capabilities and processes.

A4. Competitively low hourly labor rates. These competitively low labor rates compare favorably with the rates of nearly all countries which represent competition in device/disposables manufacturing in the Western Hemisphere.

A5. Close to zero taxes and fees. There are almost zero taxes, duties and fees involved. Trade agreements ensure that imports of appropriate products do not pay import duties in the U.S. and pay between 0% and 2% import duties in the European Union, the two largest global markets. This story needs to be advertised broadly with the other areas of strength mentioned above.

A6. Comparatively close to key markets. The Dominican Republic is geographically close to the largest markets in the western hemisphere, Europe and North America. Shipping costs have low impact on economics due to a competitively priced shipping industry.

A7. Work ethic. The Dominican worker has a strong work ethic compared to many other countries in the western hemisphere. The worker is comparatively more flexible and loyal. In contrast, certain other countries have an aggressive litigious environment, and abusive collective bargaining practices.

A8. Sector exports already account for a material ten percent of total FTZ exports. This business can be developed to account for a much larger percent of FTZ exports.

B. Internal Weaknesses

B1. Traditionally moderate, uncompetitive device/disposables business development programs. This weakness is contrasted with the Irish, Singapore, Canadian, and Mexican business development programs. This area is the single largest recommended strategic thrust for the Dominican Republic. The thrust is provided in the form of several integrated recommended programs in the Recommendations chapter of this report.

B2. Lingering Perception of macroeconomic and political instability. Real or perceived macroeconomic instability issues for headquarters operations of the high tech company manufacturing in the FTZs.

For example, the steep fluctuation in the exchange rate of the Peso over the past two years is reported by the plant General Managers to headquarters offices as part of their monthly reports. This creates instability in the unit costs of manufacturing and assembly and concern if not displeasure at MNCs. These companies need to demonstrate performance stability to its shareholders.

The Peso exchange rate shifted from DR \$17 to the U.S. dollar as recently as 2003, to a high of DR \$50 more recently, then down to DR\$40. As of May 2005 the exchange rate is DR \$29.

The temporary lower unit costs caused by a devaluation of the Peso are soon forgotten. Corporate leaders have selective memories and scrutinize continuous strengthening of a local currency like the Dominican Peso and the consequence of escalating costs.

B3. Shortage of technically specialized personnel. There is a need to expand the country's capacity and overall availability of technically specialized personnel. Currently the high tech device/disposables manufacturers do not have enough technical staff with appropriate skills and experience to meet their needs. As a consequence these companies enter a situation where they are competing by "stealing" each others talent.

A company doing an evaluation of the Dominican Republic will determine quite easily from the General Managers of the plants in the FTZs that this is an issue. This weakness is a constraint which could be a deciding factor in a recommendation to not move forward with a plant in the country.

B4. Discontinuity in public sector programs. A lack of historical continuity in government development and other programs caused in part by changes in government administrations is an issue that needs to be addressed deftly with all companies "interviewing" the FTZs for a potential manufacturing site.

A lack of continuity also includes turnover of government officials. Turnover is perceived by the companies who seek to place plants in the country as an issue. The perception is

that the government official, as a result of being in the position a relative short duration of time, will not have the appropriate experience or expertise to meet customer needs.

B5. The cost of electricity is very high. These costs are very high compared to essentially all markets against which the country competes. The cost is as much as twice as high as markets such as NAFTA countries.

One of the companies in the FTZ states their electricity bill represents up to 40% of their overall wages and salaries bill, a figure which is completely out of proportion with other countries where the company has manufacturing plants. This represents a challenge to their business.

B6. Limited breadth and depth of capabilities in local packaging and labeling industries. This negatively impacts the needs of the device/disposables plants operating in the FTZs. Also, sometimes the quoted price of packaging is not competitive. The consequence is that many of the packaging and labels have to be designed overseas and imported into the FTZs. The manufacturers instead need to simplify processes and buy products from Dominican companies.

B7. Inadequate capabilities in the country to provide services. Specific needs include laboratory, other testing and industrial air conditioning services. Due to this limitation the manufacturers have to send products, raw materials and components for laboratory and testing services, by air to locations such as North America. This adds to complexity of processes, costs and time.

Countries such as Puerto Rico (due in part to the capabilities of a large pharmaceutical manufacturing industry set up starting in the 1960s), and Mexico (due to its being one of the top twelve global pharmaceutical markets and having capabilities for a population of some 90 million people) offer these needed services to its medical device/disposables manufacturers.

C. External Opportunities

C1. Investment emphasis on a limited set of products and services industries. Promote the device/disposables industry as a very large, long-term, high growth, and high tech manufacturing sector opportunity.

C2. Each device/disposables plant addition means a stream of country benefits for decades. The above opportunity is due in part to higher plant entry and exit barriers associated with high tech manufacturing. The plants have high tech components including machinery, equipment, skilled workers, and high level engineering skills in several engineering fields. The plant may be expected to have a very long life cycle in the Dominican Republic. As the country will continue to compete favorably in lower labor rates long term, it will become even harder for a company to justify leaving the Dominican Republic.

C3. Creation and implementation of an Effective Business Development Program. Prior overseas business development programs in this industry were moderate to non-existent over the years.

C4. Implementation of a visibly strong public- private sector partnership. The partnership should integrate the country's business development program.

C5. Effective marketing of the DR's well established competence in device/disposable manufacturing. Market the story outlined under the internal areas of Strength. The story will include experience, expertise in high tech manufacturing and assembly, globally approved plants by the most demanding of health regulatory agencies, and the bottom line: globally high quality product at competitively low total unit cost of manufacturing.

C6. Relative geographical closeness to key western hemisphere markets

C7. Capitalization on enactment of the CAFTA- DR agreement after it occurs. The trade agreement will help anchor the Dominican Republic more favorably to the long term stability and growth of certain industrialized economies. A parallel may be drawn with Mexico's economy which became more stable and has enjoyed more rapid growth since the country anchored its future with NAFTA, starting in 1994. Parallel benefits of long stability and growth may be expected by the recent 10 European countries entering as EU members.

D. External and Internal Threats

D1. Lack of an effectively implemented business development program may result in a moderate to flat sector plant yearly volume growth long-term.

D2. WTO direction to remove prohibited FTZE subsidies by 2009. If there is no clarity around how the country will handle the elimination of the FTZE subsidies in 2009, some companies who are considering establishing a manufacturing plant in the Dominican Republic, could delay their decision. The companies may wait until they see clear long-term fiscal reforms which they hope will remove the uncertainty surrounding the elimination of the WTO-defined subsidies for the FTZs.

Owners of potential manufacturing plants are generally risk averse. They may see this outstanding issue as a large swing factor in assessing the overall manufacturing, assembly and packaging conversion costs.

The government has the opportunity to expeditiously address the current differential programs between the FTZ Parks, and the companies doing business in the country beyond the FTZ Parks.

D3. Clean environment to attract manufacturing plants. Improve the environmental image outside the FTZ Parks which are the only candidates for new device/disposables

plants. Due to their high tech nature, these plants must be free of unclean areas, dust, and microbiological contamination.

The roads and surrounding areas that lead into at least two FTZ Parks that could be selected by a potential manufacturing plant are not clean. Examples are the road for about the length of a kilometer leading into Itabo, and the road leading into San Isidro. They contain substantial deterioration, debris, rusting piles of metal, or a huge number of mountains of rubble.

When conducting an evaluation to establish a plant in the FTZs the plant evaluator will have a mindset to protect the quality and medical safety of the products to be manufactured. As a result the evaluators are very concerned with cleanliness. The environment mentioned above negatively impacts a person making a recommendation to establish a plant in the FTZs. A clean-up program will contribute to enhancing the country's competitiveness in attracting new plants and not turning away the evaluators.

D4. New competitor entries. The Eastern European countries may enter into the device/disposables manufacturing industry in the next x years. These countries provide a well educated workforce and currently have a cost base that is competitive versus Western Europe.

Longer term, India may enter manufacturing in this sector with very low labor rates, and very good engineering capabilities needed by manufacturing companies in this sector. China is manufacturing some products in this sector now. The longer term threat is that they will receive very large capital investments to establish massive plants in their country.

These represent long term threats. These threats can be overcome by the Dominican Republic if it executes an effective long term business development program to attract manufacturing plants in this sector.

SECTION VI
VISION

SECTION VI

VISION

The Dominican Republic has an excellent potential to become a leading country in the manufacturing of global high quality, competitively low-cost medical devices/disposables for the western hemisphere markets.

The above vision statement is based on most of the significant internal strengths and external opportunities mentioned and described in this report.

The country will achieve its potential by capitalizing on its key competitive advantages:

- Competitive lower labor rates in the Western Hemisphere.
- Almost zero tax and fee impact on manufacturers' imports, manufacturing conversion, and exports. Also, almost zero duties on imports in Europe and the U.S.
- Demonstrated manufacturing of high quality device/disposables for over ten years. (List key companies in the FTZs).
- Global exports from FDA, European Union and Japanese Healthcare agency approved plants.
- Comparative geographical closeness to the largest markets in Europe and North America which account for three quarters of world demand.

Additionally, the country will need to develop and implement an effective business development program. This business development program is pivotal in allowing the country to cross the bridge and turn into a major player in device/disposables manufacturing.

SECTION VII
RECOMMENDATIONS

SECTION VII

RECOMMENDATIONS

A. Recommended Strategies

The main strategies recommended are based on findings in the Dominican Republic; the nature, profile, large size and large yearly growth rate of the global device/disposables market; the Dominican Republic's competitive position compared with its larger country competitors; and a S.W.O.T analysis.

The following main strategies are recommended:

A1. Industry focus. The Dominican Republic should focus its strategic efforts and promotion programs solely on the very large, high growth medical device/disposables industry.

The country should focus its efforts on the total industry, not just on the part of the industry that is classified within Harmonized System Code 90. The country should maintain its focus on the industry and not attempt to expand its programs and resources on the other industries included in HS 90. These industries include Optical and Photo industries.

A2. Positioning. The Dominican Republic offers well established core competence in the manufacturing of device/disposables that meet the needs of manufacturers globally.

The core competence is based in part on the country's benefits and ability to make the highest quality global devices/disposables at competitively low costs.

Global product quality is demonstrated by the existence of plants that have attained and maintain FDA, EU, and Japanese Healthcare agency approvals. These agencies assure the highest product quality. The low cost is driven by competitively low hourly labor rates by country competitor standards. It is also driven by almost zero tax and fee impact, and almost zero import duties in Europe and the U.S. The country also has a manufacturing base which is comparatively close to the largest markets, with favorable work ethics. The DR represents an excellent choice for Western Hemisphere customers to establish a high tech device/disposables plant in the country.

A3. Products. The country should pursue attracting manufacturing of all products that meet the following device/disposables manufacturing requirements.

- When labor intensive processes.
- Labor represents a material piece of the overall total Cost of Goods Sold.
- Machinery, equipment, and technology processes for all but the highest technology products. The highest technology processes may include highly automated, high precision, very high speed processes. Examples include

implantable cardiovascular devices, selected imaging devices, laser and nanotechnologies.

- When technically qualified personnel are further developed and the number rises to meet current and future volume demand, pursue products with higher value Cost of Goods Sold components. These may include laboratory, quality control, molding operations, machine tooling of component parts of the finished product.

The strategy will meet the objective of attracting increasingly more sophisticated high technology product manufacturing plants. As mentioned, the nature of device/disposables used by patients and consumers is such in medical performance and safety needs that the industry needs high technology manufacturing facilities and capabilities.

The product strategy involves developing business for a larger segment of the total industry.

A sample list of product and product group candidates that are targets for manufacturing in the Dominican Republic is included in Appendix E. A product manufacturing analysis is provided within Chapter III, DOMINICAN REPUBLIC INDUSTRY. This analysis provides the reasons behind decisions on manufacturing sourcing alternatives. A list of products and product groups with limited or no potential is provided in Appendix F. The reasons for product inclusion in this Appendix are provided immediately below the heading of the Appendix.

A4. Customers (Companies)

A4a. First priority companies. Pursue the 15 device and disposables companies that currently have manufacturing plants in the Free Zones to add plant volume.

Due to the nature of the industry in which the roughly largest 120 companies have approximately one half of the global \$190 billion industry, most of the companies operating in the Free Zones have very large additional manufacturing unit volume needs. A rough estimate is that there is potential to double and triple the volume of manufacturing in the FTZ at most of these companies. Achievement of this strategy alone would take exports of devices/disposables to over one quarter of the country's exports, and dramatically increase employment opportunities in the sector. It is much easier to increase business with existing customers than to develop business with a new customer.

Most of these 15 companies, as well as many competitors globally, operate their manufacturing sourcing decisions centrally. The responsibilities as to where to manufacture existing and new products generally lies at world headquarters.

The decisions on what, where, how, and when to manufacture generally are not made by top management of the plants operating in the Dominican Republic. With this in

mind, fresh approaches should be made to develop connections at company headquarters.

Due to continuing staff turnover at all companies, the people currently in charge of manufacturing decisions may not be familiar with a personal visit to the Dominican Republic, the FTZ and their plant in the FTZ. This plant could be one of a three dozen, or substantially more in-house and outsource manufacturing plants. No additional plant or significant new additions to plant capacity happen without review and evaluation visits to the plant location, in this case, the Dominican Republic. The objective of approaching headquarters offices should be only to persuade headquarters to visit the Dominican Republic. Once the visitor/s is in the country and FTZ, the selling process can commence.

A4b. Second priority companies. The target companies should include the top 2% of the companies in the industry which account for roughly one half of global sales. This list of companies amounts to approximately 120 firms. A list of many of the largest companies is provided in Appendix D.

Product approach with the largest companies in the industry. The larger firms generally have a broad set of product lines and products. Some or all of these are focused in certain specialty sectors. Examples include cardiovascular, orthopedic (musculoskeletal), and ophthalmic medicine. Very broad categories include catheters, endoscope products, diagnostic imaging devices, safety engineered devices, patient monitoring apparatus. Large disposables categories include surgical sutures, intravenous lines, disposable clothing, disposable operating room dressings, gauze, bandages and hospital diapers.

Industry products are in the multiple thousands. Many of the largest 120 companies have a portfolio of products that can consist of several hundred products. As the specialty areas covered by the top companies are broad and as their product portfolios are also broad, the marketing approach with these companies should avoid a focus on specific products or product areas. we cannot expect to have the expertise to discuss technologies and manufacturing processes for each product in a target company.

Instead, the person who markets the Dominican Republic FTZ device/disposables plants should only mention the name of the broad types of products manufactured by that company. The names of the products of the company may be gleaned from the company's website or a source such as Hoover.com. The person should be able to converse with the target company that manufacturing capabilities in the Dominican Republic are sophisticated; including for example, globally large Clean Rooms and sterilization capabilities.

Due to the high technology nature of the manufacturing plants, a seasoned manufacturing professional at these large companies will know immediately if a person is well versed in device/disposables manufacturing. The representative should let the

large company decide which of the many products in their portfolio they consider effective candidates for manufacture in the Dominican Republic.

A4c. Third priority companies. These include the medium size companies globally. There are many companies in this vast segment that hold good potential for manufacturing. However, there are many factors that need to be considered in approaching these companies. It is therefore recommended that the business development effort with these companies be materially lighter than with the 15 current companies and top 120 companies.

An important point regarding the potential of this third priority strategy is that these medium size companies generally manufacture smaller volumes of product compared with the larger companies, thus reducing the medium size company potential in the Dominican Republic. Furthermore, many of these companies are not as financially sustainable as the largest companies, and are subject to instability from the potential for mergers and acquisitions in an industry which is rapidly consolidating around the world.

A4d. Small companies. Smaller companies should be excluded as business development targets. They make up most of the companies in the industry, but are much less financially stable. Many close or divest operations due to lack of financial sustainability. Smaller companies are more dynamic in their decision making compared to the fewer large companies and are more nimble in their decisions to shift manufacturing both in and out of locations. As they do not have the leverage to operate across many country borders, and they do not have the sophistication in sourcing capabilities, they are more likely to have their product made in their home base country.

A5. Promotion Program

A5a. High level invitation letter. A high level letter should be sent to Chief Executive Officers (CEOs) of selected target companies, signed by the President of the country.

It has been demonstrated that high level letters are required to overcome the competitive distractions in today's overly crowded competition for business. Letters to lower levels of management may not be effective. A letter from a lower level Government official may mean in some cases that the company will not know who the Government Agency represents and what influence it has within the country. This may result in distraction and non action.

In practice, a letter from a President reflects respect and a high level of interest. An overly busy CEO, will either have his or her assistant handle, or write a cryptic note to a senior leader within the organization, which might be something like "Mary, please review", or "Tom, please handle". An innocuous note from a very large company CEO, on a letter from a country President, may be perceived as an invitation for analysis, resulting in a response, and perhaps a visit to the Dominican Republic by manufacturing and or finance management to carry out a preliminary manufacturing plant evaluation.

The one-page letter should contain the benefits of real substance offered by the Dominican Republic, and include the key points mentioned under the subheading VISION, above.

A Visitor Action Plan needs to be executed for any person conducting an evaluation visit. The Action Plan will lay out who is accountable, what the public relations program will consist of, how coordination will take place among the different stakeholders.

A5b. Campaign for visit programs. An effective, formal, accountable, and time bound long term Public and Private Sector program should be orchestrated and carried out to persuade target companies to come to a Visit Program in the country.

A visit program is critical to a company deciding to establish a plant in the country. In effect, the visit constitutes an “interview process” which all stakeholders in the Dominican Republic should welcome enthusiastically and energetically.

Manufacturing specialist visitors will be favorably impressed with the technical capabilities being achieved in the device/disposables plants in the Free Zone. Signature companies may include Baxter Cardinal Health, D&G (Tyco Int'l), J&J. A new plant will only be established after an in-country interview and in-depth evaluation process. It is suggested the visit program be co-chaired by the Public and Private Sectors.

A suggested visit program outline follows:

- Day 1. Arrival of evaluator/s and Welcome Dinner; ten-minute Country, FTZ Overview Presentation hosted by Public-Private sectors.
- Day 2. (Or, Day 2 and Day 3). Visits to selected owner companies of FTZ; perhaps with one 15-minute Presentation. Brief plant tours of selected plants. Agenda to be amply spaced so there is no potential for programs being cut short or running late. Closing Dinner. Decisions on chairing or co-chairing to be made based on the size of the opportunity.

A5c. Trade fairs. A Public Sector program involving CEI-RD and or CNZFE- with or without private partners should be developed and implemented. The program should consist of investing and participating in a few target global device/disposables design and manufacturing trade fairs.

The Public Sector with Private Sector input needs to have a ready-made Booth and exhibit capabilities that will be shipped to each trade fair.

The objective of investing in the trade fairs needs to be specific: it should persuade a potential customer to visit the Dominican Republic to conduct a study of the competitiveness and desirability of locating a plant in the country. There should be generous quantities of brief brochures, hand out leaflets, perhaps Question and Answer sheets which rapidly educate the reader on the many pertinent aspects in device/disposable manufacturing in the country. The printed media will provide features,

advantages and benefits for potential customers. Promotional materials need to be created with expertise and support of an advertising or communications specialist. The quality of the local language used in the materials should be flawless in order to protect the credibility and image of the program.

The profile of the people managing the Stand and Exhibits is pivotal for success. The profile of the person should include:

- Very good knowledge of the local language.
- Articulate, attractive, good selling skills.
- Basic knowledge of the device and disposables manufacturing story in the FTZs. The person should have toured a couple of the device/disposables plants in the FTZs.
- Well-versed in the benefits offered by the Dominican Republic. Capable of anticipating and responding to questions with brief and credible answers.

If needed, a person with the appropriate profile should be hired as a part time consultant to get the job done. Countries such as Ireland and Singapore have achieved this level of effective professionalism.

A6. Geographical target markets. Target markets should include the entire western hemisphere. This target includes three quarters of the world market.

The eastern hemisphere should not be included as a target market. The reasons include the following. The western hemisphere target is a vast one; all strategies and limited resources need to be focused. Eastern hemisphere country markets are very distant geographically; generally their cultures and languages are very different to the culture and language of the Dominican Republic. As a quite highly regulated industry, capabilities and a material degree of expertise is required to secure Ministry of Health approvals for new products and new manufacturing sources, such as the Dominican Republic. This is certainly the case in the largest markets, Japan and China. Significant Administrative Barriers to Trade exist in many Asian countries. All of the factors mentioned above represent entry barriers of substance to developing manufacturing business for the eastern hemisphere.

B. Other Recommended Programs

The following programs are recommended to accelerate attraction of medical device/disposables manufacturing plants to the country.

B1. Technically specialized education capacity. It is recommended INFOTEP focus substantial resources on developing and achieving appropriate technically qualified personnel in the country so that supply rises to meet the current and new company demand for these personnel.

A person visiting the country to evaluate the attractiveness of establishing a plant in the country will return to his or her home country with some knowledge and concern with this issue. If this issue becomes a critical point in turning away the manufacturing person who conducted the evaluation, the company will be politically correct and not share that technical skills were a major concern and turned into the main cause in the company deciding against establishing a facility in the FTZs. There is a strategic opportunity as well as threat to address this need.

It is recommended INFOTEP conduct surveys with private sector support and respond to the need to prevent new companies from turning away from the country and ensure the existing companies have their needs met.

The surveys should have the objective of clearly assessing the nature of the specialized gaps between supply and demand. The surveys should then be implemented in the form of specialized training programs in a manner that the country will supply the skills sets needed by the existing companies and in anticipation of companies that seek to come to the country. The surveys should be conducted in a manner that implementation of training courses start right away.

Specialized personnel may consist of Industrial Engineers who are versed in very specialized technologies and processes. They may consist of engineers with degrees in mechanics, electronics, chemistry, biology, microbiology.

Currently the demand for this level of personnel outstrips supply in the country. As a result there is a fair amount of “stealing” of appropriately qualified personnel among different companies in the device/disposables and other high tech products in the Free Zones. This is being fed back to headquarters offices of the manufacturing companies in the monthly reports issued by the General Managers or Plant Managers. The issue also contributes to the equivalent of “high maintenance” headaches and distractions in training and retaining specialized personnel. Instead, the plant needs to focus on making high quality product more productively.

Implementation of such training programs is a strategic commitment to country competitiveness against an array of country competitors such as Mexico, Costa Rica, Puerto Rico, Canada and the U.S.

Recommendation. Government agencies should emulate countries such as Ireland and Singapore until the Dominican Republic has reached a country capacity in this strategic area. These countries paid the invoices submitted by the manufacturing companies involving specialized training, or had a partnership to pay for half of the specialized training.

The current INFOTEP program that pays for exceptional, specialized training is viewed as a good start. Having stated this, the assessment is that the program is not responsive to the needs and fast timing of today’s digital world. The program’s approval process involves layers of decision making. The perception is that an approval of a

training course overseas for a company involves perhaps some one hundred steps- a lengthy, cumbersome process.

Leadership of the high tech manufacturing plants doesn't have much productive time to trigger, manage, follow-up, and ensure timely approval of INFOTEP paying for a specialized course. The time needs to be invested instead in making high volume, high quality product at very low cost with minimal distractions.

B2. Electricity. A long term program needs to be developed and executed which helps lower the globally uncompetitive high costs of electricity.

B3. Local services industry. It is recommended a study be conducted to determine the magnitude of needs for services in the Free Zone for which there are no or limited capabilities in the country.

The objective of the study is to assess and stimulate the development of local capabilities to address unmet needs of Free Zone and other companies. Some device/disposables companies indicate that the country, unlike its geographically nearby competitors, Mexico and Puerto Rico, does not have a range of capabilities to offer. As a result, the companies have to send their laboratory and other testing needs overseas, to headquarters and other locations. These processes are laborious, entail long lead times, and add cost to the overall manufacturing process. They become high maintenance processes.

The lack of adequate services is a weakness which may be converted into an opportunity. The opportunity may stem from conclusions of the study that there are needs of sufficient breadth, depth and critical mass that a Dominican entrepreneur may capitalize on developing an enterprise to meet the previously undefined needs of client companies. The study could stimulate a former Plant Manager of one of the FTZ companies to capitalize on his or her expertise to start such an enterprise.

B4. Packaging and labeling industries. Some FTZ companies indicate that unlike such industries in Mexico and Puerto Rico, the Dominican Republic does not have packaging and labeling industries with sufficient capabilities to meet the needs of the high tech companies in the Free Zones. As a result these companies must rely on longer supply lines from overseas countries, must invest in more capital in the form of higher inventories, and deal with more intricate logistics and shipping programs to meet their large array of needs in the packaging and labeling fields.

The packaging industry in the Dominican Republic in some instances has the product capabilities that meet the needs of the companies in the Free Zones, but is not price competitive with other countries. It appears the overall tax impact of approximately 32% of sales on the local capital companies in the country is high and renders them less competitive. It is understood a fiscal reform program is under review.

B5. Communication and image. Programs should be put in place to develop websites to attract Foreign Direct Investment and accelerate attraction of more manufacturing companies in the high tech areas to the Dominican Republic.

There are many websites in place, established by several of the agencies in the public sector, such as CEI, CNZFE, and the private sector such as ADOZONA and owners of the Free Zone Parks. Many of these websites are primarily in the Spanish language, and have limited capabilities in the English language.

As is known, the English language is the main global language of commerce. This language is the primary language of more than half the markets of device/disposables globally. Therefore, the web sites should be global, customer oriented, and focused primarily outside of the Dominican Republic. These web sites should allow any visitor to read the full web site in either Spanish or English.

The web sites should be redeveloped to have more overseas customer orientation, and to anticipate questions potential customers may have with ready answers.

The Dominican Republic should borrow extensively from the excellent website models used by Ireland, Singapore and Canada. These websites market the country capabilities in meeting customer needs in effectively and attractively. The Dominican Republic has significant competitive advantages versus other countries and these should be displayed and spelled out clearly for all to read.

As there are so many websites in the Dominican Republic, it is recommended each one dovetail well with all others so the reader from a potential customer has clarity on the role, accountability and benefits provided by each organization. There is an opportunity for some websites to more clearly answer the potential client's question: "What's in it for me?" This was not easily apparent in some websites. For these reasons it is recommended there be coordination of website enhancement. This fits with the need for close coordination in all processes to attract and retain high tech manufacturing plants.

B6. Image in areas approaching selected FTZs. Appropriate government agencies should plan and undertake a clean-up program on the roads and areas close to the entry of selected Parks. The selected Parks should include some of those that contain, and will contain, plants which manufacture devices/disposables.

As stated throughout this report, the current and potential manufacturing plants in the device/disposables fields are high tech plants. The products become in contact with the human body and in some cases are used invasively, inside the human body. The industry is highly regulated by public sector health agencies in part to ensure manufacture and use of excellent quality, sterile products. These products must be free of microbiological and other contamination. In order to meet this goal the plants in this industry are correctly focused on cleanliness. In contrast, some of the roads and neighborhoods nearby to selected Free Zone Parks are not clean and create mistrust as a site for manufacturing and assembly plants.

Whereas the entry roads to Las Américas are clean and provide a good image to a potential new plant customer, the entry roads to Itabo and San Isidro are not clean.

The general entry road areas to these two Parks contain extensive rubble in some areas, have deteriorated conditions and are dirty. The unsanitary image contrasts with the need for cleanliness and zero dust and biological contamination at the plants. This factor may well be written up in a report by a potential new plant manager conducting an environmental and plant viability study.

Positive action in this area will demonstrate commitment to competitiveness and the will to attract new investments to the country.

B7. Multilateral agency funding. It is recommended a specific, time-bound funding program be sought and achieved from a multilateral agency such as the IFC of the World Bank or FOMIN of the IDB.

The funding program should be geared to develop and accomplish some of the Strategies and Other Recommended Programs contained in this report, over a period of three years.

From the perspective of the funding Agency, this program will contribute to strengthening and accelerating the Dominican Republic's demonstrated core competence in manufacturing global high quality, competitively low cost device/disposables. This funding, will contribute to expanding the economy, increasing employment, increasing higher level value addition while increasing the level of higher skilled workforces and management.

It is recommended the utilization of the funding be tightly coordinated by appropriate bodies of the public as well as private sector. Key players in this program may include CEI-RD, CNZFE, and ADOZONA.

Due to the specialized high tech nature of the device/disposable industry potential new plant owners will only establish new plants in the Free Zones that currently demonstrate specific capabilities. The ones that will be chosen generally already meet the needs of existing industry manufacturing plants. Industry players are risk averse and seek almost guaranteed successes. The owners of these Parks should actively participate in this funding recommendation.

It is understood that an IFC funding program implemented nearly a decade ago in the Dominican Republic was controversial in the processes used involving differing exchange rates through the Central Bank. One Free Zone company volunteered this prior program was not successful, and as a consequence, this company would not access a similar funding program were it offered one in the future. It is recommended such a funding program have private and public component.

B8. One-time cash grants for larger plants. Countries such as Ireland have provided cash incentives to stimulate companies with their decision to establish a plant in the country. These programs, contained in secrecy agreements, contribute to the mix of factors which draw a company to establish a plant in a country. Whereas a manufacturing person in the company will focus on ensuring that the country offers sufficient qualified technical personnel, the finance persons and top management of the company focus on the overall financial benefits of a new plant. Companies are attracted to all incentives. Cash incentives carry added weight in the economics in the early years of a new plant, and could become a swing factor in favor of the Dominican Republic.

It is recommended the Dominican Republic assess providing such one-time incentives for larger new plants. For example, the country could negotiate a grant for a new plant which generates employment levels of over 500, over 1000, or over 2000 employees in its first three years of operation. This up front cash “investment” is be easily offset by the benefits of employment for the country and a flow of other benefits deriving from the plant, perhaps for decades.

B9. Ocean shipments. A public-private survey should be implemented to address complaints regarding lack of discipline in the schedule commitments and timing of ocean shipments to global ports, beyond core destination ports such as Miami.

Some companies in the Free Zone have manufacturing businesses which entail making ocean shipments to some ports globally. The plants have yearly contracts with selected shipping companies. These companies fail FTZ customers as well as customers at shipping destinations by changing committed ship dates, by delaying planned ship arrival and departure dates in the Dominican Republic, and by delaying ship arrival dates at destination. The consequence is that the companies must overcome this by using more capital to increase inventories of their products and provide explanations to unhappy customers. It is understood that shipping capabilities in competitor countries such as Puerto Rico are more reliable.

SECTION VIII
CONCLUSION

SECTION VIII

CONCLUSION

A key objective of this study is to assess the manufacturing and export potential of the products in the Harmonized System 90 industries.

A conclusion is that the large medical device/disposables industry classified within HS 90, coupled with substantial industry products classified in other HS Codes, represents a very large manufacturing, assembly, and packaging potential. The potential is both in size and yearly growth for the Dominican Republic. The country should capitalize on this global industry by implementing long term business development programs so that this industry becomes a leading contributor to Dominican Republic exports.

Other industries in HS 90, such as Photo and Optical industries, should not be pursued. The Dominican Republic will achieve a higher level of success by concentrating its efforts and limited resources in the device/disposables industry. It should not simultaneously distracted and dilute limited resources on the other mentioned industries in HS Code 90.

The device/disposables industry provides a global US\$80 billion manufacturing, assembly and packaging potential as measured on a Cost of Goods Sold basis. The Dominican Republic has demonstrated it has a core competence in manufacturing these products over more than a decade. Core competence stems from long term production of global quality products at competitively low costs. Key companies include Baxter, Johnson & Johnson, and Tyco International. Some of the 15 plants operating in the country have FDA, EU, and Japanese Government approvals to manufacture. These high tech plants are globally competitive players.

The industry has performed reasonably well. Its exports represent 10% of total FTZ exports, which in turn represent 80% of total country exports. The country has a profile of internal strengths and weaknesses, as well as opportunities and threats that provide a backdrop to capitalize on much higher growth than the moderate industry growth in recent years. The country has carried out very limited business development programs in the past. A vigorous long term business development program will attract a larger number of companies which in turn will stimulate a much higher rate of growth in exports and hard currency value added.

The Public and Private sector should join forces in establishing the industry as one of the few product and services area of higher investment and promotion focus.

ANNEX A
SCOPE OF WORK

ANNEX A

SCOPE OF WORK

**United States Agency for International Development (USAID)
Dominican Republic**

Chemonics International, Contract No. PCE-1-830-98-00015-0

Scope of Work

**Export Competitiveness Study on Harmonized System Code 90 Products –
Optical, Photo, Technical, Medical, etc. Apparatus**

This Scope of Work (SOW) provides the background and specific tasks required to contract a consultant to prepare a strategic report on the HS Code 90 products in the Dominican Republic (DR), examining the opportunities for and constraints on the Dominican Republic's competitiveness in this sector, and recommending a strategy with specific initiatives to resolve near-term barriers to growth and set the stage for accelerating industry export development.

BACKGROUND

The export sector has been an important source of growth for the DR. Over the 1990-2000 decade, DR exports increased from US\$850 million to US\$4.8 billion. Three important factors influencing the growth in exports were the proximity to the US market, the Free Trade Zones that provided incentives for investment in the DR, and the textile and apparel quota system that provided market advantage to the DR.

The Central America, United States (US), DR Free Trade Agreement (CAFTA-DR) was signed on August 5, 2004, and will probably be ratified by all the legislative bodies in every country during 2005. This provides duty free entry to the US market, subject to some constraints. The Agreement is likely to significantly enhance trade between the participating nations, creating new opportunities, as well as possible threats for specific sectors.

The Free Trade Zone (FTZ) system will change significantly. Under current WTO rules, FTZ benefits are considered export subsidies and must be phased out by 2009 for all countries with a per capita income greater than \$1,000 (a formula has been established to adjust the threshold income level, originally set in 1994, to account for inflation), including the DR.

The DR export sector must prepare for these challenges. The Export and Investment Center of the DR (CEI-RD), the Dominican Association of Free Trade Zones (ADOZON), the National Competitiveness Council (NCC) Secretariat and USAID/DR have been engaged in discussions on how USAID/DR can assist them in meeting the challenges facing the sector.

The activity described below will assist the above organizations to collaborate in the development and implementation of strategies to address these challenges. The objective is to analyze the potential of the HC Code 90 Products export sub-sector to increase production and exports and become a leading growth sector for the DR economy. As part of the analysis of export growth potential, the Consultant will identify the constraints, domestic or foreign, that must be addressed for the sub-sector to fulfill that role, and recommend actions to be taken to address the constraints. These recommendations will be utilized by CEI-RD, ADOZONA and the NCC Secretariat to implement export development strategies necessary to accelerate export growth in the HC Code 90 Products sub-sector and to address the constraints to accelerated growth in the sector. They may also be used to develop and conceptualize assistance – both donor and public sector – to the industry.

As sectors that have served as traditional sources of growth in the Dominican economy mature, there is a need for the identification and promotion of new growth sectors that will serve as growth poles. The DR is fortunate to have several sectors which appear to have rapid growth potential. What is required is an analysis of their growth prospects, the sources of competition and the policy or other constraints that could limit that growth.

The export **group** HS Code 90 Products – Optical, photo, technical, medical, etc. apparatus accounted for US\$414.9 million of DR exports in 2001. The overall growth in the annual value of Dominican exports from this product group was 7% over the period 1997-2001, while the annual growth in world exports of these products increased 5% during the same period. Thus the Dominican Republic was expanding exports in a commodity group that was gaining market share in world trade. The table below presents the value of exports and growth rates for the two principal DR product groups broken-out at the 4-Digit HS Code. The total exports for these two product groups in 2001 totaled US\$393.6 million and accounted for 95 % of exports from the group.

Dominican Republic Exports for the Two Principal 4-Digit Product Groups of Optical, Photo, Technical, Medical, Etc. Apparatus

HS Code	Product Group	Value of Exports from the DR, 2001 (US\$1,000)	Annual Growth Exports Value from the DR, 1997-2001 (%)	Annual Growth of World Exports 1997-2001 (%)
9018	Electro-medical apparatus (electro-cardiographs, infra-red ray app, syringes, dental)	380,862	5	7
9031	Measuring or checking machines	12,744	160	6
	Total	393,606		

While this product group accounted for over US\$400 million of the Dominican Republic's exports in 2001, the exports are concentrated. At the 4-Digit HS Code US\$380.1 million or 92% of the exports are classified as HS 9018. When the exports are classified at the 6-Digit HS Code, the concentration persists, with US\$367.3 million classified as exports of: Instruments and Appliances Used in Medical or Veterinary Sciences; HS 901890. The main market for the Dominican exports is the U.S.A., which takes 95% of the Dominican exports of HS 901890. While world trade in these products grew by 7% over the 1997-2001 period, the exports from the DR only grew by 4%. To the extent that this lower growth rate can be reversed, this could become an even more important export product than it is now.

This is a product group in which the DR has demonstrated that it is internationally competitive. The issue is: what is the potential to build on the success to date in the sector and rapidly expand exports. To answer the Consultant will prepare a report to the Committee composed of the CEI, ADOZONA, TCB Secretariat, and USAID/DR on the export growth potential of the various products in the sector. The report will examine the opportunities for and constraints on the future competitiveness of the DR in the sector. It will recommend areas to focus on and recommend a strategy with specific initiatives, as appropriate, to resolve near term barriers and accelerate sector export growth.

OBJECTIVE

The objective of this study is to prepare a strategic report on the HS Code 90 Products sector in the DR, in the form of a SWOT analysis (strengths, weaknesses, opportunities, and threats) that will present to public sector and industry leaders a clear picture of where the DR is positioned at this time to compete in the global market place (including niches, competitors in these niches). The consultant will outline steps required to enhance this competition at both a macro level but also concrete steps that can be taken over the short run. In effect, the consultant will recommend a strategy with specific initiatives to resolve near-term barriers to growth and set the stage for accelerating industry export development.

TASKS

The Consultant will perform the following tasks:

- Interview key stakeholders in the DR, such as the CNC, ADOZONA, CEI-RD, and companies operating in the DR in this sector.
- Analyze the potential of the export sub-sectors (niches) in the HS Code 90 Products to increase production and exports and become a leading growth sector for the DR economy.
- Based on available data and the consultant's knowledge of the industry provide benchmarking background on leading competitors, including their own strengths and weaknesses, for example, known incentives provided by countries to attract foreign direct investment (FDI) in the industry.

- Describe the role that FDI plays in the industry of leading competitors. If FDI is essential to building a successful industry, what steps must the DR take to generate it?
- Identify the constraints and threats, domestic or foreign that must be addressed for the sub-sector to fulfill that role, and recommend actions to be taken to address the constraints.
- Present an outline of the report within 10 days of the assignment.
- Present a draft report to the Competitiveness and Policy Program (CPP).
- Incorporate observations made by report reviewers.
- Make a formal presentation to a wide audience of stakeholders in this sector in the DR.

DELIVERABLES AND OUTCOMES

The Consultant will deliver to USAID/DR:

- a) A strategic report/SWOT analysis on the sector of HS Code 90 Products in the DR examining the opportunities for and constraints on the Dominican Republic's competitiveness in this industry, and recommending a strategy with specific initiatives to resolve near-term barriers to growth, provide a long-term vision, and set the stage for accelerating industry export development.
- b) The report will be delivered in Microsoft Word (Times New Roman 12) in digital form and hardcopy (25 copies). English is acceptable.
- c) A Power Point presentation of the major findings of the report.

Intellectual property rights of the reports, presentations, research, data and work produced by the consultant is of Chemonics. All the drafts and materials obtained during the consultancy must be delivered to Chemonics upon completion. The consultant agrees not to publish or make any other use of the materials without previous written approval from Chemonics and USAID.

IMPLEMENTATION OF THE TECHNICAL ASSISTANCE

The consultant will be contracted by Chemonics International under a task order from USAID, and will work directly with the CPP. Lic. Lynnette Batista from the CNC will coordinate and supervise the work of the Consultant; and Dr. Rubén D. Núñez will have the same responsibility from the CPP.

LEVEL OF EFFORT

The level of effort is estimated in 23 person days and two trips to the DR. Time in and out of the country will be agreed upon between the consultant and Chemonics.

REQUIRED QUALIFICATIONS

The Consultant will have the following qualifications:

- Experience and expertise in a product area of substance within the medical device industry, preferably as the business leader of a medical device business, with accountability for all business results in many country markets.
- A minimum of 10 years related industry experience in academia, private industry and, preferably, a combination of both.
- Good oral communication in Spanish.
- Excellent oral communications skills and ability to conceptualize and identify market opportunities.
- Excellent writing skills and ability to produce a good written report and a power point presentation.

ANNEX B

PERSONS CONTACTED

ANNEX B

PERSONS CONTACTED

ADOZONA

- Gustavo A. Mejía Ricart del R., Encargado Unidad Legal
- Arturo Peguero, Presidente
- José Torres R., Director Ejecutivo

Arriol Internationl Corp.

- Jesús Rodríguez Armenteros, President

Asociación de Empresas de Zona Franca Industrial de Las Américas

- Carmen Camilo, Directora Ejecutiva

Baxter

- Víctor Galarza, Manufacturing Operations Manager

Cardinal Health

- Yacaida Almonte, Quality Engineer
- Alfredo Espinosa, Plant Manager

Centro de Exportación e Inversión (CEI – RD)

- Yadira Castillo, Especialista Promoción de Inversión
- Eddy Martínez Manzueta, Secretario de Estado
- Horacio Martínez Thormann, Investment Promotion Director Manufacture and Services
- D'aliza Peña, Especialista

Chemonics International

- Danilo Cruz-DePaula, Director
- Luis Andrés Pérez, Gerente Monitoreo y Evaluación
- Rubén D. Nuñez, Gerente de Operaciones/Especialista en Comercio

Consejo Nacional de Competitividad

- Lynette Batista, Asesora de Manufactura y Capacidad Comercial
- Laura Del Castillo, Especialista
- Andrés Van Der Horst Alvarez, Director Ejecutivo

Consejo Nacional De Zonas Francas de Exportación

- Daniel Liranzo, Sub-Director Ejecutivo

DeRoyal International, S.A.

- Pedro Jiménez, Representante, República Dominicana

INFOTEC

- Rayza Pichardo Viñas, Coordinadora Nacional Proyecto INFOTEC/Zonas Francas

Johnson & Johnson

- Tulio Marti, Plant Manager

Las Américas Industrial Free Zone

- Catherine Kelner, Marketing & Industrial Relations Manager

Parque Industria Itabo, S.A.

- Denisse Sena, Marketing
- José Tomás Contreras, Gerente General

Surgex, S.A.

- Antonine Seguin Rodríguez, Vice-Presidente Ejecutivo

USAID

- Joe Goodwin, Economic Policy Advisor

Zona Franca San Isidro

- Luis Guillermo Angarita, Vice President Marketing

ANNEX C
REFERENCES

ANNEX C

REFERENCES

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ANNEX D

LIST OF SELECTED TARGET COMPANIES

ANNEX D

LIST OF SELECTED TARGET COMPANIES

A) Selected target companies that manufacture or outsource the manufacture of their devices and disposable brands:

- 3M
- Abbott
- Accellent Inc.
- Agfa Gevaert
- Agilent Technologies
- Arrow International
- Bard (C.R.)
- Baxter
- Beckman Coulter
- B.Braun
- Bauch & Lomb
- Beckton Dickinson
- Boston Scientific
- Canon
- ConMed Corp
- Colgate Palmolive
- Datascope
- Dentsply Int'l
- Eaton
- Edwards Life Sciences
- Eastman Kodak
- Fisher Scientific Int'l
- Fujinon Inc.
- Fukuda
- Genzyme Biosurgery
- General Electric
- Guidant
- Hillenbrand Industries
- Intuitive Surgical
- Johnson & Johnson
- Kimberley-Clark
- Medtronic
- Olympus
- Owens & Minor
- Oxford Instruments
- Matsushita Electric Industrial
- Pentax

- Procter and Gamble
- Richard Wolf GmbH
- Roche
- Royal Philips Electronics
- Sony
- St. Jude Medical
- Sybron Dental Specialties
- Karl Storz GmbH
- Siemens
- Stryker Corp
- Tyco Int'l
- U.S. Surgical
- Zimmer Holdings

B) Food and drug stores that market their own knock-off or in-house disposable brands or outsource manufacturing of those brands:

- Albertson's
- CVS
- Delhaise Group
- Eckerd
- Kroger
- Publix
- Rite Aid
- Royal Ahold
- Safeway
- Walgreen
- Wal-Mart
- Winn-Dixie

ANNEX E

PRODUCT AREAS WITH POTENTIAL

ANNEX E

PRODUCT AREAS WITH POTENTIAL

For manufacture, assembly, finishing, and packaging in the Dominican Republic

Medical Devices

- Flexible and rigid endoscopes. Applications include areas such as arthroscopy, laparoscopy, colonoscopy, sigmoidoscopy, cystoscopy, bronchoscopy and laryngoscopy
- Instruments and apparatus for measuring blood-pressure
- Transfusion apparatus
- Anesthetic apparatus and instruments
- Selected electro-cardiographs parts and accessories
- Selected electro-diagnostic apparatus. Apparatus for functional exploratory examination or for checking physiological parameters
- Respiratory monitoring equipment
- Surgical instruments and appliances (4)
- Obstetrician and urology products, including drainage bags, leg bags, eliotomy and cholostomy bags, insertion kits
- Surgical instruments, such as scalpels, saws
- Dental drill components, dental drill engine parts
- Dental instruments and appliances
- Consumer rubber support products. These include wrist braces; ankle, elbow, abdominal, back supports, wrist stabilizers; anti embolism stockings; knee brace with aluminum triaxial hinges; sports tape; elastic bandages; pouch arm sling; athletic supporters

(4) Developing countries which manufacture, assemble, finish or package these products include China, Malaysia, Indonesia, and Thailand.

Medical Supplies (Medical Disposables)

- Hospital setting wadding, gauze, bandages, dressings (1)
- Adhesive plasters non sterile
- Syringes, whether or not with needles (3)
- Plastic or latex catheters, plastic cannulae and the like (3); (4)
- Blood products. Collection devices. Flexible intravenous and other lines; pumps; test tubes
- Intravenous delivery systems, intravenous access devices
- Catgut, steel, nylon, polyglycolic acid (absorbable) surgical sutures for wound closure. Only assembly. Sterile tissue adhesives for wound closure. Wound closure staplers
- Saline and other solutions
- Hospital and home use specialty (non retail-sales market) diapers of paper pulp, paper, cellulose wadding or webs of cellulose fibers
- Disposable clothing such as caps, gowns, masks and shoes

- Hospital, manufacturing and other settings
- Consumer dental floss, dental floss holders, dental picks, tooth brushes, electric tooth brushes
- Consumer dressings, stretch and non stretch bandage rolls, adhesive tape, non irritating tape paper, sterile pads, dressing sponges, rolled gauze, gauze sponges
- Consumer foot care medical products, available in over 20 forms and over 100 package styles

(1) Developing countries which manufacture these products include China, Mexico, India, South Africa, Indonesia, Thailand, and Malaysia.

(3) Developing countries which manufacture these products include Malaysia, Mexico, Thailand, China, Brazil, Tunisia, Dominican Republic, and India.

(4) Catheter types include infusion, cardiovascular, renal, neurological, and hemodynamic catheters. Some uses of the catheters follow. Infusion catheters consist of intravenous, midline, central venous, and peripherally inserted central catheters. Cardiovascular catheters consist of some ten categories, from balloon catheters to diagnostic electrophysiology catheters.

ANNEX F

PRODUCT AREAS WITH LIMITED POTENTIAL

ANNEX F

PRODUCT AREAS WITH LIMITED POTENTIAL

This includes products that may not fit the manufacturing requirements outlined under the subheading Product Manufacturing Analysis. These areas include very high tech products where the capital and scientific process represents most of the total Cost of Goods Sold; some newer products for which patents do not expire for some time; components of products which are commodities manufactured by highly specialized components making industries which supply device/disposables plants at a quality and price that cannot be matched by the device/disposables industry.

Medical Devices

- Implantable cardiac devices. Cardiac rhythm management products, such as cardiac resynchronization devices, defibrillators and pacemakers. Devices for heart oxygenation and heart surgery.
- Imaging devices such as CAT scanners, MRI machines, ultrasound equipment, and digital x-ray machines. Types of X-ray imaging include image intensifier/TV systems, computed radiography, direct capture using flat-panel detectors, charge-coupled devices.
- Laser technology equipment.
- Vascular repair, angioplasty products; coronary stents, drug eluting stents, balloon stents.
- Vacuum-assisted closure devices for severe wounds.
- Some prosthetic products and devices.
- Some ophthalmic surgery and ophthalmic medicine devices.
- Larger, heavier, medical products such as, shelving, tables, chairs and other specialty furniture for use in hospital settings, such as operating rooms. Similar products used in clinics, other institutions, elder peoples' homes, dentists offices.

Medical Supplies (Medical Disposables)

- Bone growth products such as orthobiologicals.
- Metal needles.
- Surgical gloves of vulcanized rubber (2)
- Product components or parts that are usually manufactured by a very competitive allied industry. Examples include the manufacture of strands of catgut, steel, nylon for use in surgical sutures; manufacture of nylon strands for dental use.
- Sharps disposal containers.
- Opacifying preparations for x-ray examinations, diagnostic reagents for administration to patients.
- Consumer supplies that generally are commodity-price bottled liquid products. Examples include hydrogen peroxide and alcohol.
- Creams and ointments commercialized in squeeze tubes and bottles.
- Boxes with first aid products.

(2) Developing countries which manufacture these products include Malaysia, Thailand, Indonesia, Sri Lanka, India, China, Vietnam, and Morocco. Gloves are very low price commodity products which are dependant on the prices of rubber from the few countries which have globally competitive rubber tree farms.

ANNEX G

GLOBAL NATIONAL INCOME (GNI) PER CAPITA. SELECTED COUNTRIES

ANNEX G**GLOBAL NATIONAL INCOME (GNI) PER CAPITA. SELECTED COUNTRIES (*)**

Country/ Other	Year 2002 US\$	Year 2003 US\$
Dominican Republic	2310	2070
Mexico	5940	6230
Puerto Rico	Not Avail.	Not Avail.
Costa Rica	4070	4280
Canada	22390	23930
U.S.A.	35400	37610
Guatemala	1750	1910
Honduras	920	970
Nicaragua	720	730
Panama	4020	4250
Colombia	1810	1810
Ireland	23030	26960
United Kingdom	25490	28350
Korea, Republic	11280	12020
China	960	1100
India	470	530
Singapore	21180	21230
Japan	34010	34510
By Income Ranges or Region:		
Global High Income	26550	28550
European Monetary Union	20320	22850
Global Upper Middle Income	5140	5340
Latin America & Caribbean	3310	3260
Global Middle Income	1770	1920
Global Lower Middle Income	1340	1480
Global Low Income	400	380

ANNEX H

PHOTO AND OPTICS INDUSTRIES

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The recommended product focus strategy excludes these industries thereby focusing limited resources on the very attractive device/disposable industry.

Photo industry

The photo industry has undergone significant technology shift. In a few recent years photo technology has moved to over 80% digital technology. Most of the manufacturing plants in the western hemisphere have moved sourcing to plants in Asia. Currently Asia manufactures over four fifths of all global units of photo projection products, including lenses. These include the consumer, media, film, and television industries. Key countries with most of the manufacturing include Japan, China, Korea and Taiwan. Japan dominates the global market with its branded products. It out sources manufacturing to plants within countries mentioned in the prior sentence.

The Dominican Republic should not invest in business development in this field until it has the technically specialized capacity in the form of specialized sets of skills. These are not currently available to adequately meet needs of the existing 15 device/disposables plants in the FTZs.

Film is being rapidly replaced by digital memory cards. The largest, dominant manufacturers of cards are located in China and Japan. The remaining film market is dominated by Fuji and Kodak. Fuji is known to have won most of the market. Peripherals equipment and accessories are primarily manufactured by outsource companies in Asia for companies who manufacture the leading brand name products.

Optics industry

This industry is highly segmented globally. It consists mainly of corrective eyewear, over-the-counter higher-end reading glasses, and very low-end over-the-counter reading glasses. These are retailed in many industrialized countries at 10-20 U.S. dollars, for example through large discount retail, general merchandise, food, and pharmacy chains. The industry also includes industrial safety and sportswear.

Dominant manufacturing countries consist of China, Japan, Italy, Germany, and France. The U.S. was until a generation ago a large manufacturer of eye glass components. At the time an estimated 75% of the manufacturing volume came out of U.S. plants. Currently manufacturing of frames is negligible in the U.S. The U.S. still manufactures some of the higher end lenses. There is some potential for the Dominican Republic to manufacture frames and lenses but only after the country consolidates its vision and manufacturing base in device/disposables.

The manufacturing of both frames and lenses involve sophisticated manufacturing processes with material value addition components. Many frames, for example, require some 100 manufacturing steps, involving significant labor component. This component requires substantially broad engineering capacity and capabilities, with a focus on precision processes in the overall manufacturing program.

The relatively low yearly growth contact lenses market, for a younger population which does not need the type of corrective eyewear needed by older people, is dominated by companies like Johnson & Johnson.

ANNEX I

SHIFTS IN GLOBAL MARKET SIZE

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SHIFTS IN GLOBAL MARKET SIZE

Factors that shift the overall yearly size of the Global U.S. dollar denominated global market.

The factors include:

- Large shifts in exchange rates of the major global currencies. For example, the Euro has strengthened by some 34% versus the U.S. dollar since 2001. Whereas the ECU- the predecessor equivalent mix of the Euro, was 1.29 for every 1 U.S. dollar in 1995, the Euro today is 0.78 to the U.S. dollar. This is a large swing which impacts the yearly currency size and yearly growth rate of the global market. Shifts in exchange rates of the Yen versus the U.S. dollar over the past decade have also had an impact on the size of the global market.
- There can be large changes in country unit volume market purchases from one year to the next. This may be caused by sharp cutbacks or increases in country central government purchases for the national healthcare programs.
- Large single year purchases made by a country to replace medical devices, apparatus, machinery, equipment that has become worn out or become obsolete. An offset is that the following year the country may make dramatic cuts in it purchases. For instance, Costa Rica which had a 29% reduction in total country purchases in U.S. dollar terms in 2001 due to an economic slowdown, and increased total country volumes purchased by 48% in 2002.¹
- Increased spending in product unit volume and currency terms in developing nations with successfully expanding economies. Governments in these countries increasingly meet the needs of their populations with record level purchases of device/disposables. Examples include China, India, Indonesia, and many Latin American countries. Asia has 75% of the world's 6.6 billion people. This represents a large, previously untapped market.

¹ Source: Export America, 2003