CUBAN BIOTECH AND PHARMACEUTICAL INDUSTRY: RESULTS AND PERSPECTIVES

GROUP OF BIOTECHNOLOGY AND PHARMACEUTICAL INDUSTRIES

MsC. Yodira Pérez Díaz
Business Executive
32 Enterprises

78 manufacturing facilities

21 785 Workers
- 6325 Higher education (Universities).
- 262 PhD.
- 1170 MSc.
- 719 Researchers
Cuban Biotech impact on Cuban Health

Figure 2: Incidence of meningitis in Cuba.

Figure 5: Incidence of acute hepatitis B in Cuba 1991 to 2005

3.12 - Evolución de la estructura por edades de la población de Cuba
Evolution of the age structure of the Cuban population

<table>
<thead>
<tr>
<th>AÑOS</th>
<th>Total</th>
<th>0 - 14</th>
<th>15 - 59</th>
<th>60 y más</th>
</tr>
</thead>
<tbody>
<tr>
<td>1997</td>
<td>100.0</td>
<td>36.6</td>
<td>50.0</td>
<td>4.6</td>
</tr>
<tr>
<td>1999</td>
<td>100.0</td>
<td>42.3</td>
<td>52.9</td>
<td>4.8</td>
</tr>
<tr>
<td>1991</td>
<td>100.0</td>
<td>37.4</td>
<td>57.5</td>
<td>5.1</td>
</tr>
<tr>
<td>1993</td>
<td>100.0</td>
<td>35.5</td>
<td>58.9</td>
<td>5.6</td>
</tr>
<tr>
<td>1995</td>
<td>100.0</td>
<td>36.2</td>
<td>56.9</td>
<td>6.9</td>
</tr>
<tr>
<td>1997</td>
<td>100.0</td>
<td>36.9</td>
<td>54.0</td>
<td>9.1</td>
</tr>
<tr>
<td>1998</td>
<td>100.0</td>
<td>30.3</td>
<td>58.8</td>
<td>10.9</td>
</tr>
<tr>
<td>2000</td>
<td>100.0</td>
<td>20.5</td>
<td>64.0</td>
<td>14.7</td>
</tr>
<tr>
<td>2005</td>
<td>100.0</td>
<td>19.0</td>
<td>65.3</td>
<td>15.7</td>
</tr>
<tr>
<td>2010</td>
<td>100.0</td>
<td>17.3</td>
<td>64.9</td>
<td>17.8</td>
</tr>
<tr>
<td>2014</td>
<td>100.0</td>
<td>16.7</td>
<td>64.3</td>
<td>19.0</td>
</tr>
<tr>
<td>2015</td>
<td>100.0</td>
<td>16.5</td>
<td>64.1</td>
<td>19.4</td>
</tr>
</tbody>
</table>

Proyecciones

<table>
<thead>
<tr>
<th></th>
<th>2020</th>
<th>2025</th>
<th>2030</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>100.0</td>
<td>100.0</td>
<td>100.0</td>
</tr>
<tr>
<td>0 - 14</td>
<td>16.4</td>
<td>16.4</td>
<td>15.5</td>
</tr>
<tr>
<td>15 - 59</td>
<td>62.1</td>
<td>57.7</td>
<td>54.4</td>
</tr>
<tr>
<td>60 y más</td>
<td>21.5</td>
<td>25.9</td>
<td>30.1</td>
</tr>
</tbody>
</table>

(1) Censo de Población y Viviendas. (2) Sistema de Información Estadística
BIOCUBA FARMA

Vaccines: Prophylactics and therapeutics (biosimilars and innovatives)

Monoclonal antibodies and other recombinant proteins for autoimmune diseases. (biosimilars and innovatives)

Veterinary products

Agricultural products

Pharmaceutical products (Generics)

Laboratory equipments and diagnostic kits for the early diagnosis and follow up of different diseases and programs

Medical devices and softwares of high technology for diagnostic and treatment of neurological disorders and for diagnosis and monitoring cardiovascular diseases

Natural origin products

Comprehensive Health Care Programs

1099 Products are manufactured and supplied to Cuban Health System

Source of more than 65% of Cuban Basic Drug Table
1981 – 1990
- Meningitis bc vaccine
- IFN alfa 2b
- Diagnostics

1991 – 2000
- Meningitis BC vaccine
- Hepatitis B vaccine
- Hib vaccine
- DTP Vaccine
- dT vaccine
- Tetanus vaccine
- Meningitis ACYW135 vaccine
- Leptospirae vaccine
- Typhoid fever vaccine
- Heberprot-P
- Humanized anti EGF-receptor antibody (h-R3)
- Therapeutic base-EGF cancer vaccine
- EPO
- G-CSF
- Hebermin
- Products and equipment for Neurophysiology and Neuroinformatics
- Several diagnostic systems
- SUMA system
- Heberkinasa (Streptokinase)
- IFN alfa 2b
- IFN gamma
- Allergens
- Trofin
- Interferon + ribavirine
- PPG
- Agriculture products (GAVAC, Bionematicide)
- Acubio 1
- Hebertrans
- Culture media
- New advanced generics
- Cytostatics
- Placenta derivatives
- Surfacen
- Generic Medicine

2001 – 2015
- Meningitis BC vaccine
- Hepatitis B vaccine
- Hib vaccine
- DTP Vaccine
- dT vaccine
- Tetanus vaccine
- Tetravalent DPT-HB vaccine
- Pentavalent DPT-HB-Hib Vaccine
- Meningitis ACYW135 vaccine
- Leptospirae vaccine
- Typhoid fever vaccine
- Heberprot-P
- Humanized anti EGF-receptor antibody (h-R3)
- Therapeutic base-EGF cancer vaccine
- EPO
- G-CSF
- Hebermin
- Products and equipment for Neurophysiology and Neuroinformatics
- Several diagnostic systems
- SUMA system
- Heberkinasa (Streptokinase)
- IFN alfa 2b
- IFN gamma
- Allergens
- Trofin
- Interferon + ribavirine
- PPG
- Agriculture products (GAVAC, Bionematicide)
- Acubio 1
- Hebertrans
- Culture media
- New advanced generics
- Cytostatics
- Placenta derivatives
- Surfacen
- Generic Medicine
OVERVIEW OF BIOCUBAFARMA ABROAD

- **167 invencions / 2438 granted patents**
  - Biotecnology: 2337
  - Pharmaceutical: 35,
  - Diagnostics and Medical equipments: 66

- **More than thousands publications in impact scientific journals**
- **Exporting products to more than 50 countries**
- **893 marketing approvals abroad**
- **More than 30 Clinical Trials in 18 countries**
- **Experience in more than 9 suscesfull technology transfers (South – South Cooperation basis)**
- **5 Joint Venture Companies abroad**
- **More than 70 long term established partnership for Biopharmaceuticals, worldwide**
WHAT DOES BIOCUBAFARMA OFFERS?

Biological Products
(28 marketing approvals)

91 Products / Health targeted projects

- 33 Products against infectious diseases.
- 33 Oncologic products
- 18 Cardiovascular products
- 7 Diabetes and other pathologies

**Biotechnology Medicines in Development—By Therapeutic Category**

- Autoimmune Disorders: 59
- Blood Disorders: 20
- Cancer/Related Conditions: 254
- Cardiovascular Disease: 33
- Diabetes/Related Conditions: 19
- Digestive Disorders: 15
- Eye Conditions: 8
- Genetic Disorders: 11
- Growth Disorders: 5
- HIV/AIDS Infection/Related Conditions: 34
- Infectious Diseases: 162
- Neurologic Disorders: 18
- Respiratory Disorders: 27
- Skin Disorders: 19
- Transplantation: 10
- Other: 35

*Some medicines are listed in more than one category.*
WHAT DOES BIOCUBAFARMA OFFERS?

- Innovative capacity: + 100 R&D projects (Biomedics, agriculture)
- High technology manufacturing capacities for pharmaceuticals
- International recognition in medicine and biotechnology
- Validated comprehensive health programs to achieve high social impact
- Potentialities of industry growth with access to big markets as part of opening of relationship with US

Cuba’s cancer initiatives were sufficiently eye opening to prompt Roswell Park to secure a license from the U.S. Office of Foreign Assets Control (OFAC) to partner with CIM toward the development of the country’s therapeutic lung cancer vaccine (i.e., CIMAvax).
PERSPECTIVES

- To increase impact of biopharmaceuticals in health in Cuba

- To extend long terms partnership for the manufacturing, development and commercialization of our products in significant markets

- To start and consolidate investment process in Special Zone of Development in Mariel to build new facilities for monoclonal antibodies, vaccines, pharmaceuticals.

- To introduce innovative products into the most regulated markets such as US, Europe and Japan
- Co-development capacity for early stage biopharma projects and sharing commercial opportunities with players.

- To access to clinical trial capacities for late stage development products

- Investment in Cuba and abroad creating capacities to access international markets

- Impact in health care with our programs abroad Cuba implementing our Comprehensive Health care programs

Monoclonal antibodies, Therapeutic Cancer Vaccines and other biotech products for autoimmune diseases. www.cim.cu; www.cimab-sa.com

Products from natural origin (sugar cane, bee wax, etc.) www.cnic.edu.cu; www.dalmer.cnic.edu.cu

SUMA® Technology: Laboratory equipments and diagnostic kits for the early diagnosis and follow up of different diseases and programs. www.tecnosuma.com

Vaccines against infectious diseases. www.finlay.sld.cu

Medical devices and softwares of high technology for diagnostic and treatment of neurological disorders. www.neuronicsa.com


Pharmaceutical products www.farmacuba.cu

Thank you very much!!