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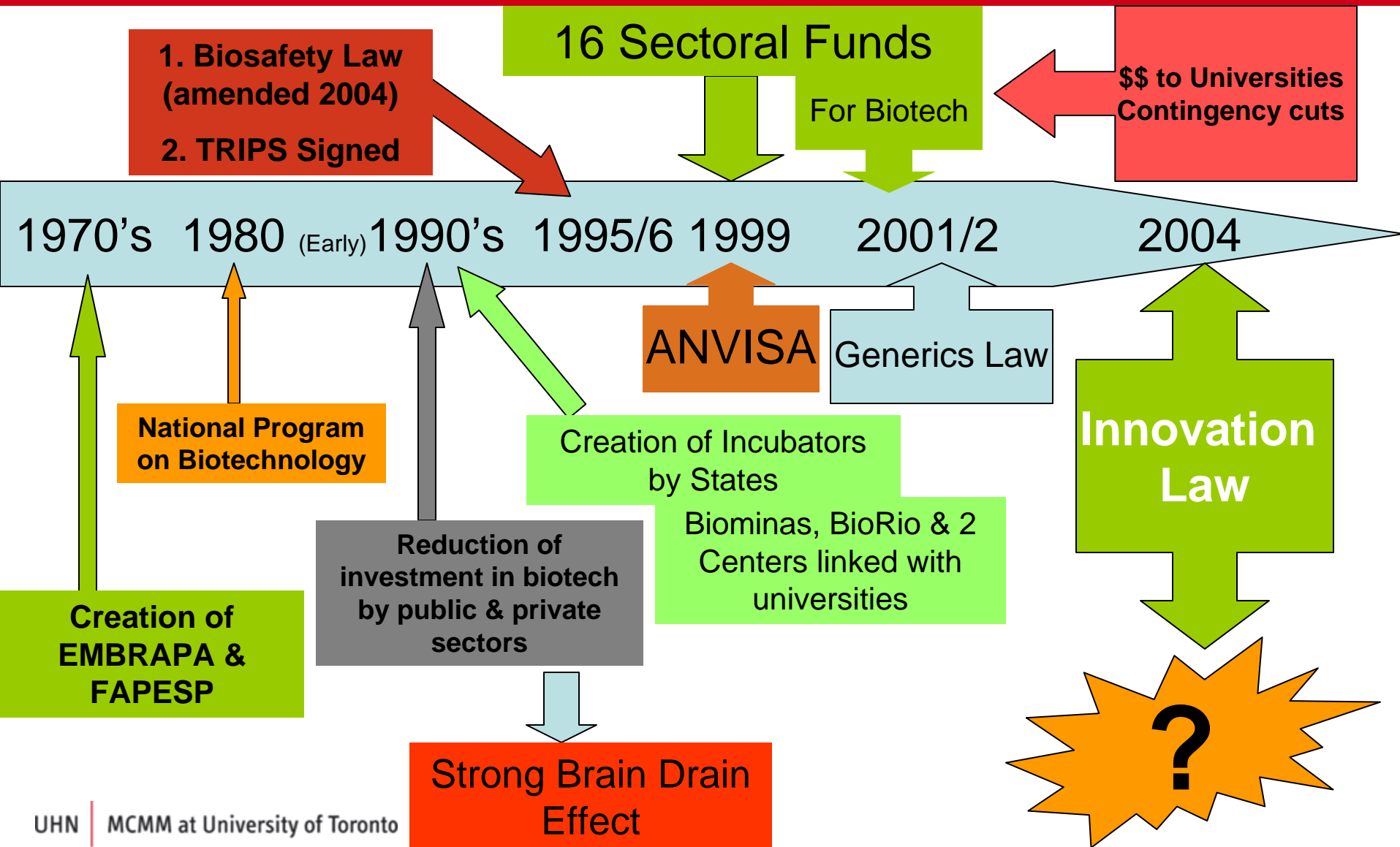
Role of the Domestic Biotech Sector in Health Product Commercialization in Brazil

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Brief History of Brazil Biotech Dev.

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Objective: to explore how the **domestic biotechnology sector in Brazil**, contributes to **development of health technologies targeted to address local/Gobla health needs**.

Main Themes Explored:

1. History of firms
2. Products/services/Capabilities & focus areas
3. Incentives & barriers
4. Type and nature of partnerships (if any)
5. Human resources
6. Financial status & environment

Brazilian Firms / Institutes

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Participating in the Study

Sao Paulo

1. Eurofarma
2. Butantan Institute
3. Aché Laboratórios Farmacêuticos
4. Recepta Biopharma
5. PeleNova Biotechnologia
6. Intrials Clinical Research
7. Coinfar
8. Biolab Farmaceutica
9. Uniao Quimica

Campinas

1. Scylla Bioinformatics

Porto Alegre

1. FK Biotechnologia



Recife

1. Hebron
2. Biogene

Belo Horizonte

1. Labtest Diagnostica
2. Katal Biotechnologia
3. Biommm Technology
4. Biocancer

Rio de Janeiro

1. Fiocruz (Biomanguinhos & Farmanguinhos & CDTs)
2. Silvestre Labs
3. Cryopraxis Criobiologia
4. Nortec Quimica
5. Gross Laboratories

Profile:

- Very old company (81yrs) → Family-Owned
- Revenues of approx. \$25 U.S./yr

Business Model: Marketing of products from SMEs in Europe/U.S.

Motto: 'Innovation Impossible'

- For most companies other than top 40 or so firms in the world
 - Costs \$1B to develop a drug so...
- So no point trying

Challenges:

- Regulatory Agency (ANVISA)
 - Lack of experienced staff
 - Mix politics with their business



Profile:

- Family-owned (35yrs old)
- Large Generics Manufacturer (>\$200M revenues)
- Products (120) for Many Indications



Growth Strategy:

- I. In-licensing of proprietary technologies from abroad
- II. Entering into biotech area via biogenerics
- III. Conducting some in-house research (incremental & radical)
- IV. Expanding/replacing Facilities to Meet FDA Standards

Profile:

- Largest Pharma Company in Brazil
 - >2300 employees
 - >\$800 M U.S. Revenues
 - Many products
 - **Acheflan** → one of top-selling medicines in Brazil



Challenges:

- Skepticism of Phytomedicines
- cGEN (Committee for Protecting Genetic Inheritance) & Phytomedicines
- Lacking preclinical infrastructure



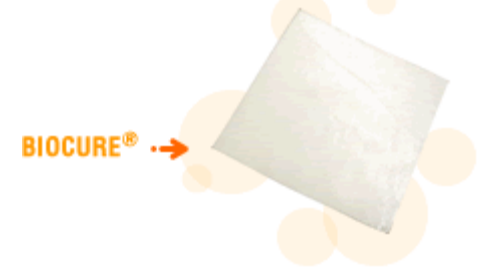
- Spin-off of Silvestre Labs
- Private Stem Cells and Umbilical Cord Blood Bank (>9000 samples)
- Conducts Research on Stem Cells
 - **Heart mal-function** (tested in 100 patients already), Type I Diabetes, Neonatal Hypoxia
 - Goal: Stem-Cell Pharma



- Pure R&D Companies
- Born Out of “Divide & Concur” Strategy
- Virtual Business Model

- Studies in Esophageal Surgery in Dogs
Researchers patented rights
- \$7M U.S. invested (VC & Angels)
- Indications:
 - Diabetic Ulcers, Pressure Sores, Surgical Wounds, etc.
- Active Ingredient Isolated (VEGF Protein)
- Testing for Other Indications
 - Burn Patients
 - Tympanoplasty Surgery
Preliminary Results → success rate ↑ 45% to 95%
 - In surgery for urinary incontinence in older women
 - Dermatological/Cosmetic Applications

BIOcure®
MEMBRANA NATURAL PARA CICATRIZAÇÃO



Ozires Silva
Chairman of The Board

- **Systemic/Infrastructure Issues:**

- Lack of GLP-certified pre-clinical facilities
- Importation of Goods (taxing and slow)
- Insufficient institutional transparency



- **Regulatory/legal Challenges**

- ANVISA (Brazilian FDA)
- CONEP [National REB]
- CTNBio [Committee Approving Work with Genetically Modified Organisms]
- cGEN [Responsible for protecting genetic diversity]

- **Cultural Issues:**

- Weak University-Industry Interaction

- **Human Resources:**

- “Universities only train university professors”
- Strict labor laws & public-sector incentive system → High-cost of employment

- **Political Issues:**

- Government Change → Drastic disturbance throughout the civil service
- Lack of sufficient coordination among policies / laws

- **IP Issues**

- Inefficient patent office (INPI)
 - 6-8 yrs to obtain pharmaceutical patents

- **Financial Challenges**

- High interest rates
- Low levels of private equity

Existing Hybrid Model:

- Some In-house R&D capacity with support from universities / research institutes

Eurofarma, Ache, Pele Nova Biotechnologiea, FK Biotechnologia, Biogene, Katal Biotechnologia (And Fiocruz, Butantan)

Short-Term:

- Divide & Conquer (Coinfar & Incrementa)
- Tapping into Ideas & Services at Universities
 - A virtual-model
Recepta Biopharma, Ache, Coinfar, Hebron, Eurofarma
- In-licensing of Technologies from Abroad → Internalize Know-how
Eurofarma, Fiocruz, Butantan

Medium to Long-term:

- Building In-house R&D Capabilities
Eurofarma, Ache

- Health biotech sector is different & should be treated accordingly
 - Need broad appreciation for the challenges associated with drug development
 - Policies need to consider sector-specific challenges
- Institutional flexibility
 - Biosafety & Biosecurity laws
- Organizational Performance
 - “Devil is in the details”
 - Structure & make up of organization

- De-risk investment in health biotech
 - Support of innovative activities
 - Identifying & removing obstacles to innovation
- Clarify role of the public sector in health product development
- Better support of innovative firms
- Attention to policy implementation

- Achéflan for Aché
- Recombinant Hep-B vaccine in India by Shantha Biotechnics
- Meningitis B vaccine in Cuba
- Gendicine (Gene therapy product) for head and neck cancer by SiBiono in China

Muito Obrigado

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Thank You for Your Attention