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# ASINFARGUA

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**ASSOCIATION OF GUATEMALAN  
PHARMACEUTICAL INDUSTRIALISTS  
TRADE UNION OF PHARMACEUTICAL  
PRODUCTS MANUFACTURERS CIG**

**TRADE UNION OF MANUFACTURERS OF  
CHEMICALS PRODUCTS FOR AGRICULTURE**

**Member of the American Latin Association of Pharmaceutical  
Industries - ALIFAR-**

**Member of Agricultural Chemical Association of Latin American  
- ALINA-**

**Member of the Federation of Pharmaceutical Industries of the  
Caribbean and Centro America - FIFCCA-**

# Intellectual Property IMPACT

- **Health**
- **Food Security**
- **Agricultural Competitiveness**
- **National Pharmaceutical Industry**
- **National Agricultural Chemical Industry**
- **International Pharmaceutical Industry of Generics and Brand Generics**
- **International Agricultural Chemical Industry of Generics and Brand Generics**

# Intellectual Property in Guatemala

- **1996, USA and Multinational companies initiate Pressures**
- **Before year 2000: "0" years protection DP**
- **Law of Industrial Property 57-2000: 20 years of patent, 15 years of data protection, The WORST LAW Of the WORLD And 5 YEARS BEFORE, manipulation of transnational companies**
- **Decree 63-2002: The same to TRIPS, similar 76-2002**
- **Decree 76- 2002: Return to "0" years of protection DP**
- **Decree 9 - 2003: 5 and 10 years of protection, pressures of Embassy of the U.S.A. and Trans National, Corruption U.S. \$ 50 million in 2003, U.S. \$ 50 million in 2004, U.S. \$ 50 million 2005, ?? 2006**

# Intellectual Property in Guatemala and Test data

- **Decree 34-2004: "0" years of protection, In agreement WTC, TRIPS, DOHA and Constitution of Guatemala**
- **Governmental Agreement 3-2005: Several Contradictions**
- **Decree 30 - 2005 = WORST than Decree 9-2003: Pressures of US Embassy and MNCs before DR CAFTA negotiations**
- **Present situation Implementation of the DR CAFTA with the U.S.A., Our Position, Government and Congress, NO MORE CONCESSIONS in Intellectual Property and other issues**
- **XX-3006: ??????? : Implementation DR CAFTA new Impositions from the USA ????**

# **VIOLATION OF THE CONSTITUTION BY THE DECREE OF Intellectual Property 57-2000 and 30-2005**

## **Articles:**

- **1 Protection of the individual**
- **2 Duties of the State**
- **3 Right to Life**
- **43 Freedom of Industry, Commerce and Work**
- **44 Inherent Rights of the Individual**
- **51 Protection of the Elder and Minors**
- **79 Farming Education**
- **93 Right to Health**
- **94 Obligation of the State On Health and  
Social Attendance**
- **95 The Health, public benefit**
- **99 Alimentation and Nutrition**
- **119 State Obligations**
- **130 Monopolies Prohibition**

# **RAISED UNCONSTITUTIONALITIES**

- **Chamber of Industry of Guatemala**
- **Civil Alliance for the Access to Medicines (ACAM, 50 organizations)**
- **World-wide recognized Guatemalan Doctors, Dr. Aldo Castañeda and Dr. Jose Barnoya**
- **National Union of Health, etc.**
- **Altogether 8 against the Decree 9-2003**
- **In the coming months it seems that further unconstitutionality will be posed**
- **Unconstitutionality by DR CAFTA, last Friday**

# **SOME DAMAGES**

- **New Product definition in the country and not in the world**
- **Protection to Products that already lost patent, for 5 and 10 years, with endless circle that never finish**
- **It does not benefit to Central America, it reduces competitiveness, monopolies are occurring by decree and eliminates national and international industries of generics**
- **Integration Intellectual Property with Sanitary Registries and Fito Sanitarries (Plant or Vegetables)**

# **SOME DAMAGES**

- **Generics medicines and agro chemicals in other latitudes, are monopolies by Decree in Guatemala**
- **It affects the Central American and the Caribbean Union Customs agreements**
- **Agriculture Chemicals, Paraquat Case, Sildenafil, etc, Bad Precedents**

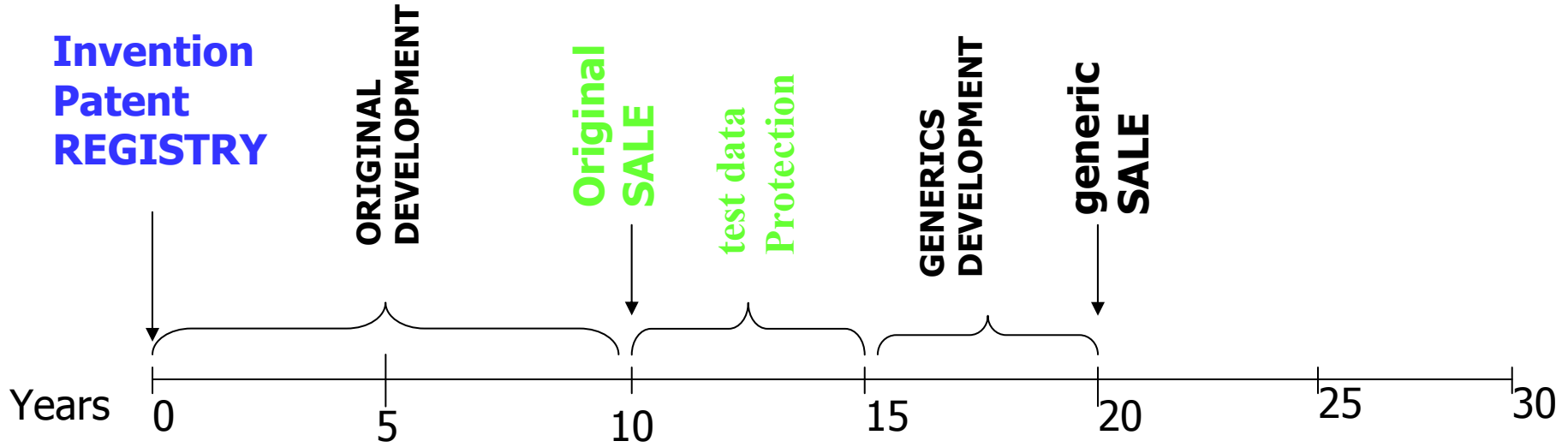


# **SOME DAMAGES**

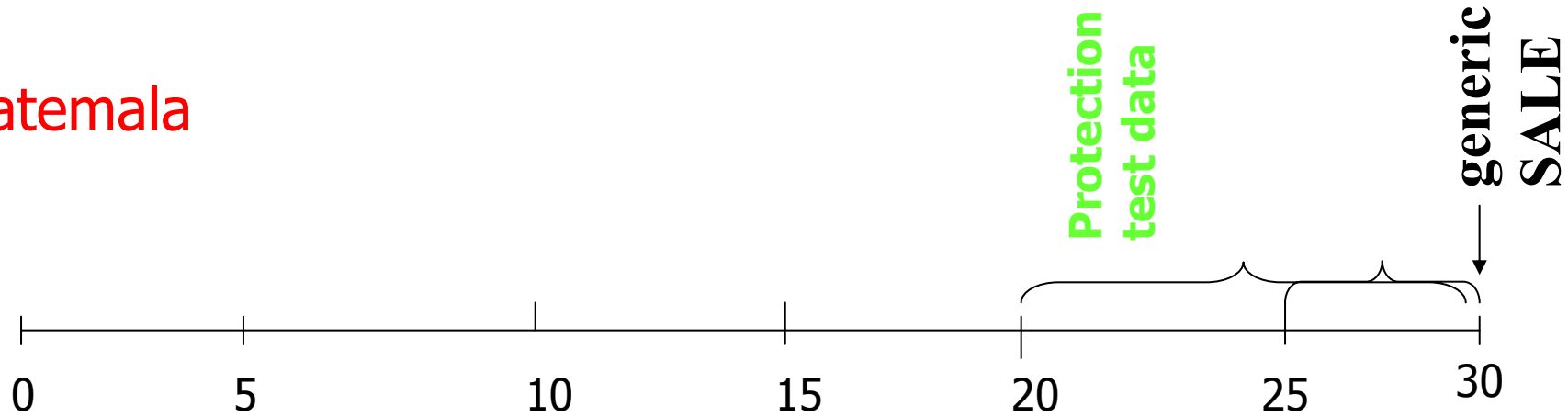
- **Additional protections, TRIPS Plus**
- **It will increase Hunger Famine**
- **Low farming competitiveness, affecting Million of Central Americans**
- **Abandonment of production fields**
- **Migration of farmers to the capital and the foreign countries, with all the social and economic consequences that it takes**

# Difference in "test data"

OMC  
USA  
Europe



Guatemala



# Difference in which is "NEW 177 bis"

OMC  
Adpic  
DOHA

Beginning 30-2005

Invention  
Patent  
REGISTRY

ORIGINAL  
DEVELOPMENT

BEGINNING  
Original SALE

test data  
Protection

GENERIC  
DEVELOPMENT

generic  
SALE

Años 1993 1998 2003 2008 2013 2018 2023

Guatemala

REGISTRY  
Invention  
no patent

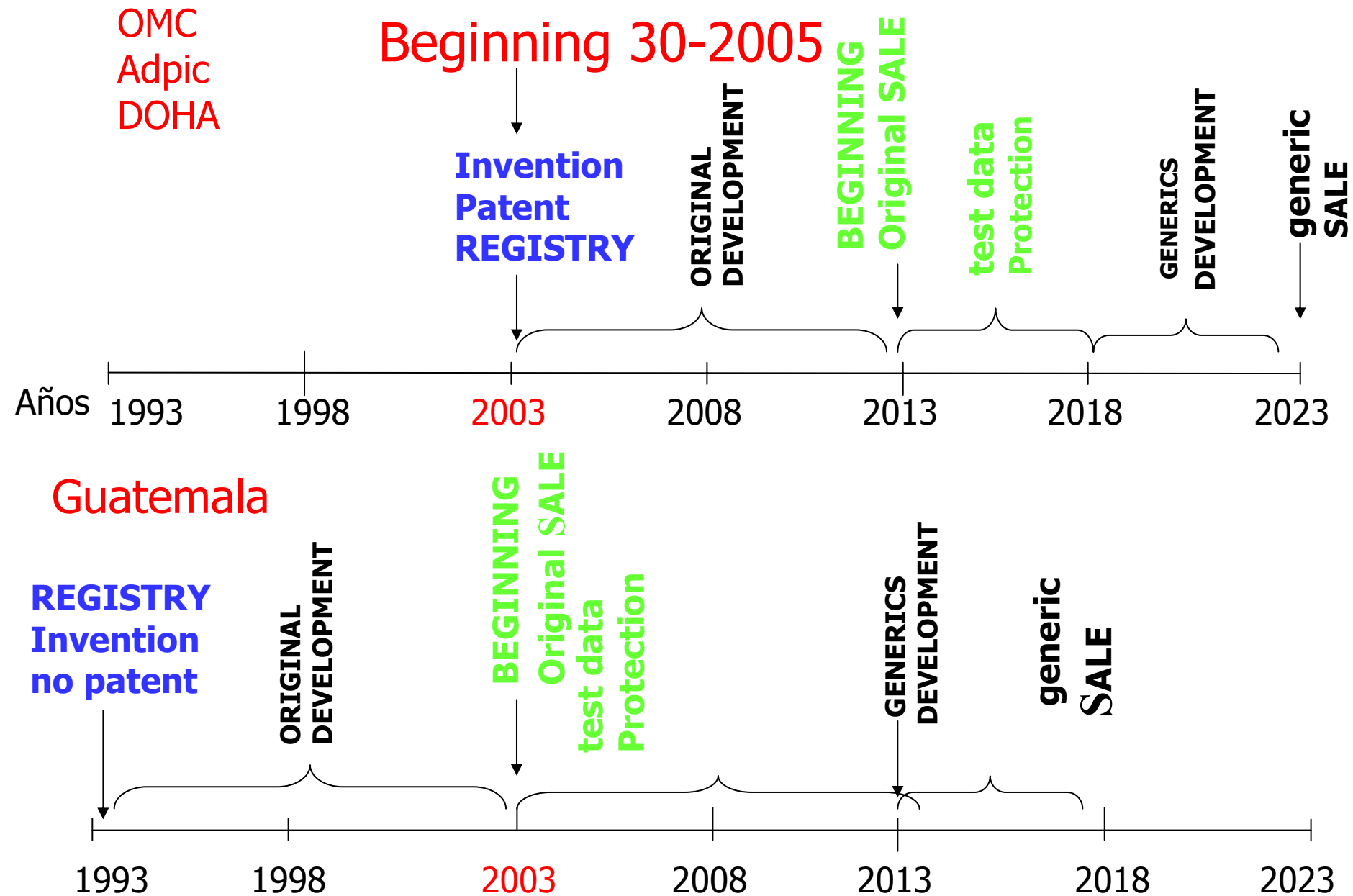
ORIGINAL  
DEVELOPMENT

BEGINNING  
Original SALE  
test data  
Protection

GENERIC  
DEVELOPMENT

generic  
SALE

1993 1998 2003 2008 2013 2018 2023



**One of the most effective tools to promote the access to Medicines and Agricultural production factors is the Competition with generics**

**The experience teaches us that the countries that stimulate the competition between different producers (**original and generic**) obtain the best prices for Pharmaceutical products and Agricultural production**

# **Because the pressures of the United States and the Transnational companies**

- **To establish a precedent, using Guatemala like an experiment and to scatter it to the rest of the world**
- **The United States and Europe are protectionists (Subsidies, etc)**
- **98% of the Agricultural Chemical Patents, have already expired**
- **The Transnational Pharmaceutical Industry is one of the greatest financial supporter of GW Bush 2 campaigns**
- **Transnational Pharmaceutical and Agricultural Chemical companies and do not want to fulfill Third Spirit of the Patents. They want to extend their monopolies and few producers and many buyers around the world, inclusively they are buying Generic companies of (Bayer, Novartis, German Merck)**

# **Filgastrim Cases, Fluoxetina, Metformina, Losartan (\* \*)**

- **Filgastrim increase of 535%**
- **Fluoxetina 83 times, 8,300%**
- **Metformina 384%**
- **Losartan 552%**
- **Quinapril 625%**
- **All are adjudged to Transnational companies**

# COMPARATIVE PRICES OTHER MEDICINES

	Drug Us	Quantity 2003	Price 2003 Brand	Price 2003 Brand	Price 2002 generic	Price 2002 generic
FILGASTRIM	cancer	3,100.00	1,167.02	3,617,731	217.79	675.149
FLUOXETINA	depression	180	16,532	2,975,760	0.198	35.64
LOSARTAN	hypertension	50	9.45	472.5	1.71	85.5
PACLITAXEL	cáncer	6500	1.201	7,806,500	556.6	3,617,900
ATORVASTATINA	hypertension	300	10.83	3,249,000	7.69	2,307,000
METFORMINA	diabetics	4,100,000	1,775	7,277,500	0.457	1,873,700
				<b>25,398,991</b>		<b>8,594,889</b>

# Warning Publications about Negative Effects

- **TIME MAGAZINE, February 2, 2004 "Why do we pay so expensive for drugs..."**
- **The 10 drugs sold in the world produced more than \$40 billions for their manufacturers in 2002**

<b>Lipitor</b>	<b>8.0</b>
<b>Zocor</b>	<b>5.6</b>
<b>Prilosec</b>	<b>4.6</b>
<b>Procrit</b>	<b>4.3</b>
<b>Norvasc</b>	<b>3.8</b>

<b>Zyprexa</b>	<b>3.7</b>
<b>Paxil</b>	<b>3.2</b>
<b>Prevacid</b>	<b>3.1</b>
<b>Celebrex</b>	<b>3.1</b>
<b>Zoloft</b>	<b>2.7</b>



# THAT SPENDING IS ONE REASON DRUG COMPANIES ENJOY HUGE PROFIT MARGINS COMPARED WITH OTHER U.S. FIRMS

## Return on revenue (2002)

<b>Pfizer Inc</b>	<b>28.4%</b>
<b>Eli Lilly &amp; Co.</b>	<b>24.4%</b>
<b>Intel Corp.</b>	<b>11.6%</b>
<b>General Electric</b>	<b>10.7%</b>
<b>Verizon Communications</b>	<b>6.8%</b>
<b>Exxon Mobil Corp.</b>	<b>6.2%</b>
<b>Walt Disney Co.</b>	<b>4.9%</b>
<b>Wal-Mart Stores</b>	<b>3.3%</b>
<b>Daimler Chrysler</b>	<b>3.3%</b>
<b>General Motors Corp</b>	<b>0.9%</b> (Time, February 2, 2004)

# **SOCIAL INDICATORS**

- **More than 9 million Guatemalans in Poverty and Extreme Poverty**
- **More than 3 million Guatemalans live with less than Q 8.00 per day (U.S. \$ 1.00)**
- **The health budget is the lowest in all Latin America**
- **The budget of Social Security increased in 400 million Quetzals from 2002 to 2003 for medicine purchase (US \$ 50 million for corruption)**
- **The Budget Minister of Health increase in 133 million Quetzals from 2002 to 2003, (US \$ 18 million for corruption)**
- **Actual Minister of health is transparent**

# **SOCIAL INDICATORS**

- **Population of 110 Municipalities of Guatemala is undernourished, hunger famine**
- **2 Million Guatemalans cannot satisfy their hunger daily**
- **Guatemala is the country that less food produces per inhabitant in the Central American region**
- **60% unemployed Population and of which has a job, 65% are in Informal Economy**
- **2 million Guatemalans have emigrated to the U.S.A.**



# ASINFARGUA

ASOCIACION DE INDUSTRIALES FARMACEUTICOS GUATEMALTECOS  
MIEMBRO DE LA ASOCIACION LATINOAMERICANA DE INDUSTRIAS FARMACEUTICAS -ALIFAR-  
MIEMBRO DE LA FEDERACION DE INDUSTRIAS FARMACEUTICAS DEL CARIBE Y CENTRO AMERICA - FIFCCA-



## DON'T PAY MORE FOR THE SAME QUALITY

THANKS TO YOU AND THE HONORABLE DOCTORS UNION, SINCE 90 YEARS AGO WE HAVE BEEN CONTRIBUTING TO IMPROVE THE HEALTH AND TO SAVE THE LIFE OF THE GUATEMALANS, WITH MEDICINES:

- SAFE 100%
- EFFECTIVE
- WIDELY PROVEN
- WITH EXCELLENT INTERNATIONAL QUALITY
- WITH SCIENTIFIC SUPPORT
- AND WITH ACCESSIBLE PRICES FOR ALL

**LEGAL BASE, NORM, REGULATION AND SECURING OF THE QUALITY, OF MEDICINES MADE BY NATIONAL AND INTERNATIONAL PHARMACEUTICAL INDUSTRY**

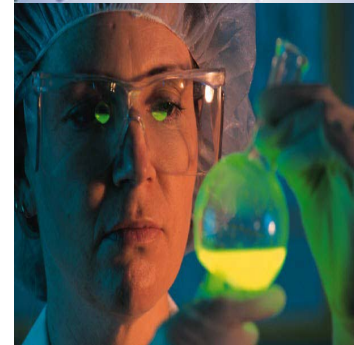
**REGULATION OF GOOD MANUFACTURE PRACTICE**

Governmental Agreement 06-2002, Norms of OPS/OMS

**REGULATION FOR THE CONTROL OF MEDICINES AND COMPATIBLE PRODUCTS**  
Governmental Agreement 712-99

**HEALTH CODE**  
Decree 90-97

**CONSTITUTION OF THE REPUBLIC OF GUATEMALA**  
ARTICLES 93, 94, 95 AND 96



# **Profile of the Guatemalan Pharmaceutical Industry**

- **It operates at an level International**
- **Quality highly recognized and proven effectiveness, fulfillment of good practices of manufacture and standards as OPS and the OMS**
- **800 different medicines**
- **Covering 80% of the institutional market (units)**
- **80% of the private market (in units)**
- **Installed capacity to export**
- **Automation and human resource highly qualified**
- **In Guatemala 525 pharmaceutical companies of all the world compete**

# Profile of the Guatemalan Pharmaceutical Industry

- A very important aspect which rebounds in the economy of Guatemala is the comparison of the medicine units made locally against the imported flowed to the market:
- 80 % of the market in **VALUES** is imported and 20% are produced locally, while...
- 80% of the **UNITS are produced** locally, whereas only 20% of the units are importa
- This means that:
  - Local manufacture takes care of the thickness of the Guatemalan population
  - Each medicine unit that is imported instead of making it locally has a extremely high cost (Almost 3 times average)

# Profile of the Guatemalan Pharmaceutical Industry

- **9,000 direct employments, technified and highly qualified, with income average superior to other industries, (45,000 people in family)**
- **150,000 indirect employments in connected industries: plastic, glass, printing, lithography, cardboard, maintenance, transports, foods, droguerías, pharmacies, construction, mass media, publicity agencies, private hospitals, etc. (750.000 people in family)**
- **We practice the ENTERPRISE SOCIAL RESPONSIBILITY, RSE**

# Profile of the Guatemalan Pharmaceutical Industry

- **Number of local producers: 91**
- **Total annual Production of the National Industry:**
- **Q 2,964 millions**
- **US \$ 385,000,000.00 (385 millions)**
- **Total exports:**
- **Q 1,386 million,**
- **US \$180,000,000.00 (180 millions)**



# Markets of exportation

- **CENTRAL AMERICA**
- **THE CARIBBEAN**
- **MEXICO (??)**
- **SOME COUNTRIES IN SOUTH AMERICA**
- **AFRICA**
- **PHILIPPINES**
- **PAKISTAN**
- **EGYPT**
- **COSTA DE MARFIL**

# **SUGGESTIONS**

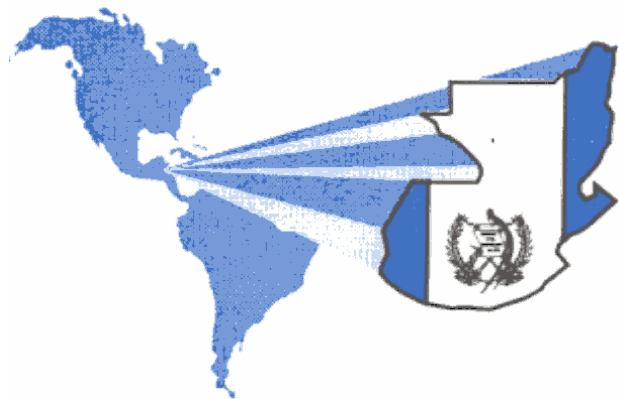
- To respect agreements OMC, Not to go further than**
- Not to go beyond ADPIC (Trips), NO ADPIC PLUS**
- To take advantage of Ministerial Declaration DOHA**
- To respect the Constitution of the Republic**
- Not to integrate Intellectual Property with Sanitary Registries, Fito Sanitary and Zoo Sanitary**
- To define Vision of Country and to become attached to it**

# **SUGGESTIONS**

- **To ask for support to WIPO and WTO to reframe what it has happened in Intellectual Property in the last 5 years**
- **To spread with events and training, what it Intellectual Property**
- **To improve our Intra Regional Commerce**
- **To diversify our Markets with Asia, Europe, South America, etc.**
- **To retake approach Goals of the Millenium of the UN**
- **To promote Farming Competitiveness**
- **Not to include Intellectual Property in "FTA"**
- **Promote Transparency**

# **SUGGESTIONS**

- **Stay very close of the Politicians**
- **To act like Latin American block**
- **To look for support in sectors of the U.S.A., Europe, India and China**
- **Create an active network worldwide to exchange experiences and to help each other**
- **Educate the politicians, trade unions, on IP**
- **Keep closed of the universities**
- **Work togheter with organizations like CIEL, American University, TWN, Tralac, SOciedad Peruana de Derecho Ambiental, ACAM, MSF, Oxfam and others**



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