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BRAZILIAN INDUSTRY POLICY AFTER 1990: FOCUSING ON THE PHARMACEUTICAL INDUSTRY

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Abstract

The present article analyses the active principle and drug sector in Brazil after 1990. It has five sections showing the government priority at the time was to maintain economic stability in spite of strengthening the national drug industry. The article analyses the actions implemented through projects and concluded that the results of such policy were not satisfactory. Results show that the country continues to depend on multinational companies which are able to control vertical and horizontal strategies at all stages of drug production in developing countries, thus benefiting from competitive advantages. Finally, it points out the measures needed for Brazil to join the active principle and drug international market.

Keywords: Industry Policy; Pharmaceutical Industry; Brazilian Economy; Public Policy: Competitiveness**.**

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1. INTRODUCTION

According to Nassif (2003a, p.115), industrial policies were in effect during the period the sector performance[3] had no long-term economic development strategies.

In 1990, the government established the PICE - Política Industrial e de Comércio Exterior (*Industrial and Foreign Trading Policy)* with the aim of giving support to industry through programs such as PBQP - Programa Brasileiro da Produtividade e Qualidade (*Productivity and Quality Brazilian Program*) and PACTI -Programa de Apoio à Capacitação Tecnológica (*Technological Capacitating Support Program*).[4]

According to Bonelli et al. (1997), Industrial Policy "was restricted to market opening[5]" between 1990 and 1994 so causing an incipient impact on national industry, besides fomenting the productive sector restructuring.

In the following years, Industrial Policy was restricted to a few sector agreements; among them we highlight the car industry agreement in 1995.[6]

The rationalization and combination of factors added to management new practices proved to be insufficient. We did not notice expressive export coefficient increment or incorporation of cooperative advantages (except for the aeronautics sector) in the international trade dynamic sectors.

The present article analyses the performance of one of the sectors benefited by Lula Government Industrial Policy in the 90s (PITCE - Política Industrial, Tecnológica e Comércio Exterior - *Foreign trade, industry and technology policy directives*): the active principle and drug sector.

The second section of the present article identifies the analyzed sector and the third shows the characteristics of the active principle and drug Industry. The fourth section compares the 1993 Competitiveness Study proposal (ECIB) with a posterior study; the 2003 ECCIB. The fifth section analyzes the new PITCE proposals to check if they are able to solve the problems identified by the Competitiveness Studies (ECIB).

2 ACTIVE PRINCIPLE AND DRUG SECTOR IDENTIFICATION: HISTORICAL CONTEXT

In the 90s, main economic policies were generally macroeconomic aiming at price stabilization and seeking to establish an adequate environment to foment development.

The "neo-liberal" ideal limited the state actions to "linear policies" and some of them were addressed to the drug sector (Frenkel et al. 2003), as follows:

- Reduced import taxes in the productive stage (from 1989 on);
- Price control liberation (1994);
- Implantation of legislation on patents (1997);

According to Frenkel et al. (2003), those measures aimed at increasing drug supply through importing and fomenting competition, what would decrease the final consumer costs and prices.

Frenkel et al. (2003) mention that previous works, such as those Silva (1983) and Frenkel (1995) wrote, have warned against the industrial "linear policy" adverse effects on drug industry. According to them, the three aforementioned measures led to:

- increased prices of chemical raw material
- Decreased domestic demand for active principle
- Reduced prices of some products
- Consequent reduced profit margin
- Increased imports
- Some specific drugs had their prices increased but their purchase amount decreased.

In 1999, the Brazilian government permitted generic drugs to be manufactured in the country and, at the same time, started operating in the drug sector. Notwithstanding the creation of generic drugs and exchange devaluation, the government did not meet two basic objectives:

a) Increased demand controlling price increasing by fomenting competition;
b) Reverted negative position of that sector trade balance.

The aforementioned facts launched a wide discussion on the pharmaceutical sector:

a) The pharmaceutical sector is included in the current government Industrial Policy proposal;
b) If the government proposals are approved, the sector will increase its capacity, as well as its technical and technological levels
c) According to authors such as Capanema (2003) and Palmeira Filho et al. (2003), there is still room for specific industrial policies;
d) According to the Studies on the Integrated Chain Competitiveness in Brazil by Frenkel et al. (2003), non-effective industrial policy and the use of "linear policies" have not been positive
e) O IBGE – Instituto Brasileiro de Geografia e Estatística (*Geography and Statistics Brazilian Institute*) registered that the Brazilian pharmaceutical Industry showed low performance from 1994 to 2003
f) In that period, the trade balance performance was negative to pharmacochemical drugs, and imports surpassed exports by far (Palmeira Filho and Pan 2003)

[3] Nassif mentions, for example, the support to Embraer and the new informatics law.

[4] The industrial policy, aiming at increasing productivity, would be strengthened in 1990 through PACTI and PBQP, which did not meet the expected results for the same reason the Sector Policy Executive Groups have failed: lack of significant incentives due to the need of fiscal adequacy and political support (Bonelli et al.1997).

[5] Commercial opening and industrial police are not synonymous. The author simplifies the instruments used when he considers commercial opening and privatizations as the main piece of the industrial and commercial policies (Bonelli et al.1997).

[6] The Brazilian Automotive Regime reduced the import taxes aliquot of capital goods, raw-material, parts and components to produce the chain intermediate and finished goods (Bonelli, Veiga and BRITO 1997).

g) According to Magalhães et al. (2003a), government has not given assistance to the pharmacochemical domestic production since 1990, and the result is our present external dependence.

h) Choosing the active principle and drug sector is pursuant with the following government argument:

We highlight the low contribution of many segments to the Brazilian external trade, such as: the information and communication technologies, fine chemical and drug industry. On the other hand, those are the sectors that most contribute to the high concentration of trade balance deficits according to the *Ministério Do Desenvolvimento Indústria e Comércio Exterior* (2004). The government proposal argument is that specific public policies can contribute to building a friendly environment for industry innovations, competitiveness and quality. In addition, some "structural" factors may prevent the "market forces" from inducing sector growth and strengthening (Frenkel et al. 2003), as it happens in the pharmaceutical sector and others.

2. ACTIVE PRINCIPLE AND DRUG SECTOR CHARACTERISTICS

Drugs classification is the following: therapeutic use, chemical structure, product types and pharmacological action (Palmeira Filho and Pan 2003, p.6). According to Queiroz et al. (1993, p.1-2) in Estudo da competitividade da indústria brasileira (*Brazilian industry competitiveness Study*) **ECIB**, the international market is divided into ethical and non-ethical products.

Ethical products are those sold exclusively when the patient has a doctor's prescription. For that reason, laboratory advertisement is directed to doctors.

The non-ethical drugs, called OTC (Over-The-Counter), do not need a doctor prescription to be sold and account for a small fraction of the world market. An additional criterion helps classifying drugs as follows:

- Generic: as their patents have already expired, they can be manufactured by any producer, not just by the one that originally obtained the patent
- Protected by patent: recent and technologically more advanced drugs, most manufactured by multinational companies, accounting for the biggest parcel of the market.

According to Palmeira Filho and Pan (2003, p.8), the drug industry production chain comprises two stages: a chemical stage when the drugs and additives are synthesized[7]; and a pharmaceutical stage that produces finished drug. The first stage usually contains two intermediate stages.

In those "sub-stages" basic chemical product and raw-material are used as input:

- synthesis Intermediate stage: any product obtained through the active principle synthesis process
- Use Intermediate stage*:* the final active principle used in drug production.

In general pharmaceutical companies have knowledge of every activity technique , but part of or the total chemical production is assigned to third parts.

The pharmaceutical stage – changing active principle into drugs – does not put significant barriers to competitors. The skills and equipment used in the process are available in the trade market (Palmeira Filho and Pan 2003).

Queiroz et al. (1993) in Estudo da competitividade da indústria brasileira **(***Brazilian industry competitiveness Study*) **ECIB** and Frenkel et al. (2003) in Estudo da competitividade de cadeias integradas no Brasil **(***Study on the integrated chain competitiveness in Brasil***)** ECCIB**,** highlight the sector structuring through progressing stages. The Comissão Econômica para a América Latina e o Caribe (*Latin America and Caribbean Economy Commission*) CEPAL classification in 1987, considers that drug industry stages in certain countries develop according to their industry capacity to carry out one or more links in the chain (Palmeira Filho and Pan 2003, p.8).

Companies incorporate each stage activities according to the technical development level of the country they are established in. The stages are the following:

- 1st stage: Research and Development (R&D)
- 2 nd stage: active principle production[8]
- 3 rd stage: pharmaceutical specialty production (drugs)[9]
- 4 th stage: pharmaceutical specialty Marketing and commercialization.

In the activities carried out in the technologically relevant 1st stage, R&D is carried out by the sector companies. In 1985, the annual minimum budget addressed to research activities was estimated at around US$ 100 million, implying that company revenue could not be, at least, less than US$ 1 billion (Frenkel et al. 1993; Palmeira Filho and Pan 2004).

In addition, to carry out all the stages until approval a company has over ten years to meet the deadline. The new product needs the approval of authorities in the country it will be purchased. The North American FDA requirements for a product to be approved include the following steps (Palmeira Filho and Pan 2003)

1) Pre-clinical tests, performed in laboratories and animals for three to six years
2) Step I: clinical tests performed in groups of 20 to 80 healthy volunteers for one to two years
3) Step II: clinical tests performed in a 100 to 300 healthy volunteers for three to four years
4) Step III: clinical tests performed in a 1.000 to 5.000 healthy volunteers for three to four years;

After finishing step III, the producer receives the FDA authorization to trade it and go to step IV, in which the consumers will be clinically followed up for two years. Only after step IV the product receives definitive approval (Palmeira Filho and Pan 2003).

[7] Up to 1930, the drugs in use were predominantly natural, while nowadays they are mostly obtained through chemical synthesis.

[8] Active principle or drug basis is the active substance that produces the desired therapeutic effect. (Palmeira Filho and Pan 2003,p.8)

[9] Pharmaceutical specialty is the finished product obtained from mixing the active principle with additives – substances used to change or complement the active principle properties.

According to Nassif (2004), investments to obtain the North American certification could reach US$ 2 million and in Europe it amounts to U$ 1 million per active principle tested.

The actions of pharmaceutical multinational companies are performed vertically: the first two manufacturing stages are carried out in their own countries (pharmacochemical industry) and the last two stages in their branches spread in other countries (drug industry), thus they benefit from the intra-company trade and from the monopoly inherent to innovations (Queiroz et al. 1993).

In Brazil, most of the subsidiary companies carry out the third and the fourth stages, some of them perform the second stage and a few carry out a small group of activities belonging to the first stage.

On the other hand, most of the companies supported by national capital carry out the third and the fourth stages; just a few perform the second stage thanks to incentives made available to this sector in the 80s.

A company or country finds many economic and institutional barriers when moving forward from one stage to next, but the medium and long term state policies can help them overcome such barriers (Frenkel et al. 2003).

In countries, such as Brazil, pharmaceutical companies do not perform their production actions vertically anymore, but focus on simpler activities as those in the 3rd and 4th stages. In the 90s the competition between big national laboratories was intensified mainly due to investments in new drugs R&D and development of generic drugs (Magalhães et al. 2003b).

According to the author, the abandonment of sector industrial policies led to changes in the domestic production structure.

The next item compares data on the 1993 and the 2003 Brazilian Industry Competitiveness studies, in order to answer some questions: Which proposals has the sector incremented? What was competition like in 1993 compared to 2003? What was accomplished concerning sector policies?

3 ASSESSMENT OF THE PHARMACEUTICAL INDUSTRY COMPETITIVENESS: COMPARING 1993 WITH 2003

By comparing data on the 1993 Estudo da competitividade da indústria brasileira **(***Brazilian industry competitiveness Study*) ECIB[10], in Queiroz et al. (1993), with data on the 2003 Estudo da competitividade de cadeias integradas no Brasil (*Study on the integrated chain competitiveness in Brasil*) ECCIB,[11] in Frenkel et al. (2003), we could identify elements that show the active principle and drug industry position.

The 1993 study refers to the sector internationalization showing that foreign companies held over 80% of the domestic drug market. In 2003, the multinational subsidiaries controlled 80% of that market.

The 1993 ECIB shows that the resources required to perform the 1st (R&D) were far beyond the national company capacity.

Concerning generic drugs, the problem was concentrated on the 2nd stage requiring less technological capacity and investment.

Regarding the patented products, the 1993 ECIB shows companies were competing for discovering and launching new drugs (R&D), and there was no perspective of medium–term competitiveness.

The generic drug production requires that tests be carried out in the 1st stage, thus allowing expansion. Production is the most important determining stage of the company trade flow - inter and intra-companies - since technical knowledge control determines the interrelation with the other stages (Frenkel at al. 2003, p.7).

If in the short term there is only room for the 3rd (drug production) and 4th (marketing and trading) stages, the sector becomes an importer of the 1st (R&D) and 2nd (active principle production) stage products and services. The introduction of a new stage leads to making the following decision: either using a vertical production system or buying products and services from third parts to meet the requirements of that new stage.

Using the vertical production brings about barriers to new stages. Purchasing presumes there is supply in the country, so the solution is to import products.

The 1993 ECIB shows a little developed chemical/pharmaceutical sector (2nd stage), in spite of the growth registered in the 80s.

Domestic deficiency impairing the expansion to the 2nd stage is due to structural factors: the multinational control trend of centralizing the pharmacochemichal activities in their home countries and the difficulties faced by national companies.

In 2003, although there was little incentive, the pharmacochemichal Industry Brazilian Association registered a group of 20 associated producers that had a significant production structure addressed to raw-material production.

According to the ECIB study the raw material production stage showed productivity and competitiveness potential. Chemical synthesis is polluting and its control may affect the product costs. But, the 2nd stage expansion in Brazil faces some barriers (Frenkel et al. 2003, p.12):

- Small market, due to a relative participation of national laboratories
- Multinational company strategy designed to import active principle from their headquarters
- According to ECCIB plants need investments and companies could overcome this problem by protecting the sector taxes temporarily
- Technological limitations on the part of national laboratories
- complex chemical processes needing specific equipment

[10] ECIB was a study carried out in 1993 by the Science and Technology Ministry, in partnership with the Unicamp Economy Institute and the UFRJ Economy Institute. The main competencies and deficiencies of the Brazilian economy strategic sectors were studied; the pharmaceutical sector was among them. The document of elaborated by Queiroz et al. (1993).

[11] ECCIB was a study carried out by the Development, Industry and Commerce Ministry in December 2002, in partnership with the Unicamp Economy Institute and the UFRJ Economy Institute. Its main objective was to study the main competencies and deficiencies of the Brazilian economy strategic sectors; the pharmaceutical sector was among them. The document of elaborated by Frenkel et al. (2003).

National laboratories that produce generic drugs are expanding their market participation. This fact strengthens local industries permitting them to have a productive scale adequate to competitiveness levels (Frenkel et al. 2003).

According to Queiroz et al. (1993) in the 1993 Estudo da competitividade da indústria brasileira **(***Brazilian industry competitiveness Study*) ECIB, the 3rd (drug production) and 4th (marketing and trading) were among the stages "chosen" by most of the national industries and by the multinational subsidiary companies with the aim of enlarging their participation in the national market of specialties.

According to the 2003 study, although from the corporative point of view the multinational companies operate in the four technological stages, they do so pursuant to the infrastructure existing in the chosen countries and their global strategies. In Brazil most of them continue operating in the 3rd and 4th stages, and some operate also in the 2nd. It is difficult for them to obtain significant and durable competitive factors when they operate in the 3rd and 4th stages, seeing that there are several expenditures.

The 1993 ECIB indicates a not much developed chemical-pharmaceutical sector, either due to multinational company strategies or to the lack of competition "culture" to operate in the 2nd (pharmacochemical) and 1st (R&D) stages on the part of domestic companies.

On the other hand, the foreign company performance used to limit the vertical process seeing that they used to import products. The use of a vertical process in 2003 maintained strong barriers to competitors, such as a lack of required technology and high investments. The state was inoperative.

The 1993 ECIB points out there was an international trend towards a spatial concentration in the pharmacochemical production. In the 2003 ECCIB, such perception increases, and so, the study proposes supporting policies addressed to a concentration of domestic producers.

In 1993, the systemic factors were considered decisive to the sector performance by ECIB. The 2003 ECIB points out that besides systemic competitiveness there was a strong government intervention, in spite of the sector being controlled by multinational companies.

Reasons for government intervention:

a) it is responsible for providing good health conditions to population
b) Ensure drug safety, efficacy and quality. The state is in charge of the supervision
c) Population access to drugs must be supervised
d) Expensive health systems and rationalization of drug use
e) Need of having protected Patents.

The state is also in charge of maintaining company competition alive. In the United States, one of the most used mechanisms is to foment generic drug prescriptions (Frenkel et al. 2003, p.30).

In Europe and France they have a price-fixing system strictly addressed to each product. Great Britain limits company profits instead of limiting product prices (Frenkel et al. 2003, p.30).

Domestic industry strengthening is another economic objective that benefits from public policy measures, seeks active principle and drug production self-sufficiency and help a country to join the international market. Table 1 shows the 1993 ECIB and the 2003 ECCIB policy proposals.

TABLE 1 – Policy Proposals, Brazil: 1993 ECIB and 2003 ECCIB.

	Year	
Proposals submitted	**1993**	**2003**
Use of the state purchasing power.	**X**	
Structuring a strong chemical sector (specially fine chemicals) through: • Fomenting creation/ strengthening the national chemical sector; • Fomenting the multinational investments in the chemical sector (vertical process); • Establishing a net of small and competitive producers to supply the fine chemical industry.	**X**	
Fomenting production modernization through: • Facilitating equipment purchasing (imports); • Controlling the production quality or imports of products with questionable quality or origin; • Supporting R&D through fiscal incentives; • Improving the qualified labor basis.	**X**	
Stimulating Government Purchases addressed to market segments that should be fomented.	**X**	
Protecting the temporary tariffs in behalf of the industrial and technological capacitating thus fomenting stages (1st and 2nd stages).	**X**	
Institutional stability with trading, patent and investment clear rules.	**X**	
Economic stability.	**X**	
Tax burden adequacy and rationalization.	**X**	
Investments in infrastructure, mainly transportation.	**X**	
Close relationship between institutes, universities research centers and companies.	**X**	
Fomenting the replacement of imported active principle by multinational companies.		**X**
Exchange policy responsibility[12] on the part of big and medium size multinational companies, as well as national laboratories[13].		**X**
Fomenting the replacement of imported active principle on the part of national laboratories.		**X**
Implantation of Tariff and tax on the importation of active principle without patent.		**X**
Severe quality control over imported active principles, mainly concerning those without patent and imported from emerging Southeast Asia countries (China and India).		**X**
Fomenting the acquisition of companies in foreign countries to improve active principles exports.		**X**
Fomenting concentration of national companies (merger and acquisition).		**X**

Source: Frenkel et al. (2003); Queiroz et al. (1993).

[12] Exchange responsibility is a sector measure where each company must maintain the balance between imports and exports. It should lead companies to replace imported active principle for their own production or products manufactured by third parts established in Brazil, local production of specialties that nowadays are imported, or the incorporation of R&D services for the headquarters, so expanding the service segment export flow.

[13] The exchange policy would be restricted in the short term to the specialty national producers. It presumes decreased imports and increased exports. Concerning the first, it is necessary an increased domestic active principle supply, for it is this stage raw-material. Concerning the second option, increase exports requires a lot of work; because it is difficult o obtain international prominence when being in the current company technological stage – 3rd -, concerning prices or real prominence due to the high level of technology international spreading.

The 2003 ECCIB points out that some measures could lead to a contrary effect or effects beyond what was intended, as follows:

- Increasing the import taxes of patented active principle to foster multinational companies to produce internally may, on the other hand, raise importing costs that would be transferred to prices without decreasing demand, seeing that such products have inelastic demand
- Increasing the import taxes of non-patented active principle to foster domestic production by the multinational companies may not change the intra-company trading dynamics
- Seeking to decrease transfer prices – concerning intra-company/headquarter/subsidiary trading – by defining a fair price may suggest an unfeasible task either to the non-patented, due to complexity, or to the patented due to monopoly
- A decreased import quantum via decreased or fixed taxes, may increase prices and decrease the population access to drugs
- Reduced tariffs to increase competition have already proven to be inefficacious. Such practice increased imports and drug prices, caused stagnation in the amounts of domestic production and high trading deficit
- The reduced active principle taxes brought in China e India products, although there was a high quality domestic production. As a consequence, the domestic 2nd stage producer lives turned out to be very difficult
- Replacing imports by manufacturing non-patented domestic products may turn the country into an active principle exporter
- Opening subsidiaries and/or purchase companies in foreign countries may be risky and requires a higher financial capacity than that of the domestic laboratories. On the other hand, it may contribute for the country to be an exporter.

When analyzing the proposals of the 1993 ECIB, we noticed that many of them were not implemented.

Regarding the investment and patrimonial restructuring of the Brazilian pharmaceutical industry, Magalhães et al. (2003b), highlight they

> Illustrate "dependency metamorphosis" in the context of trade opening, economic deregulation and macroeconomic stabilization with valuated exchange (Magalhães et al 2003b, p.33).

The multinational laboratory strategy focused on exploring the domestic market dynamism and growth potential, thus resulting in increased direct foreign investments (Magalhães et al. 2003b, p.33). According to the author, 70% of the total investments in drug industry were made by multinational companies. However, such companies invested in their production specialization strategy, what led to increased external dependence.

In 1997, Law 9.279, known as "the Patent Law", became effective in Brazil. It regulates the literary property rights and duties and had positive impact on the drug chain. The Agência Nacional de Vigilância Sanitária (ANVISA) (*Sanitary Surveillance National Agency*) was created to control drug quality, aiming at protecting the population health through sanitary control and incorporating the Secretaria de Vigilância Sanitária do Ministério da Saúde (*Sanitary Surveillance Department of the Health Ministry*) (Capanema and Palmeira Filho 2003, p.36):

In February 1999, Law 9.787 was published permitting the generic drug use and production in Brazil. In 2003, there were 49 domestic laboratories accounting for 52.2% of the products traded in Brazil (Capanema and Palmeira Filho 2003, p.31-32)

According to Guimarães (2003), the generic drug market expansion opens an opportunity of introducing new stages of drug manufacturing, thus increasing the domestic active principle production.

According to Frenkel et al. (2003), the Brazilian chemical-pharmaceutical industry competitiveness has to be discussed concerning the generic drugs.

In addition, according to Frenkel et al. (2003), generic drug production requires that tests be carried out in the 1st stage setting a precedent for domestic laboratories and multinational subsidiaries to expand their business.

10 years after the conclusions of the first ECIB - Estudo da competitividade da indústria brasileira **(***Brazilian industry competitiveness Study*), in Queiroz et al. (1993), and after comparing them with the most recent study ECCIB - Estudo da Competitividade de Cadeias Integradas no Brasil: impactos das zonas de livre comércio **(***Study on the Integrated Chain Competitiveness in Brasil: free trading zone impacts*), in Frenkel et al. (2003), it is possible to identify elements that were included in the 2003 study but not in the 1993 study:

1. The domestic companies are generally smaller than the congeneric foreign companies
2. There is room for policies containing instruments addressed to increasing their size and interaction, as well as for new product trading
3. A technological policy involving every industry stages in medium and long term perspectives and associated to the domestic production of new active principles able to be patented and of those with expired patents would enable increased domestic laboratory exports
4. Incrementing the multinational company participation would stimulate the main domestic laboratories to implant the 4th stage activities in other countries through establishing branches or local partnerships that have good knowledge of financial/commercial market and logistics.
5. The combination of trading policy traditional instruments with industrial policy and a rigorous quality control over imported products would foster the domestic raw-material production.
6. Making free microeconomic decisions is fundamental in market economy, but they have to be regulated when the resulting decisions altogether affect the economic system producing macroeconomic unbalance and crisis.

According to Magalhães et al. (2003b), an adequate industrial policy could accelerate the active principle vertical process to formulate drugs in the country, mainly the generic ones.

4 PRESENT INDUSTRIAL, TECHNOLOGICAL AND TRADING POLICY

On November 26th, 2003, the government, through the Ministério do Desenvolvimento, Indústria e Comércio Exterior (*Development, Industry and Foreign Trade Ministry*) launched the PITCE - Diretrizes de política industrial, tecnológica e comércio exterior **(***Directives on industrial, technological and foreign trading policy*) determining the Industrial and Technological Policy functions:

1. Seeking international competitiveness patterns
2. Increasing company innovation capacity
3. Maintaining institutional safety by preserving agreements signed national and internationally
4. [Organização Mundial do Comércio (*World Trade Organization*) OMC, Mercosul (*South Common Market*)]
5. Inducing the creation of dynamic comparative advantages;
6. Proposing horizontal e vertical measures;
7. Setting goals and awarding prizes for efficiency;
8. Establishing a time period and limiting the benefits awarded through assessing the results in order to preserve efficiency.

To that purpose, the document determines four lines of action (MINISTÉRIO DO DESENVOLVIMENTO INDÚSTRIA E COMÉRCIO EXTERIOR 2004):

a) Technological innovation and development: strengthening public and private research institutions, restoring equipment and technical team, supporting technological extension projects

b) External insertion: Brazil shows a performance below its capacity with a growth tax bellow the world average (4.6% per annum, against the world average 7.5% per annum between 1984 and 2002). Brazilian export schedule also contains products that have low dynamics external demand, low technological contents, low added value and instable external prices

c) Industrial modernization showing three aspects; first, productive and management capacity difficulties; second, privileged local clusters and use of the already existing potentialities; third, atomized treatment is not fomented.

d) Productive capacity and scale: some intermediate sectors retook investments that are very close to their installed capacity. In such sectors, public policies are necessary according to capital and credit conditions.

e) Strategic choices: areas of dynamism, intense knowledge and innovation responsible for the mobilization of large amounts of R&D.

Among the aforementioned actions, the latter – strategic choices – has a closer relationship with the four sectors initially supported by the new Industrial Policy and benefited from a set of measures (Table 2). The four sectors are the following:

- Software
- Semiconductors
- Capital goods
- Active principles and drugs.

TABLE 2 – Policy Proposals Addressed to Industry in general, Active Principle and Drugs in Brazil

Technological innovation and development: • Developing capacity to carry out R&D • Stimulating public and private companies and institutions for them to generate patents and share innovations with the whole production system • Supporting R&D activity internalization
External insertion: • Export support through simplified procedures and tax reduction • Fomenting the internationalization of national companies • Trading prospecting and market expansion • Brazil image strengthening • Supporting the removal of external tariff and non-fee barriers in the agribusiness • Transportation infrastructure modernization.
Industrial modernization: • Prioritize local clusters • Address company groups.
Capacity and productive scale: • Supporting capital and credit for the intermediate sector (input) expansion using almost the installed capacity limit • Fomenting the development of bigger company system, more compatible with the international corporation dimensions (Consortium, local nets and arrangements, merger)
Fomenting the domestic production of active principle and drugs.
Generic drug program strengthening.
Biodiversity exploration.
Public laboratory foment.

SOURCE: Ministério do Desenvolvimento, Indústria e Comércio Exterior (*Development, Industry and Foreign Trade Ministry*) MDIC (2004)

According to Gastaldoni (2004), the Competitiveness Forum on the Pharmaceutical Production Chain was established in May 2003, seeing that this area is a priority for the Government industrial policy.

Five work groups (WGs) were created (Gastaldoni 2004, p.3)

WG-1 Access to drugs, government purchases and social inclusion

1. WG-2 Investments
2. WG-3 foreign trading and taxation
3. WG-4 Technology
4. WG- 5 quality regulation.

WG-1 has a social function aiming at improving the population access to the RENAME generic drugs. However, priority is given to those that are important for public health and have a high production and/or import scale by manufacturing pharmacochemical products and drugs which are of strategic importance to the country. WG-2 is coordinated by Banco Nacional de Desenvolvimento do Extremo Sul (*Far South Development Bank*) BNDES.

Pursuant to Palmeira Filho (2004), the Programa Setorial da Indústria Farmacêutica (Profarma) (*Pharmaceutical Industry Sector Program*) was created for the Government industrial policy purposes. According to the author, BNDES has created the so called Chemistry for Health comprising 14 projects and an investment of US$ 600 million, of which US$ 300 million will be financed by the BNDS itself. Profarma is divided in three subprograms, as follows:

1. Profarma – supporting the country productive capacity expansion, the improvement of metrology quality standards and company adequacy to the Agência Nacional de Vigilância Sanitária (ANVISA) (*Sanitary Surveillance National Agency*)
2. Profarma – National company strengthening through fomenting merger, acquisition and incorporation among small and medium companies, so leading to the creation of bigger size and /or more vertical companies with national control
3. Profarma – Research, Development & Innovation - RD&I, aiming at fomenting research, development and innovation activities in the country.

WG-3 deals with foreign trading and is coordinated by the MDIC. This work group aims at ensuring an increased domestic production. The group discusses subjects such as import aliquot, tax burden and tracing imported/exported chemical substance (Gastaldoni 2004, p.3).

WG-4 is coordinated by the Science and Technology Ministry and the MDIC. It aims at fomenting research, development, technological and marketing niche monitoring, as well as the development of pharmaceutical productive chains within academic environment (Gastaldoni 2004, p.3). WG-5 is

responsible for active principle and drug regulation and quality.
Table 3 and 4 show the policy proposals by the work groups.

TABLE 3 – Policy proposals by the work groups (WGs 1 up to 3) created in the Competitiveness Forum on the Pharmaceutical Production Chain

Submitted proposals	WG 1	WG 2	WG 3
Effective Acceptance of the Essential Drug National Registry.	**X**		
Development of actions which foment rational prescription of drugs.	**X**		
Modernization of official pharmaceutical laboratories, seeing that they are very important for health policy.	**X**		
Incentives (fiscal, infrastructure, HR capacitating and technology) to pharmacochemical R&D, drugs and biotechnology, as well as active principle and drug increment in Brazil.	**X**		
Reduction of industry idle capacity, improving the out-of consumer market population access to drugs by using public resources.	**X**		
Increased participation of national active principle and drug production, fomenting the expansion of generic drug and phyto-therapeutic products.	**X**		
Optimization of the use and improvement of public resource spent on drugs.	**X**		
Public purchases should support Brazilian companies with more vertical production and protect the socioeconomic rationality.	**X**		
Government should purchase preferably domestic products, but they should comply with safety, efficacy and quality criteria.	**X**		
Development of policies addressing medicinal plants and phyto-therapeutic products.	**X**		
Regulation of health research and technological development in the country.	**X**		
Price incorporation mechanism review for imported active principle aiming at fomenting the local production.	**X**		
Profarma Creation – Production.		**X**	
Profarma Creation – Domestic company strengthening.		**X**	
Profarma Creation – RD&I.		**X**	
Retaking the import tax TEC levels for pharmacochemical products. • With production in Mercosul – taxes from 12% to 14%; • With production in Mercosul – taxes of 2%.			**X**
Retaking the import tax TEC levels for drug products: • Using pharmacochemical products produced in Mercosul – taxes of 14%; • Using pharmacochemical products not produced in Mercosul – taxes of 8%; • Drugs not manufactured in Mercosul – taxes of 2%; • Medicines used for AIDS treatment, oncology use, not manufactured in Mercosul– 0%.			**X**
Tax burden reduction to foment domestic production to replace imported products.			**X**
Using the chemical product tracing system (CAS)[14] to facilitate the correct identification and information collecting on imported and exported chemical products.			**X**
Export red tape reduction to speed up the issuing of the Export Certificate or Register Certificate.			**X**
Drug regulation for exporting purposes exclusively.			**X**
Improved agility concerning controlled active principle and drug exports and imports.			**X**
Improved agility concerning the analysis of national product requests for changing some chemical product import tariffs.			**X**
International negotiation with economic blocs and countries by using traditional tools, such as tariff protection.			**X**
Improved agility concerning the analysis of procedures addressed to applying antidumping and compensating measures.			**X**

SOURCE: Ministério do Desenvolvimento, Indústria e Comércio (*Development, Industry and Commerce Ministry*) MDIC (2004)

[14] CAS (Chemical Abstracts Service Registry Number) is the number that identifies all the chemical substances existing in the product.

TABLE 4 –Policy proposals by the work groups (WGs 4 and 5) created in the Competitiveness Forum on the Pharmaceutical Production Chain

Submitted proposals:	WG 4	WG 5
Defining targeted-drug sin cooperation with the Health Ministry, to develop national pharmacochemical;	**X**	
Public purchases should select domestic drugs to stimulate their production;	**X**	
Fomenting partnerships between education and research/company institutions;	**X**	
Capacitating human resources in several areas, including process management;	**X**	
Research infrastructure strengthening;	**X**	
Strengthening quality control of bio-equivalence, bio-availability and pharmaceutical equivalence services;	**X**	
Immediate implementation of two national reference files: a) services and equipment available in the already existing education and research institutions, and b) skills already existing in the active principle, drug and phyto-chemical segments;	**X**	
Recovery of the prior operation models of the RHAE - Recursos Humanos para Atividades Estratégicas (*Human Resources for Strategic Activities*) program used for human resources capacitating and based on the technological development institutional proposals.;	**X**	
Invitations to bid, in partnership with other ministries, addressed to supporting efficacy study projects (clinical essays) directed to phyto-therapy product trading;	**X**	
Equipping the INPI - Instituto Nacional de Proteção Industrial (*Industrial Protection national Institute*) by using its own resource collection to foment its technical and administrative personnel capacitating, so that they are able to perform their legal functions in behalf of the country;	**X**	
Investing in technological innovations and new pharmaceutical forms to meet market demand;	**X**	
Identification of new pharmaceutical forms/formulas to support technological innovation projects;	**X**	
Opening new credit lines addressed to shared risk [Financiadora de Estudos e Projetos (Study and Project Financer, under the Science and Technology Ministry) FINEP and Banco Nacional de Desenvolvimento do Extremo Sul (*Far South Development Bank*) BNDES] to finance those projects;	**X**	
Supporting immune-biological product projects addressed to technological domain in order to produce vaccines and inputs;	**X**	
Human resource capacitating in several areas to meet the aforementioned demand;	**X**	
Support to research nets addressed to new molecule R&D;	**X**	
Creation of special credit lines to finance pre-competitive partnerships;	**X**	
Use of chemical product tracing systems (CAS);		**X**
Further sanitary requirements addressed to imported active principles and drugs, mainly concerning government purchases;		**X**
Supporting measures addressed to phyto-therapy product domestic production;		**X**
R&D regulatory milestone implementation;		**X**
Sanitary Surveillance National Agency (ANVISA) strengthening by improving and qualifying the technical team, and sanitary legislation strengthening.		**X**

SOURCE: Ministério do Desenvolvimento, Indústria e Comércio (*Development, Industry and Commerce Ministry*) MDIC (2004)

We wonder if the aforementioned proposals are sufficient for the national industry to growth. It is important to know whether or not the proposals comply with modern industrial policies. So, it is fundamental to set horizontal measures - systemic competitiveness; and, vertical – sector intervention – measures. Table 5 shows the horizontal policies.

TABLE 5 – Horizontal Policies.

Horizontal Policies
Export fomenting.
Coordination of the institutions in charge of implementing the short and long-term economic policies.
Price stability.
Taxation efficiency.
Regulatory milestone and infrastructure problem overcoming (education e labor qualifying, energy, transportation, communications).
Long-term credit and financing.
Incentives to spend on education and R&D.

Hence, in the short term the low value added and technological content products will attach greater weight to the Brazilian export Schedule. Concerning cooperation between institutions, it already exists between the MDIC - Ministério do Desenvolvimento, Indústria e Comércio (*Development, Industry and Commerce Ministry*), MCT - Ministério da Ciência e Tecnologia (*Science and Technology Ministry*), MS - Ministério da Saúde (*Health Ministry*) and BNDES (2004) – Banco Nacional de Desenvolvimento Econômico e Social (Bank for Economic and Social Development). The initial step, Industrial Policy design, is the easiest one. But, the most important step is carrying it out and following the results, when Industrial Policy has taken on the role of co-helper to reach the economic goals.

Tax efficiency has been impaired by the high debt/GNP relationship that does not permit the government to have mobility concerning fiscal policy. Expenditure structure is not able to change and income increasing has reached its limit; tax burden is over 35% of the GDP.

In addition, the 2004 tax reform contributed to increase the national production burden. Therefore, except for quota change in financial applications that reduced the over-two-year application withholding tax and for the IPI reduction addressed to capital goods, we did not notice any improvements.

The country bridges, roads and harbors are far from supporting the increased production. Besides that, power generation is also facing problems and most industry sectors is operating beyond there capacity, some over 85% (IPEADATA 2004) due to domestic recuperation and external trading good performance.[15]

Our analysis also includes vertical policies. PITCE proposal to the Active Principle and Drug sector and the GT recommendations include all the proposals of prior studies – table 3 and 4.

Table 6 recovers the main vertical measures. The measure containing the Performance Requirements addressed to foreign risky investment is the only one which is not mentioned by the GTs.

[15] By the time the present work was completed the project that establishes the regulatory milestone was still being voted in the National Congress.

TABLE 6 – Vertical Policies

Vertical Policies
Export fomenting, including improving the export Schedule and replacing imports competitively, through identifying the industrial structure lacking or weak links that bring about economy vulnerability, because they contribute to the payment balance negative performance.
Prioritized development and intra and inter-sector integration of domestic industrial complexes without abandoning the competitiveness aim and export strategies.
Credit support, via BNDES, for restructuring and fomenting technological *upgrade*, besides the credit strengthening addressed to machinery and equipment exports and acquisition.
Subventions and direct and indirect fiscal-financial assistance through reducing tax burden or awarding credit and subsides, such as prime interest rate loans.
Performance and counterpart requirements for sectors assisted by governmental benefits.
Temporary and selective tariff protection for specific sectors to be developed.
Foreign risky investment performance requirements.
State purchase use and direct intervention in the restructuring of determined sectors.

5 FINAL CONSIDERATIONS

It is necessary to engage in a wide discussion that places industrial policy at the core of public policies – as it seems to be the case of the current government proposal. But, there is also the need of leaving the proposal behind and progressing to carry it out.

The "actual" Industrial Policy between 1993 and 2003 was limited to vertical actions reaching just some economic segments, so industry was not provided with the dynamism required to a long-term sustainable economic growth, and problems remain unchanged.

When we compared the 1993 ECIB and the 2003 ECCIB, the latter seems to be more complete than the former. This characteristic may be owed to the fact that the sector has progressed a little – or almost nothing – concerning the 1993 recommendations. After ten years, the problems pointed out in 1993 remain the same and, in some cases such as the import increasing, even became worse. As we have already mentioned, no public policies were created to foment a significant change or recuperation in the sector. Next, we highlight some 2003 ECCIB characteristics – aforementioned – which were diagnosed by Frenkel et al. (2003).

a) It is necessary to change the national family company profiles, by increasing their sizes and interaction so that they can face the big multinational company competition
b) It is necessary to internationalize national industries through branches or partnership with other country local companies, in order to increase the active principle production and improve its exports, and even export drugs
c) It is necessary to retake import tariffs on active principle and on drugs with expired patent in order to foment national production
d) It is necessary to foment the second stage (active principle production); and
e) It is necessary to have a rigorous quality control, mainly over unknown/doubtful origin imported products
f) It is necessary to establish an exchange responsibility concept for companies to maintain the equilibrium of their trading balance.

It is too early to foresee weather the PITCE will be successful or not in reducing the active principle and drug foreign dependence, as well as whether domestic production and demand will grow and make the country be promoted to the position of a great player in the active principle and drug world market. But we can assure that the PITCE measures – aforementioned – comprise a complete answer inserted in what we here conventionally call "modern industrial policy".

However, it is important to overcome the initial step, the PITCE design, and go forward with the most difficult step, the measures and result control carrying out. It is also true that we cannot expect the industrial policy to be successful by itself, thus we have to rethink the government position concerning economic policy decisions and the short-term excessive priority. In addition, there is a general consensus that the active principle and drug sector success depend on the inclusion of over 50 million Brazilians prevented from buying drugs due to income restrictions.

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