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Preliminary notes for a comparative analysis between England, Brazil and Argentina

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Social Welfare, Health and Pharmaceutical Industry: preliminary notes for a comparative analysis between England, Brazil and Argentina

Ignacio Godinho Delgado*

Presentation

This paper is an initial result of the ongoing research on the relationship between the health system and the pharmaceutical industry in Brazil, Argentina, and the United Kingdom[1]. The original idea was to evaluate how the changes that took place in the international regulatory environment, with the creation of the WTO (World Trade Organization) and institution of the TRIPS (Trade-Related Aspects of Intellectual Property Rights), were affecting the domestic industries of Brazil and Argentina, as well as the government responses of the two countries to the intensified pressures on the national health systems, due to increased drug prices and supply problems that were resulting from the erosion of productive capacity of the domestic pharmaceutical industry in both countries. Observation of the Brazilian case, however, stressed the expansion of the roles played by the health sector in the Brazilian government, which since the beginning of the current century, has been developing into a prominent actor in the formulation and implementation of *industrial policy* for the pharmaceutical industry. To the extent that Argentina's industry displayed great similarity to Brazil's (by its imitative bias), yet their national health systems present contrasting features and trajectories (Brazil's being formally public and universal, with a strong private presence in provision, and Argentina's, with access predominantly employment-related), it seemed to us that this could help elucidate the different national responses to the dilemmas raised by the new regulatory environment. Including the UK in the research was motivated by the disposition to assess, in the same international scenario, how the relationship would be carried out between a pharmaceutical industry on the cutting edge and a health system constantly cited as a reference in the public provision and universal access to health services.

The research strategy to be developed in this work involves the analysis, along general lines, of the structure of industrial production in the targeted countries, and especially the identification of the perceptions and actions taken by the relevant actors (governments, especially in the health area, and representative bodies of the industry), in relation to the agenda that affects the two sectors, especially within the arenas in which health policy and industrial policy for the pharmaceutical industry are defined. There is much to do in these two dimensions, for the three countries, and, in

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[1] I am grateful for the comments of Ken Shadlen, Ligia Bahia, Pedro Gabriel Godinho Delgado and Valéria Lobo. Thanks also to help of Adebiano Rodriguez, Ana Clea de Souza Santos, Camila Rodrigues de Oliveira Dias, Maedison de Souza, Nittina Bianchi, Guilherme Schneider, Fernando Vianinni, Fernando Silveira Jr.e Tâmara Letícia Horsti Corrêa. I am grateful to Joseph Quin who translated the text of the manuscript in Portuguese. All responsibility for what is written is, of course, exclusively mine.

the case of Brazil and Argentina, to focus more closely on the role of the industry bodies in the arenas present in the two countries. In the British case, it was possible to go a little further in this direction by the contact we had with the documentation of the *Pharmaceutical Industry Competitiveness Task Force* and *Ministerial Industry Strategy Group*.

The paper is a preliminary and partial result of the surveys and reflections developed[2]. It consists of four sections. The first one discusses the relationship between health systems and the pharmaceutical industry, and outlines a framework for studying the relevant actors in the health area, as well as the agenda and arenas in which it develops. The second section outlines the recent trajectory of the health systems in Brazil, Argentina, and the United Kingdom. The third describes the key events in the relationship between health and pharmaceutical industry in the three countries, in the scenario defined by the institution of TRIPS. In the Final Considerations the elements developed in the previous sections are connected, and the possible consequences of different national settings described for the evolution of the pharmaceutical industry and the health systems of the countries under review are examined..

1) Welfare, Health, and Pharmaceutical Industry

In recent years, the pharmaceutical industry has been at the center of debates in the health area. This prominence contrasts with its absence in classic debates that focused on different social actors to explain the origin and format of the various systems of social protection and health care in the contemporary world. In fact, the State, the public bureaucracies, and the workers have been the most prominent actors in the study of the rise of the Welfare States (Pierson, 1994; Skopkol, 1992, Esping-Anderson, 1990; Przeworsi, 1989). In the same vein, different figurations that, in capitalist society, frame the relationship between workers, employers, the State, and petty-bourgeois sectors, involving distinct coalitions, were also cited to explain the institutional forms that accompany affirmation of the State as the main actor in the processes of social protection (Swaan, 1988). Besides these actors, in the specific context of the health care system, a prominent role has been attributed to the power of physicians - and how the State limits their actions - to explain the prevalence or otherwise of universal and public formats in the organization of health care (Freddi & Bjorkman, 1989; Swaan, 1988). In turn, the characteristics of the institutional system, particularly

[2] It should be noted that the work under discussion developed in the confluence of two research projects that we coordinated in Brazil: *Actors and Trajectory of the Health System in Brazil (1988-2011)* and *Varieties of Capitalism and Comparative Industrial Policy: the case of Brazil and Argentina*. In the first, developed with support from the Rectory of Research at UFJF, focus is on the evolution of the Brazilian health system agenda since 1988, when the *Unified Health System* (SUS) is established, ensuring the right to universal access to health, highlighting the heated debates in the arenas in which various actors seek to interfere in its course. The second, coordinated by myself and Eduardo Salomão Condé, is developed under the Research Stream: *State, Varieties of Capitalism, and Development Policies in Emerging Countries* at the *National Institute of Science and Technology - Public Policies, Strategies, and Development* (INCT-PPED), and uses the approach on the *varieties of capitalism* as an heuristic resource to evaluate the trajectory of industry and industrial policy directed at the pharmaceutical and software sectors in Brazil and Argentina in the new scenario defined by the institution of TRIPS.

decision-making processes, have been identified as factors that affect the impact of using the social actors' resources of power (Pierson, 1994; Immergut, 1996).

In a synthetic view of different formulations, the social protection systems can be classified as universal, corporate, and liberal (Esping-Anderson, 1990; Rimlinger, 1977; Korpi, 1978; Titmus, 1958). In the first, full access for citizens to the various benefits and services predominates, funded by general taxes. In the second, the presence of occupational mechanisms in defining access is highlighted, with the funding done through compulsory contributions from workers and employers. Finally, in liberal systems, *means tests* for public system access by the needy population are highlighted, funded by several taxes, along with significant private offering of various services. In the characterization of health systems, the access mechanisms and ownership of the "medical factors of production" have been considered central elements (Albuquerque & Cassiolato, 2000; Almeida 2008; Lobato & Giovanella, 2008). At one extreme, there are the cases where the public health system prevails, funded by taxes, with guaranteed universal access to care. At the other, liberal medicine and the private insurance companies prevail, predominated by the private hospital network. In an intermediate position are systems that guarantee universal access, but where provision is fundamentally private. Lastly, the systems in which access to health services is effected through insurance predominantly related to employment, combined with varying degrees of private ownership of the factors of production.

To a certain extent, the pharmaceutical industry seems an actor indifferent to the formats acquired by the systems of social protection and health care, once assured of private-company predominance in supplying medicines. In fact, one can verify the presence of a significant pharmaceutical sector in countries with different configurations of social protection and health care systems. The USA., paradigm of a system of liberal social welfare, with a strong presence of the private sector in health care, leads the world production of medicines. Germany, paradigm of a system of corporate welfare and health care based on employment-related insurance, ranks third in world production (BDO, 2008). Sweden, paradigm of a universal system of social welfare, with public control of the hospital network, holds a significant presence in the export of drugs, despite the small size of its economy, and at least, one company in the country, combined with British capitals, stands among the largest in the world. [3] England, in turn, saw the processes of retraction of the social policies in various areas but retained public ownership of the factors of medical production, despite all the initiatives for health system reform, alongside a pharmaceutical industry that until recently ranked fifth in world production (Pierson, 1994; Leys, 2004; BDO, 2008).

Ultimately, the share of public spending on health is significant in countries with different formats for welfare and health care systems, showing different forms and intensities to handle the market imperfections in health care, whether in medical care, or in the supply and demand of

[3] Refers to Astra-Zeneca, which occupied the sixth position in worldwide sales of medicines according to data from the IMS, 2006, according to ABDI, 2008.

medicines. [4] On the other hand, the State's presence as a significant component of pharmaceutical demand (an industry responsible for a key input in health care) reduces the uncertainty about the profitability of productive activity, that, although marked by high costs in research and clinical trials, enjoys reduced barriers to entry associated with factor costs, from the moment a drug's active ingredients become general knowledge. Thus, if the emergence of public health systems may be associated with the presence of *market failures* linked to healthcare and to the production and consumption of drugs, it is not far from to pharmaceutical industry *interests*, despite the apparent absence of the pharmaceutical industry in the founding moments and in the coalitions which define the format acquired by the health systems and social welfare systems in various countries.

Once the national health systems are established, relations with the pharmaceutical industry are effected through the State's regulatory actions levied on production, consumption, and medicine prices, to control risks and increase access. This is the reason for the appearance of agencies responsible for authorizing the production, sale, and prescription of drugs, based on the evaluation of their therapeutic properties and potential risks to the health of users. Moreover, in most cases, drugs are price-controlled by public agencies, with varying levels of pharmaceutical industry involvement. Policies such as authorizing the manufacture of generic drugs, moreover, aim to increase access, encourage competition, and reduce the pressure of drug prices on public budgets. On the other hand, in addition to government procurement, as indicated above, the State's participation is also crucial in the formation of human capital and in research investment, which support investment decisions in the pharmaceutical industry. To this extent, although the relationship with the national health systems is not always effected by the specific agency of the sector, the pharmaceutical industry appears as one of the decisive actors in its operation, seeking to influence its agenda to a greater or lesser extent. Likewise, the State's regulatory actions, its presence in funding research, and its purchasing power have always been important elements in determining the course of drug production and in making business decisions.

However, the health systems and the *health-industrial complex* operated, until recently, in specific tracks. Their reciprocal relations and even their potential interpenetration, along the

[4] Among the developed countries in the OECD, the US had a 45.8% State share in total spending on health, Germany, 76.6%, Sweden 81.2%, and 87.4% in the United Kingdom. In the same year, Brazil participated with 47.9%, and Argentina with 45/5%. (Vargas, Maldonado & Barbosa, 2008). *Market failures* related to the market for health services and medicines are basically associated with *information asymmetry* and *adverse selection*. If taken as commodities, medical care and drugs involve a set of characteristics that clearly distinguish them from other commoditized goods: *risk*, problems associated with the *relationship between principal and agent*, various *externalities*, that further the frequent occurrence of *moral hazard*, especially when providers, in the case of medical care, lack incentives for guaranteeing services not covered by health insurance contracts, or, conversely, prescribe unnecessary procedures to increase their earnings. It is noteworthy, also, in medical practice, the identity between activity and product, the ethical compulsions involved in the allocation of resources, the uncertainty of results, the required credentials for treatment authorization, the lack of portability of the service, the occurrence of indivisibilities. In the case of drugs, what should be noted is the presence of the physician as mediator in the consumption, reducing consumer sovereignty, the restriction on free allocation of the factors arising from the patent system, the presence of barriers to entry, defined institutionally rather than by the cost of the factors, the unpredictability of circumstances (diseases) that motivate their use, the unique pricing structure; the inelasticity of demand. (Albuquerque Cassiolato, 2000; Leys, 2004; Arrows, 1963; Reekie 1975; McIntyre, 1999).

trajectory of national health systems, focused on here, were not obscured by institutional arrangements that would allow, on the one hand, direct interference from the health systems in the industrial policies aimed at the production of drugs and medical equipment, or even on the other, were guaranteeing institutionalized access by industry to the operational definitions adopted in the health systems management context. Ultimately, this paper suggests that there is reasonable evidence to suggest that this line of demarcation is being exceeded. The environment that furthers this double movement is in the establishment of TRIPS, amidst the creation of the WTO, its founding moment, as will be treated further on, by the pressures that are being unleashed on health systems and on domestic industries linked to the health-industrial complex.

In passing, it should be noted that the definition of the paths taken by national health systems does not occur only endogenously, based on the relations between the different participating actors, such as providers, professionals, managers, input suppliers, and customers[5]. In fact, the ideological choices of the parties and coalitions that appear on the political scene, the more or less diffuse pressures of more inclusive social actors such as the trade union movement and businessmen; the formulations born in the academic environment and the action of think tanks together with public opinion are a relevant part of the environment in which the problems, the issues, and proposed solutions to face the dilemmas of national health systems emerge. As a backdrop, in this context of cross-pressures, the more general problems and macroeconomic options, that enhance or constrain the specific options of the health area, are of great interest.

However, the presence of such actors in defining the direction of national health systems tends to fade in the course of its routine operation, though it is of great importance in the *critical moments* when the regulatory frameworks in which each national system will operate are established, i.e., the definitions of the ownership of the medical factors of production, the requirements and conditions for access to health services, the regulation of the activities of area professionals, besides the public sector relationship with private providers and suppliers, i.e., linked to the role of segments such as health insurance, private hospitals, various sectors of the *health-industrial complex*, and pharmacies. From there, the outside social actors' preferences and willingness to act, in relation to the problems and issues pertaining to the health area, tend to appear very heterogeneous, in most cases forming from initiatives triggered by endogenous actors. To this

[5] It is impossible to discuss here all the issues involved in the process of agenda setting of a given policy. Interests, institutional constraints, past choices, ideas, structural and conjunctural pressures, and critical events tend to operate in mixed ways in the composition of the environments that promote the entry of an item on the agenda (Howlett & Ramesh, 1995), either when its analysis is grounded in the idea of diverse streams of problems, solutions, and politics (Kingdom, 1995), or when emphasis is on the creation of "policy monopolies" in the midst of processes marked by punctuated equilibrium (Baumgartner & Jones, 1999). We share the suggestions of Gourevitch (1986) concerning the role of crises in the determination of rearrangements in the coalitions established among societal actors, mediated by the presence of certain institutional forms and ideologies, affecting the choices of more comprehensive policies. In the case of sectoral policies, however, although the presence of societal actors is relevant at critical moments - in which such policies are defined in connection with the more general choices, for example, the consolidation of the welfare state in postwar Europe - it is nuanced by the role exerted by endogenous actors in the formulation of the problems and presentation of alternatives, tending to fade in "normal" times.

extent, notwithstanding the influence that outside social actors can exert jointly with spheres such as Parliament and "public opinion", the issues for public debate about the health area emerge primarily in the interaction between the endogenous actors.

We can identify eight endogenous actors directly related to the operation of the health system. Their interests, and the means of power at their disposal, to act in matters relating to the operation and the agenda of the health system are varied, but cross-relationships can develop that affect their willingness to act on issues where convergences are possible [6]. The arenas in which the participation of different actors is effected depends, of course, on the institutional structure defined within the basic framework. However, the weight conferred by the various actors to each arena will depend on the possibilities of working with the means of power available in each arena, and on the effectiveness each has in decision making. Thus, in some cases, certain actors prefer to operate on the idea of deflating certain arenas, especially susceptible to the articulation of conflicting interests, pressing for the formation of more susceptible arenas.

Among the endogenous actors mentioned above, in first place in terms of relevance is the *government*, which, notwithstanding the different coalitions and ideological perspectives that define its preferences and choices, its actions are often limited by constraints of the macroeconomic and institutional environment, as well as by past choices in the process of structuring national health systems. In second place, the *public health bureaucracy* appears prominently, its organization directly linked to the prevailing forms in the context of national health systems, although tending to be attuned to prospects to strengthen its public character. In third place, the *hospital networks*, with different characteristics depending on the form of ownership of its constituent units, which develops a special interest in issues related to the financing of the public system and the regulation of its links with service providers. In fourth, the area professionals, especially *physicians*, who by their credentials, affect the structure of the demand for drugs and health services, and can develop relationships of affinity and / or conflict with the other actors, especially regarding issues related to the regulation of the limits of the profession, and to remuneration for their activities. Fifth, the *health-industrial complex*, in various sectors and segments, supplier of inputs and equipment for the system, whose commercial strategies may involve preferential relations with doctors and hospitals,

[6] As an illustration of cross-relationships, what stands out is the connections between physicians and the pharmaceutical industry, constantly treated in the literature (Reekie, 1975; McIntyre, 1999). In turn, the relations between industry and users have been the subject of growing concern in the legislative sphere in Britain. The Report of the Health Committee of the House of Commons, *The Influence of the Pharmaceutical Industry*, highlights industry participation in the financing of consumer organizations that promote disease awareness campaigns, which ends up, sometimes inappropriately, pressuring the health system to accept certain medications, besides circumventing existing restrictions on the advertising of medications (UK-House of Commons, 2005). We find *exit* actions, from arenas impervious to certain interests, in turn, in the actions of organizations representing hospitals and doctors which, in the National Health Council (CNS), in Brazil, try to give little weight to the arena, with reduced presence at their meetings, given the significant weight of actors sympathetic to the defense of the intensification of public regulation on health. Ultimately, in 1998, with the creation of the National Health Agency (ANS), the Brazilian health system gained a more defined institutional duality, with the presence of two central regulatory arenas, the CMN and the ANS, responsible for regulating the private sector (hospitals and health plans). The inspiration here is Hirschman and his distinction between exit, voice, and loyalty to delimit organizations' responses to situations of institutional decay, however, useful to analyze the behavior of social actors in conflict situations (Hirschman,, 1970)

as well as seeking joint influence with arenas deciding on regulatory policies and government procurement in the health area. Sixth, the *drug distribution and sales sector*, whose duties also depend on the more general regulatory environment of the system. *Private health insurance*, especially interested in the regulation of the services they offer, affecting the relationship with the government, the area's bureaucracy, and doctors. Finally, the *users of the services*, virtually interested in all issues on the agenda of the health system, but the most affected by the *asymmetry of information* that envelops the supply of drugs and health services. Their profile and organization are determined by the different forms of national health systems, influencing in their degree of segmentation and capacity to associate.

The table below shows the actors mentioned, the main issues that affect their interests, the key arenas in which they operate, and the most significant possibilities for emergence of cross-links based on the interests of each.

Table 1

Actors, Agenda, Arenas, and Cross-Relations in Health Systems

Actors	**Agenda - Themes of Interest**	**Arenas**	**Cross-Relations**
Government / Ministries or Departments of Health	Financing - constraint of macroeconomic policy and of disputes with other government agencies Regulation - all topics in the area	- health counseling - health and drug plan regulatory agencies - Parliament - public opinion	With all actors and arenas
Health Area Public Bureaucracy / associations representing public servants	Financing Regulation - all topics in the area, particularly the relationship between public sector and service providers	- health counseling - health and drug plan regulatory agencies - Parliament - public opinion	With doctors, hospitals, and government
Professionals, especially physicians / associations professional counseling	Financing Regulation - in particular issues concerning the regulation of professional practice, compensation, and the regulation of relations between public sector and service providers	- health counseling - health plan regulatory agencies, - Parliament - public opinion	With hospitals, government, health plans, pharmaceutical industry
Hospitals / representative associations	Financing Regulation - in particular issues concerning relations between public sector and service providers	- health counseling - health and drug plan regulatory agencies - Parliament - public opinion	With hospitals, government, health plans, pharmaceutical industry
Health-Industrial Complex (especially pharmaceuticals) / representative associations	Financing Regulation - in particular the patent system and rules and regulations on production, marketing, and consumption	- regulatory agencies of drug use - regulatory agencies of intellectual property rights - Parliament - public opinion	With hospitals, government, doctors, health plans
Pharmacies	Regulation on the distribution and selling medicines	- regulatory agencies of drug use - Parliament - public opinion	With hospitals, government, health plans, pharmaceutical industry
Health Insurance / representative associations	Regulation	- health counseling - health plan regulatory agencies - Parliament - public opinion	With hospitals, government, health plans, doctors
Service users	- In theory all issues	- health counseling - Parliament - public opinion	- With all the actors and arenas

The identification of the arenas, agendas, actors, and their cross-relationships, in the context of national health systems, is important for investigating the possible coalitions forged in defense of various measures associated with the development of the health systems agenda in a certain time period, but it is beyond the scope of this paper to examine them at this time. In this paper, though we may partly make use of the same frame of reference, our interest, as already noted, is to analyze the relationships between the pharmaceutical industry and the health systems in Brazil, Argentina, and England, in the environment generated by the institution of TRIPS, which defines a more rigid regulatory framework in the area of intellectual property rights. Ultimately, so far, the relative permissiveness of patent systems guarantees, with greater or lesser presence of multinational companies, in Brazil and Argentina, the creation and development of drug production in domestic economic spaces, through processes of imitation, not always accompanied by the creation of conditions for the production of active ingredients, controlled by a small group of countries where innovative activity in the pharmaceutical industry is concentrated (Gadelha, 2006; Gadelha, Quental, & Fiallho, 2003; Frenkel, 2001; Furtado & Urias, 2010; Selan, Kannebley & Porto, 2008; Santoro, 2000; Katz, 1987). Thus, the State's regulatory actions concerning the production, marketing, access, and pricing of medicines were performed in a space where external constraints were substantially lower, while this could proceed in a relatively autonomous manner in relation to the health systems, although informed by their interests.

Institutional changes for the mandatory public provision of various medicines, technological changes and legal provisions that affect the cost of research conducted by the pharmaceutical industry add to the provisions of TRIPS in the sense of rising health costs, bringing, as stated above, the pharmaceutical industry to the center of the debates that currently surround the health area, besides leading the agencies that run the national health systems to the center of the controversies and policy formulations for the production of medicines. However, although this movement may be relatively obvious in developing and non-industrialized countries, it is not unfamiliar to the trajectory of health systems and industry in developed countries with an innovative pharmaceutical industry, either because the pressures on health systems there also becoming more pronounced, leading to the search for alternatives to reduce the cost associated with medicines, or because domestic industries, while innovative, require a significant presence of the State, both to defend their interests in international regulatory arenas, and to create competitive advantages internally, in order to strengthen them in an international environment of bitter competition. In this case, the relationship with the health system becomes a crucial variable, by virtue of its importance in the domestic demand for drugs and for its potential significance for certain stages of the production of drugs, such as research and clinical trials.

We will consider, therefore, the recent trajectory of national health systems in Brazil, Argentina, and England, pointing out, also, the main bodies that are of direct interest to the industry within the governments of each of the countries analyzed.

2) Health Systems in Brazil, Argentina and United Kingdom

The health systems of Brazil and Argentina came up with a similar configuration, with access defined by occupational profile and funding secured by compulsory contributions from employers and employees (Delgado, 2001; Menicucci, 2007; Piola & Cavalcante, 2006; Obras Sociales, N.D.) The Brazilian Institutes of Retirees and Pensioners (IAPs), created in the 1930s, and the Argentinean *social works* (Obras Sociales), driven by the creation of the Social Service Commission in the 1940s, ensured its members health care according to criteria differentiated by the professional category they represented.

In Brazil, however, a series of changes were defining the construction of a public and universal system, open to all citizens, although middle and high income segments prefer using private practice and health plans to access the private hospital network, whose presence is stronger than its Argentinean counterpart. It is worth noting the establishment of the Social Insurance Organic Law (LOPS) in 1960, which standardized benefits and services under the different IAPs in Brazil; the creation of the National Institute of Social Security (INPS) in 1966, which unified the system's administration; and, ultimately, the 1988 Constitution, which established universal access to public health services, with the creation of the Unified Health System (SUS) (Teixeira & Oliveira, 1986; Delgado, 2001; Werneck Vianna, 1988; Bahia,2005). Under the Charter of 1988, resources from other sources would be added to worker and employer contributions to fund *social security*, proclaimed as an order to bring together health, assistance, and social insurance in a single institutional arrangement.[7] However, a unified agency to manage Social Security was not effectively created. Thus, in the health area, the governing of the system remained under the direction of the Ministry of Health, created in 1953, formally supported by the National Health Council and by the Health Conferences. The Ministry of Health, in turn, assigned management of resources and the services network to states and municipalities, following nationally defined accreditation criteria. In the Charter of 1988, the services provided by the private hospital network were defined as components of *supplementary care*. However, since public hospitals represent a minority share in the *supply* of beds in the system as a whole, the SUS is always contracting services provided by the private network.

The fiscal difficulties of social security, the budget constraints derived from the macroeconomic policies pursued by the different governments in Brazil since 1990, and the ambiguity in defining the sources of funding were eroding the prospect of a unified budget for social security, besides facilitating the ever-more segmented operation of public health and supplementary care (Ugá & Marques, 2005; Bahia, 2005; Menicucci, 2007). The creation of the National Health

[7] There is a clear inspiration in the Beveridge Report and in the health system in England, among the proponents of the SUS (Delgado, 2001; Werneck Vianna, 1988). However, the weight of past choices take their toll on its implementation. During the Brazilian military regime, a strong network of private hospitals took shape. Despite its characterization as *supplementary* in the 1988 Constitution, it would eventually fulfill a significant role in the provision of SUS services, besides attending private demand, conferring, since its beginnings, a mixed character on the Brazilian health system.

Agency in 1998 consecrates the dissociation of the two systems by erecting a regulatory arena distinct from the National Health Council, hitherto the unified instance of deliberation about the Brazilian health system agenda (Menicucci, 2007). In turn, funding the public system presented a trajectory marked by uncertainty. The creation of the Provisional Contribution on Financial Transactions (CPMF) in 1997 defined a funding source specifically for the area, distinct from what should be the social security budget, and in 2000, Constitutional Amendment 29 established that 10% of federal taxes and 12% of state taxes should be allocated to health. The CPMF, however, was abolished in 2008 and Constitutional Amendment 29 has not yet been regularized.

Notwithstanding the difficulties mentioned above, the creation of the SUS functioned positively in improving the health of the Brazilian population. Primary health care expanded considerably, and access to secondary and tertiary care was universalized, though operational bottlenecks remain, due to the dominance of the private provision of hospitals and laboratory tests, leading often to litigation involving the SUS and private hospitals. In turn, the public system has been guaranteeing free access to medicines and more complex treatment, these with a positive disposition by the private network, since in quaternary care the SUS pays the hospitals high prices. To a great extent the results of the operation of the Brazilian health system appear in the improvements of several indicators in recent years. [8]

In Argentina, as in Brazil, the public health system coexists with the private sector, with significant presence of private hospitals and a small share of private health plans (medical pre paid). However, while in Brazil the public sector participation in the coverage is high, in Argentina it is less than that provided by social work, national and provincial, managed mostly by unions, which in good measure, hire private sector services (see table 2)[9]. The social works carry on the mutualist experience that took place in the country until the 1940s, being formally integrated into the health system in 1944 (*Obras Sociales*, N.D.). In the 1950s and 1960s they experienced a major boost, but in 1960 were responsible for the coverage of less than 30% of the Argentinean population.

[8] Brazil shows lower health indicators than those shown by Argentina, in part due to the origin and trajectory of its economic and social formation, marked by a bias of pronounced income concentration. However, the country's health indicators have changed significantly in recent years. According to World Health Organization (WHO) data, life expectancy in Brazil rose from 67 to 73 years between 1990 and 2006, while the probability of dying before age five (per 1000 live births), dropped from 56 to 20 in the same period. In turn, infant mortality, which in 1997 was 31.9 per 1000 live births, fell to 20 in 2007. These numbers are still high, but indicative of an effective process of improvement (DATASUS, N.D.). Also the generally positive user assessment of the SUS in relation to the system may be seen. According to a survey from the Institute of Applied Economic Research (IPEA), among the Brazilians who actually use the system, 34% find the service good, 42% find it regular, and 27.6% feel it's poor. It is possible, however, to observe express dissatisfaction with care in urgent and emergency services departments (31.4% of respondents), in health posts (31.1%), and by medical specialists (18.8%) among actual SUS users, within the context of a generally positive assessment. What is curious is the high rate of dissatisfaction with the SUS by respondents who do not use the system. Among these, only 19.2% found the services good, 46.5% find it regular, and 34.3% find it poor or extremely poor.

[9] The table is just one illustration of how to structure the coverage of the two systems, obtained from a single source. The data of Argentina, presented in the publication cited here, were collected in Mesa-Lago (2005) and Brazil were obtained in ANS. In the Argentine case is attributed to lack of data the fact that the numbers added together do not reach 100. Meanwhile, in Brazil access to the public sector to the NHS is franchised to those who use private insurance.

Table 2

Health Coverage as the nature of provider (%)		
	Argentina (2001)	Brasil (2003-2006)
Public Sector	37,4	80,4
Private Sctor	7,9	19,6
Social Work	51,2	-
Double Coverage	3,2	?
Total	**97,7**	**100**

Source: OPAS/OMS (2007)

In Argentina the administrative unification of social works, such as occurred in Brazil with the INPS, was not pursued, despite efforts in this direction seen during the military governments in the 1980s. Nor was a public system of universal access established, though the creation of the *National Institute of Social Works* (INOS) and the *Redistribution Fund*, in 1970, had been succeeding in raising health care coverage to more than 70% of the population, yet without eliminating the inequalities stemming from differentiated resource availability to the various social works (Piola & Cavalcante, 2006). Care in the public sector, funded by taxes, is a principal duty assigned to the provinces, while the central government is present, with the precincts and superintendencies of the Ministry of Health, created in 1949, besides other decentralized agencies and the National Institute of Social Services for Retirees and Pensioners, whose budget was incorporated into the national budget. The private sector is integrated into the system through individual health insurance, as well as through the management or provision of complementary services offered by several social works.

Beyond the financial difficulties of social works, the great dilemma of the health system in Argentina has been its reduced capacity for coordination (Maceira, 2003; Maceira, Cejas & Olaviaga, 2010). In the absence of an effectively unified system, various initiatives have been undertaken to confer a certain homogeneity to the service, beyond the *Redistribution Fund* noted above, namely, among others, the *Obligatory Medical Program* and the *Remediate* (Remediar) program, of 2002. The first establishes a minimum threshold for the care given by the social works and the obligation, on the part of social work and private health plans, to fund a portion of the drugs used by people enrolled in them. The second aims to ensure the basic provision of medicines for the neediest people (Argentina, N.D.; BDO, 2008; Homedes & Ugaldi, 2006; Tobar, 2004)[10]. In any case, Argentina, despite the general deterioration of social conditions since the late 1990s, especially after the 2001 crisis, has health indicators superior to most Latin American countries.

[10] Already, the creation of the *Federal Health Board* brings together federal and provincial health care authorities, but unlike the National Health Council and the National Health Agency of Brazil, it does not involve relevant stakeholders, such as doctors, hospitals, and industry.

The participation of private providers alongside the public sector relates Brazil's health system closely to Argentina's. They differ, however, in access (universal in Brazil, occupational in Argentina), in coordination (pronounced in Brazil, reduced in Argentina), in composition of the supply of services (in Brazil there is no network of employment-related insurance) and in the structure of health expenditures, although in this case, there is a tendency toward relative similarity[11].

As for the relationship of the health system with the pharmaceutical industry, the most important agencies in the two countries are the *National Health Surveillance Agency* (ANVISA) and the *National Drug, Food, and Medical Technology Administration* (ANMAT**)** (Maceira, Bumbak, Barbieri & Peralta, 200**5**). The first is responsible for evaluation, authorization, and registration of medicines launched in the Brazilian market, but has much broader responsibilities than its counterparts in other countries. It is also responsible for supervision of the drug distribution and sales network, and participates in controlling prices, since it directs the Pharmaceutical Market Regulatory Chamber, an interdepartmental body created in 2004 to define the rules on setting drug prices. In addition, since 1999, it participates in the process of patent registration, a principal duty assigned to the National Institute of Industrial Property (INPI), through the provisions of the Provisional Measure No. 2.006/1999 and subsequently by Law No. 10.196, of 2001 that established the "prior licence", although its effectiveness is diminishing (Shadlen, 2012).

ANMAT, in turn, is only responsible for the evaluation, authorization, and registration of medicines launched in Argentina. Patent registration is done at the *National Institute of Industrial Property* (INPI), supervision of the distribution network is the responsibility of the *Health Supervision Directorate of the Ministry of National Health and Environment*, and control of drug prices rests with the *Secretary of Commerce of the Ministry of the National Economy*. In fact, however, drug prices in Argentina are not subject to regular monitoring (Maceira, Bumbak, Barbieri & Peralta, 200**5**).

In its general features, the British health care system is distinguished from Argentina's by the prevalence of its public character and its universal access. In relation to Brazil's system, there is a marked difference in the residual, although growing, presence of private providers in the UK. Moreover, both through the operation of its health system, consolidated for decades, and its trajectory as a developed country, the United Kingdom shows health indicators much better than Brazil and Argentina (see table 3).

[11] Some data on the health systems of both countries are presented ahead, in Table 3, along with information about the UK. It stressed that, despite the difficulties presented in the construction of the SUS in Brazil, the control of the Ministry of Health in the distribution of resources from the Treasury, to the federal units, using criteria and centralized monitoring, distinguishes the Brazilian system from Argentina, marked by the great autonomy of social works and the federal units, which are supported with funds from payroll taxes and other sources. In this sense, the SUS shows greater capacity for coordination than Argentine public system since its decentralization and the fragmentation of social work considerably increases the transaction costs for the implementation of policies requiring the participation of all segments of the system.

Table 3

Some features of public health and other indicators in Brazil, Argentina and the United Kingdom			
	Brazil	**Argentina**	**United Kingdom**
Access (a)	Universal	Related to employment	Universal
Structure of the Network Service (a)	Public and private (majority)	Public, private and "corporate"	Public (high prevalence) and private
Coordenation (a)	Middle	Low	High
Health expenditure as% of GDP (2007) (b)	8.4%	10.0%	8.4%
Government spending as a percentage of health spending (2007) (b)	41.6%	50.8%	81.7%
General government expenditure on health as % of total government expenditure (2007) (b)	5.4%	13.9%	15.6%
Physicians – Density (per 10 000 population)(2000–2009) (b)	17	32	21
Life expectancy at birth (males and females) (2008) (b)	73	76	80
Healthy life expectancy at birth (2007) (b)	64	67	72
Maternal Mortality Ratio (per 100 000 live births) (b)	77	44	7
Gross National income per capita (PPP int. $) (2008) (b)	10,070	14,020	36,130
IDH (2010) (c)	0.69 (73)	0.77 (46)	0.84 (26)
Gini (2005-2008)	55	48.8	36

Sources: a) own elaboration[12]; b) WHO - *WORLD HEALTH STATISTICS* – 2010; c) PNUD - *Relatório de Desenvolvimento Humano 2010*.

The *National Health System* (NHS) was established in 1948 based on three Core Principles: "1) that it meet the needs of everyone; 2) that it be free at the point of delivery; 3) that it be based on clinical need, not ability to pay" (NHS, ND.). Thus was instituted a publicly provided universal access health system, though it is acceptable to hire private providers, and for most of the NHS trajectory, to charge fees for prescriptions made by *general practitioners* (GPs), the gateway to the system. Some services may also be subject to specific fees. Secondary and tertiary level care is performed by salaried specialist doctors (known as consultants) in the hospital network serving the NHS, predominantly public. Despite its recent growth, the private network attends only 12% of the British population (Boyle, 2011) [13].

The funding of the NHS is done, primarily, through general taxes, with resources defined by negotiation between the Treasury and the health area authorities, backed up by National Insurance Contributions (NICs) and, on a small scale, by direct payments and other sources. In England, more than 50% of NHS expenditures are directed to the payment of salaries and wages. The way these

[12] We must, of course, refine this classification, assigning specific weight to each variable and incorporating others. In case we are considering "high coordination" as associated with the central control of the budget and distribution of resources and strong predominance of public units in health care; "coordination medium" associated with the central control of the budget and distribution of resources and high participation of private units in health care; "low coordination", associated with small control of the central budget and distribution of resources and high participation of private units in health care.

[13] Most of this description made on the British system was based on work by Boyle (2011).

resources are distributed between different service units has undergone several changes, with alterations frequently processed in the health authorities organization below the central level. Since the 1970s, however, in an effort to address inequalities in care, mechanisms were defined for allocating resources according to indicators that, to some extent, seek to ascertain the different regional needs, rather than the historical series. Moreover, also since the 1970s, the rationalization of NHS spending was a central concern of the British government, with the introduction of various measures of performance evaluation, the outsourcing of services like cleaning and laundry, in addition to setting management standards for the health authorities.

However, the biggest turning point in the system occurs at the beginning of the 1990s, with the distinction between "purchasers" and "providers" and the constitution of the "internal market" in the public system, established by the conservative government. At that time, it was decided that the "district health authorities" and "GP fundholders" operate as resource and contractor managers, while hospitals, converted into "NHS trusts" were detached from the health authorities and gained greater autonomy to compete for resources available for contracting of services.

The return of Labor to power in 1997, with Tony Blair, was accompanied by the intention of breaking with the "internal market," judged as leading to the fragmentation and dissipation of resources. In its stead was proposed "what it termed ‘integrated care, based on partnership and driven by performance’, rejecting both the ‘command and control system’ of the 1970s and the market system of the 1990s" (Boyle, 2011: 347). Among the main objectives of the proposed changes stood the reduction of inequalities in care, by setting national standards for health care, and establishing strong partnerships between the NHS and local authorities.

In an initial phase, reform actions focused on the first goal mentioned, in particular the establishment of national standards of care, and monitoring mechanisms. Most notable are the definition of the *National Service Framework* (NSF), the creation of the *National Institute for Health and Clinical Excellence* (NICE) and the *Commission for Health Improvement* (CHI). The first aimed to “set national standards and define service models for a specific service or care group”; “put in place programmes to support implementation” and “establish performance measures against which progress within an agreed time scale would be measured”. NICE, in turn, was intended to ensure that “treatment decisions were based on the best clinical evidence available”. In this direction, guidelines should be published “based on systematic reviews of the available evidence, on the use of particular medicines or other forms of treatment” (Boyle, 2011, 350). Finally, CHI was intended to ensure that the management of service providers was guided by the principles of what was called "clinic governance." From the *NHS Performance Assessment Framework*, the CHI assessed the management of hospitals based on indicators such as waiting time, schedules, lateness, delays in care, among others. According to Boyle, with the creation of the CHI, it was “the first time all NHS provider and purchaser organizations were subject to systematic external review on clinical as well as financial performance” (Boyle, 2011, 352). Along with the implementation of such

measures, the *Health Improvement Programmes* were defined, to increase the capacity and quality of care in the NHS.

The creation of *Primary Care Trusts* (PCTs) in 2002 was an unfolding of the objective of bonding the NHS more tightly with local communities, alongside other measures such as the effort to enhance participation of commune-based services in service delivery, reducing the role of hospitals, contemplated also in later measures[14]. On top of the PCTs, the *Strategic Health Authorities* (SHAs) were established, responsible for monitoring services, in terms of quality and performance, in certain areas. The PCTs, however, were the decisive element of the proposed reform, because with them a new structure of purchasing was instituted, replacing the "district health authorities" and the "GP fundholders" created in the early 1990s. The expectation was that they “fully engage their frontline staff and local communities and partners in their plans for improving health and health services” (Boyle, 2011, 358). Thus, the PCTs would be the touchstone for the creation of “integrated care, based on partnership and driven by performance”, rejecting the “command and control system” and the “market system”.

The creation of the PCTs did not eliminate, however, the distinction between "purchasers" and "providers", the central idea of the "internal market", which would end up being reinforced by other measures taken by the labour government. Noteworthy are the creation of the *Foundations Trusts* (FTs), with more autonomy than their predecessors, the *NHS Trusts*; the introduction of *Payment by Results* (PbR) to hospitals; the increasing use of the private hospital network to achieve certain goals such as reducing queues, and *last but not least*, the establishment/creation of *Practice-based commissioning* (PBC), which restored, to some extent, the opportunity for GPs to operate as purchasers, such as in the previous model. The joint impact of all these measures in the expansion of the health services market would later be a subject of concern for the government that, in 2006 and 2010 issued guidance on the contracting and provision of services (Boyle, 2011)

The period from 1998 to 2007 is marked by intense activity in the proposal of measures, for which there isn't space to describe here. Ultimately, they seek to achieve different objectives, such as raising the possibility of patient choice, decentralization of services, the definition of national quality standards and mechanisms for monitoring care and management, the refinement and expansion of collection and recording of information, the strengthening of research activities in health, among others. In reaching for such goals, the labour government promoted an unprecedented increase in resources intended for the NHS, expanding the hospital network, the different service offerings, and the staff employed. There is evidence that quality and access goals were achieved, but not so for inequality in provision, one of the primary objectives of the reform process initiated in 1997 (Boyle, 2011). In turn, the persistence of the "internal market" and the expansion of the

[14] As the provisions of the White Paper, *Our Health, Our Care, Our Say*, from 2006.

mechanisms and organs of regulation and control suggests that the goal of building a third way, between the market and centralized command, remained distant.

The government of Gordon Brown (2007-2010) reduced the reform furor of Tony Blair, but, the resumption of government by the conservatives in 2010 came accompanied by the announcement of another round of reforms in the NHS. The White Paper *Equity and excellence: Liberating the NHS*, presented in 2010, and the *Health and Social Care Bill*, submitted to Parliament in 2011, reinforce some of the principles espoused in the previous administration, such as the patient's right to choose, and accentuate the trend toward deeper market relationships in the system, but significantly alter their organization. The role of the *Secretary of State of Health* is reduced in managing the NHS, which would be left to a new non-departmental body, the *NHS Commissioning Board*. The *Strategic Health Authorities* (SHAs) and the *Primary Care Trusts* (PCTs) are eliminated, and *GP consortia* are instituted for commissioning the healthcare and purchase services. A new body is created to receive complaints and monitor the performance of local providers, the *Health Watch*. Hospitals are being urged, also, to convert fully to *foundation trust*, and increase their opportunities for fundraising, including the approval of augmented treatment offered to private patients. Various organs become extinct, also, such as the National Institute for Health Research (NIHR), the Health Protection Agency (HPA), and the Human Fertilisation and Embryology Authority[15].

The body responsible for the evaluation, authorization, and registration of medicines in the health system in the UK is the *Medicines and Healthcare products Regulatory Agency* (MHRA), an autonomous agency attached to the Department of Health. It is also responsible for monitoring the effects of drugs after market launch. Its operation is guaranteed by Treasury resources and, mainly, by fees paid by businesses that require licensing of medicines.

In large measure, the NHS itself provides the population's access to prescription medicines, by way of reimbursement mechanisms. Community pharmacies, which are linked to the NHS by the *Pharmaceutical Services Negotiating Committee*, prevail in the British landscape

Drug prices are set in the *Pharmaceutical Price Regulation Scheme* (PPRS). Created in 1957, it is an arrangement that circumscribes the negotiation between the NHS and industry, especially the *Association of the British Pharmaceutical Industry* (ABPI), to ensure reasonable and stable prices for the NHS (in the majority of cases the scheme is reviewed every five years), as well as profit margins for the industry which stimulate innovative activities.

Given the weight of the NHS in the demand for drugs and the prevalence of innovative industries, other agencies and programs are important for the relationship between the health system and industry in the UK. In passing, among those that have received major attention from industry,

[15] See White Paper *Equity and excellence: Liberating the NHS*, presented in 2010, and the *Health and Social Care Bill*, submitted to Parliament in 2011, besides *Health and Social Care Bill – Explanatory Notes.* At the time this paper was written, had not yet been completed in the British Parliament the resolution on the reform proposals made by Cameron.

could be named: the *National Institute for Health Research* (NIHR), the *National Programme for Information Technology* (NPfIT), and the *UK Clinical Research Collaboration* (UKCRC). The first, created in 2004 from the integration of earlier initiatives, acts as an instrument of coordination between the NHS and the universities, in order to identify the innovative ways of prevention, diagnosis, and treatment of diseases. The NPfIT, of 2010, is charged with implementing an integrated IT infrastructure in the NHS as a whole, reinforcing the initiatives of *Connecting for Health*, launched in 2005, with the goal of creating an integrated information system that involves data of various nature, including information on patient procedures and clinical performance. Finally, the *UK Research Collaboration* was launched by the Chancellor of the Exchequer in 2004 with the purpose of building a unified approach to health-related research in the UK, promoting partnership between the major bodies that influence and fund health-related research, articulating the NHS, academic departments, regulatory bodies, industry, and patient groups.

3) Pharmaceutical Industry and Health in Brazil, Argentina, and England in the post TRIPS scenario

a) Pharmaceutical Industry and Health - post TRIPS

The pharmaceutical industry is currently one of the most dynamic sectors of the world economy. Between 2006 and 2010 the market for ethical drugs grew by an average of 4.8% per year (Datamonitor, 2010). Intense merger and acquisition activity has marked the industry, increasing its concentration, especially in the context of different therapeutic classes. The ten largest companies that in 1999 accounted for 34% of sales, in 2007 increased their stake to 45.1% (Vargas, 2008, 13). In 2010, the four largest held 25% of the market for ethical drugs (Datamonitor, 2010). There is also a high regional concentration of consumer markets. Despite the expected growth of the Latin American and Asian markets, in 2007 Europe and North America accounted for 77% of drug sales (Vargas, 2008:18). As a result, drug research and production prioritizes diseases with higher incidence in developed countries (heart disease and cancer). It is estimated that only 3% of R & D investment is directed to produce drugs for diseases that represent 90% of the total, which affect mainly the underdeveloped or developing countries (AIDS, malaria, respiratory and gastrointestinal diseases) (BDO, 2008: 39)

The acceleration of concentration in the pharmaceutical sector has been attributed to rising costs for research and development, to some extent due to changes in the technological paradigm associated with the production of drugs, but also to the procedures required for approval of their sale[16]. In the 1990s the average cost of developing a drug, from its early stages to consumption,

[16] The new approach would be one marked by overcoming the empirical method of trial and error, and by the introduction of rational planning of scientific research in discovering new molecules, making use of computer resources and processing research in multidisciplinary bases in various fields of chemistry and of biology. In this process, government support, collaboration with other agencies makes the firm, ultimately, the manager of processes that take place even outside its limits. (Vargas, 2009).

would increase from US $250 million to US $360 million in relation to the previous decade. The same would be seen in relation to average product development time, which would rise from 11.6 years in the 1970s to 15.3 years in the 1990s (Vargas, 2008: 11). In fact, by the time it reaches the consumer, the production of a new drug involves a number of steps, requiring a significant accumulation of basic research that yields the discovery of a molecule, followed by the securing of patents, conducting clinical trials in various phases, the registration, pricing, and the cost-effectiveness analysis of the product. It should be noted that, especially in the first stage of this process, the State's participation in financing is significant, whereas in other stages its regulatory action is relevant.

The presence of barriers to entry defined by the domain of the innovation process, and not by the cost of physical assets, combined with the prevalence of a competitive standard that relies substantially on product differentiation within the different therapeutic classes, as well as aggressive marketing strategies, make the pharmaceutical industry a differentiated oligopoly (Gadelha, 2006; Gadelha, Quental, & Fiallho, 2003; McIntyre, 1999). In this case, the importance has been highlighted, of protecting intellectual property rights (for industry, patents) to guarantee returns to offset the costs involved in innovation activities, and, as is often pointed out, to ensure incentives for its continuity (McIntyre,1999; Reekie, 1975). Indeed, the transnational pharmaceutical industry was a key player behind the US pressure for insertion of the intellectual property theme in the Uruguay Round of GATT negotiations, which resulted in the establishment of TRIPS (Chaves, Oliveira, Hasenclever, Melo, 2007). Hence the space is restricted for the development of national pharmaceutical industries positioned basically to copy medicines produced in the centers possessing greater capacity for innovation, assured until then by the prevalence of lax norms in the regulation of intellectual property rights, especially those relating to the system of patents.

With TRIPS, signatory countries must respect the terms of 20 and of 7 years, respectively, for patents and utility models, which guarantees, during this period, exclusive control in the production of goods associated with any invention on the part of the holders of intellectual property rights on products and processes that meet the requirements for patentability, i.e. novelty, inventive step, and industrial application (Chaves, Oliveira, Hasenclever, Melo, 2007; Shadlen, 2005). There were, however, defined transitional periods for adaptation to the agreement in developing and underdeveloped countries, situations in which the norms would have their applicability mitigated (as in pipeline patents, parallel imports, and compulsory licenses). Moreover, from the WTO Doha Declaration, of 2001, the definition of criteria for use of the compulsory licensing mechanism, limits for their use, and compensation for the owners was assured to the signatory countries, in the specific case of drug production. Likewise, in 2003, at the WTO Ministerial meeting held in Cancun, mechanisms were guaranteed so that countries unable to sustain the domestic production of drugs subject to compulsory licensing could make agreements with other countries equipped with such

capability, but not from industries holding patents, for developing the production and sale of drugs defined as essential (Roffe, Spenneman & Braun, 2006; Abbott, 2006)

The forms of inclusion of different countries into TRIPS were not homogeneous. India, for example, used all the time allowed for adaptation of its patent legislation to TRIPS, and mobilized internal resources to build a pharmaceutical sector with increasing participation in the international market, to which developing and underdeveloped countries often turn in the face of difficulties in obtaining medicines important to their national health policies. At the other extreme, countries such as Chile, Singapore, and Jordan signed treaties with the United States that aggravate provisions of TRIPS, such as the recognition of pipeline patents, the link between patents and registration, the setting of restrictions on the use of compulsory licensing, the protection of data not disclosed for obtaining registration, the setting of restrictions on patentable material for the revocation of patents (Chaves, Oliveira, Hasenclever, Melo, 2007; Shadlen, 2005; Correa, 2006; Pugatch, 2006).

The institution of TRIPS highlighted the problem of access to medicines in developing countries, lacking a research based pharmaceutical industry, bringing it to the center of the health policy agenda. In various markets, the price of drugs has risen considerably since the 1990s. Furthermore, dilemmas surfaced involving the provision of certain patented drugs in cases of epidemic outbreak or obligation to supply free of charge, as is the case, respectively, in South Africa and Brazil in relation to drugs for AIDS. Finally, the downturn of several national pharmaceutical companies was noted in the sector's rising trade deficits. A number of strategies have been used by countries that do not host the industries holding patents on major drugs launched in recent years to deal with problems associated with access to patented medicines: international partnerships, policies to stimulate competition, use of loopholes present in TRIPS and other regulatory provisions, promotion of domestic production of medicines (Berger, 2006; Widdus, 2006; Rovira, 2006). To a large extent, the use of such strategies favored a growing interpenetration between the actions of their own health policies and those related to industrial and technological policy. The trajectories of Brazil and Argentina, to be outlined presently, suggest, however, that the format of the policies pursued is affected not only by macroeconomic constraints, by the ideological choices of the leadership, and by the coalitions agreed to among the main actors, but also by the possibilities of mobilizing the health system to achieve the objectives of industrial policy tied to the health-industrial complex.

In the developed countries also, the pharmaceutical industry became the subject of more captive attention of health policy. In a context of rising health costs, in which drugs play an important role, and of budget constraints, the regulatory, price control, and government procurement policies acquire increasing importance. Observation of the British case, however, reveals that it is not just a health area effort to limit the impacts of pharmaceutical industry actions on the budget, nor even, conversely, an industry move to guarantee space in the market share represented by public procurement. Beyond ensuring the preservation and expansion of its space in the public demand for

drugs, threatened to a certain extent by the health area measures to control and rationalize spending, the pharmaceutical industry research based in the UK sought a closer relationship with the health area to achieve two objectives: mitigating constraints to the expansion of the pharmaceutical market in the UK deriving from the nature of the country's health system, and enhanced NHS participation in industry research, in order to operate as an additional element of British comparative advantage in the face of international competition.

We will consider, therefore, the most important elements of the trajectory of Brazil, Argentina, and Britain, regarding the relations between the health area and the pharmaceutical industry since the mid-1990s.

b) Brazil

The first presidential term of Fernando Henrique Cardoso in Brazil (1994-1998) was marked by an enthusiastic adherence to the tenets of neoliberalism[17]. Much of the agenda of market reforms advocated by multilateral agencies was carried out, many state enterprises were privatized, restrictions on imports and on the attraction of foreign capital were reduced, the the currency peg between the real and the dollar was instituted as an additional element to control inflation, resulting in a significant increase in consumption. A corollary of this policy was the rejection of the adoption of sectoral industrial policy measures. Ultimately, the intention was announced of strengthening the science and technology infrastructure and overcoming the bottlenecks in physical infrastructure, basically with the assistance of private capital, that would accompany the exposure of Brazilian industries to foreign competition, seen as the mechanism *par excellence* to promote its modernization.

It is in this environment that Brazil's adherence to the TRIPS takes place. Unlike many developing countries, Brazil waived the use of the transition periods provided for in the treaty, fully accepting the TRIPS provisions immediately applicable only to developed countries, and going further, recognizing pipeline patents. Only one aspect in intellectual property law in Brazil would clash with this gesture of surrender or presumption: Article 68 of the law provided the Brazilian government the possibility to challenge the patents issued if, in three years, the companies holding them did not start production of the patented product in Brazilian territory (Shadlen, 2005). Later on, in 2001, when the country decides to produce the drugs for AIDS in several public laboratories, based on this article of law, it will be a subject of dispute with the US in the WTO context (Shadlen, 2005; Homedes & Ugalde, 2006) .

The impact of economic liberalization, exacerbated by the adoption of foreign exchange parity and by the acceptance of the new international regulation on intellectual property, was significant on the pharmaceutical industry. Domestic industries, born and raised in an environment

[17] The following paragraphs about Brazil, are anchored in Delgado, 2005 and Delgado, Condé, Salles and Esther, 2010 and 2011.

of permissiveness in patent legislation , manteve uma reduzida participação nas vendas no mercado interno na década de 1990, alcançando 28,2% em 2000 (Capanema & Palmeira Filho, 2007). At the same time, the price of drugs rises considerably, with an increase of more than 30% of its average value in dollars between 1995 and 1998 (González García *et alli*, 1999). In turn, the sector's trade balance saw its deficit rise sharply. The pressure on the health budget that this causes is further accentuated by the Brazilian health policy determinations that requires the government to provide free drugs for those who need them, as is the case with AIDS. Moreover, as we have seen, the health area of the Brazilian government passed through the 1990s against a backdrop of great uncertainty regarding its funding sources, since the social security money intended for it ceased to exist as the system matured.

In Fernando Henrique Cardoso's second term it is possible to observe significant changes in the scenario described above. With the crisis of 1998, the parity exchange rate policy foundered, and the sectors termed *developmentalist* were reinforced in the ruling coalition. Though without fanfare and noticeable change of course, industrial policy measures like the *sectoral funds* and the *competitiveness forums* are gaining importance, even if timidly, under budget constraints resulting from the growing indebtedness of the country in the previous years, despite the privatizations. In the health area, however, a coalition forged between the government and segments of domestic industry supporting generics legislation (Shadlen, 2009a), which forced the government to give preference to such drugs in government procurement, would represent a first drive in the recovery of the domestic pharmaceutical industry. In addition, the government tightens the system of patenting products related to health, with the establishment of the mechanism of prior approval, in 2001, by which ANVISA comes to retain the prerogative to review the patent registration, although such a legal device has lost power in later regulations[18].

The Lula government rehabilitates the idea of industrial policy, and, in his first quadrennium (2002-2006), sets the production of the active ingredients of drugs, as well as the production of medicines, as a priority, among the sectors highlighted as "strategic", in the Industrial, Technological, and Foreign Trade Policy (PITCE), together with semiconductors, capital goods, software, and "technologies that lead to future" (biotechnology and nanotechnology). Among the measures identified for the sector are included: the creation of PROFARMA, a line of financing from the National Bank for Economic and Social Development (BNDES); the foundation of HEMOBRAS, a company for production of hemoderivatives; the creation of the Center for Drug Research and Development (CPDM); and the installation of the Forum of Competitiveness in the Pharmaceutical Industry.

[18] As Shadlen (2009b) that arises from the lack of support of the measure by segments of the Brazilian pharmaceutical industry that develop incremental innovations, which would support the INPI in its dispute against ANIVISA the full control of the evaluation of patents.

In Lula's second term, the government relies upon the instrument of compulsory licensing to break the patent on Efavirenz, a drug used to treat AIDS, activating the first time this instrument, although it was previously used as a threat to bargain prices with multinational suppliers of medicines to the Brazilian government (Shadlen, 2012; Homedes & Ugalde, 2006). Within the scope of industrial policy for the pharmaceutical industry, it is again announced as part of programs of mobilization in strategic areas, in *Productive Development Policy* (PDP), in the initiatives planned for the health-industrial complex, which would also involve the production of medical equipment, reagent materials, diagnostic devices, hemoderivatives, immunobiologicals, chemical intermediaries, and vegetable extracts for therapeutic purposes, in addition to active ingredients and medicines for human use.[19] The initiatives proposed by the PDP were linked to the actions of the Ministry of Health laid out in the program *More Health*, which combines actions to expand health care with measures to stimulate the health-industrial complex. The strategy defined for the sector was the focus, with wider access. The targets set were the reduction of the trade deficit and the development of technology for local production of 20 strategic products for the SUS. Understood as challenges to be addressed, the list includes: reducing the vulnerability of the National Health Policy; increasing the investment in innovation; the growth and diversification of exports; consolidation of the supply chain and strengthening of domestic enterprises; modernization of the management of the public laboratories network; in addition to attracting producers and R & D centers from technologically advanced foreign companies. Besides tools such as Profarma, resources from Financier of Studies and Projects (FINEP), an agency of the Ministry of Science and Technology, subsidies provided in the Law of Innovation, and the *Good Law* (which defines export and innovation subsidies) it is noted that government procurement would be a decisive aspect of the proposed policy, announcing a willingness to reform legislation in order to ensure priority to domestic production and prices that stimulate innovative activity. Management of policy would be conducted by an executive committee composed of representatives of the Office of the President of the Republic, the Ministry of Science and Technology, the Brazilian Agency for Industrial Development, BNDES, under the direction of the Ministry of Health, through the Secretary of Science, Technology and Strategic Inputs (SCTIE).

In the Dilma Roussef government, the actions for the health-industrial complex are included among the programs planned for *Mechanical, Electro-electronic, and Health Systems* (Brazil, 2011). In the planned governance structure there appears an executive committee, assisted by a sectoral competitiveness council. In addition to the instruments of credit and subsidies, the *Greater Brazil* program places further highlighted emphasis on the use of government procurement as a

[19] The programs mobilized in strategic areas would also include the programs for information and communications technology, nuclear energy, the defense-industrial complex, nanotechnology, and biotechnology.

measure of industrial policy, anticipating changes in legislation, to ensure a price premium of 25% to domestic production with innovative content[20].

The measures provided for in the PDP in 2008, concerning the use of government purchases to stimulate innovation, were not carried out, as they involved major changes in the legislation, of doubtful course in the Brazilian Congress during the Lula government. In the Dilma government, it is likely that they will be effectively implemented, if indeed it is a government priority, given the ample majority of its support base in the Congress

The set of initiatives developed since 1999, with the legislation on generics, allowed a significant recovery of the national pharmaceutical industry (Furtado & Urias, 2010, Vargas, 2009; Cunha, Araújo, Mello & Leite, 2008) and an increase in its relative share in domestic sales in Brazil, reaching 41% in 2007 (Capanema, Palmeira e Filho, 2007). The relative position of Brazil in the Latin American market changed as well. Until 2001 the Brazilian trade balance in the production of medicines is negative in the relationship with Latin America and the Caribbean, primarily due to the trade deficits with Argentina, also equipped with significant domestic production[21]. Thereafter, Brazil begins to show positive balances in regional trade, including with respect to Argentina, which ceases to show a surplus in the bilateral relationship in 2002. In global trade, however, the goals of trade deficit reduction are far from being met. Ultimately, the expansion of generics consumption attenuated the dilemmas created by the untimely accession to TRIPS in the 1990s, but did not increase Brazilian participation in the production of active ingredients, of pharmaceutics, nor did it enhance the innovate capacity of Brazilian companies.

c) Argentina

Despite the tenacity with which Argentina, during the governments of Carlos Menem (1989-1999), sought to align itself with the neoliberal prescriptions, the country adopted a posture more pragmatic than Brazil's in its adherence to TRIPS. It is true that the creation of ANMAT and INPI at the beginning of the decade pointed toward the definition of an institutional environment that was intended to be suitable for development of an industry, in some measure, based on research

[20] Of note is the *Health is Priceless* program to distribute drugs for diabetes and hypertension in the *Here's a Popular Pharmacy* network, structured from an agreement of the Ministry of Health with the private pharmacy network.

[21] The two countries show growing deficits in trade of pharmaceuticals. In 1998 the Brazilian deficit was US$ 1,018,145,723; in 2007, US$ 2,770,594,667; in 2011, US$ 5,045,882,676. Argentina, in 2008, showed a deficit of US$ 479,770,548; in 2011, US$ 668,404,377. Both countries, however, have predominated, among the countries of the region, in the Latin American market. Regarding Latin America and the Caribbean, Brazil displays repeated trade deficits until 1998, but since then the relationship with the region is in surplus. In 2011, the Brazilian surplus with the region is US$ 433,248,179. The findings reveal a positive performance in Argentina's relationship with the region, but on a declining path. In 2009, its trade surplus was US$ 349,695,038; in 2011, US$ 260,092,776. In bilateral relations, in 1998 Brazil showed a deficit of US$ 19,508,019. Already in 2001 it had reached a surplus of US$ 3,752,964, which continued to increase, reaching US$ 35,957,168 in 2011. However, there are signs of change. In 2012 the country shows so far, with Argentina, a deficit of US$ 99,937. Data obtained on the platforms Aliceweb and Aliceweb – Mercosur, from Ministry of Development, Industry and Foreign Trade of Brazil. Accessed on February 9, 2012.

and innovation. However, Argentina, even absorbing prematurely the postulates of TRIPS (changes in legislation in this direction take place between December 1994 and April 1995), only consolidated its patent legislation in 2002 (Tobar, 2004). The country took advantage of the transitional period granted to developing countries, in order to adapt its businesses to the new scenario. With this, an abrupt acceleration was avoided, of the downward trend in the participation of Argentinean companies in the country's pharmaceutical market, ongoing since the 1980s, as occurred in Brazil. In 1996, Argentinean companies held a 53.9% share, vs. a 59.8% share at the opening of the decade, in the value of domestic sales (Gonzalez Garcia, 1999).

In turn, other elements of the Menem government's drug policy stimulated the market and helped increase revenues for pharmaceutical companies, although the impact on the health of the Argentine is controversial. Since 1991, medications that were not subject to prescription could be freely sold in shops other than pharmacies. In addition, drug prices were freed from any control (Gonzalez Garcia, 1999; Tobar, 2004). This policy led to a marked increase in drug prices, although this phenomenon was not unique to this country. Between 1991 and 1995 the average price of drugs in Argentina rises by almost 100%. Thereafter, price growth slows reflecting reduced demand, a harbinger of a serious downturn in the market for drugs that would occur at the beginning of the next century. In any case, in the 1990s, revenue from the sale of drugs rises by 80%, even with the 11% drop in sales (Gonzalez Garcia, 1999). Moreover, given the downturn in the pharmaceutical industry in Brazil, Argentina showed recurring industry trade surpluses until 2001, when the drug market in the country collapses.

The Menem era in Argentina closed in 1999, with the rise of Fernando de La Rua, of the Radical Civic Union (Romero, 2006; Chudnovsky, 2004; Keifman, 2004; Bonvecchi, 2004; Vadel, 2006). Engulfed by the fiery maelstrom of economic crisis that befalls the country, accompanied by vigorous protests from the population, facing losses from the end of the currency peg, de La Rua resigns in 2001. Then follows a series of ephemeral governments, until the rise of Eduardo Duhalde, of the Justicialist (Peronist) Party, in January 2002. Finally, on March 25, 2003, Nestor Kirchner assumes power, elected by the Justicialist party. In fact, the political turmoil was fueled by the country's economic plight. Argentina experienced three years of recession, saw unprecedented levels of expanding unemployment and poverty, became asphyxiated with its foreign debt. The contraction of Argentina's GDP in this period is comparable only to countries that have experienced war[22].

In this scenario, the reduction in demand for drugs, obscured in the 1990s by the revenue obtained in a setting of high prices, is compellingly verified. The sales of drugs, in units, declined in

[22]According *Unctad Handbook of Statistics*, in 1998 the total GDP of Argentina was US$ 299,097.95 billion and GDP per capita US$ 8,284.81. In 2002 the total GDP and GDP per capita were much smaller than the half of these values: respectively US$ 102,041.76 billion and US$ 2,710.84. In 2006 Argentina had not yet recovered the values from 1998. The GDP total was U$ 217,300.73 billion and GDP per capita US$ 5,552.69 (Delgado, Condé, Salles e Esther, 2011). About Argentina’s crisis and further development of economic policy in the country see Ferrari & Cunha, 2008 and 2009.

2002 to 50% of 1995 rates. In a scenario marked by 22% unemployment and with over 50% of the population thrown into poverty, access to drugs became a national emergency situation, by reducing the purchasing power of families (accounting for 73% of drug purchases) and the income of social works, given the reduction in contributions from workers and employers. In 2001, for the first time in fifteen years, the pharmaceutical industry in Argentina saw falling revenues.

The measures taken by the Duhalde government to address the problem of access to medicines ultimately set the stage for support of the pharmaceutical industry in Argentina in a later period, without setting, properly, an industrial policy for the sector (Tobar, 2004). The first of these measures was the Remediate program. With 60% of the funds guaranteed by the Inter-American Development Bank, its purpose was to distribute 36 types of drugs, in 43 presentations, through the Centres for Primary Health Care network, to 15 million Argentineans, identified as unable to guarantee themselves the provision of essential drugs. Originally planned to operate until 2006, the program still appears on the site of the Argentine Ministry of Health, but does not seem to have the same scope.

Another prominent measure is the legislation on generics (Tobar, 2005; Hayden, 2008). In fact, unlike the Brazilian legislation that establishes requirements for proof of bioequivalence in the production of drugs whose patents have expired, Argentina's legislation aims to induce doctors to indicate the name of the compound of prescription drugs, even alongside the indication of brand name drugs. Together with the definition of a reference price of the drugs, such a measure was intended, in some way, to inhibit the upward price trends in the pharmaceutical market, educating consumers about the options at their choice.

Finally, the institution of the Compulsory Medical Program (PMO) that, along with establishing a standard of care to be observed by health services providers, forced health plans (prepaid medicine) to cover 40% of the cost of medicines prescribed in the treatment of its policyholders (Tobar, 2004). Thus, an arrangement was created that reduced, in part, the difficulties of access when associated only with household spending.

In the years after, one can not speak of the existence of an industrial policy for the sector in Argentina, although localized actions have taken place. In the *Industrial Strategic Plan* launched by the Argentine government in 2011, the balance of policies pursued between 2003 and 2010 highlights the passage of cooperation agreements, between universities in Argentina and companies, to develop some research, the promotion of initiatives in the field of biotechnology and cloning, the launch of a technology platform in gene therapy, the creation of an industrial plant dedicated to tissue bio-engineering, the creation of the Institute for Tropical Medicine in Missiones, and the creation of the Center for Research and Development in Industrial Biotechnology, with support from the National Institute of Industrial Technology (INTI) (Argentina, 2011). In turn, the Plan lays out the intent to ensure the growth of Argentine production at a rate of 20% per year until 2020, to replace imports, strengthening domestic production of active ingredients, and to support the

modernization of industrial plants and the development of segments such as biotechnology, without, however, indicating the instruments that would be used for this.

Ultimately, the measures taken at the beginning of the decade, combined with the economic recovery observed since 2003, furthered by renegotiating Argentina's debt and by exchange rate policy, seem to have helped support domestic demand, allowing the continuation of an industry that made little headway in the affirmation of a profile marked by innovation, much less engineered the production of generic medicines in the strict sense. In fact, the production of similar products seems to be a hallmark of Argentine industry. In any event, in 2010, the production of medicines by the national laboratories attained 59% of domestic sales in Argentina, a mark achieved largely by virtue of the withdrawal of some multinational companies from the country in the most acute moments of the crisis, which led to the purchase of some industrial plants by Argentine laboratories (Argentina, 2011).

d) England

Unlike Brazil and Argentina, the UK pharmaceutical industry is fundamentally research based, with a high innovation profile. Among the 75 best-selling drugs worldwide in 2007, 55% were from the USA, 19% from the UK, and 10% from Switzerland. By 2006, the pharmaceutical industry in the UK appeared in fourth place in terms of aggregate value, behind only the US, Japan, and Germany (Owen, 2010). Two British companies, GlaxoSmithKline and AstraZeneca appeared, in 2007, in second and fifth position among the ten largest companies in the world, when it comes to sales of medicines. Both are an expression of the ability of British firms to respond to the pressures of the competitive environment in the sector, resulting from major merger at the dawn of the twentieth century.In the UK the pharmaceutical industry is the most important manufacturing activity, and its contribution to the country's GDP is less only in relation to finance and tourism. The sectoral trade balance is consistently positive, having shown in 2010 a balance of £ 7,133 million[23].

According to the ABPI, much of this success stems from unique conditions in the UK environment:

> Britain’s strong intellectual heritage in pharmaceuticals and bioscience, the receptive commercial environment fostered by the Pharmaceutical Price Regulation Scheme (PPRS), and a highly skilled workforce have, for many years, allowed the UK generally and the NHS in particular to benefit from modern pharmaceutical discovery and development[24].

[23] As publication of the Office for National Statistics (2011) in 2010 the UK exported £ 19,289 million Pharmaceutical Preparations and £ 1,858 million Basic Pharmaceutical Products, and imported, respectively, £ 12,500 million and £ 1,414 million.

[24] ABPI, *Pharmaceuticals and the UK economy*. The partnership, which the ABPI date of creation of the NHS, there is, however, since World War II, with the mobilization of the British government to guarantee the replacement of imports made in Germany (Corley, 2003). This moment of affirmation of the British pharmaceutical industry, corresponds in some ways, to the *wartime triangle*, which according Swaan (1988), reconciles the business with the state intervention and the

The presence of a network of high quality teaching and research, and of tools to support scientific research, complement this "successful partnership with Government, policy makers, and healthcare professionals to ensure that the most effective innovative medicines reach patients as quickly as possible." Also according to the ABPI, certain elements in the British environment favorable to investment, such as the presence of low interest rates and macroeconomic stability, taken as significant elements, together with the others mentioned above, add to the brightness of the "crown jewel."

For the ABPI, the firmly set guarantee of intellectual property rights reinforced the favorable conditions of the British environment, and, therefore, the organization was heavily engaged in the defense of TRIPS. However, in the late 1990s, things did not seem to go so well. In November 1999, the CEOs of AstraZeneca, Glaxo Wellcome, and SmithKline Beecham seek out Prime Minister Tony Blair (1997-2007) to alert that the

> traditional factors that underpinned the UK's past success in pharmaceuticals were no longer on their own sufficient to guarantee good performance, and an initiative was required to ensure the UK retained its competitive edge. They expressed particular concern about issues relating to market access, and intellectual property protection (UK-DH-ABPI, 2001: 3)

This meeting resulted in the creation of the *Pharmaceutical Industry Competitiveness Task Force* (PICTF), bringing together representatives from government and industry, directed by Lord Hunt, Secretary of Health, and Tom McKillop, CEO of AstraZeneca. In 2001, the PICTF presents its Final Report with diagnosis of the problems experienced by the British pharmaceutical industry, and some guidelines for overcoming them. Highlighted are the intensifying competition in the international market and the attractiveness of other markets, by the presence of more favorable taxation and operating conditions, underlining the importance of dealing with problems like the tensions present in the process of building the single European market, the support of a favorable environment for health research in the country, and to "resolve issues over the potential impact of NICE on market access for new medicines" (UK-DH-ABPI, 2001: 5).

The PICTF Report presents the results of the work of five groups set up in its formation: 1) Developments in the UK Market, 2) Intellectual Property Rights, 3) Regulation of Medicines Licensing, 4) Science Base and Biopharmaceuticals, 5) Clinical Research, 6) Wider Economic Climate. All deal with issues that will remain on the industry's agenda in subsequent years, with greater or lesser intensity. There is, at this point, however, a clear emphasis given to the issues raised by the groups 1 and 2. Group 3 focused mainly issues regarding standardization of procedures in Europe. Group 4 emphasized the need for a more positive relationship between the industry and the NHS, to speed up procedures for clinical research, suggesting the creation of a Research Governance Framework. Group 4 made general recommendations about bringing universities and industry closer together, recommended a reassessment of immigration law, and made suggestions

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workers, encouraging the development of modern social policies and in the case at hand, the development of the pharmaceutical industry.

for changes in the penal code to punish animal rights extremism. Group 6 suggested the modernization of tax legislation.

In meetings that followed under the Ministerial Industry Strategy Group (MISG), a permanent forum created from the PICTF to adjust the relationships between government and industry, the problems noted in the structure of the pharmaceutical market in the UK go beyond the debate on the role of NICE, but in the PICTF Final Report they gain great prominence. NICE was established in 1999, at a time when NHS expenditure on drugs reached its highest level thus far[25]. Although having a distinct bias, it embraced the policy of buying generic drugs, in order to rationalize drug expenditures in the system. For the industry, however, it is seen as a factor to inhibit the uptake of new medicines in the NHS, in influencing medical prescriptions. The use of cost effectiveness criteria in prescription guidelines was challenged, pointing out that in other countries such criteria are taken into account only for setting reimbursement. In its recommendations, the Report suggests future review of the role of NICE, the incorporation of industry in defining the NSF, and in passing, points to the need to expand the drug market extra-NHS, albeit with the suggestion to allow GPs to prescribe drugs not on the system's reimbursement list and to offer private care, on the premises of the NHS, for patients enrolled in it. It also suggests studying a way for the industry to make use of data collected by the NHS information system in "its search for improved use of medicines, and the development of new medicines." (UK-DH-ABPI, 2001: 31)

The subject of intellectual property gained prominence by virtue of the debate spawned in the EU for its regulation in the single market. The issues highlighted are access to new medicines by developed countries, under the Doha Declaration, and the conditions of data exclusivity, on the permission of clinical trials on patented products, an issue that mattered primarily to manufacturers of generic drugs. The position of the industry, followed by the British government, was to defend the permission of the tests only 10 years after registration of the patent, plus one year for tests on new applications (10 + 1).

The partnerships established by the PICTF have continuity in the meetings of the MISG, which included representatives from industry and members of the Department of Health (DH), Department of Trade and Industry (DTI), and eventually being able to count on the participation of representatives of the Treasury (HMT), of the Department for International Development (DfID), and other bodies such as the MHRA and NICE. In such meetings (two per year), the subjects collated in the PICTF were treated and the possible arrangements between government and industry established. As is seen in the PICTF Final Report, in the early years the discussions on the pharmaceutical market conditions in the UK, and the issues relating to regulation of the single market in Europe, held the spotlight. However, statements about the decline of the British

[25] As a table by the NHS contained in the document "Agenda and minute - November 2008", from Ministerial Industry Strategy Group (MISG), between 1980 and 1998 the purchase of drugs rises from 7.7% to 11.8% of the total NHS spending. In 1999 it reached 12.3%. Thereafter it fluctuates between 11 and 12%, to register a decline only in 2006 when it goes to 10.5%.

pharmaceutical industry, connected to propositions about changes in the tax system, and on the conditions under which clinical trials were conducted in the country, become increasingly important.

The major problem noted in the English drug market was the slow response to the launch of new products, compared to other countries. While England had access to a relatively agile system of assessment and registration of such medicines, uptake was slow, despite the indication of a slight improvement in the first two years after the publication of the PICTF Report. Of course the criticism of NICE remains, but tends to be easing, with the realization that even the drugs included in its guidance reveal poor performance, with regard to their uptake by the NHS. At one meeting, the representative of NICE suggested an agreement for a concerted effort to find solutions for such medicines, freezing the debate on the functions of NICE. Meanwhile, at various times industry representatives point out that the problem may be related to the nature of the care system in England, which would not give patients the freedom to choose the doctors they prefer, along with the demand for more resources for the NHS to purchase medicines.

The debate on European issues is marked by the constant reiteration of the government's commitment to defend industry positions in the European forums, even if accompanied by appeals, on the issues of access to medicines in developed countries, especially in relation to AIDS and malaria treatment, for industry to allow more flexibility. On issues such as data exclusivity and price regulation the arrangements are clearer. Besides the 10 + 1 position on the first issue, the industry argued that European prices be regulated only on the drugs subject to reimbursement by public health systems. Throughout the process, industry representatives considered the possibility of accepting the proposal that finally prevailed in 2003 (8+2+1, on eight years of data exclusivity, two years of market exclusivity, and one year for use in new applications), for fear that the scenario could worsen if the European decision were taken after the entry of new countries, planned for 2004. Even so, the hostility toward the pharmaceutical industry in the EU is repeatedly protested, which is described in 2004 by Tom McKillop as a "disaster." The debate on prices, on the other hand, would persist in the European Union in the years following (UK-MISG, 2004a).

At meetings of the MISG of the first years following the PICTF Report, the theme of the decline of the British pharmaceutical industry appears continuously. While recognizing the permanence of various favorable conditions for the operation of the industry in England, such as the teaching and research network, and the macroeconomic environment, industry representatives point to problems in the differences in taxation for some countries, like Ireland. The demand to reduce the corporate tax rate charged to the industry is viewed, however, as difficult to address by government, due to their impact on other industries, beyond pharmaceuticals. Discussions record, however, convergences and agreements for the granting of tax credits for investment in R & D, defined in 2002 and subsequent years.

Finally, at various times difficulties are indicated in conducting clinical trials in the UK. Basically, such difficulties would be related to the price charged at the NHS units, which would be 25% higher than in other European countries, and to bureaucratic obstacles to their start-up.

In 2004, Tom McKillop notes that the MISG lost its focus and needed to be "revitalized." (MISG, 2004b) Frictions in industry relations with the NHS were common in the debates about the price of drugs, and in relation to the provision of increased use of generics in the system. In 2004, they are accentuated because of the negotiations on the PRRS in 2005, which had mandated a 7% reduction in drug prices, a measure considered by the ABPI "unnecessary given the fact that medicines prices have fallen in real terms by some 15 per cent over the past ten years, and that the NHS's medicines budget is remaining steady at about 12 per cent of expenditure"[26].However, according to Tom McKillop, the adversities in the European and international scenario, by virtue of the difficulties in the regulation of matters of interest to the industry, in the first case, and the affirmation of China and India as formidable competitors in the drug market, in the second case, made that moment "the right time to refocus the MISG again." . On behalf of the government, Lord Warner, of the DH, noted that "there was a need to move away from both sides sharing their views, and to work together and look more strategically over the next 5-10 years" (MISG, 2004b) . Thus was created the environment for defining the Long-Term Leadership Strategy, launched in July 2005, to lay out the actions to be taken to allow the reaffirmation of the British pharmaceutical industry. [27]

Until early 2007 the work to prepare the *Long-Term Leadership Strategy* (LTLS) is carried out. At meetings of the MISG, the unveiling of the European guidelines on conducting clinical trials sharpens the perception of the ground lost in the UK. From the government, the creation of the UK Clinical Research Collaboration (UKCRC) is presented as a mechanism to create an environment in the UK that provides value for money in conducting clinical trials efficiently and effectively. This includes action to address slow start up of trials in the UK (which will have a knock on beneficial impact on costs) and to introduce a transparent costing system[28].

The Long-Term Leadership Strategy is released in early 2007 under the auspices of the ABPI and the DH, with the identification of

> three particular issues where progress needed to be made: 1. The NHS and industry working more effectively together to provide increased access for patients to cost-

[26] As stated by Vicent Lawton ABPI's president of ABPI (ABPI, 2004).

[27] It is curious to note that, although among members of government and of industry the perception of a tremor in their partnership intensifies, on a more general plane what stands out is concern over the "influence of the pharmaceutical industry," which, according to the House of Commons Report published in 2005, would be too close to several organs, including the MHRA and the DH. Regarding the latter, even the report points to a possible contradiction between operating as a body responsible for the conduct of public health and of policies directed to the pharmaceutical industry, suggesting that such a function should be effectively allocated to another sphere of government. (UH-Commons House, 2005). Meanwhile, although the industry has seen the discount affected the price of drugs harmful to their interests in the 2005 PPRS, other areas of the British government evaluated negatively in relation to the interests of the NHS. In the 2007 report, the Office of Fair Trading notes that the NHS could have saved spending on medicines if it had purchased generic drugs in some cases, suggesting, replacing, then the PPRS for a further arrangement, value based pricing. (OFT, 2007).

[28] As stated by Louise Wood, of Department of Health (UK-MISG, 2005).

> effective new medicines; 2. The UK Government working with the European Commission and Member States to improve the European environment for the pharmaceutical industry, through the Commission's High Level Pharmaceutical Forum; 3. Improving the regulatory environment for medicines (UK-DH-ABPI-MISG, 2007: 3).

The working groups assembled for the formulation of the LTLS are also indicated as responsible for implementing its recommendations. It would be up to the Partnership Working Group to ensure the development of a guidance of the DH to orient the joint work between the NHS and the industry, create a best practice toolkit, and ensure ongoing training for both partners, encouraging "mutual understanding, trust, and cooperation." Identifying variations in the uptake of new medicines in England, the LTLS suggests that the group work toward promoting the optimization of the system's capacity to adopt innovation, through financial planning, expansion of the information available to the NHS, promotion of actions for personal and professional development towards increased best practices in adopting innovation and, last but not least, "support for NICE and implementation of its guidance" (UK-DH-ABPI-MISG, 2007:7).

It would be up to The European Working Group to provide inputs for the High Level Pharmaceutical Forum (HLPF), with the perspective of the UK, to discuss issues relating to price, relative effectiveness, and patient information. To do so, besides the suggestions for conducting studies on the presence of sectors linked to the bioscience industry in Europe, and the publication of the NERA study on investment decisions in the pharmaceutical industry, it recommends to the British government to defend industry positions on price, relative effectiveness, as well as to support actions such as the Innovative Medicines Initiative. Finally, it even suggests that the UK government defend, in the European forum, the G10 recommendations and present the British model of information to patients as an example to be followed by Europe.

It would be up to the Regulatory Working Group to work towards promoting the improvement of the British and European regulatory environment, in order to enhance the competitiveness of the country and the region. To that end, it recommends the joint effort of the MHRA and the industry in the discussion of new regulatory requirements, the harmonization of European directives on clinical trials, the UK government's commitment to adoption and unification of electronic procedures for submitting applications for registration in Europe, the creation of a network of centers of excellence in pharmacovigilance in the UK by the MHRA, the unification of procedures for pharmacovigilance in Europe, the enhancement of communication between the MHRA and industry on safety concerns in the European environment and on the development, safety, and risks of medicines.

The LTLS *vision of the future* on the industry in the UK involves four central aspects. The first is improvement of the British environment for translational clinical research "to create a more innovation- and research-friendly NHS." The second would be the affirmation of the UK as a "world-leading centre for measuring the impact of medicines when used in clinical practice," in

particular through recovery of the data collected by Connecting for Health. The third would be increased partnership between the NHS, regulatory bodies, and the industry “to improve patient care and facilitate access to medicines.” Finally, the empowering of patients, to permit them “to take control of their own health and provide input to medicine development and regulatory decision-making” (UK-DH-ABPI-MISG, 2007: 9-10).

It is not possible at present to make an assessment of the implementation of the recommendations made. The MISG shows records of successful actions in the partnership with the NHS, some results in the area of regulation, and difficulties on the European scene (UK-MISG, 2009a). The partnership with the NHS, however, is the touchstone of the long-term strategy, since it is crucial for the uptake of new medicines, for the development of research in general (given the prospect of recovery of the data from Connecting for Health to evaluate the clinical effectiveness of medicines), and to conduct clinical trials. In the assessment of 2009, the Working Partnership Group highlights the definition of best practice guidance, for creation of the toolkit, the development of partnerships with NICE, although at every moment in the MISG meetings, the criticism of the agency reappears. Also, few results appear concerning the recommendation of training of NHS staff by the industry. Since *in the NHS sphere* the implementation of actions depends on the disposition of their instances, often additional efforts need to be made. The Working Partnership Group logs meetings with leaders of the SHAS and with clinical directors to stimulate partnerships, in MISG meetings there appear complaints about problems created by the PCT for enhancing the uptake of new medicines, and documents of the DH register difficulties in implementing their policies. All this seems to suggest that while the recommendations may be implemented, they may not be producing the desired results.

On the other hand, under the MISG other groups were created to address more specifically the topics of interest to the industry, like the MISG Clinical Research Workgroup, the Early Access Working Group, or even defined initiatives for the development of the biopharmaceutical industry. The first group, which in 2008 launched a report with several suggestions, aims to find alternatives to deal with the United Kingdom's loss of position in commercial clinical research, having declined from second to eighth position since 2000 (UK-MISG, 2008). The second group aims to regulate access to new medicines, regardless of their full release or assessment by NICE, such as risk sharing devices, such as the Innovation Pass, introduced at the suggestion of the Office for Life Sciences. Finally the development of the biopharmaceutical industry entails the establishment of forums such as the NIHR-NHS/Biopharmaceutical Industry R&D Leadership Forum, the release of the Strategic Vision for the UK-based Bioscience Industry, and the proposed Office for Life Sciences, welcomed by Prime Minister Gordon Brown (2007-2010), from the suggestion forwarded by industry leaders.

Beginning in 2008, the scenario of crisis lends prominence to the demands of industry for the adoption of fiscal measures in favor of the sector. Specifically, revision of the corporate tax rate and allocation of resources for small and medium enterprises is demanded, as well as the creation of

the Consortium Relief, a system of shared ownership of small and medium enterprises that facilitates access to several benefits, beyond the institution the Patent Box, a mechanism to discount taxes levied on income from innovative products. At the dawn of the Labour government, in the Gordon Brown administration, most of these measures are contemplated, and more positive procedural guidelines for the industry in negotiations on the PPRS are announced as well, with the creation of the Innovation Package, for "encouraging uptake through measures such as a new horizon scanning process, of new uptake metrics, and the piloting of prescribing incentive schemes" (UK-BIS, 2009: 8 - 9).

As seen in the previous section, the return to control of the British government by the Conservatives in 2010 is accompanied by a new round of reforms in the NHS [29]. Among them, a measure that could have a direct impact on the pharmaceutical industry is the replacement of the PPRS by the pricing system set on the value-based principle, in the next round of negotiations between the NHS and the industry. Amid calls for their affiliates to strive for acceptance of the PPRS in force, the ABPI showed its support for the new scheme, stressing, however, the importance of preserving the incentives for innovation that would be a feature of the PPRS. In meetings with industry, the government, in turn, requests its cooperation to define the criteria to be adopted in the new scheme.

Finally, the Conservative governmentt had recently announced a willingness to fast-track several industry proposals relating to the uptake of new medicines in the NHS and its increased collaboration for research. In particular, the ABPI applauded the "automatic inclusion of NICE recommended treatments (…), meaning that clinicians now truly have the choice to prescribe the medicine that they think most appropriate for their patients"; "the establishment of a NICE Implementation Collaborative (NIC) (…) bringing all partners into the process of helping with barriers to patients accessing medicines"; the "emphasis on clinical trials, aiming to re-establish the UK as a thriving centre for research" and the "better access to health data, with appropriate protection for patient confidentiality", which "opens up the UK's unique offering to provide a true picture of health challenges and benefits within the NHS" (ABPI, 2011)

4) Final Considerations

Despite the limits of the study carried out so far, the description of the trajectory of the health systems and policies developed by the governments of Brazil, Argentina, and the United Kingdom since the 1990s, presented in the previous sections, shows an increasing interpenetration between the actions pertaining to health policy in the three countries and those related more specifically to industrial policy for the pharmaceutical industry. In a general way, such interpenetration was favored by the regulatory environment created by the presence of TRIPS,

[29] The government of David Cameron kept the arrangement set in 2001 for coordination between industry and government, changing, however, its name, which becomes Ministerial (Bio-Pharmaceutical) Industry Strategy Group.

which increased pressure on health budgets, by virtue of the increased price of medicines, in several cases, and in the case of various developing countries, of the weakening of *imitative* national industries in providing medicines for national health systems. Such pressure adds to the expansion of measures, in the legislation in Brazil and Argentina, for the free provision of medicines to different groups of users. In the UK the public provision of medicines, given the nature of the British health care system, has long been widespread.

In a general way, directly or indirectly, the actions defined in the health area for the provision of medicines to the health systems in Brazil and Argentina were connected to policies aimed at the recovery of the domestic industries, in both countries, affected by the new regulatory environment, though different in rhythm and form. In Brazil, the untimely and almost unconditional acceptance of the terms of TRIPS lowered the importance of the domestic pharmaceutical industry in the 1990s and impacted the supply of medicines for the health system, in the period marked by great uncertainty as to their funding sources. At the end of the 1990s, however, Brazil redefined, somewhat, the mechanisms of its linkage to TRIPS, with the creation of prior approval, and the use of provisions of patent law for domestic production of certain components of AIDS medication, whose provision must, by law, be given freely to those who need it. Moreover, the legislation on generics and the adoption of various industrial policy measures for the sector, combining public funding and government purchasing, allowed a significant recovery of the national drug industry's influence, though insufficient to reduce the sector's trade deficit, and ensure, thus far, a significant increase in the innovative capacity of domestic industry. The connection between health policy and industry support policy in Brazil, on the other hand, begins to proceed more directly, with the creation of the SICT in the Ministry of Health, which becomes, in 2008, manager of industrial policy for the health-industrial complex.

In Argentina, for its part, adherence to TRIPS was accomplished with the use of the transitional period granted to developing countries, which allowed a significant recovery of domestic production in the 1990s, driven, also, by measures liberalizing the pricing and marketing of medicines. But by the end of the decade, and more especially, in the early years of the current century, Argentina saw the collapse of its pharmaceutical market in the wake of the debacle of the neoliberal experiment in the country, living through three years of recession between 1999 and 2002. The crisis in the supply of drugs was accompanied by emergency health measures that, with free public provision of various drugs and the establishment of mandatory payment of part of their costs by social works and health plans, opened the way for assistance to Argentina's national industry - which even increased its share in domestic production with the withdrawal of several multinationals from the country during the most acute moments of the crisis - although a loss of position is seen in relation to Brazilian industry, which, since 2001, has shown a positive sectoral trade balance, in contrast to previous years. The emergency health measures that collaborated with the recovery of Argentine industry, however, have only a weak connection with the adoption of

industrial policies for the sector. There is no record of the establishment of financing measures or a purchasing policy with a set purpose of activating domestic industry, much less the creation of institutional channels for linking the health area, the pharmaceutical industry, and the areas of the Argentine government responsible for industrial policy in the country.

The British case, in turn, shows that the interpenetration movement mentioned above is no stranger to countries equipped with an innovative pharmaceutical industry, and that have not experienced a drug supply crisis. Also, in such countries, the effects on drug prices affect health budgets, in an international scenario marked by the presence of various pressures to reduce public spending, given the hegemony of neoliberal perspectives and of deregulation of various markets on a global scale. In the UK, however, the interpenetration movement alluded to above, goes beyond issuing measures to reduce health care spending, such as the creation of NICE and attempts to expand the use of generics in the NHS. The British pharmaceutical industry intensively sought closer proximity with the health area, aiming to redefine the conditions in which the drug market operates in the country, and create competitive advantages for companies based in the United Kingdom, in international competition, alongside demands in the tax area. In this sense, it signaled, in relation to the expansion of the British drug market, for the adoption of measures altering various aspects of the health system in the UK, such as measures concerning the *right of choice* for patients, as a way of increasing the consumption of new drugs, relaxing control of the regulatory bodies over prescriptions, and ultimately, expanding the drug market extra-NHS, although there is little clarity on the measures to be taken in this latter direction. As regards the use of the NHS as a mechanism to award the UK advantageous conditions in new drug research, the industry proposals relate to the facilitation and containment of prices for running clinical trials in the NHS, and to the use of the system's database to evaluate the clinical effectiveness of medicines.

Since 2002, Brazil and Argentina are governed by teams that seek to distance themselves from the neoliberal experiments of the 1990s, despite the reduced willingness to confront macroeconomic orthodoxy, especially in the Brazilian government. Both governments, however, are taken as *developmentalist*, by the express willingness to stimulate domestic production via state action. Both, likewise, sought to extend their support to the national business communities in their countries. It is not, therefore, in the perspective of the leadership nor in the coalitions that support them, that one can understand why Brazil's and Argentina's policies toward the pharmaceutical industry, although geared to the defense of the national segment of the industry, take on another form. Ultimately, it is suggested here that the different configurations of health systems in the two countries affect the possibility of their use as an instrument of industrial policy.

In Brazil, the relative centralization of the public health system, which lacks a network of employment-related provision, nor has the regional fragmentation of Argentina, favors the adoption of policies more active on the part of the central power. The presence of a significant network of private hospitals servicing the SUS, on the other hand, is a real limitation to the expanded use of

government procurement in acquiring drugs, which tends to focus on those that are used in special programs. The strategy of activation of industry through government procurement is a bet in government circles, that resonates in the national segments of the Brazilian pharmaceutical industry. Despite the Brazilian public health system's structure, government spending on health is minimal, and there is a certain national consensus that it must rise, which may actually come to pass with the regularization of Amendment 29. In this case, besides the increased provision of public services, the purchase of drugs is tending to rise and flow, not only through drug distribution programs, but also through a wider hospital network. In this case, the bet noted above may mark the way for building a coalition that also involves the area bureaucracy and the users. Working against this perspective are the fragmentation of business organization in Brazil, and the interests of other endogenous actors, mainly private hospitals and pharmacies, that favor the industry's easier alternatives, because they only reinforce the mixed character of the Brazilian system of health.

In Argentina, the absence of noticeable state apparati for the conduct of industrial policy is a legacy of decades of erratic development in this direction, aggravated by the neoliberal experiment. In the specific case of health care, the fragmentation of the national system and its decentralization complicate relations with the areas of government responsible for industrial policy. The already substantial weight of public expenditure on health (although fragmented in public networks in the strict sense, and in social works) does not leave much room for a strategy like such as Brazil are drawing. The combination of regulatory measures that create some stability in the drug market, with the definition of mandatory partial funding of drug costs, by health plans and social works, with the liberalization of prices and treatment, represents a path that tends to strengthen market relations. In the Argentine case, the fragmentation of the actors is reinforced by the fragmentation of the structure of the health system, leaving little room for change. The fact that, after its passage, no comprehensive programs for sectoral industrial policy involving the health area have been formulated seems to demonstrate that the notion of its permanent integration never arose, unlike Brazil and the United Kingdom, which have national health systems with a much more pronounced level of coordination than Argentina's. To what extent are the fiscal difficulties of the Argentine government and the institutional inertia in the health system insurmountable goals in changing this scenario? Or, on the other hand, in the absence of active industrial policies, is it possible to discern effective changes in the imitative bias of Argentine industry, relying solely on market incentives and on the functioning of intellectual property rights?

In the UK, the production of medicines reaches levels that exceed on a grand scale the uptake capacity of the British market. While British production holds 10% of the global drug market, the UK consumer market represents only a 3% share of the world market. In the UK, on the other hand, government health expenditures are already high. For the pharmaceutical industry there is a clear limit to expansion of the English market through the NHS. Among the goals set by the partnership between the government and British industry in 2001, with the creation of the PICTF,

was the expansion of the internal market's uptake capacity. Another was the creation of competitive advantages using the NHS for increased clinical testing and research. To what extent, however, may these goals be contradictory with the ongoing reforms in the NHS, and eventually, with each other? The relaxation of prescription regulations, the rise of the *power of choice for patients*, favors the course followed since the beginning of the 1990s toward expanding the autonomy of system units, with the increase of their market regulation. In a certain way this can encourage increased uptake of new medicines, but also reduce the capacity for central coordination toward this end, as reflected in the documents of the DH confirming the importance of the NHS instances in keeping up with the measures for increasing the uptake of innovative medicines agreed to with industry. In turn, if the NHS tends to fragment into increasingly autonomous units, might this not raise transaction costs for their use as a research instrument in British industry?

Of course it is not possible to answer such questions that will depend on political choices, on the coalitions, and on the weight of the legacies on the power of the social actors. There is much to elucidate on such choices, coalitions, and legacies. In the later stages of this study, we seek to advance in this direction, identifying the perspectives of the different actors present in the area of health, stressing the options of its representative bodies, as well as the coalitions that it seeks to secure, through, the analysis of its activity in the arenas in which health policy and industrial policy for the pharmaceutical sector are defined. On another occasion, it is interesting to expand the investigation, focusing on national cases in which health systems and industries, of a nature diverging from the case collated here, arise.

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