Public-private articulation in the production of vaccines in Mexico

La articulación público-privada en la producción de vacunas en México

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ABSTRACT This paper analyzes the process of privatization of health care services through the Public-Private Articulation (APA). The production of vaccines in Mexico is studied through the case study of Biological and Reagents Laboratories of Mexico, LLC (Birmex), company responsible for the production, distribution and research of biologicals and reagents in Mexico. We specifically focused on Birmex's performance during the Influenza A, subtype H1N1 virus pandemic. The results show that as a result of the liberalization and deregulation policies, there is an opening of public services to supranational corporations.

KEYWORDS Public-private partnerships. Influenza A, subtype H1N1 virus. Influenza vaccines.

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RESUMEN *El artículo analiza el proceso de privatización de la atención a la salud: la Articulación Público-Privada (APP). Específicamente estudia la producción de vacunas en México, tomando como caso los Laboratorios de Biológicos y Reactivos de México, S.A. de C.V. (Birmex), empresa paraestatal, responsable de producir, distribuir e investigar biológicos y reactivos en México. Interesa destacar el comportamiento de Birmex durante el periodo de la pandemia de influenza de 2009, producida por el virus de la influenza A subtipo H1N1. Los resultados muestran que gracias al impulso de las políticas de liberalización y desregulación, existe una apertura de los servicios públicos a las corporaciones supranacionales.*

PALABRAS-CLAVE *Asociaciones entre el sector público y el privado. Subtipo H1N1 del virus de la influenza A. Vacunas contra la influenza.*

Introduction

The Public-Private Articulation (APP) in Mexico has been developing under the shelter of health sector reforms initiated more than two decades ago. Today, in a context of absolute dominance of neoliberal policies and the progressive loss of social rights, it is clear that the main reason of the APP is to transfer public resources to the private sector.

This paper analyses how the public-private articulation works, specifically in the production of vaccines, considering the case study of the Biological and Reagent Laboratories of Mexico, LLC (Birmex), a parastatal company affiliated to the health sector and coordinated by the Ministry of Health (SSA), responsible for producing, distributing and researching biologicals and reagents in Mexico. We analyse the performance of this company during the pandemic of the influenza A, subtype H1N1 virus.

The Superior Audit of the Federation (ASF), the highest instance in the matter at the national level, audited Birmex several times. The documents resulting from these audits provide abundant information on the role played by this company in the supply of vaccines.

The hypothesis that guides this analysis states that the APP is a privileged mechanism to privatize public goods, currently fully legalized by the Public-Private Partnership Act (LAPP). In the literature on the subject it is common to find different ways of naming the same concept, i.e., 'mixture', 'articulation', 'association' or 'collaboration'. In this work we decided to call it 'public-private articulation', since we consider that this denomination connotes the precise and complex forms of relationship between the public and private spheres and, in addition, combats the conceptual tendency to conceive them as entities that share common interests, under conditions of equality and neutrality.

Public-Private Articulation in Mexico

Public-private articulation, as a tool to meet the diverse needs of health systems, is not a recent phenomenon. In fact, in most countries, neoliberal reforms have favoured their expansion. In Mexico, until the 1980s there was a clear predominance of the public health sector, but since the beginning of the new millennium there has been a strong tendency to increase the participation of the private sector in the provision of public services.

In the Latin American region, several authors have extensively discussed this issue from the perspective of Social Medicine and Collective Health. The first works on the subject were disseminated in the nineties. The book 'Política de saúde: o público e o privado' (Health policy: the public and the private) addresses the issue in a number of articles, including Laurell's (1996), who argues that in a neoliberal context the main objective of public-private articulation is to serve the accumulation of capital, for which it is necessary to commodify or re-commodify health care, i.e., to privatize it. In this respect she states that:

> It is important to emphasize that the commodification of the service-benefit is the necessary basic condition of privatization, without which it would make no sense. The only 'privatization' that does not depend on this condition would require the private sector assuming healthcare outside the mercantile nexus [...] the commodification of health services is thus the heart of the privatization process. (LAURELL, 1996, P. 33).

Although it is necessary to take into consideration the particularities of the socio-historical context in each of the countries of the region – the author warns –, specifically the type of healthcare organization established through the previous social pact, the phenomenon of commodification occurs to a

lesser or greater extent in all the cases.

It is possible to verify the commodification in Mexico: it is enough to observe the great variety of suppliers, clinics, health insurers, laboratories, pharmaceutical companies, etc., that make up the so-called 'unorganised markets in health care delivery'.

This type of public-private articulation constitutes a complex scheme where public funds of the Federation and private capital participate in a legal-contractual framework. The practice as such is not new in the country, because the investment of private capital, both national and international, has been a decisive factor in the creation of the local infrastructure through the usual models of state contracting: concessions, service contracts, leases and public works. However, the difference between the public-private articulation and these contracting schemes lies in the source of financing: in order to avoid spending large sums provided by the Treasury, funding must come mainly from the private sector. Thus, public expenditure is replaced by private expenses, amortizable in the long term. In this way, private investment recovers and makes a profit.

Although the benefits of public-private partnerships for social works have been weighed, critical comments point out that public-private partnerships are often not functional and do not meet their explicit objectives. For example, Clara Craviotti, researcher at the National Research Council (Conicet), says:

> If the orientation towards the common good of the public actors is weak and their competences insufficient, it is possible that public-private cooperation may end up aiming at transferring resources to the latter sector. (CRAVIOTTI, 2008, P. 188).

The author also points out that if participation is hampered by "resistances of some actors or inability of others to vocalize their demands, the public-private articulation schemes may serve limited purposes" (CRAVIOTTI, 2008, P. 188). The privatization processes have shown their inability to respond to the demands of the environment, since the results have been very poor and in some cases even negative. In this regard, the World Health Organization (WHO) report 'Health systems financing: the path to universal coverage' (ETIENNE; ASAMOA-BAAH; EVANS, 2010) recognizes that public services reach higher levels of efficacy and equity when compared to private systems, but contradictorily, despite this recognition, the final suggestion of the report continues to be the stimulus to the purchase of services by private sector. The reports argues that, in evaluations of efficiency and equity of health systems, it is usual to minimize the benefits of the public sector and ignore the weaknesses of the private.

From the official perspective, Nigenda *et al.* (2003) establish a difference between 'public-private collaboration' and 'privatization'. According to these authors:

> Privatization has been associated with the transfer of assets from the public to the private sector in terms of ownership, management, finance or control. It has also been linked to a process of reduction of governmental influence in the function of regulation, which is strictly aimed at facilitating the participation of the national and multinational private sector in the provision of services and administration of the financing of state and parastatal institutions. (NIGENDA *ET AL.*, 2003, P. 229).

However, it is striking how they affirm without presenting any data that our country predominantly presents a situation of collaboration rather than privatization, since from their point of view "The participation of the private sector has not involved a transfer of institutional assets from the public sector" (NIGENDA *ET AL.*, 2003, P. 229).

That is, there is controversy regarding the effectiveness of the APP in making more efficient the provision of social services in

general and healthcare services in particular.

Here we present and analyze some of these positions, specifically referring to the production of vaccines in Mexico and in particular the role that Birmex plays as an articulating instance between the public and private sectors to guarantee access to biologicals against seasonal influenza and the influenza A, subtype H1N1 virus.

Production of vaccines in Mexico. A process of sanitary sovereignty loss

Vaccine production in Mexico began in 1939 at the National Institute of Hygiene. By 1970, when that entity became the National Institute of Virology, recognized by the WHO as a Regional Reference Centre for Vaccines, it reported a significant production of biologicals, particularly those required by the health sector for fighting rabies, measles, tetanus and poliomyelitis. That year our country was among the first seven places in the world as a producer of the Pan American Health Organization (PAHO) Expanded Program on Immunization (PAI) (SANTOS, 2014).

In this regard, Alejandro Alagón Cano, a member of the Institute of Biotechnology of the National Autonomous University of Mexico (Unam) and a specialist in serum and biological production, observed that the technical capacity to produce the antigens has shown a reduction that began with the administration of Carlos Salinas de Gortari (GOMEZ, 2009). The Mexican government did not invest in infrastructure and dismantled the institutes responsible for producing vaccines. This coincides with the beginning of the neoliberal project in Mexico. Gómez (2009) notes that in an intervention, Alagón Cano stated that:

> For decades, the country was a leader in vaccines, produced in the National Institutes of Hygiene and of Virology created in 1956 and 1960, respectively, and produced 90% of the required vaccines. From 1977 these agencies merged with other dependencies of the Health Sector. (GÓMEZ, 2009, N.P.).

In 1999, during the administration of Ernesto Zedillo, the General Management of Biologicals and Reagents was reduced to the state company Birmex. Against this backdrop, when the viral triple vaccine (SRP) was introduced in 1998, our country ceased to be self-sufficient in the production of vaccines (SANTOS, 2002).

Later, the Official Journal of August 3rd, 2007 recognized the need to reactivate the national production in order to stop depending on the international offer and, through an agreement of the General Health Council, established "the obligation to develop an operative multisectorial strategy of the National Plan for Preparation and Response to an Influenza Pandemic" (BIRMEX, 2014). In addition, the Board of Birmex was instructed to take

> the necessary measures to carry out the negotiations and contracts required to initiate and maintain national production of seasonal and pandemic vaccines against influenza virus as soon as possible. (BIRMEX, 2014).

In April 2009, when the Secretary of Health and Welfare recognized the emergency of the influenza A, subtype H1N1 virus, in

> Mexico operated a National System of Epidemiological Surveillance (Sinave) with obsolete models and insufficient material and human resources [...] only 1.3 million antivirals were available; 2 public health laboratories unable to detect the virus. (LEAL-FERNÁNDEZ, 2010, P. 69).

At that time it became necessary to guarantee doses of vaccines against this disease, since the

> National Plan for Preparation and Response to an Influenza Pandemic – designed by the Ministry of Health in 2005 – simply did not exist. (LEAL-FERNÁNDEZ, 2010, P. 69).

From the standpoint of self-sufficiency, the panorama of vaccine production in Mexico is discouraging. Not enough vaccines have been produced since 1998, not even those considered by the National Vaccination Scheme (ENV). Currently, the company only manufactures antibacterial vaccines and scorpion and snakes antivenin. And most of the vaccines included in the ENV are purchased from the private sector (BIRMEX, 2014).

The coincidence of the dismantling of vaccine production with the implementation of the structural policies dictated by neoliberalism through different international agencies occurs in a context of gradual deregulation, indicating that it was a clearly calculated process. Throughout this process, Birmex plays a central role as an articulating company between the public and the private sector. Its function is to directly transfer public money to the private sphere. Similarly, the deregulation of the sanitary legal framework, carried to extreme levels by the Public Private Partnerships Act, whose purpose is to 'regulate' public-private partnership projects, turns the private initiative into a supplier of the activities and the services of the public administration, often financed with public funds. This law fully legalizes the illegal in order to finish the looting of the nation.

In addition, the PPP is also facilitated by trade agreements such as:

> The World Trade Organization (WTO) and regional agreements such as NAFTA that replace the domestic laws and regulations of member countries, including those related to public health. Under these agreements, governments at all levels face a loss of sovereignty in the formulation of public health and social security policies. (SHAFFER *ET AL.*, 2005, P. 3).

Birmex and the public-private articulation in the production of vaccines

Birmex began operating in 1999 as a State majority-owned company. Its functions are the production, commercialization, distribution and export of vaccines (BIRMEX, 2014). It has legal personality and owns assets, characteristics that allow it to legally carry out national and international transactions with little supervision by the corresponding health authorities, potentially facilitating the discretionary use of resources.

The main objective of this company was to produce vaccines, especially influenza, an objective scheduled in an annual goal that has not been reached to date. Its core activity is the purchase of vaccines from international pharmaceuticals, mainly from the United States, Canada and France (RODRÍGUEZ-ÁLVAREZ; LEÓN ROSALES, 2010). Glaxo Smith Kline, Merck Sharp & Dohme and Sanofi Aventis are among the companies that sign agreements with the Mexican state-owned company. The latter, a world-leading company, signs with Birmex under the specialized vaccine division Sanofi Pasteur.

In 2004, due to the increased morbidity and mortality associated with seasonal influenza in the young and the elderly, Mexico included it as a priority and since then the government has offered free vaccination for all children under three and adults over 60 year old. Each year, Birmex imports, controls and distributes nearly 20 million doses of seasonal influenza vaccine, which are delivered to the institutions of the Health Sector (Mexican Social Insurance Institute, Institute of Social Security and Services of State Workers, Popular Insurance, States' Departments of Health, Pemex health services and the Armed Forces, etc.) and are applied during national vaccination campaigns (RODRÍGUEZ-ÁLVAREZ; DE LEÓN ROSALES, 2010).

Birmex during the epidemiological contingency by influenza A, subtype H1N1 virus

Before the declaration of the epidemiological contingency by influenza A, subtype H1N1 virus, the mechanisms for responding to such crisis were deployed almost in an improvised way. In that circumstance, Birmex was granted a very large power as an intermediary for the purchase and distribution of vaccines and supplies for all public health institutions.

The first antecedents of this situation dates back to the Fox administration (2000-2006), with the reform of the General Health Law (LGS) of May 2003, which mandates support for influenza pandemic preparedness and response activities (ASF, 2009B). This document also agreed that all expenses arising from this contingency would be funded by the Fund for Protection against Catastrophic Expenses (FPGC).

Latter, in 2007, in the face of the possibility of an influenza epidemic, measures were recommended to ensure timely care, and in 2009 at the first extraordinary session of the Technical Committee of the Social Protection System in Health's Trust Fund was agreed to request a loan from the World Bank to face the epidemic. In August 2009, in response to the declaration of the pandemic, the Technical Committee of Social Protection System in Health's Trust Fund of the National Commission for Social Protection in Health (CNPSS) authorized 1.158.325,5 thousand pesos for the acquisition of the pandemic vaccine against influenza A, subtype H1N1 virus (ASF, 2009B). It should be noted that the head of the CNPSS stressed that health services such as chronic renal failure, haemophilia, adult leukaemia and heart attacks, among others, were discontinued due to the resources being used for fighting the pandemic (ASF, 2009B).

In that same year, Birmex signed an agreement with Sanofi Pasteur, stipulating that the pharmaceutical company would establish a plant in the Mexican state of Ocoyoacac with an investment of 1.725 million Mexican pesos (SANOFI-PASTEUR, 2015). The intention was to produce the antigens for 30 million vaccine doses per year to prevent seasonal influenza and up to 90 million in the case of a pandemic. While achieving this ambitious goal, Birmex would be responsible for the subsequent phases of manufacture and distribution in Mexico, for which it would build the 'Cuautitlán Multipurpose' Plant to formulate, fill, pack and condition the vaccine.

Although the legal responsibility for producing the vaccines was borne by Birmex, on this occasion, Sanofi acquired all the rights to produce and sell the vaccine to the entire public health sector. The purchase of 20 million doses cost the Mexican government 2 billion pesos (ALCÁNTARA, 2009), an amount of doses that was insufficient during the pandemic.

The commercial agreement between Birmex and Sanofi Pasteur was signed by the then presidents Felipe Calderón and Nicolás Sarkozy with the support of the SSA, and counted with a budget and a grant from the WHO to acquire technology for the production of the vaccine (PONCE-DE-LEÓN *ET AL.*, 2011). The original plan of the Mexican government expected to begin producing vaccines against seasonal influenza by 2011; so far this has not yet occurred.

The ASF evaluation conducted in November 2010 – 'Reducing Preventable Diseases through Vaccination' (ASF, 2010) – indicates that the Ministry of Health did not comply with the applicable regulations related to the purchase of pandemic vaccine for the Influenza A, subtype H1N1 virus. In addition, these agreements were plagued by irregularities that questioned the effectiveness and efficiency of the health interventions carried out on that occasion and were reported in three audits of the ASF. For example, the documents that would regulate

these actions were not published in the Official Journal of the Federation, preventing from exercising the consequent legal effects on the responsible agencies.

Birmex appears as an intermediary between the laboratories (Sanofi Pasteur and Glaxo Smith Kline) in all acquisitions, including those made by social security institutions and the armed forces. For the non-entitled population, the vaccine was distributed through the National Centre for Epidemiological Surveillance and Disease Control (Cenavece), but also had Birmex as a mediator. The audit states that this intermediation resulted in more expensive vaccines than if they had been purchased directly from laboratories (ASF, 2010).

The weakness of the legal framework in force at that time is evident in the contract signed with Birmex. The section on Ministry of Health's obligations established

> that the manufacturer and Laboratories of Biologicals and Reagents of Mexico, LLC are released from any responsibility arising from the application of the vaccine, including lack of efficacy or failure to meet the safety profiles of the vaccine. (ASF, 2009B).

and the Ministry is "obliged to keep them safe from any claim or demand" (ASF, 2009B), an unacceptable clause because the contracts indicated that the vaccine for influenza A, subtype H1N1 virus was subjected to an approval process for use in humans through clinical trials aimed at proving effectiveness and safety.

The situation that prevailed due to the chaotic action of the health authorities of our country in the face of the pandemic is also evident in the analysis of only a few of the many data provided by the second audit 'Supplies to Respond to the Influenza A H1N1 Pandemic' (ASF, 2009A), which oversaw the use of these resources. For example, it mentions that of the 13.085.290 doses of the pandemic vaccine for influenza A, subtype H1N1 virus, 8.277.330 were distributed without receiving the product's sale and distribution authorization (ASF, 2010) issued by the Federal Commission for Protection against Health Risks (Cofepris), an omission that makes it impossible to guarantee the vaccine safety and effectiveness. In addition, the agency failed to demonstrate the destination of the 4.188.030 missing doses (ASF, 2009A).

Discussion

The actions of the Mexican government in the face of the epidemiological contingency of influenza were strongly criticized both in the Mexican press and from the academic perspective. For example, Menéndez (2014) considers that the State's delay in informing the Mexican population about the pandemic and the incorrect attribution of a high number of deaths caused the preventive measures to be strongly criticized:

> To the point of considering the possibility that the new pandemic did not even exist and that it was an exclusively media event. Moreover, constant criticism was directed at the way in which the official Health Sector informed the population, accusing it of hiding data, exaggerating the problem and promoting an alarmist campaign for political and economic reasons. (MENÉNDEZ, 2014, P. 16).

From the epidemiological point of view, the studies practically confirm that the severity was much smaller than what the mass media reported to the public. For example, one of the studies shows that between March 1st and May 29th, 2009, the Mexican National Surveillance System identified 41.998 cases of acute respiratory tract disease, of which 25.127 (59.8%) were tested for etiological diagnosis. Of these, 5.337 (21.2%) were identified with influenza A, subtype H1N1 virus. By May 29th, 2009, 97 people had died due to this virus (GARCIA-GARCIA *ET AL.*, 2009).

On the other hand, according to data from the Institute of Diagnosis and

Epidemiological Reference (Indre) of Mexico, the outbreaks began in late January and not during April, the month in which the Mexican government decreed the health alert. In total, 14 outbreaks attributable to different types of virus were identified from January to May 2009 (NORIEGA; MONTOYA, 2009). Some local studies showed the following data: in the health jurisdiction of Tlalpan, of the 660 persons with all the symptoms of influenza A, subtype H1N1 virus, only 18% was diagnosed with the virus; 14.6% with seasonal influenza A or B, and the remaining 67.4% was negative. At the National Institute of Nutrition (INN), of the 487 patients with symptomatology, only 8.8% were due to influenza A, subtype H1N1 virus; 9% to seasonal influenza and 82.2% was negative. In the National Institute of Respiratory Diseases (INER), an institution where a great alarm was generated, of the 164 patients studied, only 18.3% tested positive for influenza A, subtype H1N1 virus; 3% for seasonal influenza and 78.3% was negative. In Médica Sur, one of the most renowned private hospitals in Mexico, only 1.5% of the patients studied tested positive for influenza A, subtype H1N1 virus; 11.4% for seasonal influenza and 87.1% was negative (NORIEGA; MONTOYA, 2009). In this regard, Forcades (2010) points out that the plan to respond to a possible influenza pandemic was elaborated by the WHO in 1999 and was carried out:

> [...] In close collaboration with a group of scientists from the European Scientific Working Group on Influenza (ESWI), funded entirely by pharmaceutical companies with direct interests in the promotion of antivirals and vaccines for influenza. This Regulation allows for the so-called 'pandemic vaccines' to be patented and for companies holding these patents to negotiate legally binding pre-contracts with the governments of the different WHO member countries, at a monopolist price and with as many secret clauses deemed appropriate. These pre-contracts are automatically activated immediately after the global pandemic alert level 6 has been declared. (FORCADES, 2010, P. 246).

Against this backdrop and considering the statistical inconsistency, the Parliamentary Assembly of the Council of Europe requested a group of experts to carry out the research, which mentioned in its main conclusions the urgency of some global health agencies such as WHO and some European bodies involved in the issue to take the necessary measures to avoid the repetition of what happened in the 2009 pandemic. That report also highlighted:

> The unacceptable power relationship established between governments and pharmaceutical companies in negotiating contracts, and particularly points out the undue pressure that companies have exerted on governments, forcing them to make decisions about the suitability and characteristics of national vaccination campaigns without adequate information (for example on the advisability of double-dose vaccination). The report also mentions that, without justification, vaccines against pandemics have been sold at a much higher price than seasonal vaccines and denounces the transfer of the responsibilities of the company that markets the product to the governments with regard to the compensation for serious illness or death from the vaccine. (FORCADES, 2010, P. 246).

In this regard, Menendez points out that:

> The President of the Health Commission of the Parliamentary Assembly of the Council of Europe, the epidemiologist Wolfgang Wodarg, on January 12th, 2010 requested the WHO to explain why they had declared the influenza A, subtype H1N1 virus pandemic when it presented a very low lethality, even much lower than seasonal influenza, and also reported that a group of people working for WHO were closely associated with the chemical-pharmaceutical industry. (MENÉNDEZ, 2014, P. 30).

Leal-Fernandez indicated that the influenza vaccine was at that time the business

of the century: "the profits of transnational laboratories were already historical. Glaxo, Sanofi-Aventis and Novartis closed 2009 (fourth quarter) with revenues of 500 and 400 Md, only for the sale of the vaccine" (LEAL-FERNÁNDEZ, 2010, P. 77). The Mexican government purchased 30 million vaccines against influenza A, subtype H1N1 virus from Sanofi Pasteur and GlaxoSmithKline, but the biggest beneficiary was Sanofi that in 2004 had signed a research and development agreement with the federal government for manufacturing vaccines in the country in the event of an influenza epidemic.

However, in subsequent epidemiological analyses, some authors estimated the number of non-recorder deaths that occurred worldwide, indicating that the magnitude of the pandemic was actually significant. For example, mortality was 15 times greater than that reported, reaching more than 250.000 deaths (DAWOOD *ET AL.*, 2012). Influenza-related deaths due to influenza A, subtype H1N1 virus fluctuated between 123.000 and 203.000. However, mortality from this cause was very similar to that of seasonal influenza, which also showed a change regarding the affected age groups, who were mostly people younger than 65 (SIMONSEN *ET AL.*, 2013).

That is to say, the consulted bibliographic references on this epidemiological event show that there is a scientific debate regarding both the relevance of declaring the pandemic in 2009, as well as the international agencies assessment regarding the pandemic's seriousness.

Although Menéndez does not epidemiologically analyse the problem, he considers that "[...] the declaration of pandemic and the urgent call for the manufacture of a vaccine had the goal of favouring pharmaceutical laboratories" (MENÉNDEZ, 2014, P. 30). This author agrees with Craviotti's assessment that these types of processes are fundamentally due to the fact that

> the policies of liberalization, deregulation and privatization adopted within the framework of the neoliberal model boom are linked to the State's loss of legitimacy as planner and regulator of development. (CRAVIOTTI, 2008, P. 186).

From the standpoint of institutional participation, Macías-Richard (2010) indicates that access to viral immunity is in the hands of very few business firms, including national and international entities and institutions. On the one hand, there are multinational corporations responsible for the design, development, production and marketing of vaccines in a market that handles about 10 billion dollars in annual sales. On the other hand, there are multilateral institutional actors (international organizations and national detection centres) that have the power to concentrate the updated samples and recommend to WHO the strains that will serve as the basis for the annual production of vaccines.

An example of the above is the Global Vaccine Action Plan 2011-2020 (GVAP) (WHO, 2011), funded by various international institutions, including the WHO itself and the Bill and Melinda Gates Foundation. Mexico's adherence to this plan implied the signing of agreements for technology transfer between several transnational pharmaceutical companies and Birmex. The aforementioned agreements establish that pharmaceutical companies will sell the antigens and Birmex's sole responsibility consist of formulating, packaging and distributing the vaccines within the national territory, implying in fact to give up the chance of being producers of the antigens.

Regarding this state of affairs, Macías-Richard (2010) observes that there are decentralized entities with broad attributions and with greater power of commercial negotiation, located in the headquarters of the most developed economies. They have a set of powers that allow them to exercise exclusive regulation (authorization to produce

and distribute vaccines); sign collaboration contracts (research and development), and agree with the multinational pharmaceutical companies on the timing and amount of the supply, as described above for the 2009 pandemic case in the agreements between Birmex, WHO and Sanofi. The World Bank also played a key role in granting the millionaire loan for the purchase of biologicals and the antiviral (Tamiflu).

By way of conclusion

There is certainly a debate, especially with regard to the seriousness of the pandemic and the relevance or real need to declare the phase of maximum alert. Unfortunately, as can be inferred from reading the articles by Dawood *et al.* (2012) and Simonsen *et al.* (2013), due to the absence of statistical records and conditions to perform the laboratory diagnosis in the most affected countries, there is no reliable empirical data that allows us to establish in precise terms the epidemiological dimension of the event.

However, regardless of this debate, the number of irregularities highlighted by the national press – and accurately detailed and repeated by the ASF's audits to Birmex – provided the ideal scenario for the transfer of large flows of public money to the vaccines and antivirals manufacturing industries. Such irregularities are explained by the process losses socialization and profits privatization, a worldwide increasing trend. This fact, in addition to weak regulatory frameworks widely exemplified in previous sections, shows that the pandemic led – even partially – to a process of re-commodification in order to produce vaccines and provide an essential public service for the health of the population. Such circumstances seriously compromise the country's health sovereignty.

We agree with Menéndez when he states that:

> There is no doubt that there is a business of disease and care-prevention that, in the case of the new influenza, requires urgent research, design and production of vaccines demanded by the health authorities of most countries and the WHO; a business that is controlled by private companies, largely subsidized by the governments. (MENÉNDEZ, 2014, P. 29-30).

On the other hand, by addressing private public articulation, Craviotti argues that "new forms of regulation – both in terms of norms and mechanisms of public-private articulation – of a more inclusive nature are required" (CRAVIOTTI, 2008, P. 195). From her perspective, the way this partnership has been implemented does not lead to substantial improvements in the quality of public services and, in some cases, the effects have even been negative.

Finally, following Shaffer *et al.* (2005), we consider that the changing conditions of global trade and the passive and unconditional acceptance of governments pose enormous challenges to public health, specially: the privatization and the reduction of public services; the progressive nullity of government sovereignty in the regulation of services, composition and content of medicines and acquisition of equipment; the rejection of state supervision of adequate working conditions and the environment; and the excessive power of multinational corporations and international financial institutions regarding domestic policy decisions.

We also consider that this picture is part of a clear process of privatization that develops silently and with little attention from legislators and the media. For this reason, making them socially visible is an obligation of scholars and those interested in the subject, but always together with actions tending to encourage the participation of large population groups directly affected by the issue. ■

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Received for publication: April, 2016
Final version: October, 2016
Conflict of interests: non-existent
Financial support: non-existent