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Health Science, Technology and Innovation Policy (ST&I/H): an update for debate

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Abstract *The text presents an updated proposal for a Health Science, Technology and Innovation Policy in Brazil, following the huge political turmoil in the country since 2019 and the COVID-19 pandemic since 2020. The proposal is presented in five sections: Scientific Research; Productive Innovation; Health Technology Assessment and Incorporation; Intellectual Property in Health; New challenges posed by the Pandemic. The authors take part in the Advisory Committee in Science, Technology and Innovation of the Brazilian Association of Collective Health.*

Key words *Health science and technology policy, Innovation in health, Health Technologies assessment and incorporation, Intellectual property in health, COVID-19 Pandemic*

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Explanatory Note

This text was prepared under the auspices of Abrasco's Science, Technology and Innovation Advisory Committee and is signed by the committee members who have formally contributed to it. It had as its starting point a previous document, prepared based on the contribution of Abrasco and the Brazilian Center for Health Studies (CEBES) to the 8th National Symposium on Science, Technology and Pharmaceutical Assistance, promoted in December 2018 by the National Health Council. A few months later it was published in the journal Ciência & Saúde Coletiva under the title "Policy of Science, Technology and Innovation in Health"[1]. The original text was written after the emergence of the conjuncture of "Ponte para o Futuro" ("Bridge to the Future") a 2016 document that marked Michel Temer's government program which included, among other orientations, the Constitutional Amendment 95 which froze Brazilian public spending for 20 years. However, the Jair Bolsonaro conjuncture had not yet been inaugurated, in which Temer's economic policy was radicalized and the weakening of democracy in the country emerged with force. Furthermore, at the end of 2019 there was the outbreak of the pandemic caused by SARS-CoV-2, which impacted all dimensions of political and social life. These facts imposed this review and update, which aims to contribute to the topic and open a debate about it.

Introduction

The ST&I/S policy proposed by Abrasco has as broad guidelines: (1) the plurality of scientific approaches; (2) the emphasis on sustainable technologies as well as an understanding of the limits of technologies and access to them; (3) the emphasis on research activities that incorporate the concept of health as a human right. In addition to these three guidelines, this policy aims to value south-south cooperation and, at the national level, to face regional inequalities and defend the use of instruments of positive discrimination in scientific and technological activities. The global environmental crisis has become a central item on national political agendas and its fight against that crisis has the Sustainable Development Goals Agenda (SDG) launched by the UN as the most comprehensive reference for the global debate on values and future planetary projects. The presence of health on the agenda is relevant and the scientific and technological dimensions occupy a central place, both in the understanding of its social, cultural and economic interactions, as well as its decisive role in achieving the SDGs. In the design of a ST&I/S policy, the environmental dimension must occupy a prominent place.

Finally, Abrasco considers the dialogue and exchange of experiences with other national and international entities in the scientific and technological field essential to the development of its policy.

A ST&I/H policy is composed of at least four pillars: The Unified Health System (SUS), the productive basis of health goods and services, the critical mass and the scientific and technological infrastructure in health and also the various regulatory and articulating instances of the activities of the three components. These four pillars have been eroded by mistaken political decisions and the proposals contained herein aim to contribute to correcting this path of destruction, designing a path for the future. The text is organized into five sections, namely: Health research; Productive innovation; Intellectual property; Technology assessment and incorporation; Lessons from the pandemic regarding ST&I/S policy.

The organization of the text is theoretically supported by the rich conceptual repertoire of national, regional and sectorial innovation systems, originally imagined by Christopher Freeman and Bengt-Åke Lundvall, mainly in the Science Policy Research Unit (SPRU) of the University of Sussex in the second half of the years 1980 and later spread across several other centers focused on the economics of technology and innovation, including in Brazil. That conceptual frame has been critically coupled with the most recent contributions offered by Mariana Mazzucato since 2011, which emphasize the role of the State as an entrepreneur, more than just an articulator of the components of innovation systems. In the case of the Brazilian health sector innovation system, the presence of the State is centrally occupied by the SUS, but also by other entities such as development agencies, public and private industrial companies and service providers other than the SUS. Although the main focus of the creators of the innovation systems model, as the name suggests, is the productive innovation coming from the companies, the document also embraces the role of the offer of knowledge, that is, scientific and technological research.

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Health Research

The term health research as used in this section comprises the scientific and technological effort linked to human health carried out in higher education institutions and research institutes. It corresponds to what the North American specialized literature calls STEM (science, technology, engineering and mathematics), plus the human and social sciences. In this sense, health research is just a chapter of the ST&I/H policy, whose integrity requires the presence of the themes contained in the other sections of this document and possibly others, not covered here.

In Brazil, scientific and technological research in health has a tradition that predates the SUS and dates back to the first half of the 20th century with Manguinhos, the São Paulo institutes (Adolfo Lutz, Pasteur, Butantã, Emílio Ribas), the Evandro Chagas Institute in the Northern state of Pará (created as the Northern Experimental Pathology Institute), the Rockefeller Foundation, the SESP Foundation, the USP School of Public Health, among other institutions. However, between comings and goings, a more recent relevant step in the structuring of a health research policy was taken with the realization, in 1994, of the 1st Conference on Science and Technology in Health convened by the National Health Council (CNS) and organized under the auspices of the Ministries of Health, Science and Technology and Education. Among its resolutions, we highlight the one that stated that "the S&T policy in health is a component of the national health policy", and the other, of an institutional nature, which proposed the creation of a science and technology secretariat in the Ministry of Health. This idea only came to fruition in 2003, almost ten years later. In 2004 there was the 2nd Conference, also in Brasília and also convened by the CNS, which for the first time proposed an explicit policy in this field, as well as an agenda of research priorities.

A health research policy must embrace three vectors that delimit it, as follow:

• health-disease transitions (promotion, prevention, cure, rehabilitation), including the biological, clinical, epidemiological and social mechanisms that determine them;

• the health systems and policies included here, the components that provide services and the industries that produce medicines, vaccines, diagnostics, equipment and health materials;

• intersectorality in health and the relationship between health and society.

Hence, the design of a health research policy from the perspective of this document should embrace all these components and dimensions present in the three axes, which demands a transdisciplinary perspective that articulates the fields of biomedical sciences, clinical and epidemiological research, of human and social sciences and health planning and management, without any reductionism.

This approach avoids limiting the efforts of scientific and technological creation to the immediate operational needs of SUS managers, despite their importance. If the health research agenda as suggested here is an expanded agenda, the whole field should be embraced, particularly at a time when a spatial and temporal approximation between research results and the solution of health problems is observed all over the world. health. The spatial approximation refers to the increasing interpenetration of physical environments of scientific and technological research with research/development units in companies and in government management. The temporal approximation refers to the growing appreciation of tools aimed at a rapid translation of scientific and technological acquisitions into market innovations, which in the field of health research has been called "translational research".

And this, therefore, points to the need for synergy in the formulation of the policy and its actions with the managing bodies of the SUS, which is responsible for about 1/3 of the Brazilian medicine market, 90% of the vaccine market, 50% of the healthcare equipment market and 100% of services of all types and degrees of complexity provided to all Brazilians by constitutional mandate. On the other hand, this policy must dialogue with the group of critical mass in human health, which in Brazil holds the largest number of programs, students and professors in Graduate Studies, as well as the largest number of researchers involved with research projects, according to data available from the federal research support agencies.

According to the Directory of Research Groups in Brazil managed by the National Research Council (CNPq), in 2018 there were 31,345 research projects that contained the keyword "human health", most of them belonging to groups linked to the health sciences. But according to the same source, around 30% of these research projects belong to groups whose predominant research field in their activities was not the health sciences. Therefore, a ST&I/S policy, as proposed here, must have as object of its reflections, proposals and actions driven to the whole

set. It is worth noting that the year 2018 most likely does not reflect the current situation of the Brazilian scientific and technological effort at the federal level. Its use here stems from the halt in publishing (and possibly collecting) structured information about this effort since that year. This is revealed by consulting the Science and Technology Ministry website, where figures on the national expenditure on science, technology and innovation disappears from 2018-2019 on. The precariousness of the information currently made available by the graduate studies platform (Sucupira Platform) and the disaster that occurred in 2021 in the management of the National Research Council systems suggest that the monitoring and evaluation of the Brazilian Science, Technology and Innovation policy will depend on the reconstruction of these data sources and their dissemination channels. A more recent report updates the figure up to 2020 and confirms this paralysis in the publication of data on the scientific and technological effort in Brazil[2].

Since 2000, the Department of Science and Technology (DECIT) and other components of the Ministry of Health have been providing good services to the development of health research. In this trajectory, should be mentioned the co-management partnerships – including co-financing – of programs and projects carried out with development agencies and other organizational components that already exist in the Ministries of Education and Science and Technology as well as in the states financing agencies.

Linked to the Ministry of Health, despite having great operational autonomy, the role of the Oswaldo Cruz Foundation (Fiocruz) and, in a more restricted thematic scope, the Evandro Chagas Institute stands out in health research in Brazil. Unlike other institutions that carry out research in this field, they are mission-oriented as befits research institutes, and that mission is to serve the SUS. Also in this description of institutions with health research activities, the group of institutes linked to the governments of the federation units should be mentioned, especially those in São Paulo, which have a long tradition.

However, most of the health research activity in the country, when measured by publication in specialized journals and published books, originates in universities, colleges and teaching and research institutes not directly linked to the SUS, and come mostly from its graduate programs. The ST&I/S policy must embrace all institutions that contribute to the advancement of scientific and technological knowledge in health.

In a program to recover our scientific and technological capacity in health, organizational forms of work capable of multiplying the energy present in the most capable critical mass and, at the same time, contributing to the geographic decentralization of Brazilian research, should be valued. In this line, the modality of network research work stands out, which highlights the successful program of the National Institutes of Science and Technology (INCTs) sponsored by the Ministry of Science and Technology, which should be expanded and strengthened. It is worth noting that in this program, the field of health research is the best represented among all, with about 1/3 of the 101 networks supported in the first call in 2008.

The resumption of government actions aimed at the internationalization of Brazilian research, which have been interrupted since 2017, will also be highly recommended. Regarding the size of the national critical mass, the rates of scientific cooperation with other countries are far below the potential. The experience of the "Science without Borders" program should serve as an embryo for this resumption, naturally, stripped of its weaknesses.

In the field of biomedical research, one of the main current challenges has been the difficulty of deciphering the complexity of diseases that are increasingly responsible for a large part of the burden of disease worldwide, including among Brazilians – non-communicable chronic diseases. In parallel, the research policy must point to the diseases that affect the most vulnerable segments of the population – the diseases that affect neglected populations. On the other hand, the paths already opened by gene editing technologies, as well as the advance in knowledge of cell differentiation mechanisms, offer a broad road for biomedical research. These challenges are global and the insertion of the country in this globalized dynamic will imply an adequate selection of targets articulated with the national nosology. The relevant contribution of Brazilian biomedicine and clinical research in the Zika and Chicungunha outbreaks and in the current COVID-19 pandemic are good examples of this adequacy. On all these fronts, it is increasingly imperative to critically understand the relationship between the local and global dimensions of scientific and technological research in health, which signal cooperation dynamics, but also asymmetries and tensions. It is, therefore, about problematizing the very idea of global health, in its historical and also contingent contours, and,

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in this way, reflecting on the challenges to be faced and the place that the country aims to assume in this scenario.

On the border between biomedical research and epidemiology, it is worth remembering a possible change of approach in the field of diagnosis. Instead of individual diagnoses, looking for something already known and for which there is already a recognized disease, what is called metagenomic epidemiology grows in importance, based on massive sequencing of clinical samples to discover the pathogens present – already known or not.

In the field of epidemiology, a major challenge in the coming times seems to be the use of information contained in medical records and other routine sources of health care or linked to other social policies as a data source in research, which has been recently regulated in the country. The challenge lies in the improvement of technologies capable of guaranteeing the quality of information in these databases to the requirements of scientific investigation. And also, in the ethical-legal control capable of benefiting science without jeopardizing individual citizenship rights. In another key, it is understood that Brazilian epidemiology has been changing its level with the dissemination of large cohort studies, from the pioneer birth cohorts in Ribeirão Preto-SP, Pelotas-RS and the ELSA/Brasil study, sponsored by the Ministry Health and development agencies.

One of the main marks of the human and social sciences in this century has been an overwhelming incorporation of social dimensions that were once less valued in their repertoire. These dimensions, such as gender, ethnicity, age group and other possible identity dimensions, are increasingly articulated with others that are more settled for a better understanding of the social phenomenon, such as social class and religion. For scholars of the social determination of health and disease, these acquisitions are essential and their presence is growing in the repertoire of social research in health. Another important front with regard to the contribution of the human and social sciences has been the analysis, developed in recent decades, on science as a social activity, a collective enterprise that is made viable, in determined historical contexts, through repertoires, protocols, values, shared spaces and practices, involving actors from the scientific world as well as actors from other spheres of social life, such as politics and economics. In a scenario marked by denials and questioning the expertise and credibility of science, the reflections promoted in the field of the so-called social studies of science and technology on the historical and social processes of production of scientific consensus gain even more relevance to the debates and policies that aim to strengthen the relationship between science and democracy.

Special mention must be given to clinical research. The rapid growth of research projects involving human beings means that surveillance of the risks faced by participants should be the object of equally growing attention. The structures for ethical review set up under the aegis of the National Health Council – the CEP/CONEP system – have been playing an important role in mitigating these risks and ensuring their preservation and independence are important items on the health research agenda. The permanent pursuit of solid standards of scientific integrity is a central dimension of the ST&I/S policy. It has an important incidence in clinical research, usually close to commercial interests and is a central object in the work of bioethicists.

The succession of epidemic episodes that have been taking place in Brazil and in the world alerts to this very probable entanglement of biomedical, clinical, epidemiological, social and environmental variables in their determination and dynamics, called syndemic[3]. The COVID-19 pandemic is the most serious episode, but by no means the only or the last. In Brazil, there are recent outbreaks of sylvatic yellow fever invading urban environments, as well as a range of pathologies associated with the *Aedes aegypti* mosquito. The growing risk of new catastrophic events resulting from communicable diseases poses a great challenge for policy makers, managers and researchers in the field of health, which, therefore, will require scientific and technological contributions. Within the scope of the research infrastructure necessary to face these challenges, the setting up of level three biological safety laboratories, which do not yet exist in the country, will be a priority. This is an important example of investment that is currently limited by the austerity policy focused on reducing public spending, whose main landmark is Constitutional Amendment 95.

Finally, a research agenda must look to the investigation of the SUS metabolism itself, its management, policies, weaknesses and successes, as well as the development of non-public components of health services, subjects of cyclical crises and usually prone to resolve them at the expense of the SUS' achievements.

Productive Innovation in Health

According to the Oslo Manual in its last edition (2018)[4], the concept of innovation refers to new or significantly improved goods or services introduced in the market and it is in this sense that the term "Productive Innovation is used here".

The basic principle that guides the proposals of this subtitle is that the fundamental element for the advancement of productive innovation in health is the strengthening of the Economic-Industrial Health Complex (CEIS) understood as an articulated and harmonious development of its components: scientific-technological, industrial and health care services. The strengthening of the CEIS cannot take place in isolation, as it is supported by various segments of the manufacturing industry not directly linked to health, such as the chemical complex, the electronics complex and the metal-mechanical complex. Therefore, the strengthening of the CEIS will find better conditions to advance if it is linked to a broader proposal of industrial policy.

One of the relevant policies that emerged from 2008 in the field of SUS was the Productive Development Policy (PDP). Its conception derived from the need to seek synergy between industrial development with local technological and production and the expansion of the population's access to medicines, vaccines and health equipment, as well as promoting a better allocation of resources in the purchase of these products.

The basic mechanism put into practice by the policy was to encourage the formation of partnerships in which a private company and a public laboratory undertake to deliver a product identified by the Ministry of Health as strategic within a specified period. In this process, there was always a commitment to falling prices throughout the process and technology transfer from the private company to the public laboratory. On the other hand, the Ministry of Health would grant exclusivity to purchase the product for a determined period (usually five years, reaching up to 10 in the case of biological products). By the end of 2017, the Ministry was purchasing about 20 drugs and vaccines from these partnerships. According its information, between 2008 and 2016 the development of this policy generated savings of about R$ 4.5 billion (~US$ 850 million) in the acquisition of these products, as well as allowing some degree of technological absorption by pharmaceutical companies and public laboratories. Analysis of 186 purchases made between 2009 and 2014 through the PDPs showed savings in resources in 37 of the 39 medications evaluated[5].

After the important, albeit frustrated, initiative of a Federal programme called "Medicines Central" (*Central de Medicamentos*) in the last century, the PDP was the first major initiative in the field of public health related to the Health Productive Complex. Its strengthening is a priority task. However, from 2017 onwards, this policy was gradually deconstructed, reaching today a situation of complete disappearance.

The technological capacity building mechanism used in partnerships was usually the transfer of technology for a particular product from the private partner to the public laboratory. This mechanism has been widely used in Brazil for many years in the field of vaccines, with great success. But for it to be successful it is necessary that public laboratories are adequately prepared to be able to absorb the technologies involved in each partnership. There is evidence that several public laboratories do not yet have this capability.

The PDP had been emphasizing partnerships involving mature technologies or even those in a phase of decline in their life cycle. This is not serious, given that the local production of products that incorporate these technologies can bring gains in price and technical training in public laboratories. But it is necessary to extend policy actions not only to the transfer of technologies that are already mastered, but to the development of original Technologies, "from the bench".

For its management, the PDP created some important instances. The main one was the Executive Group of the Health Industrial Complex (GECIS), conceived to bring together government entities involved in the operation of the policy. GECIS had attached to it a Competitiveness Forum that brought together public and private partners and their representative entities. In addition to it, the policy also created instances for selection, monitoring and appealing to decisions already taken.

However, the institutional model that embodied the PDP was dismantled. The GECIS was extinguished in December 2017 under the Temer government and in 2019 the Bolsonaro government extinguished the Department responsible for managing this policy (Department of Industrial Complex and Innovation in Health).

As a SUS tool, the PDP needs strong articulation with government agencies whose missions are involved in it. The most important are the

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National Institute of Industrial Property (INPI), the National Agency of Sanitary Surveillance (ANVISA), The National Bank of Economic and Social Development (BNDES) and the Financing Agency of Studies and Projects (FINEP). As for the first, it is important that priority be given to the examination of patents involving essential products that are candidates for partnerships, and the public interest must always be observed. As for ANVISA, it is also necessary to prioritize the examination and granting of sanitary registration for these products. The BNDES is relevant both to support and financing industrial projects and in the formulation of industrial policy as a whole. FINEP is relevant for its role in technological development and supporting projects in the bench. Naturally, the last two institutions need to be profoundly restored in terms of their mission and operational capacity, so that they can fulfill the role they once played in STI/H policy.

One of the most important characteristics of the global panorama of medicines is the growth of those produced by biotechnological routes. In these, there is no possibility of applying the concept of "generic medicine", as a result of the complexity of their molecular structure. Therefore, the category of biosimilars was created for them, applied to products launched on the market after the end of the patent protection period for the original product. This issue generated an international controversy about the possibility of a biosimilar being able to replace the original, as it is not a perfect copy, as happens in the case of a generic drug. The decision on the interchangeability between the similar and the original is a decisive issue for public health, given the growing importance of biosimilars in the treatment of chronic diseases such as cancer and rheumatic and autoimmune diseases. Like the successful generics policy, it is considered here that interchangeability should naturally be expanded, ensuring the concepts of safety and efficacy. With regard to incorporation by SUS, its cost-effectiveness and cost-utility must also be guaranteed.

Along with the determining role of the industry, a ST&I/H policy in which the SUS plays a central role forces us to emphasize the important participation of productive innovation linked to health care services. Technological innovations in this field can bring about great advances in the population's health care, as evidenced by programs of great impact that already exist, such as the technologies involved in the National Immunization Programme and in the Family Health Strategy. In general, in these cases, innovation resides in the virtuous articulation between existing technologies, which in no way detracts from their relevance and creativity. On the contrary, sometimes this virtuous articulation is capable of producing radical innovations, such as the creation of the Brazilian national day of immunization against polio. In the field of services, innovations tend to be less about products and more about processes, and researchers in the field of health planning and policy, as well as the social sciences, play a central role.

The main responsible for the increase in health expenditures around the world is the increase in drug prices, and many countries have been improving control mechanisms to counteract this trend. In Brazil, price control began in 1999/2000 with a National Congress Investigation Commission on (CPI) on medicines prices, followed by the enactment of the Generics Law and the creation of the Medicine Market Regulation Chamber (CMED) in 2003, which to this day fulfills this mission. The efficiency of CMED's performance can be measured by examining the evolution of average drug prices between 2000 and 2017, which fell by about 20% (data from Brazilian Census Office and ANVISA), with a significant growth in access to the population. This price regulation policy must be maintained, with the aim of expanding access and rational use of medicines. Even though the incentives for technological development and innovation in the pharmaceutical industry must be pursued, they must be subordinated to the essential mission of medicines and vaccines, which is to mitigate suffering and save lives. And the price of medicines is fundamental in this regard.

Intellectual Property

The relationships between intellectual property and public health policies have long been an object of tension and dispute. In recent years, the success of generic drugs policies in several countries and the deepening of initiatives by the US and the European Union to include restrictive clauses related to the patent regime in their free trade agreements have contributed to them. Among others, these provisions broaden the scope of the granting of patents, increase the periods of patent protection, prohibit access to data and prohibit or hinder the use of the flexibilities of the TRIPS agreements aimed at public health.

Despite a leadership position in the construction of TRIPS flexibilities, Brazil has given its intellectual property policy, expressed in Law Nº

9,279, of May 14, 1996, a direction that, among other problems, practically excluded the sanitary agenda of its concerns. In other words, it reinforced the commercial interests and put aside the public interest. This, in the name of a supposed "judicial security" that would be essential to guarantee the investments of pharmaceutical multinationals in the country.

A fair assessment of the role of intellectual property protection through patents in the field of industrial health products requires the construction of a model that favors the public interest, expressed in the rational expansion of access to these products through health policies. On the industrial production side, what must be guaranteed are adequate incentives for innovation, capable of stimulating the development of new and better products. On the side of public reason, it must be guaranteed that the right of access to these products is not overruled by frivolous patents or by the extension of their protection periods. Moreover, this right, in Brazil, is inscribed in the health chapter of the Federal Constitution and is expressed in the principles of universality and integrality.

Responsible for the application of intellectual property law in Brazil is the National Institute of Industrial Property (INPI). As a State agency, it has been systematically neglected, both due to the lack of investments and the growing quantitative lack of a cadre of patent examiners to meet its needs. Instead of adequately resolving this situation, the latest INPI directorates have been proposing patent granting schemes that, if implemented, will directly attack Brazilian sovereignty, in addition to provoking a flurry of lawsuits to settle doubts about granted patents.

Two important facts have recently taken place in the field of intellectual property in Brazil. The first was the decision of the Supreme Court (STF) declaring the single paragraph of article 40 of the 1996 Intellectual Property Law unconstitutional. That provision allowed for adding the time INPI takes to examine a patent to the monopoly period, which is 20 years. This had been producing an extension of the patents' lifetime, which delayed the launch of generics and biosimilars (cheaper and locally produced) on the market. The lawsuit remained in the Supreme Court for over ten years and certainly the pandemic emergency contributed to its being put on the agenda.

The second fact, also resulting from the pandemic, was the approval of a new law, simplifying the enactment of compulsory licenses in Brazil in situations of health emergency. The Brazilian law on intellectual property was approved in 1996, just two years after the global harmonization on patents, carried out in 1994 at the inauguration of the WTO, which defended the views of patent holders, countries in the Northern Hemisphere (10 pharmaceutical companies own approximately 40% of the world drug market – four Americans, two Swiss, one French, one British, one Chinese and one Japanese). Our law was very permissive with these interests, even though it included the provision of the compulsory licensing mechanism in emergency situations, after the approval, in 2002, of the TRIPS flexibilities in public health. It was this device that allowed the decree of the first and only compulsory licensing in Brazil in 2007 – the antiretroviral drug Efavirenz.

The law recently passed in Congress represents a positive loophole in Brazilian legislation regarding intellectual property. The law now approved causes a crack in this legal environment that is unfavorable to the expansion of access to health products, as it makes the licensing process more agile. It may pave the way for a change in Brazil's position in the field of intellectual property. The approved law will not cause immediate impacts in the case of vaccines against COVID-19. This is because there is a complex path between reading a patent and turning it into a product. It is necessary to know how to make the product, and for this it is necessary to have local industries that are technologically and productively capable of following this path. In the case of vaccines, the two Brazilian industries (Butantã Institute and Oswaldo Cruz Foundation) that have this capacity already have voluntaries licensing agreements (CoronaVac and AstraZeneca). But it is an open crack that, for the ST&I/S policy, it may mobilize researchers, both in the area of health law in search of widening the gap, as well as science and technology economists in the propositions of industrial policy in health.

A strategy that has been put into practice by countries in the Northern Hemisphere is the inclusion of restrictions on access to medicines and health products through patent bans included in any free trade agreements signed by those countries. This strategy must be strongly opposed by Brazil, and the research community is responsible for producing evidence to support this resistance.

Technology Assessment and Incorporation

Alongside the price increase, and in a complementary way, the uncritical launch of new

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industrial healthcare products on the market has attracted worldwide attention. The line of defense of national health systems – universal or not – to mitigate this impact, which is financial, but also concerns the safety of users, has been the development of evaluation mechanisms for such products with a view to their incorporation into the public market. These products, with the technologies embedded in them, make up a gigantic, highly internationalized, oligopolized and research-intensive industrial segment. Its total value exceeds a trillion dollars. Such characteristics give it an enormous power of political pressure on health systems, having, in recent decades, created a situation in which, in some cases, companies that own technology ownership start to rule the health systems. With regard to the SUS, the annual federal expenditure on these technologies nowadays (not counting the extraordinary expenses of fighting the COVID-19 pandemic) reaches a figure above R$ 20 billion (~US$ 3.8 billion), without also taking into account the expenses of states and municipalities. This increase contrasts with the containment and even the reduction, in real terms, of the health budget.

The 2nd Conference on Science, Technology and Innovation in Health in 2004 established a strategy for incorporating technologies into the SUS as an instrument for improving the regulatory capacity of the State. The implementation of the strategy, led by the Ministry of Health from 2005, culminated in a new health technology management policy, whose purpose was to maximize health benefits, guaranteeing effective, safe and equitable technologies.

The new strategy was implemented through two movements. One, aimed at comprehensive care and institutionalization of regulatory processes in the government sphere, with the creation of the National Commission for the Incorporation of Technologies in the SUS (CONITEC), formalized by Law Nº 12,401/2011. The other is aimed at a Health Technology Assessment (HTA) policy with the objective of providing rationality to the process of technological incorporation. To this end, the Brazilian Network for Health Technology Assessment (REBRATS) was created in 2008, involving government cooperation with universities, teaching and research institutes, teaching hospitals and state and municipal management bodies. Its mission has been to form a critical mass and spread the practice of ATS in the country.

The model adopted by CONITEC established deadlines for decision, criteria, standardized flows and procedures, expansion of the participation of state and municipal managers, health councils, medical professionals and public consultation with society. However, the ecosystem of technology management for the SUS remains incomplete and biased. Applications for incorporation happen out of line with the priorities of public health policy. There is little participation of users, patients and managers in decision-making processes. The legitimacy and timeliness of recommendations and decisions are not always achieved. Decision-making processes are often not explicit or supported by high-quality studies. Pressures from business actors, mainly Pharma industry are perceived in the profile of medications and procedures to be incorporated into the SUS for the treatment of chronic diseases, most of which are expensive. Minority investments are made in preventive interventions or those aimed at primary or even secondary care and in procedures for vulnerable populations.

REBRATS provided standardization, dissemination of methods, staff training and increased collaboration between researchers in Brazil. Research promotion actions increased HTA studies and economic analysis, promoting the expansion of training centers and research. However, the network and its members lack an active role in promoting the interaction of knowledge to support coverage decisions, the performance assessment of technologies already incorporated and the identification of new and emerging interventions that are relevant to the health situation. in Brazil.

In a democratic regime, the judiciary is an appropriate instance where citizens make use of their claims, justified whenever the administrative sphere fails in its obligations. However, as of 2005, an epidemic of lawsuits began in Brazil with the aim of forcing the SUS to provide health products and services, in particular high-cost medications, not incorporated into its procedures. The lawsuits filed against managers at the three levels of the SUS (federal, states, municipalities) frequently impose an unfair allocation of resources, often causing inequalities in distribution and access.

To try to solve the problem of judicialization, Law Nº 12,401 was enacted in 2011 whose objective was to regulate the integrality of the SUS. Unfortunately, after not very resolute decisions by the Federal Supreme Court, this Law started to be ignored by judges, sustaining the epidemic of lawsuits. Despite some advances arising from actions by the National Council of Justice (CNJ)

aimed at guiding judges, the issue is far from being resolved. However, the importance of such measures by the CNJ being taken in full harmony with the actions of CONITEC should be highlighted. Within the SUS, this should be the "gold standard" of scientific evidence with a view to incorporation. Improving the actions of CONITEC and REBRATS and respecting the terms of Law Nº 12,401/2011 are essential requirements for mitigating the epidemic of lawsuits, keeping the doors of justice open for demands that effectively result from SUS failures.

Despite the advances that result from the work of CONITEC, the manager of public health policy must play an active role in establishing their priorities. CONITEC was conceived to serve the SUS and not the commercial interests of the industry. And it is also up to the research community to generate evidence capable of contributing so that course corrections can be implemented.

What the pandemic teaches us and its repercussions on ST&I/S policy

The COVID-19 pandemic has posed challenges in the field of CT&I/S that will not be extinguished with its end. A process that is still ongoing, it is not possible at this time to identify a definitive set of these challenges. Therefore, without intending to exhaust them, here are some important points that have been learned.

The pandemic made clear what had been insinuating a few decades ago. In the middle of the last century, especially with the advent of antibiotics, there was the illusion that communicable diseases would be a problem that had already been solved and that chronic non-communicable diseases became the new challenge. Certainly, the latter now account for most of the global burden of disease, but the HIV/AIDS epidemic (and the multidrug-resistant tuberculosis it has exacerbated), the diseases transmitted by the *Aedes* mosquito (Dengue, Zika, Chikungunya and urban Yellow Fever), outbreaks of Ebola, SARS, MERS and H1N1 Influenza already indicated that something was changing. The pandemic made this clear and established.

Initially referred to the countries of the Northern Hemisphere, epidemiologists called the emergence of chronic non-communicable diseases (NCDs) as a phenomenon of a "nosological inversion"; but COVID-19 has unquestionably shown that this is much more of a "nosological addition". Communicable diseases are here to stay, not just among the poor countries of the world, as usual, but across the planet. Everything indicates that this new panorama is linked to the consequences of the impacts produced in the current stage of the Anthropocene. This would have started with the 19th century, but it is in the current phase of the 20th/21st centuries that a great socio-environmental disaster is being produced. In particular, the last epidemic and pandemic episodes have been expressions of 'spillovers', that is, the leap of pathogens from animals to humans, which are and will remain constant threats. It must therefore be clear that communicable diseases are not retreating enemies, that we can win and let go. In reality, they are perennial and multifaceted threats, to be faced with constant and intense surveillance. If this is true, measures to mitigate the return of communicable diseases as a global problem are linked to the introduction of fairer and more sustainable models of economic and social development. The construction of these models depends, in large part, on a scientific and technological approach, and the ST&I policy must address it. But this review of the role of communicable diseases does not rule out the fact that CNCDs are currently responsible for most of the disease burden worldwide, including in developing countries. And here too, the pandemic brought learning, starting with the increase in the difficulties in caring for CNCDs, due to the collapse of some components of the health systems stressed by the fight against COVID-19.

A second learning experience that came from COVID-19 is the reinforcement of the idea of integrating knowledge and complexity. The disease caused by SARS-CoV-2 clearly exposed this idea. Their biology is different from that of their SARS- and MERS-causing cousins. In its pathophysiology, what was thought to be a respiratory illness turned out to be a systemic condition. In terms of the clinical approach, there were surprises with a heterodox evolution, in which prodromal symptoms rapidly transformed into severe disease, without the patients' good general condition being consistent with the severity of their actual respiratory function. In the epidemiological field, monitoring the population's immune status was also surprising due to the low presence of antibody carriers when the situation is compared with the experience of other viral epidemics.

In the planning of health services, the speed of illness and the severity of some of the patients proved to be greater and more intense than the routine organization was prepared to support.

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On the social environment, inequality was made clear with unusual clarity, expressed in markers of gender, ethnicity, race and class, as a structural dimension of Brazilian society. Costs that will certainly have effects far beyond the temporality of the emergency. Here we return to the idea that the COVID-19 pandemic is a syndemic, as mentioned earlier in this text.

It is also worth mentioning the impact of COVID-19 on the public perception of science. In this sense, contradictory effects can be noted: on the one hand, society's expectations regarding the benefits of science and technology are intensified. On the other hand, the political uses of uncertainties (given the provisional nature of consensuses and the way in which they are accessed by the general public) amplify doubts and insecurities and, in this way, hinder the implementation of the very measures to fight the pandemic. In addition to these dimensions, services, life in society in the world of work, affection, leisure, etc., were also unexpectedly disorganized, as well as the economy of countries, some of which were already quite fragile even before the pandemic. These expressions of complexity brought about by the pandemic are also here to stay. Increasingly, the one-dimensional approach to health phenomena of this magnitude tends to obsolescence.

A third learning experience, this Brazilian one, was the recognition of the SUS as an essential tool in the field of public policies by a significant part of the Brazilian population. This belated recognition should not subside after the end of the pandemic. This means giving the SUS adequate political and financial support to fulfill its mission.

In parallel with the recognition of the SUS, the pandemic brought to light the recognition of the weaknesses of the Economic-Industrial Health Complex (CEIS) in the country. The global race for materials, equipment and vaccines against COVID-19 demonstrated that the subordination of CEIS to a harmonious complementarity of global supply chains did not work during the pandemic and will probably not return to work anytime soon, given the current trade war between the global powers. The most eloquent example came from the geopolitical race for vaccines (United States, China, Russia and the United Kingdom) when it became absolutely clear that the exercise of political power overcame any humanitarian as well as health considerations, despite the fact that the WHO created a mechanism (COVAX) to ensure a minimally equitable distribution of vaccines.

In the case of Brazil, a country classified as upper middle income, with a very reasonable industrial capacity, global production chains did not work for masks, syringes, respirators, and especially for essential components of vaccine manufacturing by Butantã Institute and Oswaldo Cruz Foundation. It is true that Brazil's failure also depended on the political and diplomatic disaster to which the federal government submitted the country. However, what remains as a lesson is Brazil's degree of self-sufficiency in various industrial segments, and in particular, medicines and vaccines will have to increase. Therefore, it is necessary to seek the financial and political reinforcement of bench research activities and, above all, the articulation between this and the agents of productive innovation. A fundamental measure to have resources for this involves the immediate repeal of Constitutional Amendment 95 and the confrontation of successive initiatives to overthrow the budget floors of health and education.

Finally, the pandemic demonstrated with great intensity and clarity the importance of engaging society as a whole in the world of science, technology and innovation. Particularly in countries like Brazil, where there was a disastrous approach to confronting COVID-19. However, all over the world, the societal dimension of the pandemic has demanded a gigantic flow of technical information from specialized sectors, aimed at the population in general. This flow has served both to disseminate guidelines of good technical quality and to mitigate the effects of denial and anti-scientific guidelines coming from different sources, in the Brazilian case mainly from the federal government. One of the most notable expressions of these information channels amplified by the pandemic was the presence of health professionals, epidemiologists, biomedical researchers, managers in the field of health and social scientists in mainstream media. The challenge that we believe must survive the time of the pandemic is to keep these channels open, making scientific and technological dissemination a central and fundamental instrument of public health policy.

Collaborations

R Guimarães designed and prepared a preliminary version of the text. All other authors participated equally with substantive contributions in the sections corresponding to their specific areas of interest and competence.

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