

A look at the Industrial Economic Health Complex and Translational Research

Um olhar sobre o Complexo Econômico Industrial da Saúde e a Pesquisa Translacional

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ABSTRACT The concept of the Industrial Economic Complex of Health (Ceis) interrelates with the concept of translational research as it brings the scientific and technological development of the academic-productive system closer to the use of knowledge by the society. The traditional 'triple helix' concept is extended to include the social use of innovation providing concrete results for the health sector. In this broad conception, the translational dimension was privileged: the need for formation of the strategic agenda, technological platforms, induction of specialization in science and technology institutions, transformation of technology transfer into innovation capacity with results for universal access within the Unified Health System (SUS). Translational research includes, in one single strategy, the knowledge and the production of goods and services required for health and welfare, yet making them accessible for the society, articulating the context of scientific, academic and industrial development in the country. This paper is aimed at explaining the reference concept: reducing health vulnerability, allowing knowledge to reach the citizens and setting the agenda for research and innovation.

KEYWORDS Health policy. Translational medical research. Diffusion of innovation. Public health.

RESUMO O conceito do Complexo Econômico Industrial da Saúde se inter-relaciona com o conceito de Pesquisa Translacional na medida em que aproxima o desenvolvimento científico e tecnológico do sistema acadêmico produtivo à utilização do conhecimento pela sociedade. Amplia-se o conceito tradicional da 'hélice tríplice' para incluir o uso social da inovação, proporcionando resultados concretos para o setor saúde. Nesta concepção ampliada, a dimensão translacional foi privilegiada: a necessidade de formação da agenda estratégica de plataformas tecnológicas, a indução de especialização em instituições de ciência e tecnologia, a transformação de transferência de tecnologia em capacidade de inovação com resultados para acesso universal no âmbito do Sistema Único de Saúde (SUS). A Pesquisa Translacional inclui em uma mesma estratégia o conhecimento e a produção de bens e serviços necessários à saúde e ao bem-estar, assim como o acesso da sociedade a eles, articulando o contexto do desenvolvimento científico, acadêmico e industrial no País. Este trabalho procura explicitar o referencial conceitual, ou seja: reduzir a vulnerabilidade em saúde, permitindo que o conhecimento chegue ao cidadão e que marque a própria agenda de pesquisa e de inovação.

PALAVRAS-CHAVE Política de saúde. Pesquisa médica translacional. Difusão de inovações. Saúde pública.

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Introduction

In the context of the Industrial Economic Complex of Health (Ceis), and yet taking into account the perspective of the public health, the Translational Research (PT) will only occur when there comes to be the citizen's universal, equalitarian and integral access to research and to both scientific and technological results.

Historiography about the public health in Brazil is intertwined with the development of the national scientific and technological development itself, as it acknowledges that the sanitary and bacteriological medicine of the early 20th century started to guide experimental research¹. During the first half of the 20th century, the health and the atomic physics areas took turns in the process of institutionalization of Brazilian scientific and technological policies, materialized in the consolidation of the National Council for Scientific and Technological Development (CNPq) in 1951².

With the creation of the Health Ministry (MS) in 1953 (Law Nr. 1920/1953)³, governmental actions for health promotion, prevention and preservation – for instance, the national immunization campaigns – were concentrated under the MS. Fragmented in the social context's web of private and welfare models, health systems based on private and welfare models intensified their remodeling during the seventies, influenced by the criticism of civil organizations and by the performance of the Collective Health area itself – a movement that led to the implantation of the Unified Health System (SUS), warranting to the MS the management of the system, based on articles 196 to 200 of the Citizen Constitution of 1988⁴. After Law 8080/1990⁵, was passed, states, municipalities and the Federal District started to coordinate actions in the realm of the MS, based on the principle of conciliation of financial, technological, material and human resources with the Union in order

to offer health assistance to the population in the SUS context.

The SUS and the MS, the federal manager of the system, became responsible for conceptualizing, coordinating and operationalizing Science, Technology and Innovation (CT&I) processes in health, aiming at the development of the sector, expecting to increase the scope of low, medium and high complexity technologies based on Brazilian industrial and productive sectors.

The consolidation of the Ceis⁶ concept starts bringing closer to each other the scientific and technological development and the productive system, besides the use of that knowledge by the society, thus enlarging the traditional 'triple helix' approach in order to include the social use of innovation and its diffusion among the society. Public policies on health are also defined, aimed at concrete results, such as increasing the production of subsystems based on chemistry and biotechnology, with mechanic and electronic bases, and of services, including incremental innovations that could lead to radical innovations in the health sector. In the developed conception, centrality and the translational dimension were privileged: the constitution of a strategic agenda, specialization in science and technology institutions, transformation of technology transference into innovation capacity, leading to the incorporation of results and increased access to health in the SUS's realm. The junction between medical-sanitary and scientific-technological dimensions aimed at the reduction of inequities in health is a complex phenomenon that was meant to materialize the scientific research assimilated in the universal access to SUS.

The process of translational research is, thus, an intrinsic perspective in the Ceis approach, and this paper tries to clarify this conceptual reference, that is: the vulnerabilities, in the health sector, of mechanisms allowing knowledge to reach the citizens and branding the very agenda of research and innovation.

Impulses for the national health sector

Following the Brazilian Constitution⁷, it became necessary to sustain actions structuring social and regional equity, without disregarding the sustainable development and the increasing role of the country in the international geopolitics, in order to support growth and the significant consumption by the health internal market. On the basis of the State's functions as promoter and stimulator of scientific development, of research, of scientific and technological capacitation and of innovation, it is crucial to consider the public policies of economic and social development – a movement that started in the country in the first decade of the 21st century.

In Brazil, the network supporting the health sector through prevention, promotion, treatment and rehabilitation activities and actions characterizes the Ceis. Challenges for maintaining this complex in the country are expressive and shape the Brazilian scenery as a unique case in the international market, due to its dimension and considering it can rely on SUS, a universal health system.

Despite the high aggregated value of the products used in the Ceis in the country, an expressive amount is acquired by imports from countries endowed with an endogenous and strong basis in the development of innovative products. Because it requires a production focused on innovation, and an endogenous basis producing consumption goods with high aggregated value – indispensable for health assistance for the population in the realms of prevention, cure and mitigation –, the country starts using technologies most of which are produced in countries that have already attained high levels of capacitation and specialization. The situation is further worsened by the population's ageing and by increases in chronic and rare diseases, which challenge public and private health systems.

According to Brazilian Institute of Geography and Statistics (IBGE), the health

sector, which includes the demand for medicines, health products and services, stands for 9% of the Gross Internal Product (PIB)⁸. It also includes 10% of the country's qualified workers and 20 million indirect jobs. As to Research and Development efforts (P&D), there is growth potential, justified by recent innovations; however, this sector is responsible for 35% of the total expenditure on Research and Development in the country⁹. The income resulting from the commercialization of biological medicines, specifics, generic, new and similar was as high as 70 billion *reais*¹⁰ in 2017.

The National Policy of Technological Innovation in Health (PNITS) identifies the Ceis¹¹ as the productive and innovation system in health, prioritizing the industrial segments of chemical, pharmaceutical, biotechnological, mechanic, electronic and health materials. In its definition are also included workers offering services in the health area, irrespective of their juridical nature, besides public organs and either public or private entities working on research, innovation, development, production and provision of services in the health area, including Science and Technology Institutions (ICT) and Official Public Laboratories (LPO).

However, although the actors taking part in this productive and innovation system have been quoted, larger integration of the actions in the sense of promotion and effective translation of knowledge are still in need. Lacking the well-established productive basis foreseen with the consolidation of Brazilian IECH, there is no effective translation of knowledge and assistance to fulfill the citizen's needs on the basis of knowledge produced in either the academy or in the institutes. Under the Ceis' structure, the connection between researches and social benefits may be made clear, not limited to the generation of knowledge in order to produce wealth and investments returns that will be sent out of the country. Thus, what Ceis is aimed at is the fulfillment of both the SUS' and the social needs.

Due to the potential for putting into motion economic activities and work for the

production, distribution and commercialization of supplies and products, the Ceis appears as an independent productive system (after all, a system will not be complete without interdependence), shaping one of the main productive complexes of the Brazilian economy, involving industries and services, high intensity knowledge and qualified labor.

Nowadays, besides being still employable, the term is also widened to incorporate the new technologies of the fourth industrial revolution^{12,13}, possibly being the basis of

[...] a national project of development simultaneously anchored on the constitution of universal systems and in strong, sovereign, dynamic, opened to global knowledge and socially oriented productive and innovation bases⁴.

Ceis is part of the National Innovation System (SNI) on health, configured as an articulated system of both public and private institutions. In Brazil, there is some confluence of actions that are translated into programs and policies for the national development, visualized in industrial development policies which follow national development policies of products considered to be strategic for the attainment of SUS' programs and policies. However, there is currently the need for a general alignment between health policies of the Health Ministry and actions by other institutions to which the development of Ceis is subjected. It is also necessary to modify the management model of research and production performed by public institutions and to move forward the capacity to formulate and evaluate the Health Ministry policies and the regulations for innovation.

An important need for alignment refers to both the academic research and Science and Technology Institutions (ICT) and the needs of the population that are influenced by the generation of new products. An effective translation of the academic environment knowledge to either the productive or the

services environments is still not a reality in the Brazilian context. Connections between the ongoing technological evolution and projects of the '4.0 Industry', personalized medicine and cell and genic therapies are still required, as examples that exert pressure on public and private health systems budgets in Brazil and worldwide.

It is important to analyze translational research in the context of the Ceis considering aspects of the national macrostructure. As to regulatory, infrastructure and capacity creation systems, one must evaluate the inclusion, in the existing regulatory environment, of structuring aspects of productive conditions that enable industrial operations and their flow. Furthermore, human resources must be available to lead projects aimed at the translation of knowledge (turning knowledge into action)¹⁵ all over the development process of medium and high complexity products, from the desk development to the employment of products/services in public policies of health assistance.

The systematic and evidence-based translation of knowledge must be the guiding and connecting element along the steps of the translational research, employing the concept of stages, from T0 to T4¹⁶, for sustained actions of scientific researches implementation in practical situations in the real world. Due to internal influential elements and to the diverse inter-institutional arenas, it is important for a country to be acquainted with the elements involving knowledge translation, as well as the multiple barriers to be surmounted for developing elements to face up to difficulties for making translational research effective¹⁷.

In the current maturity stage of Brazilian Ceis, it is forceful to define the elements and difficulties for the successful accomplishment of translational research in order to surpass the historical Brazilian difficulty in translating research efforts into products and solutions for the population's health. However, the new frontier to be conquered is the development of platforms that promote further specialization

of public agents, which would progressively replace the role of technological and teaching institutions for the dissemination of the translational science in the country.

It is thus relevant to associate the elements of translational research that can drive forward the Ceis and the value to be generated for the society, based on the production of knowledge and on making it operative in innovations. It is also possible to relate the importance of translational research to increasing the aggregate value of Ceis, based on the results of its efforts, expressed in a larger number of registered products that are incorporated into public and private health systems and effectively used in hospital beds and in the municipalities' health services.

The necessary requisites of quality for products and services cannot be disregarded, as well as their superiority over the existing treatment, which justifies both the efforts and the expenses in the continuous search for new products and services. It is this bond with innovations regarding the access that confirms Ceis as a privileged space for the translation of knowledge for the society into what is more critical and inherent to the concept of health: the quality of life today and for the future generations.

The process of transformation of laboratory, clinical and humanistic findings into interventions that improve public and personal health conditions, based on the transformation of interventions or products for diagnosis and therapy into behavioral procedures and changes, is the concept proposed by the Advanced National Center of Translational Science for this procedure. In the context of the Ceis use, the translational research rises from the incentive and improvement of Research and Development (P&D) projects, predicting the integration with research institutions and with both the private and the public entrepreneurial sectors. Such incentive may arise from finance programs and edicts that count on results for this kind of research (the basic one), related to the effective connection with

the next stage of research or development – that is, the environment of production of toxicological studies and evaluation of how health-safe products are (medicines or equipment) under the T0 concept. Following the PT development from the perspective of strengthening the Brazilian Ceis, one can relate the actions for the concretization of clinical studies on T1-T2, where researchers integrate their own knowledge to results of the clinical trials required to testify the effectiveness of medical interventions (medicines and health products) among specific populations. At this stage, the integration between regulatory systems, infrastructure and training is important for the continuity of actions aimed at products development.

At the moment when the results of the transition steps from T2 (clinical trials) to T3 (research on effectiveness, sanitary register and commercialization of the product) come to consolidate, the project validation required started some years earlier should now be effective, waiting for the long desired registration of the products by the national regulatory health agency. At this stage, the shorter the time elapsed until the product is commercialized, the better the knowledge translation among researchers of multicenter studies and the pharmaceutical companies in charge of the formulation of accomplished products and pilot samples that require the national regulatory agency to register the product. One may infer that success results from fulfilling the rules under which the clinical studies were performed, with the consistent approval of design protocols of the regulatory agency and with the least number of technical corrections requirements for the approval at the registration stage.

The configuration of Ceis in Brazil involves the support to health actions, since it supports the provision of resources and products for programs and policies of pharmaceutical attention on the part of both the public and the private sectors. Thus, when the T4 stage is reached on the way to PT, the actions carried

out by health services managers are affected at the very moment they get acquainted of a new product entering the market. On their turn, they can activate their technical chambers of incorporation of new technologies – in the public realm, the Permanent Committee for the Incorporation of Technologies in the SUS (Conitec) and the National Committee for the Regulation of Health Assistance (Cosaúde), a consultative organism, concerning demands of Brazilian private market. This stage allows for getting closer to the citizen by means of programs and policies of pharmaceutical assistance, and of the organized and evidence-based access to new health technologies, thus closing PT path in a desired model.

However, it should be observed that PT models must be plunged into, which might well be the most important contribution of this paper. The existence of a dynamic and innovative Ceis, able to absorb knowledge and offer social value to the citizens is the critical link that, in a way, is neglected in the PT approach. The Ceis and their dynamics configure the crucial moment that determines the effective potential of the translation of knowledge and technology innovation, necessarily having a territorial and local dimension, unavoidable in the process of innovations for the society.

High complexity technologies – models in evidence

The processes of development and production of Medical Assistance Equipment (EMA)¹⁸ and/or high complexity technologies for health, as described by Merhy¹⁹, contribute to social advances in most countries worldwide. Putting into motion the private initiative and/or the industrial sectors, integrating economic dimensions in health protection networks, they allow for the reductions of iniquities in health, making more technologies and technological innovations available in the health area.

For every contemporary country, the maturity in this strategic sector is reflected in the index of national production of advanced technologies, in the sector's autonomy and, ultimately, for fulfilling social demands regarding technological infrastructure in health assistance, which are permanent concerns for the governments and for the maintenance of State policies. The organization of modern health systems gradually turned into complex structures offering health services that use large-scale products, processes, procedures and technical norms. By means of political and social actions, this process came along with the increasing search for universal population welfare, which should emerge as a central dimension through the preservation and recovery of human health, counting on medical-sanitarian interventions as the basic factor in this composition²⁰.

In Brazil, since 2009, based on the delineation of the Ceis concept, public policies developed in the realm of the Health Ministry, linked with SUS, have improved the number of partnerships among the federal government, the universities and the private initiative, thus stimulating the triple helix²¹ in the enlarged version mentioned earlier that itself incorporates the social benefit and the organization of complex systems, open and dependent on the trajectory (path dependence) – a characteristic that defines the Ceis concept itself. Those actions were meant to support the modernization of the productive industrial health park through the development and production of medicines, supplies and/or equipment and medical devices clearly aimed at the health assistance with diversified epidemiological approaches. Some examples are the collectives that suffer from diseases such as aids, cancer, vaccine-preventable diseases, diabetes mellitus, hepatocellular carcinoma, neo-natal treatments, among others.

Brazilian Health Ministry's departments must incorporate the look of the civil society over health actions – for instance, in the technical chambers, for the incorporation of new

technologies, and for the definition of health policies, in the health councils. Systemic actions are set in operation aiming at increasing the scope of technologies and new technologies for health that are available to health systems through the productive system and the relationship involving the State, regulation and the market. Several policies are engaged with the attainment of those aims, trying to encourage the transformation of ideas and/or academic research into products and processes which can be commercialized, to be (or not) delivered to the market or assimilated by the health system – that is, fulfilling technical rules for good practices of regulatory organs and institutions, e.g. the National Agency for Sanitary Surveillance (Anvisa), the National Institute of Metrology, Quality and Technology (Inmetro), the National Committee for the Incorporation of Technologies to the SUS (Conitec), the Health Attention Secretariat (SAS/MS), the Ethics Committee on Research/National Committee on the Ethics in Research (CEP/Conep), the Brazilian Network of Evaluation of Health Technologies (Rebrats).

The Brazilian industrial sector on Health is endowed for R&D on technologies and supplies, as already acknowledged concerning the pharmaceutical sector and the productive sector of medical equipment. However, those investments give an advantage to actions that prioritize the partnership between the Health Ministry and the universities, promoting the interaction between the academy and public/private sectors. This partnership contributes for changing basic and experimental research originated in the universities into products and/or processes to be assimilated by the market and by the society through the Unified Health System (SUS) and the private segment (supplementary and out of pocket health).

Over the last decades, Brazil has inserted technological development and innovation into its national policy, enlarging the invested resources and creating the legal health framework in 2004 and a new legal framework in

2016, for science, technology and innovation (CT&I). This recent history of the legal framework of CT&I that aims, among other factors, at approximating the academy to the market, under the perspective of the public-private partnership, is a big opportunity for strengthening the innovation system and the national industrial competitiveness²⁽⁴⁸⁾.

The field of health research policy itself has demonstrated the increasing importance of translational research to the IECH. The incentive Award on Science, Technology and Innovation for the SUS – an event taking place since 2002, encouraged by the Health Ministry among the scientific community – is aimed at praising researchers all over the country and their research efforts, considered essential for the development and maintenance of the country's public policies on health. In 2017, the award was granted to the following axes: four PhD theses; four Master dissertations; two published papers; three successful experiences of the Research Programs for the SUS (PPSUS); and four projects of products and innovation in the health area.

In the category Products and Innovation in Health – 2017 SUS Award –, the winner projects were: 1) Sofia: research project and development of a final national prototype of ablation solution for the treatment of liver cancer that generates innovation in the area so as to make it possible to be commercialized internationally; 2) Device for Cerebral Focal Hypothermia (DFHC): development and medical application of a prototype to be used in perinatal asphyxia or post-cranium encephalic traumatism (TCE); 3) Portable medical device for the treatment of wounds and tissue cicatrization in diabetes patients that can be assimilated by SUS as a cover in diabetes treatment; 4) Research project, development and implementation of a robot for the performance of surgery procedures of laparoscopy, particularly for the manipulation of the endoscope.

In practice, this result reflects partnerships between the Health Ministry and the

universities, aimed at the development and production of technologies able to assist the health needs of the population, since it encourages the transformation of ideas into processes and protocols that may be incorporated by the public health system and by the systems of the private health dynamics. Divulging these

[...] experiences will allow managers to observe good practices and opportunities for improvements in this arduous and risky activity – the foment of research, development and innovation in health assistance²⁴.

For instance, concerning medical equipment, the biomedical engineering is responsible for the technical part of the production, and turns to be the leader in the process. However, for this sort of development, besides the technical/technological part, other activities are fundamental, such as: planning pre- and clinical researches; technical meetings with Anvisa (discussions), systematic revisions with meta-analyses; workflow; economic, social and political impacts; social groups involved; information systems on health and epidemiological surveillance.

In this context, one may ask: in Brazil, does the transformation of technology-based findings into clinical and health practices for the population reach satisfactory indexes? Are the efforts to take research results to hospital beds being consolidated? Answers are not easy, but for improving those transformations, processes in Translational Research (PT) and epidemiological research must be consolidated in the genesis of Technology-Based Research Projects.

Over and above the contexts of techniques, processes and technologies, political, social and human aspects must be present in Translational Research activities on health, aiming at the transposition of the Death Valley²³. PT goes beyond the inter-disciplinary process in science, technology and innovation and, according to Guimarães²⁴,

[...] it should take into account aspects related to scientific research, technological development, clinical research, the industrial productive process, the world of regulation, the commercialization of products and, last but not least, the health systems themselves.

According to Reis²⁵, Epidemiology,

[...] is a fundamental discipline in the field of public health oriented to the comprehension of the health-disease process in the realm of populations (societies, collectivities, communities, social classes, specific groups etc).

The interaction between these doings and practices in health, joined along with the biomedical engineering, would increment technological research activities with a marketing bias, thus increasing the chances for the assimilation of products, processes and protocols by the health systems.

In the same direction, the Brazilian scientific scenery demonstrates that universities have an important role in the processes of development and production of technologies, often surpassing the processes performed by the private sector. However, it is clear that Brazilian academy, despite its good reputation concerning scientific and technological development, evidences reduced participation in the transference and/or licensing of new technologies,

In fact, the classification of technologies as low, medium and high complexity is itself static from the Ceis perspective of, since the innovation process is, by definition, a technical, institutional and social process²⁰. For instance, in the introduction of a new vaccine, the development of the product is only part of the process. The system's organization, training people, the society's adhesion to the vaccine-prevention (the anti-vaccines movement is currently one of the main barriers beyond technology) are interlinked and inescapable dimensions. The Ceis must emphasize this systemic perspective, otherwise the society will

have useless products. The Ceis' translational perspective thus requires the articulation of all the dimensions of innovation, surpassing the cognitive barriers of the innovation process.

From this perspective, one can catch a glimpse of the insertion of actions linked to PT promoting the approximation of social actors (public policies, health managers, health operators, regulatory organs, health systems) to the context of innovation in health in the reliance of reduction of iniquities in the health sector.

In a similar direction, the dynamics of the health productive system that aims at transforming ideas into products able to be assimilated by the SUS, will necessarily involve innovation and Ceis strengthening²⁰. However, it is forceful to analyze the 'expectation horizons'. Koselleck²⁶ coined these two expressions, acknowledged as historical categories, to understand the historical time that intertwines past and future lines.

The Ceis concept⁶ can strengthen the interaction between government, university and private initiative, as it warrants, through investments, safe conditions for the technological innovation scenery and also from the perspective of social technologies. When releasing financial support for a technological research for the development and production of medical equipment, the Health Ministry characterizes a space of experience, that is, an environment able to generate innovation that goes beyond the research laboratories. An expectation horizon is progressively established and must cross the Death Valley to access the market; and next, another challenge: going through the evaluation of health regulatory organs to make sure the final equipment fulfills the needs of the health system.

Experiences for PT from the PDP

In the context of foment policies to Brazilian Ceis, Partnerships for Productive Development (PDP) can be structured as an instrument for

strengthening PT, resorting to SUS' buying power to stimulate the national production of products considered as strategic for policies directed to both the assistance and the national public production.

It can be inferred that the PDP could not be the PT target, due to their perspective of use of technologies obtained through technology transference, not through basic research. However, those projects are expected to stimulate new developments and incremental innovations that are developed from improvements identified in the processes of knowledge internalization in the country. Nevertheless, as demonstrated in the innovation literature, market and return horizons are the most powerful tools for leveraging the production involving incremental and radical innovation – a typical translational instrument rarely seen as such, as it links production, innovation and public acquisitions, using the State's buying power to make products accessible to the society.

As to the governance in the realm of the Health Ministry, it is urgent to align the support areas involved with the PDP, concerning both acquisition actions and development efforts of the local industrial capacity and its maintenance in environments of conjunctive changes – particularly as to policies. It would not be reasonable for the Brazilian government to invest public financial resources in the development of the local productive basis supported by State policies of endogenous bases and, and, on the other side, stimulate imports of rival products in the short term.

The best use of existing tools, policies and programs to support Ceis can be accomplished with transversal and inter-institutional foment programs and strategies to amplify the results. Thus, when aiming at improving the PT, and mirroring the practice of the Technological Fund of the National Development Bank (Funtec/BNDS), it is suggested to resort to the participation in processes of summons elaboration and public calls; of Finep (Innovation and Research Financing); EMBRAPPI (Brazilian

Company of Industrial and Research and Innovation); SCTIE (Science, Technology and Strategic Supplies Secretariat) and CNPq (National Council for Scientific and Technological Development).

The main regulatory, political and structural challenges for Ceis involve the regulation and implementation of recent decrees (CT&I and PNITS) and better articulation of government organs for the formulation of public policies and fomenting actions and financing P&D and PD&I, considering the regulatory agencies – for instance, the National Sanitary Vigilance Agency (Anvisa), State and Municipal Sanitary Surveillance agencies (local visas), the Ministry of Agriculture, Cattle breeding and Supplying (Mapa), National Technical Commission of Biosecurity (CTNBio), National Council for the Control of Animal Experimentation (Concea) and Council for the Management of Genetic Patrimony (CGEN). Better interaction between inter-institutional agents allows for the best performance in the development of new products on their route to be used by the society.

Investment in basic, technical and specialized training of human resources is required to take part in the diversified chain of the IECH, to attend the actual needs of both the pharmaceutical and the health industries (services, health products etc.), along with the development of expertise related to the regulation of products and processes.

A revision of the current legal framework of the PDP is also required for continued improvement, reduction of deficient cases, such as the definition of the process and administrative flow for the evaluation by technical and deliberative commissions; and also for the internalization of technologies through the finalization of technology transference processes. Governance structures in the realm of the Health Ministry must technically evaluate the regulatory merit, so as to make policies successful when following regulatory recommendations, as well as the proposal of a better alignment between the research and the use of solutions by the society, according to the translational perspective of knowledge.

Final remarks

The main or best forms of action for the development of Brazilian Ceis involve a clear definition of a national strategy and of coherent and stable policies in a context of strong global asymmetries, conjuncture and political changes in the country, and constitution of practices that are typical of oligopolies, which limit the access to essential health products. It is, in fact, this systemic and structural perspective that, beyond generic conceptions and devoid of analytical contents, contributes to the establishment of a favorable environment, with juridical security and predictability for actions to strengthen the Ceis as an opportunity for the development of innovation and fulfillment of the social needs and the Unified Health System (SUS) in Brazil.

This definition of a strategic environment can also contribute to attract investments and to internationalize the Ceis in the perspective of global health, to stimulate both internal and international demands for new products and processes that incorporate social benefits. The current structure of development of products and services in the Ceis requires an articulation ruled by policies and proposals, besides action abilities of the actors involved and of interested institutions. Summing up, it can be stated that strengthening the Ceis is in the strategic nucleus of the perspective of the Translational Research, as it places, in the same strategy, the knowledge, the production and the society's access to products and services required for health and welfare, articulating the context of scientific, academic, industrial and health services development in the country.

Joining the agendas of current and mainly future needs of an universal, integral and equalitarian system requires an integrative locus – the Ceis –, so as to ensure that we will not run a 'poor SUS for the poor'. As innovation and production are inserted as the central axes of public policies for the SUS, the paradigm that separates the assistance to social needs

from the generation of academic and institutional knowledge shall be extinguished.

Should there be no strategic thinking on the future of IECH and tools to make use of the research that brings closer to each other the creation of innovative products and practical solutions for the citizens, the country will not overcome the dependence and vulnerability of the system, thus breaking the productive bases on which the translation would occur to make universal access possible.

Collaborators

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