Interview: Marco Fireman – Vice-Minister and Chairman, National Commission for the Incorporation of Technologies (CONITEC), Brazil



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Marco Fireman, vice-minister and chairman of the

National Commission for the Incorporation of Technologies (CONITEC); a board that advises the Brazilian Ministry of Health on the inclusion of new health technologies in the public healthcare scheme, discusses the crucial role of civic participation in public consultations, and documents the numerous actions undertaken to foster it. Last, he calls for a more efficient use of the government's resources and for stronger innovation incentives from the government.

Could you give our readers an introduction to the National Commission for the Incorporation of Technologies (CONITEC) and clarify its role within the Brazilian health system?

The National Commission for the Incorporation of Technologies (CONITEC) was created under federal law in 2011. Since 2012, it advises the Ministry of Health with regard to the incorporation, exclusion, or alteration of all health technologies in the Sistema Único de Saúde (SUS) *[the world's largest public healthcare system, ed.]* as well as in the constitution or alteration of clinical protocols and therapeutic guidelines.

The systematic study of the benefits, risks, and costs of a new incorporation is highly technical and scientific work. To this end, a team of specialists from the best universities and Brazilian hospitals

carries out evaluation studies of health technologies on behalf of CONITEC. Additionally, the Secretariat of Science Technology and Strategic Inputs has created the Department of Management and Incorporation of Health Technology (DGITS), which acts as an executive secretariat providing technical and administrative support to the CONITEC Plenary.

It should be noted that the establishment of CONITEC was highly innovative in Latin America. Indeed, Brazil is the only country in the region to strictly base the selection of new technologies entering the public health system on scientific evidence.

Which perspectives come into play when assessing the inclusion of health technologies into the SUS?

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The incorporation and exclusion of technologies in SUS is based on the presence of scientific evidence demonstrating that the technology is at least as effective and safe as its counterparts already included in the scheme. Additionally, holistic economic evaluations should prove that the product has an equal or greater positive impact for the population. Lastly, CONITEC takes into account the patient's perspective, with aspects such as dosage convenience, social and ethical impact, and unmet needs.

In parallel to HTA (Health Technology Assessment) criteria, CONITEC has also considered organizational aspects, such as logistics, accessibility, training, and sustainability, which appear to be critical factors in a country like Brazil with important regional differences.

What have been some key technologies that were recently included into the SUS after receiving positive reviews from CONITEC?

The list of products recently included in the SUS corresponds to the diversity of our population's needs. We have included treatments for widely prevalent diseases around the country such as Hepatitis C, products to facilitate treatment adherence in the case of Alzheimer's disease, such as Rivastigmine® Patch, as well as products indicated in the case of rare diseases such as Tobramycin® for cystic fibrosis and Laronidase® for Mucopolysaccharidosis I among others.

Why are such health innovations so important to Brazil?

Brazil invests around BRL450 billion (approx. USD 140 billion) in health. Around 50 percent of that sum is allocated to the development of new drugs, state-of-the-art technologies, and biologics. However, the efficient management of resources – lack thereof – hinders the significance of health

outcomes in terms of savings, access, and services.

Investment in innovations should be prioritized – but they remain expensive. R&D should be seen as a means to reduce the cost of innovative drugs in the country. In doing so, this would alleviate the financial pressures on the payer and improve the service delivered to Brazilian patients.

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Why is civic participation in public consultations crucial and how have you fostered it?

The evaluation of technologies does not limit itself to a scientific analysis. A sound technology evaluation will also encompass ethical and equity considerations. More specifically, transparency and social participation are crucial to ensure that the interests of patients and Brazilian society are at the centre of the process of evaluating new technologies. Therefore, we are looking to pioneer a bottom-up participatory process of evaluation.

CONITEC's legal framework already provided for the inclusion of civic participation in all matters under analysis, but in CONITEC's first two years of operations, very few citizen participants would engage with the evaluation processes, demonstrating that the taxpayer had not understood what was at stake.

Along with the realisation that only a bold communication plan would help us promote social participation in the process of technological incorporation, we developed a digital platform to collect public reviews and opinions of consultations. This tool has been running since 2015 and has allowed us to elaborate and update our clinical protocols.

The same year, and with the aim of fostering the general public's understanding of CONITEC's action, we created an initiative called "Reports for Society". This document summarizes CONTECT's evaluation reports in simple terms. Out of the 220 public consultations conducted by CONITEC, 60 have been converted into the "Reports for Society" format. We are looking forward to extending the coverage of this format to a larger portion of the evaluation reports conducted by CONITEC. In turn, these initiatives should help increase the public's willingness to participate in such evaluations.

What would you highlight as your main achievements since August 2016 and what are your strategic priorities to further strengthen CONITEC's processes, transparency, and technical expertise moving forward?

CONITEC has actively sought to increase greater civic participation in the evaluation of new drugs and processes. For example, in 2016, we published a framework, available on our website, to help the general public on how to take part in consultations. Additionally, that same year, we set up a monthly newsletter, started interacting on social networks such as Twitter or YouTube, created a mobile application, and launched “CONITEC in Evidence”, a bi-weekly videoconference program on health technology assessment.

Thus, we witnessed a fourfold increase in the number of regular contributors to CONITEC’s public consultations. Not only do we have 30 thousand people regularly contributing to our public consultation, the relevance of their contributions has also improved. As a result of this increased participation, CONITEC’s recommendations on the inclusion, exclusion and alteration of the SUS list are better than in the past.

Additionally, CONITEC’s evaluations have been improved, leading to total or partial reconsideration of the initial recommendation on certain occasion. Before 2014, only six subjects had their recommendation changed due to the contributions of the society. Since we took upon ourselves to help the general public contribute, 16 recommendations were at least partially revised.

Nevertheless, the organization does face challenges like difficult case assessments. Indeed, the evaluation of Brazil’s most judicialized drug, abiraterone acetate, is underway, and CONITEC will be evaluating treatments for rare diseases such as Pompe disease, Fabry, Mucopolysaccharidosis II, and Familial Amyloid Polyneuropathy in the coming months. These treatments generally come at a very high cost for the payer, and for the Ministry of Health as a consequence of the judicialization. More specifically, since healthcare is considered a constitutional right in Brazil, the government regularly face lawsuits with regards to the inaccessibility of certain treatments in the country. In many cases, the government has to pay for the treatment of patients, regardless of whether they are included in the SUS or not. Judicialization represents an imposed legal distortion contrary to the intent of careful evaluation and universal access to healthcare. The high cost associated with this loophole negatively impacts budget planning and we have made a major effort in the Ministry of Health to reduce the judicialization.

I am also looking forward to implementing a more integrated technology evaluation in terms of carrying out an overall assessment of a specific disease. With this regard, we are reinforcing our technological horizon monitoring as well as the opportunity cost of withdrawing technologies with several therapeutic alternatives from the SUS.

What are the main development options you envision to further strengthen partnerships with other agencies within Brazil's Ministry of Health as well as on the international stage?

CONITEC would not have been able to improve the quality of its contribution to the health system in such a short period of time without leveraging the numerous partnerships it holds with institutions dedicated to the evaluation of technologies.

The collaborative efforts of CONITEC with INAHTA (International Network of Agencies for Health Technology Assessment), GIN (Guidelines International Network), EUROSCAN (The International Information Network on New, Emerging and Obsolete Health Technologies), HTAi (Health Technology Assessment International) and RedETSa (Health Technology Assessment Network of Americas) have allowed CONITEC to be a part of the Health Technology Assessment Patient Involvement book presented in Rome at the 2017 HTAi annual congress. The book reports on the Brazilian experience and is likely to affect how other Latin American countries act on the matter.

Currently, CONITEC is considered the reference for Latin American technology assessments structures, and also represents its regional peers within the technology assessments structures.

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