From Regulatory Compliance to Process Improvement in Healthcare

Some of the authors of this publication are also working on these related projects:

Project   Methods, Techniques and Tools for Rigorous Development of Open Distributed Systems View project

Project   Object-based compiler development View project

From Regulatory Compliance to Process Improvement in Healthcare

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# From Brazil to the Rest of the World

Talk Overview

1. Introduction;

2. The Brazilian Healthcare (Equipment) Sector Regulation;

3. Research Data and Methodology on Regulatory Compliance;

4. Healthcare Equipment Regulatory Compliance Findings;

5. Regulatory Process Improvement Cases;

6. Learned Lessons and Take-Aways.

1. Introduction: The Healthcare Ecosystem in Brazil
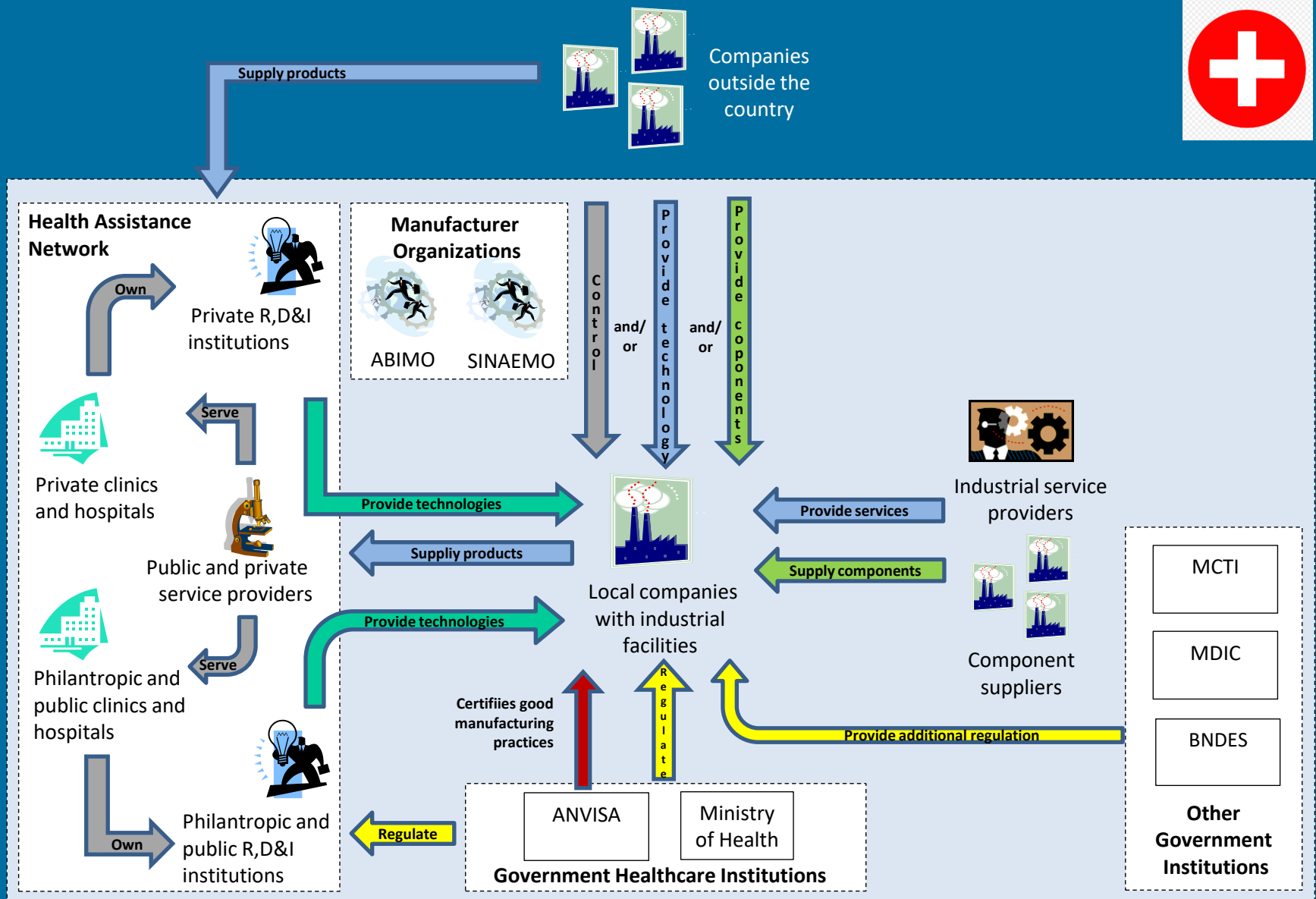
1. Introduction: Healthcare Regulations

- Healthcare is an important economic sector in every country due to its contributions to social and economic development (cf. UNDP Sustainable Development Goals);

- However, few sectors are as heavily regulated as the healthcare sector:

  👍 Public welfare and corporate advantages (benefits);

  👎 Sometimes excessive, costly and increase time-to-market;

- Moreover, the healthcare regulation is often goal-oriented:
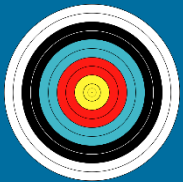
  This means that the regulation embodies propositions to maximize compliance benefits, provided the achievement of previously established public policy goals.

1. Introduction: Healthcare Equipment Compliance

- Regulatory texts (laws, standards and contracts) frequently refer to system and software requirements (technical requirements in the regulation);

- Are there any connections between regulatory compliance and technical requirements in healthcare regulations?

  Specifically, is regulatory compliance <u>time-to-benefit</u> dependent upon <u>technical requirements in regulations</u>?

  We conducted <u>an exploratory case study</u> on the periods of time taken by companies to obtain benefits due to their compliance with sanitary control, tax benefit and financial incentive regulations;

- This empirical study answers these questions focused on <u>healthcare equipment companies</u> established <u>in Brazil</u> with businesses in the <u>diagnostic imaging equipment segment</u>;

1. Introduction: Diagnostic Imaging Equipment

X-Ray equipment, mamographs and angiographs

Ultrasound equipment

Computerized tomography equipment

Magnetic resonance equipment

1. Introduction: Regulatory Process Improvement

- Can healthcare equipment goal-oriented regulatory processes be better understood and improved?

  Specifically, are there opportunities to <u>improve healthcare equipment regulatory processes</u> by applying process mining techniques?

- We answer these questions by presenting here <u>two process improvement cases</u> performed in recent years, based on a high-level mapping of healthcare equipment regulatory processes in Brazil.

- These cases contribute to <u>better balance public policy goals and corporate benefits</u> in goal-oriented regulatory processes;

2. The Healthcare Regulation in Brazil

- The Health Regulatory Agency (ANVISA) is in charge of formulating and enforcing sanitary control measures on the production, marketing and usage of products and services in Brazil;

- The Ministry of Development, Industry and Commerce (MDIC) and the Ministry of Science, Technology and Innovation (MCTI) formulate, analyze and grant tax benefits;

- The Brazilian Development Bank (BNDES) provides funding for this sector;

- We study three different types of regulation here:

  Healthcare Sanitary Control (ANVISA);
  Financial Incentives (BNDES);
  Tax Benefits (MCTI/MDIC);

2.1 Healthcare Sanitary Control Measures

- Law 6.360/1976 (SSP) establishes health protection and sanitary control measures. It provides a definition of healthcare product registries:

(SSP 3.X) <u>Registry</u>: Registration, in the proper book, after the concessionary order of the head of the Ministry of Health organizational unit, under the order number, of the products referred to in (SSP), with their names, manufacturers, provenances, purposes and other elements;

- Important <u>requirements on registry processes</u> and on the production, marketing, sales and delivery of <u>healthcare products</u> are:

(SSP 12) No product covered by (SSP) can be manufactured and commercialized before registration;
(SSP 12.§1) Registrations are valid for 5 years and may be revalidated under the same registration number;
(SSP 12.§4) Registration and revalidation only come into effect after publication in the Official Press;

2.1 Healthcare Sanitary Control Measures

- There are <u>requirements on companies</u> that deal with medicines/equipment:

(SSP 50) The operation of each company will depend on the Ministry of Health authorization in view of the indication of industrial activity, nature and species of products, and insurance of its technical, scientific and operational capacity;

(SSP 53) Companies are obliged to maintain technically qualified personnel to cover production species in their establishments;

- ANVISA Resolution 185/2001 (REG) regulates the creation, change, revalidation and cancelation of <u>registries</u>. Important requirements are:

(REG A 1.2.1) Medical products are classified at levels I, II, III or IV depending on the risk to the consumer, patient, and operator;

(REG 4) The manufacturer/importer shall present on the equipment surface: a) manufacturer identification; b) equipment identification; c) serial number; d) ANVISA registration number;

2.2 Financial Incentive Regulation

- BNDES finances the development of Brazil using the Workers Assistance Fund (FAT) as its main source of funding. FAT allows BNDES to apply resources only in <u>financing projects and products with local content</u> <u>or</u> that <u>comply with local value-addition basic production process</u> (PPBs);

- BNDES performs <u>accreditation</u> activities: officially recognizing that a company has the manufacturer status and that a product is a machine, equipment, component or industrial system which meets the requirements to obtain BNDES funding;

- A BNDES Board of Directors (BoD) Resolution <u>regulates the accreditation process</u>. (CFI) It establishes obligations for manufacturers such as:
    - **(CFI 4)** Take responsibility for product quality, warranty, price, technical assistance, delivery times and customer assistance;
    - **(CFI 5)** Ensure no violation of intellectual property rights arising from accreditation requests or accredited products;
    - **(CFI 16)** Only sell with BNDES financial support products which comply with the descriptions provided during accreditation;

2.2 Financial Incentive Regulation

- In requests of accreditation due to the <u>attainment of indexes (≥ 60%)</u>:

(CFI 17) For the accreditation of a product based on its local content, value and weight indexes must be attained together:

(CFI 10) The value index is calculated as $I_v = (1 - X/Y)*100$, where X is the foreign content cost and Y is the sales price;

(CFI 11) The weight index is calculated as $I_w = (1 - X_w/Y_w)*100$, where X_w is the weight of imported components and Y_w is the product weight;

- In requests of accreditation due to the <u>fulfillment of PPBs</u>:

(CFI 18) Only Information and Communication Technology (ICT) products in the scope of Law 8.248/1993 (ITL) qualify for accreditation due to the fulfilment of PPBs;

(CFI 18.I) PPB fulfilment is evaluated based on tax rebate authorization documents (called habilitations) jointly issued by MCTI/MDIC, and on other documents requested by BNDES;

2.3 Tax Benefits
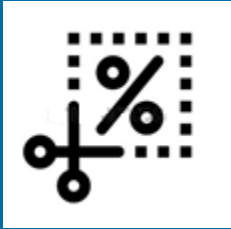
The Brazilian Law 8.248/1993 (ITL) <u>ensures rebates of manufacturing taxes on ICT goods</u> in exchange for the application of percentiles of corporate revenues in R,D&I activities, so long as production steps are performed according to some PPB;

- Decree 5.906/2006 (ICR) defines that <u>joint ministerial ordinances published in the Official Press establish PPBs for ICT products</u> and also that <u>companies can claim tax rebates</u> by sending requests to the responsible ministries;

- In turn, the MCTI/MDIC Ordinance 101/1993 establishes a <u>generic PPB</u>:
  (GPP 1) ICT products manufactured in the country have local added value only if they satisfy the following production process steps:
  (GPP 1.I) Assembly and welding of all electronic components on printed circuit boards (PCBs);
  (GPP 1.II) Assembly of electrical/mechanical parts, totally disaggregated at component level;
  (GPP 1.III) Integration of PCBs, electrical and mechanical parts, assembled according to (GPP 1.I-II), in order to form the final product;
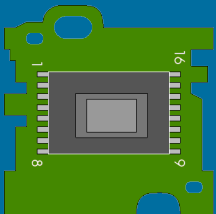
2.3 Tax Benefits

- It is possible to seek compliance with PPBs established in other ordinances:

Mnemonic	Equipment Model/Category	Ordinance #	Date
GPP	Any ICT Equipment	101	07/04/1993
CT	Computerized Tomography Equipment	24	09/02/2010
MRI	Magnetic Resonance Imaging Equipment	26	09/02/2010
DUS	Doppler Ultrasound Equipment	256	21/08/2013
FXR	Fixed Digital X-Ray Equipment	19	28/01/2014
MXR	Mobile Digital X-Ray Equipment	24	05/02/2014
PET-CT	Positron Emission Tomography Equipment	26	05/02/2014
NA	Other Not Covered by the PPB Legislation	-	-

- These pose distinct production requirements on each kind of equipment:
  (FXR/CT) Locally mount connections with X-Ray emission tubes and assemble detectors, as well as align them in relation to each other;
  (DUS) Buy or produce, according to respective PPBs, transducers and PCBs implementing signal detection, processing and output functions;
  (MRI) Locally assemble the magnet and fuel the hydrogen coolant;
- Each of these ordinances also requires local software installation and configuration. They also require that computers, printers, power generation/ management/distribution systems are manufactured according to PPBs;

3. Research Data and Methodology

- First, we collected all the documents related to the <u>diagnostic imaging equipment regulation</u> in force in Brazil until 2017 (already presented);

- Then, we adopted the business intelligence solutions of BNDES to obtain the sales financing of diagnostic imaging equipment between 2008 and 2017 (correspond to 50-80% of the actual sales). The manufacturers were also requested to inform additional sales performed without financing;

- We also <u>collected and cleaned administrative records</u> from many sources:

  1. Accredited companies and products:
     `www.bndes.gov.br/SiteBNDES/bndes/bndes_pt/Galerias/Convivencia/ Credenciamento_de_Equipamento/conteudo.htm`

  2. Registered companies and products:
     `consultas.anvisa.gov.br/#/saude`

  3. Companies and products with PPB tax benefit habilitation:
     `www.mctic.gov.br/SISEPIN/leiDeInformatica/empresasHabilitadas`

3. Research Data and Methodology

- We performed <u>data adjustments</u> to recognize under a company the tax benefit habilitations issued to subsidiaries. Also, we recognized under some companies the registries, habilitations and accreditations granted to other entities, due to merger and acquisition processes that happened in the studied period;

- Then we applied a <u>temporal filter</u> to generate our samples only with data between 2008 and 2017, due to regulatory transitions: (REG) was passed just in 2001, (ICR) in 2006 and BNDES adopted PPB as accreditation criteria in 2007;

- The demographics of the studied companies and products is:

Company	Origin	Product #	Product Types	PPBs
A	South America	8	DUS	Yes
B	South America	3	Other	No
C	South America	1	Other	No
D	North America	11	CT,DUS,MRI MXR	Yes
E	North America	1	FXR	No
F	Europe	16	CT,DUS,FXR,MRI,Other	Yes
G	Europe	12	CT,DUS,FXR,MRI	Yes
H	Asia	8	CT,DUS,MRI	Yes
I	South America	2	Other	No

3. Research Data and Methodology

- We also formulated the following definitions of <u>relevant (event) dates</u>:

d_e^*: Establishment of a PPB;

d_h^*: Tax benefit habilitation;

d_r: Registry of an equipment;

d_a^*: Accreditation of an equipment;

d_{fs}^*: First sale of an equipment with financing;

d_{os}^*: First sale of an equipment without financing;

$d_s^* = min\ (d_{fs}, d_{os})$: Date of first sale;

- We then coined definitions of calculated <u>time-to-benefit measures</u>:

$\Delta_{eh} = d_h - d_e > 0$: Time from PPB establishment to habilitation;

$\Delta_{rh} = d_h - d_r$: Time from registry to habilitation;

$\Delta_{ra} = d_a - d_r$: Time from registry to accreditation;

$\Delta_{ha} = d_a - d_h$: Time from tax benefit habilitation to accreditation;

$\Delta_{afs} = d_{fs} - d_a > 0$: Time from accreditation to first sale with financing;

$\Delta_{ros} = d_{os} - d_r > 0$: Time from registry to first sale without financing;

$\Delta_{rfs} = \Delta_{ra} + \Delta_{afs} = d_{fs} - d_r > 0$;

$\Delta_{rs} = min\ (\Delta_{rfs}, \Delta_{ros})$;

4A. Regulatory Compliance Data Analysis

- We arranged our measures in a <u>factorial design</u> through a correlation matrix. Some are correlated by definition, so we investigated the other ones;

- Observations of measures are <u>statistically independent</u> from one another. This allowed us to perform <u>statistical tests</u> to determine whether distinctions in observations happen randomly;

- Our <u>data samples</u> do not follow a <u>normal distribution</u> and are <u>arranged in groups of different sizes</u>. The adoption of <u>non-parametric</u> tests were required;

- We applied <u>Kruskal-Wallis tests</u> to determine differences between group means. They rank all observations and compare group average ranks. The <u>null hypothesis</u> is that all groups have the same mean (that is, the same average rank). The <u>main hypothesis</u> is that some groups have distinctive means;

- We also performed <u>post-hoc variance analyses</u> to identify groups which are significantly different from others. We used a significance level (LoS) of 0.05;
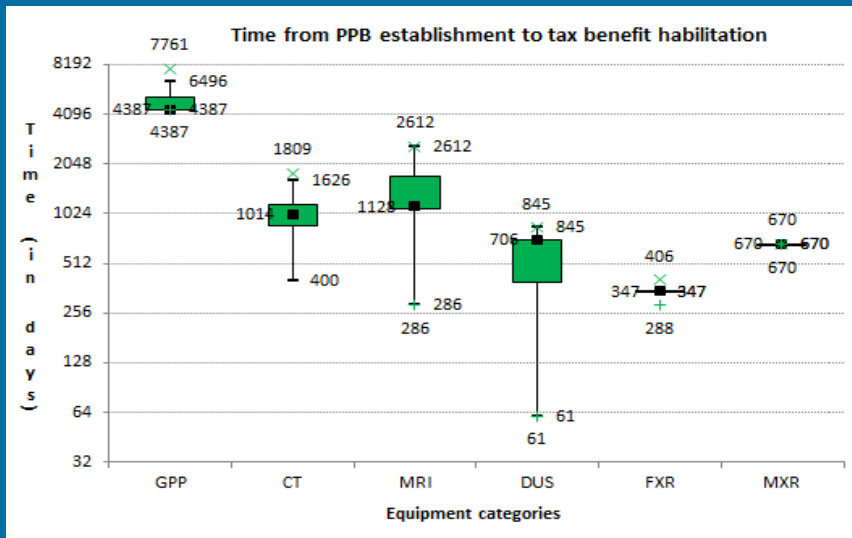
4B. Regulatory Compliance Research Findings

1. Tax Rebate Time-to-Benefit:

(RQ1) Does tax rebate time-to-benefit (Δ_{eh}) depend on the technical requirements posed on diagnostic imaging equipment?

Our statistics:

- 54 observations in 5 groups;
- H = *30.5974* with 4 degrees of freedom;
- p-value = *0,000004 < LoS*;
- Post-hoc: (GPP) ≠ (DUS) ≠ (CT+MRI);

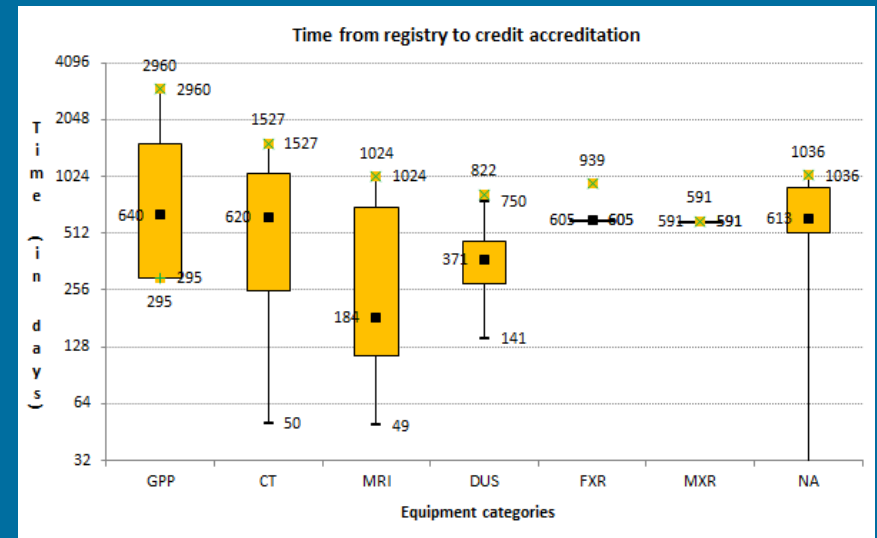**Box-plot of tax rebate time-to-benefit measures**

2. Credit Time-to-Benefit:

(RQ2) Does credit time-to-benefit (Δ_{ra}) depend on the technical requirements posed on diagnostic imaging equipment?

Our statistics:

- 55 observations in 6 groups;
- H = *6.2915* with 5 degrees of freedom;
- p-value = *0.2788 ≥ LoS*;
- Δ_{ra} average was 565 days and standard deviation 484 days;
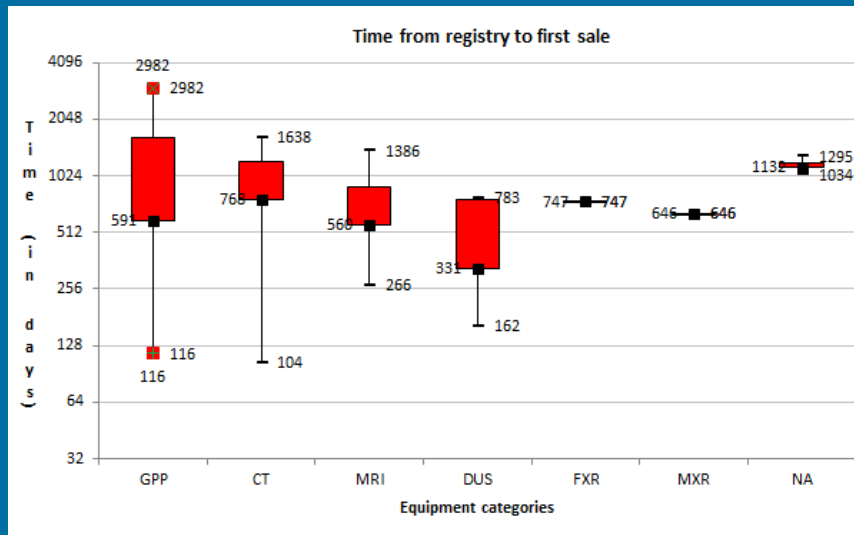

Box-plot of credit time-to-benefit measures

4B. Regulatory Compliance Research Findings

3. Market Entry Time-to-Benefit:

(RQ3) Does market entry time-to-benefit (Δ_{rs}) depend on the technical requirements posed on diagnostic imaging equipment?

Our statistics:
- 62 observations in 6 groups;
- H = *9.1642* with 5 degrees of freedom;
- p-value = *0.1027 ≥LoS*;
- Δ_{rs} average was 734 days and standard deviation 536 days;

Box-plot of market entry time-to-benefit measures

4. Threats to Validity:

The main threats are internal ones, related to data collection, data adjustment and derived data computation:

- We adopted multiple and sometimes seemingly divergent data sources;

- Data collection followed a sequential procedure, not random sampling;

- Adjustments were necessary to deal with M&A transactions;

External validity was not among our concerns, because the context of study was just local to the Brazilian economy.

5A. Regulatory Process Mapping

The low level of abstraction was evident in our empirical study: the underlying regulatory processes were hidden underneath statistical models and analyses;

So we considered process models obtained from mining, They are used to describe business/regulatory processes, guide automated executions, communicate with stakeholders etc;

- In process mining, we use the following terminology (cf. van der Aalst 2016):
    1. A case is a process instance, that is, an execution of a process;
    2. An activity is a well-defined task in a process model;
    3. An event is an occurrence of a process activity;
    4. A trace is an ordered sequence of process events;

- Here, each case corresponds to the lifecycle of an specific diagnostic imaging equipment. The studied activities correspond to the relevant events that may happen during the equipment lifecycle;

5A. Regulatory Process Mapping

- Our event log is an orthogonal aggregation of data in our original dataset, containing 62 cases and 251 events, corresponding to the activities of registration, accreditation, habilitation and sales;

- We adopted the ProM toolkit to deal with event logs. ProM imported our event log using the Smart Importer Tool (adopts the IEEE 1849-2016 XES Standard). The ProM Causal Activity Discovery Tool was also used.
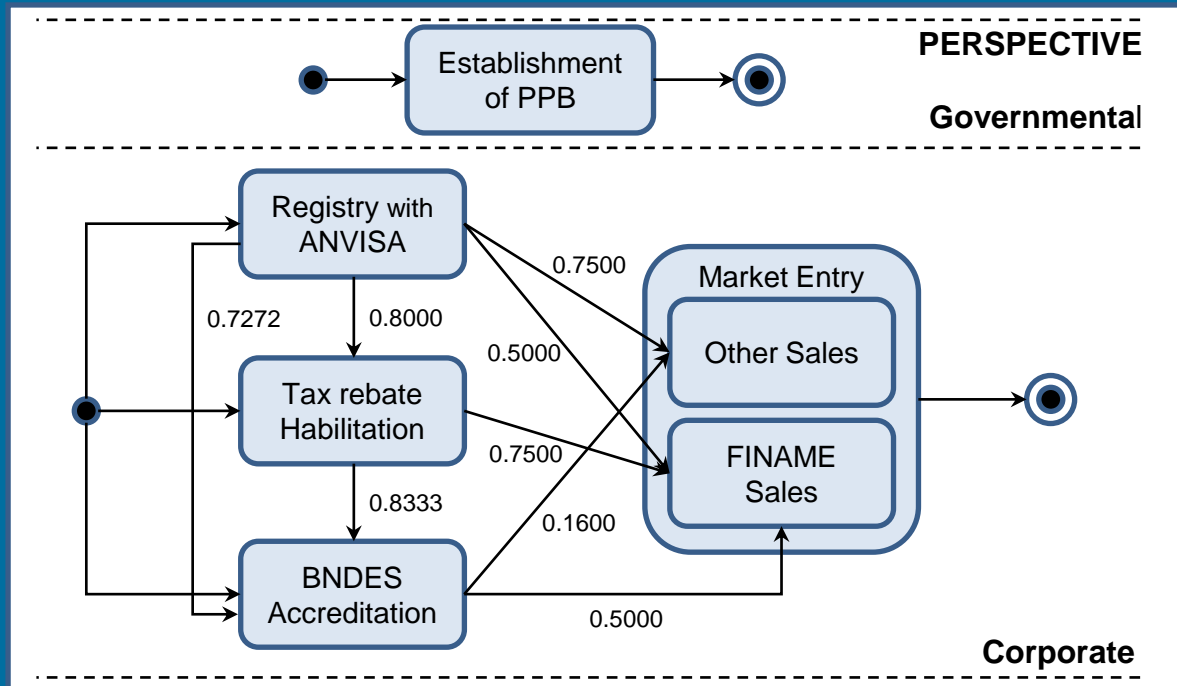
5B. Regulatory Process Improvements

- From 2015 to 2017, BNDES conducted studies to:

    1. Reduce the duration of benefit granting processes;
    2. Increase their efficacy towards public policy goal achievement;

- The following actions were then triggered within BNDES:

    1. Process mapping and requirement elicitation activities;
    2. New accreditation regulation proposed to the BoD of BNDES;
    3. Digitization of the submission and analysis of requests;

- All the proposed improvements became in force in January of 2019, with:

    1. Change from the index attainment accreditation criteria to another one based on a product structure index plus elective quantifiers;
    2. Implementation of automated systems and elimination of paperwork;

5B. Regulatory Process Improvements

Since 2015, there has been a dispute mediated by the World Trade Organization (WTO) on the compliance of the PPB regulation with international trade agreements and standard commercial practices;

- In January of 2019, the Appellate Body of the WTO settled the discussion:

  1. The PPB legislation is admissible, provided the elimination of exemptions or reductions of taxes affecting the competition between similar products;
  2. The nested or recursive definitions in PPB establishment ordinances should be eliminated;

- The following ongoing actions have been taken by MCTI/MDIC:

  1. Change of production taxes by general tax credits in the regulation;
  2. Revision of established PPBs to eliminate nested PPB requirements;
  3. Adoption of scoring in PPBs in a way similar to the new BNDES accreditation criteria;

6A. Lessons for Medical Equipment Compliance

- Such process improvements have benefited the medical equipment segment:

    1. The introduction of quantifiers in the BNDES accreditation process and the possibility of satisfying all of them was considered beneficial, according to manufacturer organizations;
    2. The practice of issuing public consultations before revising and changing PPB establishment ordinances facilitates their enforcement and public policy goal achievement;
    3. There is an opportunity to formulate a new PPB covering the commonalities of the studied PPB establishment ordinances, bringing more benefits to diagnostic imaging equipment companies;

- As a consequence of these improvements:

    1. Changes in BNDES accreditation significantly reduced request processing times (which are now measured in days, not months);
    2. New versions of FXR and MXR were already published in the Brazilian Official Press in 27 August 2019 and their requirements can already be fulfilled;

6B. General Lessons Learned

- In more general terms, these improvements produced the following results:

1. There was an increase in the cooperation among government institutions and private companies involved;

2. The applicable regulation has been made more data-oriented and goal-driven (goal-oriented regulations tend to be improved);

3. The regulation has become more straightforward, transparent and easily enforceable, thus ensuring legal certainty;

4. The effectiveness of respective public policies is expected to increase with the foreseen sensible reduction in time-to-benefit measures;
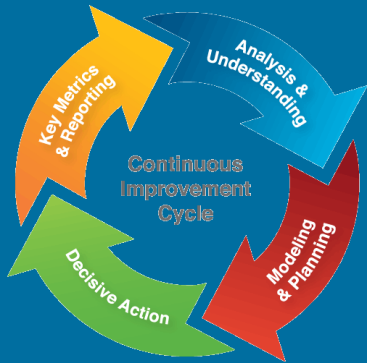
6C. Key Take-Aways

- Time-to-benefit measures sometimes depend on the technical requirements found in regulations of the healthcare equipment sector;

- Manufacturers of healthcare equipment should consider time-to-benefit measures in managing process and product variability due to economic reasons: access to tax benefits and funding;

They must be concerned not only with ensuring and analyzing compliance, but also with regulation dynamics, due to frequent regulation changes;

- Governments can effectively take advantage of process mining techniques to improve their regulatory processes;

Improvements in processes and regulations may contribute to cost-effectiveness and broader accessibility goals in healthcare;

- Society is the one who wins with regulatory compliance and process improvement!

To Probe Further

1. Carlos Henrique C. Duarte. How Long after Compliance Do You Benefit From Regulation? An Empirical Study on Diagnostic Imaging Equipment Requirements. *Proc. 41th International Engineering in Medicine and Biology Conference (EMBC 2019).* pages 41-47. Berlin, Germany. July 2019.

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