ISSN: 2047 - 0398
SPECIAL ISSUE – V|4|N|5|, January | 2015

COMPETENCES FOR INNOVATION IN ELECTROMEDICAL EQUIPMENT: A Brazilian Perspective

Alexandre Barbosa Marques, M.Sc. (*Corresponding author*)
Professor of Administration
Centro Federal de Educação Tecnológica Celso Suckow da Fonseca
Rio de Janeiro, Rio de Janeiro, Brazil. CEP: 20.271-110.
&
Doctoral Student, Graduate Program in Chemical and Biochemical Technology Processes
Universidade Federal do Rio de Janeiro (UFRJ) / Escola de Química (EQ)
E-mail: *proalexandre@gmail.com*

Adelaide Maria Antunes, D.Sc.
Professor of Graduate Programs
Universidade Federal do Rio de Janeiro (UFRJ) / Escola de Química (EQ)
&
Senior Specialist
Instituto Nacional de Propriedade Industrial (INPI)
E-mail: *aantunes@inpi.gov.br*

Flávia Chaves Alves, D.Sc.
Professor of Graduate Programs
Universidade Federal do Rio de Janeiro (UFRJ) / Escola de Química (EQ)
E-mail: *falves@eq.ufrj.br*

José Maldonado, D.Sc.
Professor of Graduate Programs
Fundação Osvaldo Cruz (FIOCRUZ) / Escola Nacional de Saúde Pública (ENSP)
E-mail: *jose.maldonado@ensp.fiocruz.br*

ABSTRACT

The aim of this proposed method for mapping the competencies for innovation required by Brazilian manufacturers of electromedical equipment is to help revert these companies' and Brazil's relative competitive disadvantage in the global medical, dental, hospital and laboratory equipment market. This industry has a growing structural trade deficit, which has a major impact on the country's future health policies. A critical analysis was conducted of a study by Alves (2005) in the light of the specific features of the business environment in which electromedical equipment manufacturers operate, which were identified through a literature review. As a result, a new list of basic competencies adapted particularly to these target companies' needs was formulated.

Keywords: *Competences for innovation. Electromedical equipment. Medical device industry*

1. INTRODUCTION

Identifying and understanding how innovation competences affect the competitiveness of electromedical equipment manufacturers is a way of helping companies and government entities responsible for health and the economy tackle the competitive disadvantages seen in the medical, dental, hospital and laboratory (MDHL) equipment industry as a whole. This article aims to identify the competences that companies producing electromedical equipment require in order to innovate.

The analysis presented here is based on the Health Industry Complex, which has proved to be a useful analytical tool for comprehending how the rationales of health and economics interact in the healthcare arena, which is now understood as having considerable economic, political, and social importance[1], with great potential for knowledge production and a distinctive production and innovation dynamic. Social concerns about the welfare of the population, the role of the state, and economic issues have a great influence on how innovations are developed and introduced to the market by medical, dental, hospital and laboratory (MDHL) equipment manufacturers (GADELHA *et al.*, 2012).

The Health Industry Complex, demonstrated schematically in Figure 1, encompasses three sub-systems[2], of which the mechanics, electronics and materials industry sub-system is the main focus of this article. This sub-system encompasses the MDHL equipment industry, which is highly dynamic in market, technology and innovation terms. Manufacturers of hospital and medical equipment constitute part of this sub-system, including electromedical equipment manufacturers, the target of this investigation.

Generally speaking, the MDHL equipment industry has a great influence on the healthcare services provided. It has a positive impact on the economies of developed countries, especially their trade balance, the number and size of the businesses involved, and job creation.

In view of the significance of its economic and social ramifications for Brazil, this industry has attracted the attention of both domestic and multinational companies, as well as government bodies, including the ministries of health, planning, and industry and commerce.

It is clear from the industry's trade balance, previously analyzed economic data, and a variety of prior studies (ABIMO/FGV, 2013; GADELHA *et al.*, 2012; ABDI, 2009; ABDI/CGEE, 2007) that Brazilian MDHL equipment producers as a whole[3] face a competitive disadvantage, especially when the equipment is more sophisticated, which, depending on the product in question, tends to be imported or produced locally by subsidiaries of multinationals.

Before Brazil opened its economy in the 1990s, the situation was less unfavorable because a number of products were manufactured inside the country. However, since then, Brazil has ceased to produce, for instance, implantable pacemakers, more complex laboratory apparatus (for the time), and radiological equipment, the production of which has been completely taken over by multinationals (MANFREDINI, 2006, cited in GADELHA *et al.* 2012). Broadly speaking, Brazil's MDHL equipment industry has proved unable to keep pace with technological progress, even as a follower[4]; it has demonstrated a relative incapacity to introduce more advanced technological innovations, even at a lag behind market leaders.

From 2003 a number of political and institutional measures were taken to support the mechanics, electronics and materials sub-system of the Health Industry Complex as a whole and the Brazilian MDHL equipment industry in particular. These included the Program to Support the Development of the Health Industry Complex, launched by the Brazilian Development Bank (BNDES) in 2007; the More Health program, launched in the same year by the Ministry of Health; and the Industrial Development Policy, launched in 2008 by the Brazilian president's office (GADELHA *et al.*, 2012).

Meanwhile, projections made in 2012 indicated that domestic demand would continue to grow: investments in health would rise as the national health system provided a broader offer of services, socio-economic group C expanded with the influx of people from lower income groups, and the population continued to grow and age (MARQUES *et al.*, 2013).

While expectations of increased demand could present an opportunity for MDHL equipment manufacturers, it is important to remember that opportunities like this "will not result in innovation unless the companies have the competences they need to respond" (TIDD *et al.*, 2008, p. 157).

Predictably, in 2013 the MDHL equipment industry's trade deficit rose, reaching US$4.16 billion (ABIMO, 2014), up on the 2012 figure of just over US$3.73 billion. The hospital and medical equipment sector recorded a deficit of US$97.74 million – over 20% of the total deficit that year[5] (FGV/ABIMO, 2013).

The method adopted for this study was documental research. The main sources consulted on the theory of competences for innovation were: François *et al.* (1999), Alves (2005), Landim *et al.* (2013), Marques *et al.* (2013), Gadelha *et al.* (2012), Pierone *et al.* (2010), Leão *et al.* (2008), and Gutierrez & Alexandre (2004). Sector reports were also analyzed, especially FGV/ABIMO (2013), IEMI (2010), ABDI (2009), and CGEE (2007). In addition, analyses were also made of the Ministry of Finance's Growth Acceleration Program, the Ministry of Health's More Health program, and the Ministry of Development, Industry and Foreign Trade's Greater Brazil Plan. Some technical regulations applying specifically to electromedical equipment and its manufacturers were also consulted.

The article is divided into three sections. The first contains the theoretical review, subdivided into a description and analysis of the MDHL equipment industry and a review of the concept of competences for innovation. The second section presents a proposed questionnaire for mapping competences for innovation, highlighting how it

should be adapted to take account of the specific features of the target industry. The third and last section sets forth the concluding remarks.

2. LITERATURE REVIEW

2.1. The MDHL equipment industry and electromedical equipment manufacturers

The MDHL equipment industry is extremely diverse, encompassing widely differing innovation, production and commercialization rationales. For this reason, the companies were classified in order better to organize and define the scope of the research. The ABIMO[6] classification was used for this purpose, which is based on what markets the companies operate in: hospital and medical equipment, implants, laboratory equipment, supplies, dental equipment, and radiological equipment. The hospital and medical equipment sector[7] includes the following categories (ABIMO, 2014):

- furniture (non-electrical): beds, tables, shelving, armchairs, cabinets, etc.
- electromedical equipment: operating tables, incubators, anesthesia machines, autoclaves, respirators, cardiac monitors, ECG machines, surgical lights, infusion pumps, dialysis equipment, diagnostic imaging equipment, etc.
- surgical instruments: tweezers, scissors, scalpel handles, forceps, etc.
- physiotherapy equipment: bars, walking frames, ultrasound equipment, SWD equipment, hydrotherapy equipment, paraffin wax baths, etc.
- housekeeping: washing machines, irons, centrifuges, sterilizers, etc.

As there is such great technological diversity even within the hospital and medical equipment sector, we chose to focus on electromedical equipment for its technology-intensive nature, impact on the trade balance, and direct relationship with the supply of healthcare services.

As this is one category within a larger industrial sector, the innovation process for electromedical equipment ends up being influenced by more general features of the broader MDHL equipment industry, which is marked by heterogeneity in at least two interrelated areas: technology itself, and business profile.

The production of high-technology equipment with higher added value[8] is dominated by large businesses – basically, subsidiaries of large international manufacturers –, which account for around 10% of all the companies operating in the sector, provide jobs for around 40% of the sector's workforce, have almost 65% of the sector's sales, and channel a significant portion of revenues into R&D, thereby maintaining the technological edge that grants them their competitive advantage.

The manufacturers of equipment using mature (medium- and low-complexity) technology[9] are mostly small, medium-sized, and medium-to-large domestic firms, which account for 90% of all the companies in the sector, provide employment for the other 60% of the workforce, but only claim just over 35% of sales (GADELHA *et al.*, 2012). Furthermore, according to Leão *et al.* (2008), here, competition is price-based, production is geared towards economies of scale, and profit margins are lower.

A second general characteristic of the MDHL equipment industry worth noting is cumulative innovation, meaning that new equipment using new technology is added to existing infrastructure, thereby putting pressure on acquisition, maintenance, and operating costs (CALIL, 2001). For example, a given diagnostic service unit will sometimes simultaneously offer MRI, CT, ultrasound and/or x-ray (GADELHA *et al.*, 2012).

The analysis of the business environment of the MDHL equipment industry, represented schematically in Figure 2, serves to identify some other characteristics of interest to this study.

First, the strong presence of the government is a factor worth mentioning, both supporting industry development, through the mediation of the Brazilian Agency for Industrial Development (Agência Brasileira de Desenvolvimento Industrial, ABDI), the Brazilian Agency for the Promotion of Exports and Investments (Agência Brasileira de Promoção de Exportações e Investimentos (Apex-Brasil), BNDES, the Funding Agency for Studies and Projects (Financiadora de Estudos e Projetos, FINEP), and others, and as a regulator, through the mediation of the Health Surveillance Agency (Agência Nacional de Vigilância Sanitária, ANVISA), the National Metrology, Quality and Technology Institute (Instituto Nacional de Metrologia, Qualidade e Tecnologia, INMETRO), and other entities[10]. This is an industry that is subject to a high degree of regulation.

The left-hand side of Figure 2 shows the first- and second-level suppliers. In this environment, the suppliers may be foreign, as they are for endoscopic cameras and hemodialysis filters, in which case domestic manufacturers must know how to conduct import operations either directly or via specialized companies.

ISSN: 2047 - 0398
SPECIAL ISSUE – V|4|N|5|, January | 2015

In the middle of Figure 2 are the manufacturers per se. They include Brazilian companies and subsidiaries of multinationals, both of which were analyzed at the beginning of this sub-section.

On the right of the figure are equipment buyers, divided into two levels. The first contains distributors, which acquire equipment in order to sell it on to second-level customers and which, depending on the case, will acquire the equipment directly from manufacturers. Meanwhile, the second level contains public, philanthropic and private hospitals, each with its own acquisition procedures. As the public hospitals make up a significant portion of the market for this equipment, manufacturers need to learn to sell their products through public tenders regulated by law 8666 passed in 1993. This is also the case whenever a philanthropic or private hospital buys equipment using public funds. Finally, when domestic manufacturers wish to sell their products abroad, they must also be capable of conducting export operations (either directly or through specialized companies), and must also make a name for themselves in overseas markets.

Two cases of failure are illustrative of the competences for innovation needed for success in the MDHL equipment industry. The first took place in the late 1980s and involved thermometer manufacturers. Furtado & Souza (2001) report that when clinical thermometers for measuring body temperature started incorporating digital technology – which was not mastered by Brazilian makers – Brazil found itself transformed from a net exporter into a net importer. In this specific case, it was the technology itself that stood in the way of the companies' success, because they did not have the technological skill-set necessary to design and manufacture this new generation of instruments, probably because of the effects of the accelerated advance of the technology frontier internationally as of the 1970s, especially in information technology and new materials.

The second case was suffered by EMI, which was a pioneer in the development and introduction of CT scanners, but failed to get a stable foothold in the market because it did not have the assets it needed to support its proven technological competences. Basically, this shows that for a company involved in innovation to be successful, it must also develop other competences beyond those directly relating to technology. These include organizational and relational dimensions, as we will see below.

2.2. Competences for Innovation

Competences for innovation, a notion developed by François *et al.* (1999), are the set of capabilities that enable companies to innovate lucratively. Alves (2005) sees them as the driving force behind innovation processes.

The first empirical research into competences for innovation was done by the French Ministry of Industry's Bureau of Industrial Studies and Statistics (Service des Statistiques Industrielles, SESSI), which investigated French industry as a whole. It used a competence questionnaire[11], the most fitting for the subsequent statistical treatment of the large mass of data generated from the sample of 5000 companies involved, out of a total of 25,000. However, it had the drawback of reflecting the subjectivity of respondents with regard to the competencies investigated (FRANÇOIS *et al.*, 1999).

This first study was organized around nine "complex" competences, providing a broad description of verifiable organizational behaviors. These complex competences are shown in Table 1. To give a clearer perception of the "broad description of organizational behavior," the complex competences were broken down into a total of 72 basic competences.

Alves (2005)[12] effected some adaptations to this model in order to investigate the existence of differences in the competences for innovation required by companies working in the plastic packaging industry. Essentially, this study compared companies that declared they had made some kind of innovation in the three years prior to the study (classified as innovators) and those that stated they had not made any innovations in the same period (non-innovators). This study also incorporated a new complex competence to the nine used by François *et al.* (1999): cooperate for innovation. The ten complex competences Alves (2005) used were then broken down into 61 basic competences.

Alves (2005) also grouped the basic competences into three categories: technical, organizational, and relational. The first category has to do with production and technology management (inside a firm). The organizational (or management) category has to do with the creation of new knowledge, human resource management, and innovation, especially in interactions between different departments. Finally, the relational category basically covers a company's capacity to cooperate, form alliances, and appropriate external technologies.

This analysis of competences under the technical, organizational and relational categories is noteworthy insofar as it sees innovation as transcending technological matters – something already demonstrated by the EMI case briefly described in sub-section 2.1.

In section 3, we go on to represent the competences for innovation proposed for electromedical equipment manufacturers, taking their specific characteristics into consideration.

3. PROPOSED QUESTIONNAIRE FOR MAPPING COMPETENCES FOR INNOVATION

This proposal is the outcome of a critical analysis of the study conducted by Alves (2005) in the light of the specific characteristics and needs of the medical, dental, hospital and laboratory (MDHL) equipment industry mentioned in section 1 and sub-section 2.1. Whenever available, information about the specific features of the target category – electromedical equipment – was used. When such information was not available, information on the hospital and medical equipment sector or MDHL equipment industry as a whole was used. Table 2 shows the ten proposed complex competences and 71 associated basic competences.

The first competence is "include innovation in the company's overall strategy," which is broken down into five basic competences: the capacity to control the quality and effectiveness of production; to make a technological appraisal of the company; to appraise new organizational formats for the company; to identify the competences of/needed by the company's workforce; and give precedence to a global view of the company by each employee. For electromedical equipment manufacturers to acquire these competences, they would not need to make any special adaptations.

The second complex competence is to "follow, anticipate, and act on market developments." This is broken down into six basic competences: the capacity to analyze products; to analyze patents; to analyze competitors' publications; to pick up on customers' responses in after-sales services or with distributors; to identify the needs of clients' clients; and to identify emerging needs or pioneering consumer behaviors.

When it comes to the basic competence concerning patent analysis, it is worth noting that patents are not widely used in the MDHL equipment industry because they are not seen as being as effective as they are in the drug industry, for instance. This is because competitors will often get around the protection conferred by a patent, thereby reducing the life cycle of new equipment to a matter of months (Ernst & Young, 2010). This is why we deemed it necessary to investigate a manufacturer's capacity to analyze any intellectual property documents filed by competitors, whatever form of protection they use.

We should also qualify what the "clients" and "clients' clients" mentioned by Alves (2005) are in the case of electromedical equipment. Here, the former are health workers – an important source of information for identifying new and often differentiated demands, and for evaluating the performance of prototypes and final products (ALBUQUERQUE & CASSIOLATO, 2000). Meanwhile, "clients' clients" are patients.

Something else included is a trend identified by Leão *et al.* (2008) for the sale of equipment in association with services and other products, which constitutes a different type of business model[13]. This trend explains at least partially the recent interest on the part of large medical equipment producers in development and production platforms based on new information and communication technologies. It is also in line with the increasing demand expressed by hospitals for integrated solutions. This integration should be considered in two ways, both of which are related to the context of e-health, telemedicine and telehealth[14], which are changing the face of traditional healthcare and have implications when it comes to the introduction of innovations in equipment. The first is that equipment interfaces with hospitals' information systems, which means manufacturers must supply not just a piece of equipment, but also related software capable of integrating it with all the hospitals' other equipment and information systems (LANDIM *et al.*, 2013). The second is that equipment manufacturers should also be ready to offer management consultancy services (PIERONI *et al.*, 2010).

We therefore deemed it necessary to investigate to what extent electromedical equipment manufacturers are considering this new commercial paradigm, and if they are, how they are preparing for it. In other words, to what extent these manufacturers are capable of reformulating their business models if necessary.

Thirdly, an analysis was conducted of the complex competence, "develop innovations." Of the ten basic competences used by Alves (2005), we judged that given the nature of the MDHL equipment industry, the two basic competences, "modify production equipment to improve productivity" and "alter the manufacturing process conditions" were equivalent to one another, so only the latter was maintained.

Meanwhile, we identified the need to investigate how manufacturers deal with the high and rising tide of regulation of MDHL equipment and its manufacturers in Brazil and around the world. Just to give an idea of the importance of regulation for electromedical equipment manufacturers in Brazil, we could name resolution #RDC 27, issued by ANVISA in 2011, and its Normative Instruction 9 of 2013 (ANVISA, 2011 and 2013); resolution 506, issued in 2008 by the National Telecommunications Agency (Agência Nacional de Telecomunicação, ANATEL) (ANATEL, 2008); and a standard issued by the Brazilian Technical Standards Association (ABNT) #NBR IEC 60601-1:2010 on electromedical equipment – part 1: general requirements for basic safety and essential performance (ABNT, 2010). There are also technical standards derived from the IEC[15] and/or ISO[16], including IEC standard 60601-2-27:2011 on medical electrical equipment – Part 2-27: particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment, and ABNT standard #NBR ISO 13485:2004 – devices for health – quality management systems – requirements for regulatory purposes. Gutierrez & Alexandre (2004) hold that the need for products, processes, and companies to adapt to such regulations has the effect of stimulating qualitative improvements[17]. For all these reasons, it was decided that the capacity to meet the regulatory requirements pertaining to innovations under development would have to be investigated.

With regard to the fourth and fifth complex competences – "organize and direct knowledge production" and "appropriate external technologies" – the critical analysis did not reveal any need to change any of the related basic competences (Table 2). In other words, the competences analyzed were deemed applicable to the manufacturers under investigation.

As for the sixth complex competency, "produce and defend intellectual property," as competitors often find ways of getting round the protection conferred by patents, the resulting life cycle of new equipment can be relatively short (Ernst & Young, 2010). It therefore seemed appropriate to address this issue more broadly than did Alves (2005), identifying not just whether the manufacturer uses the patenting system to protect its intellectual property, but also whether it is capable of using any instrument for its protection, whatever it may be.

As for the seventh complex competence, "manage human resources from an innovation perspective," alongside the seven basic competences set forth by Alves, we also added aspects of formal education and development for the workforce. As the level of education and specialization of the workforce in Brazil as a whole is low and has a negative impact on the issues investigated in the other questions in the category, it was decided that the capacity to invest in formal education or the specialization of employees should be investigated, taking into consideration the nature of the business.

In the eighth complex competence, "fund innovations," it is important to consider the high costs involved (level of investment), and difficulty small and medium-sized enterprises (SMEs) have in accessing sources of funding (SILVA *et al.*, 2011). Even though public funding entities like FINEP[18] and BNDES[19] are more aware of the specific needs of SMEs, they still have a hard time meeting all these agencies' requirements. As such, we chose to investigate the capacity of manufacturers to meet the requirements of public or private financiers, and the capacity to easily prove the investment of the funds obtained from such sources.

One measure that affects costs is the federal government's Greater Brazil Plan, which since August 2011 has reduced one of its indices, "percentage of exports over revenues," to 50%. This is used to identify whether a company is primarily an exporter. The measure has prompted the "expansion of the universe of companies benefitted by exemption from the tax on manufactured goods, and Pis and Cofins taxes, on acquisitions of inputs" (ABDI, 2013, p. 14). It also reduces the costs of companies that fulfill the legislative requirements. This specific case is illustrative of the general measures to reduce the tax burden of businesses introduced by the federal (and other levels of) government. As such, one basic competence to be investigated is a manufacturer's capacity to identify tax breaks offered by governments at any level.

Turning to the complex competence, "sell the innovation," it is important to consider both the domestic market and foreign markets. Sales to the public domestic market, one of the main consumers of electromedical equipment, are legislated by the public tender law 8666 of 1993 and subsequent related laws. Meanwhile, private customers and philanthropic institutions have their own requirements that must be met. We therefore decided it was important to investigate whether companies were capable of identifying and fulfilling the specific requirements of each target market when they sold a new product.

Furthermore, the Growth Acceleration Program for Equipment – a policy introduced by the Ministry of Finance on June 27, 2012 – states that public entities may use a "margin of preference" when making acquisitions of

equipment, allowing equipment produced in Brazil to cost up to 25% more than a corresponding imported good (Ministério da Fazenda, 2012). The capacity to harness this benefit should also be investigated.

As for foreign markets, the details of the export process should be considered, including the legislation in the country of origin and country of destination. For instance, Brazil provides companies with similar funding conditions to other countries via the Export Funding Program (Programa de Financiamento à Exportação, Proex) (ABDI, 2013). Another case is the creation of the Export Fund (Fundo de Financiamento à Exportação, FFEX) for SMEs. As such, the capacity of manufacturers to take advantage of any incentives available should be investigated.

Also with regard to exports, companies have to gain an international reputation, which is why taking part in international trade fairs is so important. Apex-Brasil is active in this arena, providing support in promoting Brazilian products and services abroad (APEX; 2012). As taking part in trade fairs, with or without APEX support, demands a degree of organization, the capacity to plan effectively for this should be investigated.

Finally, in the critical analysis of the tenth complex competence, "cooperate for innovation," no need to alter any of the basic competences used by Alves (2005) was identified.

4. CONCLUDING REMARKS

The health sector in Brazil is under pressure for a number of reasons, including the rising life expectancy of the population, changes in the epidemiological profile, the expansion of the national health system, and the growth of socio-economic group C with the influx of people from lower income groups. Most of the demand for medical, dental, hospital and laboratory (MDHL) equipment in general and electromedical equipment in particular has for many years been met by imports, exacerbating the trade deficit, and indicating the existence of a persistent systemic competitive disadvantage.

Brazil's electromedical equipment manufacturers are competing in a dynamic global industry where the cycle of innovation is relatively short. Their products, like those of the rest of the industry, have a direct impact on the healthcare on offer to the population, directly affecting the outcomes of this care (among other factors), and indirectly affecting people's quality of life.

In this context of new and varied demands (in consumption, technology, management, and relational terms), the capacity or incapacity to introduce innovations affects the competitiveness of the national MDHL equipment industry. In other words, while its limited competitiveness as a whole cannot be put down exclusively to innovation-related issues, it certainly cannot be reverted without due consideration of competences for innovation. Basically, identifying and understanding these competences is central to the planning of strategic actions on the part of business leaders and public policymakers, with a view to enhancing competitiveness and diminishing dependency on imports in health and the economy as a whole.

The mapping activity proposed here is designed to contribute to identifying existing competences for innovation and any competence gaps amongst electromedical equipment manufacturers – one of the most dynamic and important parts of the hospital and medical equipment sector in the MDHL equipment industry. In order to do so, books, articles, reports, laws, and government programs relating to the industry and the sector were consulted. The only literature relating specifically to electromedical equipment consisted of technical regulations.

After comparing the competence requirements identified in these sources with the competences listed in the questionnaire used by Alves (2005), it was decided that four of the ten groups of complex competences were suitable for the sector in question, namely: include innovation in the company's overall strategy; organize and direct knowledge production; appropriate external technologies; and cooperate for innovation. Even amongst the other six complex competences, many of the basic competences were kept unaltered.

This finding is consistent with the assumption of the original proposal set forth by François *et al.* (1999) that situations that are apparently heterogeneous may contain common characteristics, otherwise it would be pointless trying to identify the competences for innovation in any industry.

Meanwhile, confirming our initial expectations, some features specific to electromedical equipment manufacturers were identified, especially the technical regulations concerning the processes and products in this area. We also identified some characteristics that impinge on the innovation process for this kind of equipment, such as cumulative innovation, the increasing computerization and integration of products, and the important role of health workers in setting requirements and accepting new products.

These characteristics therefore demand different competences for innovation than in other industries. As such, the other six categories of competences for innovation (follow, anticipate, and act on market developments; develop innovations; produce and defend intellectual property; manage human resources from an innovation perspective; fund innovations; and sell innovations) had to be adapted in order better to reflect the specific needs of the manufacturers in question.

A final consideration is the need for this proposal to be validated. This questionnaire has yet to be submitted for appraisal by the stakeholders mentioned in the analysis of the business environment in the MDHL equipment industry.

REFERENCES

ABDI (2013), Agência Brasileira de Desenvolvimento Industrial, "Plano Brasil Maior: relatório de acompanhamento das medidas sistêmicas". Available at: www.abdi.com.br (accessed February 27, 2014).

ABDI/CGEE (2007), Agência Brasileira de Desenvolvimento Industrial / Centro de Gestão e Estudos Estratégicos, "Estudo Prospectivo: Equipamentos Médicos, Hospitalares e Odontológicos". Available at: http://www.abdi.com.br/Estudo/VIII.pdf (accessed February 27, 2014).

ABIMO (2014). Associação Brasileira da Indústria de Artigos e Equipamentos Médicos, Odontológicos, Hospitalares e de Laboratório. Available at http://www.abimo.org.br/ (accessed September 30, 2014).

ABNT (2004), Associação Brasileira de Normas Técnicas, "Norma ABNT NBR ISO 13485:2004 - Produtos para saúde - Sistemas de gestão da qualidade - Requisitos para fins regulamentares", Rio de Janeiro, RJ.

ABNT (2010), Associação Brasileira de Normas Técnicas, "Norma ABNT NBR IEC 60601-1:2010 Equipamento eletromédico – Parte 1: Requisitos gerais para segurança básica e desempenho essencial", Rio de Janeiro, RJ.

Albuquerque, E. M. *et* Cassiolato, J. E. (2000), As especificidades do sistema de inovação do setor saúde: uma resenha da literatura como introdução a uma discussão sobre o caso brasileiro, Estudos FeSBE, 1, Belo Horizonte, MG.

Alves, F. (2005), Competências para inovar: um estudo a partir da indústria de embalagens plásticas, Doctoral thesis in chemical engineering, Universidade Federal do Rio de Janeiro, Rio de Janeiro, RJ.

Alves, F., Bomtempo, J. and Coutinho, P. (2005), "Competências para inovar na petroquímica brasileira", *Revista Brasileira de Inovação*, Vol. 4 No. 2, pp 301-327.

Alves, F.; Bomtempo, J. (2007), "Como distinguir firmas inovadoras e não inovadoras: uma abordagem a partir da noção de competências para inovar", artigo apresentado no Encontro Nacional de Economia.

ANATEL (2008), Agência Nacional de Telecomunicação, "Resolução 506 de 2008". Available at: http://legislacao.anatel.gov.br/resolucoes/2008/104-resolucao-506 (accessed August 20, 2014).

ANVISA (2011), Agência Nacional de Vigilância Sanitária, "Resolução da Diretoria Colegiada RDC 27 de 2011". Available at: http://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2011/res0027_21_06_2011.html (accessed August 20, 2014).

ANVISA (2013), Agência Nacional de Vigilância Sanitária, "Instrução Normativa 09 de 2013". Available at: http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?jornal=1&pagina=755&data=30/12/2013 (accessed August 20, 2014).

APEX-BRASIL (2012), Agência Brasileira de Promoção de Exportações e Investimentos. Available at: http://www.apexbrasil.com.br/portal/ (accessed February 11, 2012).

BNDES, Banco Nacional do Desenvolvimento Econômico e Social, "Programa BNDES de Apoio ao Desenvolvimento do Complexo Industrial da Saúde - BNDES Profarma". Available at: http://www.bndes.gov.br/SiteBNDES/bndes/bndes_pt/Areas_de_Atuacao/Inovacao/Profarma/ (accessed November 5, 2012).

Calil, S. (2001), "Análise do setor de saúde no Brasil na área de equipamentos médico-hospitalares", in Negri, B. & Di Giovanni, G. (ed.), *Brasil: radiografia da saúde*, UNICAMP/IE, pp. 91-121.

DECS (2014), Descritores de Ciências da Saúde da Biblioteca Virtual em Saúde. Available at: http://decs.bvs.br/cgi-bin/wxis1660.exe/decsserver/ (accessed August 23, 2014).

Ernst & Young (2010). Pulse of the industry: medical technology report 2010.

François, J-P., Goux, D., Guellec, D., Kabla, I. and Templé, P. "Décrire les competences pour l'innovation: Une proposition d'ênquete." In: FORAY D., MAIRESSE J., eds. Innovations et performances, approches interdisciplinaires. Paris: Éditions EHESS, p.283-303, 1999.

Furtado, A. and Souza, J. (2001), "Evolução do setor de insumos e equipamentos médico-hospitalares, laboratoriais e odontológicos no Brasil: a década de 90", in Negri, B. and Di Giovanni, G. (ed.), *Brasil: radiografia da saúde*, UNICAMP/IE, pp. 63-90.

Gadelha, C. *et al.* (2009), "Complexo Econômico-Industrial da Saúde, Relatório Final do projeto PIB: perspectivas do investimento no Brasil". Available at: http://www.projetopib.org/?p=documentos (accessed October 10, 2009).

Gadelha, C., Maldonado, J., Vargas, M., Barbosa, P. and Costa, L. (2012), A dinâmica do sistema produtivo da saúde: inovação e complexo econômico-industrial, Editora FIOCRUZ, Rio de Janeiro, RJ.

Gutierrez, R. and Alexandre, P. (2004), "Complexo industrial da saúde: uma introdução ao setor de insumos e equipamentos de uso médico", *BNDES Setorial*, No. 19, pp. 119-155. Available at: http://www.bndes.gov.br/SiteBNDES/export/sites/default/bndes_pt/Galerias/Arquivos/conhecimento/bnset/set1906.pdf (accessed December 12, 2012).

Landim, A., Gomes, R., Pimentel, V., Reis, C. and Pieroni, J. (2013), "Equipamentos e tecnologias para saúde: oportunidades para uma inserção competitiva da indústria brasileira", *BNDES Setorial*, 37, pp. 173-226. Available at: http://www.bndes.gov.br/SiteBNDES/export/sites/default/bndes_pt/Galerias/Arquivos/conhecimento/bnset/set3705.pdf (accessed March 22, 2014).

Leão, R., et al. (2008), "Estudo setorial – setor de equipamentos e materiais de uso em saúde", Secretaria de Ciência, Tecnologia e Insumos Estratégicos, Departamento de Economia da Saúde, Coordenação Geral de Economia da Saúde, Brasília.

Marques, A., Antunes, A. and Alves, F. (2013), "Equipamentos médico-hospitalares: uma análise do ambiente de negócio e da estrutura industrial", artigo apresentado no XVI Simpósio de Administração da Produção, Logística e Operações Internacionais, São Paulo. Available at: http://www.simpoi.fgvsp.br/arquivo/2013/artigos/E2013_T00231_PCN72834.pdf (accessed February 28, 2014).

Ministério da Fazenda (2011), "Programa de Aceleração do Crescimento – Equipamentos (PAC Equipamentos)". Available at: http://www.pac.gov.br/sobre-o-pac (accessed September 3, 2014).

Ministério da Saúde (2010), "Mais saúde: direito de todos: 2008 – 2011", 5ª Ed., Brasília. Available at: http://bvsms.saude.gov.br/bvs/pacsaude/ (accessed November 7, 2012).

Ministério do Desenvolvimento, Indústria e Comércio Exterior, "Plano Brasil Maior". Available at: http://www.brasilmaior.mdic.gov.br/conteudo/128 (accessed November 7, 2012).

Moysés Junior, Z. (2012), "Fomento, Preços, Compras e Encomendas", palestra apresentada no 1º congresso da inovação em materiais e equipamentos para saúde (CIMES). Available at: http://www.cimes.org.br/uploads/paginas/file/Zich%20Moys%C3%A9s%20Junior.pdf (accessed November 12, 2012).

Osterwalder, A. and Pigneur, Y. (2010), Business model generation: a handbook for visionaries, game changers, and challengers, John Wiley & Sons, New Jersey.

Pavitt, K. (1984), "Sectorial Patterns of Technical Change: Towards a Taxonomy and a Theory", *Research Policy*, Vol.13, pp. 343-373.

Pieroni, J., Reis, C. and Souza, J. (2010), "A indústria de equipamentos e materiais médicos, hospitalares e odontológicos: uma proposta de atuação do BNDES", *BNDES Setorial*, 31, pp. 185-226. Available at: http://www.bndes.gov.br/SiteBNDES/bndes/bndes_pt/Institucional/Publicacoes/Consulta_Expressa/Tipo/BNDES_Setorial/201003_05.html (accessed August 1, 2012).

Tidd, J., Bessant, J. and Pavitt, K. (2008), Gestão da inovação, 3ª edição, Bookman, Porto Alegre, RS.

Figures

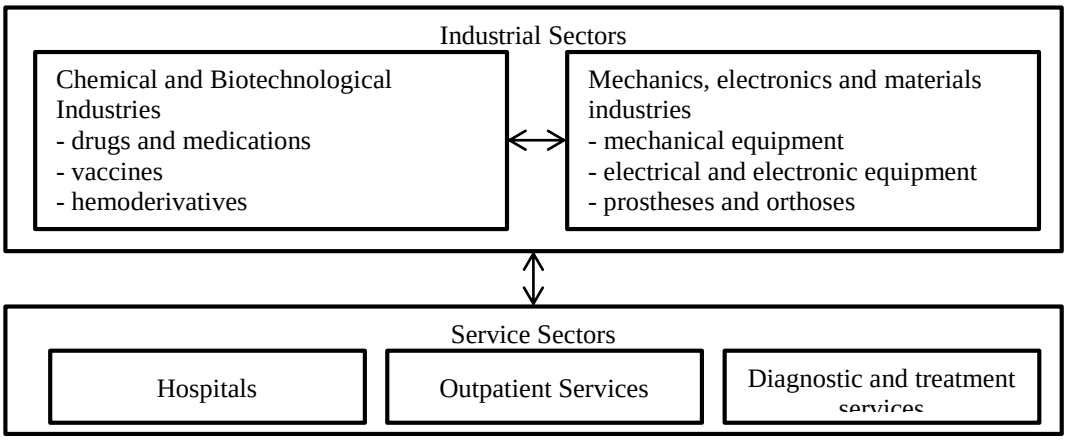

Figure 1. Overview of the Health Industry Complex. Source: Gadelha, 2003.

ISSN: 2047 - 0398
SPECIAL ISSUE – V|4|N|5|, January | 2015

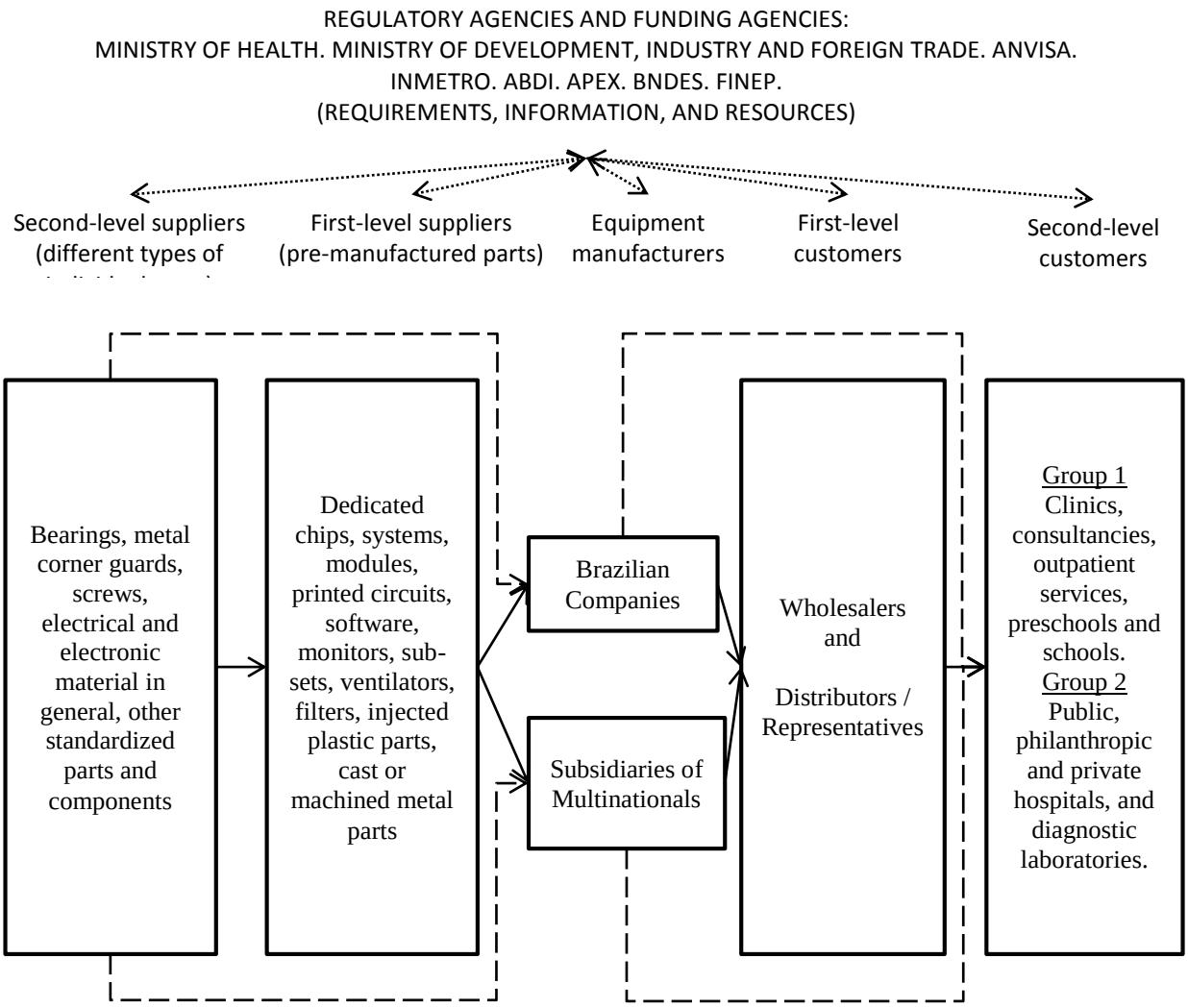

Figure 2. Business environment of the MDHL equipment industry. Source: Marques *et al.* (2013).

Tables

Table 1. Complex competences used by François *et al.* (1999).

1. Include innovation in the company's overall strategy
2. Anticipate market developments
3. Develop innovations
4. Organize and direct knowledge production
5. Appropriate external technologies
6. Produce and defend intellectual property
7. Manage human resources from an innovation perspective
8. Fund the innovation
9. Sell the innovation

Source: François *et al.* (1999)

Here, the complex competences are metacompetences, or categories of competences, while the basic competences are the behaviors by which the corresponding metacompetences are made operational. To keep the information concise and not stray beyond the scope of this study, the 72 basic competences used by François et al. (1999) are not shown in Table 1.

ISSN: 2047 - 0398
SPECIAL ISSUE – V|4|N|5|, January | 2015

Table 2. Proposed complex competences for innovation and corresponding basic competences required by manufacturers of electromedical equipment

Complex Competences	Basic Competences
1. Anticipate market developments.	Control the quality and effectiveness of production. Make a technological appraisal of the company. Appraise new organizational formats for the company. Identify the competences of/needed by the company's personnel. Give precedence to a global view of the company by each employee.
2. Follow, anticipate, and act on market developments.	Analyze competing products. Analyze the intellectual property published by competitors. Analyze publications written by competitors' employees. Identify customer responses. Find out the needs of health workers (doctors, nurses, administrators) and patients. Identify emerging needs or pioneering consumer behaviors. Reformulate the business model.
3. Develop innovations	Be structured around innovation projects. Involve all services in innovation projects from the outset. Prioritize teamwork for innovation. Prioritize mobility between services for innovation. Identify new products offered by suppliers. Make own design innovations. Quickly acquire technologically novel equipment. Quickly acquire technologically novel inputs. Alter the manufacturing process conditions for products. Meet the regulatory requirements for innovations under development.
4. Organize and direct knowledge production	Encourage the generation of new ideas. Provide a degree of autonomy for each employee to innovate. Promote knowledge sharing. Evaluate the collective production of knowledge in comparison with that of the company's competitors. Evaluate each person's contribution to knowledge production.
5. Appropriate external technologies	Find out about competitors' technologies. Monitor technologies to anticipate technologies of the future. Test external technologies. Conduct research and development. Make improvements to products and/or processes. Outsource services for research and development of new products and/or processes. Outsource services for the design of new products. Hire highly scientifically qualified employees for innovation. Acquire whole companies or parts of companies for innovation. Take part in joint ventures, strategic alliances, and other forms of cooperation for innovation.
6. Produce and defend intellectual property	Use the company's intellectual property protection mechanisms. Take account of the risk of copies and imitations from the drawing board onwards. Take measures to undervalue copies and imitations in customers' eyes. Identify own strategic knowledge and know-how. Control communication about strategic knowledge. Provide special motivation for people with strategic knowledge (remuneration, career). When professionals with strategic knowledge leave the company, ensure the company retains as much of this knowledge as possible.
	Locate current and future market specialists.

ISSN: 2047 - 0398
SPECIAL ISSUE – V|4|N|5|, January | 2015

Table 2. Proposed complex competences for innovation and corresponding basic competences required by manufacturers of electromedical equipment

Complex Competences	Basic Competences
7. Manage human resources from an innovation perspective	Evaluate disposition to innovate at recruitment stage. Evaluate teamwork capacity at recruitment stage. Evaluate everybody's performance and compensate the best. Set personnel mobility rules. Make everyone aware that they can request and choose development opportunities. Evaluate the repercussions of education/development on innovation. Invest in the formal education or specialization of employees, bearing in mind the nature of the business.
8. Fund innovations	Make a prior evaluation of innovation-related costs. Make an evaluation of the costs of innovations after they are implemented. Identify sources of private and public funding for innovation. Communicate effectively with potential funders for innovation. Fulfil the requirements of innovation funders. Easily prove the investment of the funds obtained from external sources in developing the innovation. Identify tax incentives offered by governments.
9. Sell innovations	Promote the new equipment. Decide on the target, media, and type of publicity message for the new equipment. Convey an image of the company as being "innovative and avant-garde" (facilities, communication, documents published). Identify and observe the specific requirements of each target market when selling new equipment. Take advantage of any margin of preference when selling new equipment to public customers. Export new equipment using the incentives available. Market new equipment at international trade fairs.
10. Cooperate for innovation	Make innovations in cooperation with competitors. Make innovations in cooperation with suppliers. Make innovations in cooperation with companies that use the equipment. Take the initiative in seeking out partners for the development of new products.

Source: Adapted from Alves (2005)

The underlined basic competences are the ones that have been modified or included in this proposal.

[1] According to Moysés Júnior (2012), the health sector as a whole in 2011 accounted for 8.8% of Brazil's GDP, employed 10% of the country's workforce, and had a turnover of US$100 billion.
[2] The two other sub-systems are chemicals and biotechnology, covering the pharmaceutical industry and producers of vaccines, hemoderivatives and diagnostic reagents, and the services sub-system, which covers hospitals, laboratories, and diagnostic and treatment services (GADELHA *et al.*, 2012).
[3] One exception to this rule is the dental equipment sector, the only one with a trade surplus. In 2012, its trade balance exceeded US$13 million, while the other sectors of the MDHL equipment industry continued to record growing trade deficits (FGV/ABIMO, 2013).
[4] The technological strategy adopted by "followers" focuses not on the introduction of original innovations, but on the capacity to rapidly introduce equivalent innovations or improve on those of the pioneering company.
[5] Imports of hospital and medical equipment fell by around 1% from 2008 to 2009, while exports dropped by 25.2%. With this, the segment's trade balance fell to –US$393,263,374.00 (IEMI, 2010).
[6] Brazilian Association of the Medical, Dental, Hospital and Laboratory Equipment and Devices Industry.

ISSN: 2047 - 0398
SPECIAL ISSUE – V|4|N|5|, January | 2015

[7] The hospital and medical equipment sector is one of the most dynamic in the MDHL equipment industry. This dynamism has been evaluated in terms of the growth rates seen in recent years, the meeting of domestic demand, sustainable sales abroad, and relatively higher technology-intensiveness (GADELHA *et al*., 2012).
[8] This fits into the category of "specialized suppliers" according to the terminology adopted by Pavitt (1984). In this case, the main sources of technology are the design, manufacture, and operation of equipment.
[9] For these manufacturers, close interaction with customers in order better to identify their needs is a way of boosting the incremental generation of new or substantially improved products.
[10] Equipment under health surveillance is regulated essentially by ANVISA and occasionally by ANATEL, which both set the respective technical regulations. INMETRO is responsible for organizing the activities needed to evaluate whether the equipment is in compliance with the regulations in question, which are conducted by laboratories accredited to do the tests and measurements required.
[11] François *et al.* (1999) identified four possible questionnaires, each of which has certain inherent strengths and weaknesses. For more detail on each of them, see François *et al.* (1999) and Alves (2005).
[12] Alves *et al.* (2005) conducted empirical research into competences for innovation in the petrochemicals industry. As there was little methodological difference between Alves (2005) and Alves & Bomtempo (2007), and because of space and scope constraints, this article only details the 2005 study by Alves.
[13] "A business model describes the rationale of how an organization creates, delivers, and captures value" (OSTERWALDER & PIGNEUR, 2010, p. 14). The business model canvas has nine building blocks: customer segments, value propositions, channels, customer relationships, revenue streams, key resources, key activities, key partners, and cost structure.
[14] Because of the scope of this article, the conceptual differences between e-health, telemedicine and telehealth will not be explained; we merely note that generally speaking, all these concepts have to do with the use of IT&C in health. For further information, see DECS (2014).
[15] The International Electrotechnical Commission is an international organization that sets standards in the fields of electrotechnology and electronics.
[16] The International Standardization Organization issues standards for every area of knowledge except those covered by the IEC.
[17] These authors also warn that "there is a fine line between technical regulations and the setting of non-tariff barriers" (GUTIERRES & ALEXANDRE, 2004, p. 130).
[18] FINEP is a government-owned company under the auspices of the Ministry of Science and Technology that provides funding for innovation projects (through grants and credit lines). It also manages the science and technology sector funds, including one for health, whose objectives include stimulating private investments in R&D in the area and the technological modernization of the Brazilian hospital and medical equipment industry. These funds were created in 1999 to finance research, development, and innovation projects in the country. There are currently 16 sector funds: 14 for specific sectors like health, and two cross-sectoral.
[19] The institution uses several instruments to support the MDHL equipment industry, including traditional lines of credit, the BNDES Card (used by companies from the sector to sell their products to clinics and hospitals and to acquire inputs and technology services), and Profarma, its main program supporting this industry (PIERONI *et al.*, 2010).