

Critical Issues Report

Importing Medical Equipment into Brazil Effect of Regulation on the Cost and Quality of Healthcare

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On January 26, 1999, Law 9782 created the National Agency for Sanitary Control or Agência Nacional de Vigilância Sanitária (ANVISA).¹ The Brazilian equivalent to the United States Food and Drug Administration (US FDA), ANVISA oversees the quality of foods, cosmetics, medicines, and healthcare available to Brazilian citizens² and regulates the import of medical equipment.

Some foreign medical equipment manufacturers claim that ANVISA's methods make it difficult to export medical equipment to Brazil. They point to delays in obtaining product registration and high fees that add to the cost of purchasing the equipment. These impediments did not exist prior to ANVISA's creation.

This paper is based on information gathered during telephone interviews with equipment manufacturers, equipment exporters, Brazilian healthcare providers and professional organizations, and US government agencies. Each section includes a commentary. Although there are difficulties associated with summarizing the findings such as the perception that rules and their interpretations continually change and every experience may be different, this paper attempts to reach some conclusions and recommendations.

The purpose of this paper is to open for discussion areas where the process of importing medical equipment could be improved to the benefit of consumers, incorporating various points of views and recommendations. The paper will provide the framework for Session V titled, "Medical Equipment: Challenges and Recommendations" scheduled for presentation at SaludAmericas on October 25, 2001, in Angra dos Reis, Brazil. Although other medical products and supplies, a sizeable portion of expenditures by providers, were not part of this paper, it will be incorporated in the discussion at SaludAmericas.

Sections/issues of the paper:

1. The approval process.
2. Families of products.
3. Consistency and equality in the process.
4. Costs for gaining product approval and licensing.
5. Effects on quality and cost.
6. Expectations for the future.
7. General conclusions and recommendations.

¹ ANVISA website: www.anvisa.gov.br.

² Telephone conversation, São Paulo, Brazil, 1 March 2001.

1. The Approval Process

In order to export equipment to Brazil, a foreign medical equipment manufacturer or a manufacturers' export company must have a local office submit an application to ANVISA for approval of equipment to be imported. They must also pay a fee. The process, from the time an individual submits an application to the time the application is approved, takes approximately 90 days for smaller pieces of equipment and can take as long as six months for larger pieces of equipment.³

When approval is not granted within 180 days from the date ANVISA receives the application, the application is considered lapsed and a new one has to be filed with payment of an additional fee. There have been reports of delays as long as one year⁴ and a need to file a new application because the inspection report arrived three days after the expiration date of the original application.⁵

Although delays were extensive at first, and expensive consultants had to be hired, there are now a number of companies and people who know how to register equipment imports with ANVISA. The process currently works reasonably well.⁶ Processing applications is fair,⁷ although in some instances, application of the rules appears to be based on how the inspector handling the application interprets them.

When ANVISA began operating, approvals were based on analysis of the testing results by independent labs and other paperwork submitted rather than through actual equipment testing. As a way of gaining insight into the FDA approval process, ANVISA reportedly obtained copies of test results from the FDA.⁸ Today, less-sophisticated equipment can be tested locally, and some sources confirm that it is already tested locally. There was and still seems to be no testing capability within Brazil for higher technology equipment.⁹

There are three ways that equipment can be tested and certified by ANVISA:

1. Testing within Brazil by an Organismo Certificador de Produto (OCP) accredited by the National Institute of Metrology, Standardization, and Industrial Quality (INMETRO)¹⁰ (there are currently five OCPs accredited), or by a facility meeting the standards of INMETRO but not necessarily accredited by them. The latter must be selected and approved by the OCP.
2. Testing by foreign labs with which an OCP has a Memorandum of Understanding (MOU) (most of the OCPs have an MOU with one or more foreign labs.¹¹).
3. Testing at the manufacturer's plant by an OCP engineer.¹²

In the latter alternative, ANVISA employees visit the foreign production facilities to certify the equipment and the facility with all expenses paid by the manufacturer.^{13, 14} A certification called Report for the Analyses from the Quality and the Certification of the Equipment (RAQCE) is

³ Telephone conversation, Washington, D.C., United States, 9 April 2001.

⁴ Telephone conversation, Florida, United States, 12 December 2000.

⁵ Telephone conversation, Florida, United States, 7 May 2001.

⁶ Telephone conversation, Washington, D.C., United States, 17 November 2000.

⁷ Telephone conversation, São Paulo, Brazil, 1 March 2001.

⁸ Telephone conversation, São Paulo, Brazil, 1 March 2001.

⁹ Telephone conversation, São Paulo, Brazil, 26 April 2001.

¹⁰ Responsible for the accreditation process in Brazil.

¹¹ E-Mail from São Paulo, 8 November 2001.

¹² Telephone conversation, São Paulo, Brazil, 9 May 2001.

¹³ Telephone conversation, São Paulo, Brazil, 27 April 2001.

¹⁴ Telephone conversation, Florida, United States, 12 December 2000.

issued by ANVISA for each piece of equipment and the facility in which it is produced. With currently only one engineer apparently able to conduct those tests, there is insufficient time to inspect all the equipment ready for testing at a foreign facility. Only a few pieces of equipment are tested during each visit, and the engineer has to return multiple times,¹⁵ delaying approval and adding to the cost of exporting to Brazil.

Testing of equipment for European and US government approvals is generally performed under established industry standards rather than by the regulatory agency.¹⁶ Testing can be certified by the company or¹⁷ by an independent laboratory such as the Underwriters Laboratories (UL).¹⁸ In FDA's case, testing can be certified by a foreign lab authorized by them and in compliance with the US or harmonized standards.¹⁹ In cases where the FDA does not feel comfortable with results, the agency requires further testing by an authorized company.²⁰

The Brazilian government has taken steps to develop a capability to test equipment, but it's not clear why.^{21, 22} ANVISA's testing of medical equipment would differ with procedures followed by the FDA and the European Union agencies authorized to issue the "CE" mark. ANVISA is apparently working with at least one public university to develop testing facilities,²³ after which time they could become more restrictive as to the individuals they allow to perform the testing.²⁴

Foreign equipment manufacturers are concerned that equipment will have to be tested in Brazil, including stressing and destruction of equipment under internationally accepted testing procedures. This would replicate the same tests conducted and certified in laboratories in Europe and the US whose results are accepted by the FDA and the European Union agencies authorized to issue the "CE" mark. They fear this would increase the cost of selling medical equipment to Brazil, ultimately raising costs for healthcare providers and patients.^{25, 26}

Smaller companies that export fewer pieces of equipment per year to Brazil do not have the manpower or the financial strength to pursue approval for this market. As a result, some companies no longer sell to Brazil.^{27, 28} Locally manufactured and comparable equipment might be available; however, it would most likely be of lower technological standards.

A local hospital is sending increased numbers of laboratory samples abroad for testing to increase the chances of early detection of illnesses. They do not believe they can rely on locally manufactured diagnostic equipment.²⁹ Clearly, this results in higher costs for testing and treatment. Another hospital states it imports almost all equipment and much of its medical consumables because it does not feel that comparable items are available from local sources.³⁰

Both the US Department of Commerce and its counterparts in the European Union are working toward harmonizing standards to facilitate imports into the United States or the European Union.

¹⁵ Telephone conversation, Florida, United States, 7 May 2001.

¹⁶ Generally NBR IEC 60601.1 on General Safety Requirements and the applicable specific standards of the series NBR IEC 60601.2.

¹⁷ Telephone conversation, São Paulo, Brazil, 16 April 2001.

¹⁸ Telephone conversation, São Paulo, Brazil, 18 April 2001.

¹⁹ Telephone conversation, Washington, D.C., United States, 9 May 2001.

²⁰ Telephone conversation, Washington, D.C., United States, 9 May 2001.

²¹ Telephone conversation, Washington, D.C., United States, 17 November 2000.

²² Telephone conversation, Buenos Aires, Argentina, April 2001.

²³ Telephone conversation, São Paulo, Brazil, 26 April 2001.

²⁴ Telephone conversation, São Paulo, Brazil, 26 April 2001.

²⁵ Telephone conversation, São Paulo, Brazil, 1 March 2001.

²⁶ Telephone conversation, São Paulo, Brazil, 16 April 2001.

²⁷ Telephone conversation, Washington, D.C., United States, 5 April 2001.

²⁸ Telephone conversation, São Paulo, Brazil, 16 April 2001.

²⁹ Telephone conversation, São Paulo, Brazil, 20 April 2001.

³⁰ Telephone conversation, São Paulo, Brazil, 26 April 2001.

Almost 30 other countries have joined the effort, hoping to reduce the 30 to 32 different standards that a piece of equipment has to meet. If successful, manufacturers would only have to meet one set of standards for all of the countries involved, thus lowering development and testing costs and ultimately equipment prices.³¹

The Brazilian government is very interested in understanding the Law of Similars and wants to participate in the Global Harmonization Task Force. A US trade delegation went to Brazil in August 2000 to discuss harmonization of standards. Brazil sent a representative to a subsequent meeting in Canada and continues to show interest in the issue.³² According to a Pan American Health Organization representative, harmonization seems to be working in some areas such as radiological equipment, where standards in Brazil and the US are very similar.³³

Consistency and harmonization would mean that ANVISA would not have to replicate the thousands of employees of the FDA or the European Union's agencies authorized to issue a "CE" mark to ensure products meet standards with significant savings.³⁴ An observer said that applicable laws have changed every three to four months, and procedures may continue to change frequently in the future.³⁵

The Approval Process: Comments and Recommendations

Developing an approval process for licensing imported medical equipment requires expertise and training both in testing and the process. Delays are understandable. Many countries accept test results of medical equipment when certified by acceptable independent agencies or by some manufacturers to grant approval for the equipment's sale within their own countries. Non-acceptance of such tests can result in much higher costs for importing equipment or a manufacturers' refusal to take the time to export to Brazil.

Clearly, the quality of the testing, its validity, and the conclusions to be drawn from the tests must be evaluated. However, duplicative testing merely adds to costs and should be resisted, except in cases of suspected inaccurate test results. If testing by OCP engineers in foreign production facilities continues, OCP should quickly increase its staff of qualified engineers and improve their scheduling to permit an engineer sufficient time to approve all equipment ready for testing.

Agreement between OCP and comparable agencies in other countries on harmonized standards will result in a lower cost to manufacturers for serving the Brazilian and possibly other markets. By following standardized procedures, OCP can avoid building a large and expensive staff that would not be needed for purely approving medical equipment imports.

Costs incurred by manufacturers are passed on to the buyer and eventually to the healthcare consumer. ANVISA and OCP should make an effort to keep those costs (fees and expenses) as low as possible.

³¹ Telephone conversation, Washington, D.C., United States, 11 April 2001.

³² Telephone conversation, Washington, D.C., United States, 11 April 2001.

³³ Telephone conversation, Washington, D.C., United States, 9 May 2001.

³⁴ Telephone conversation, Washington, D.C., United States, 9 April 2001.

³⁵ Telephone conversation, São Paulo, Brazil, 1 March 2001.

2. Families of Products

Equipment can be registered individually or in “families” of equipment (i.e., where the equipment is closely comparable in design, safety, and efficacy). Although regulation seems to allow it, there are consistent complaints about approval being denied to families of products where the equipment is essentially the same.³⁶

In one instance, the difference in models amounted to one being battery-powered, while the others came with electric-power cords of different lengths. In another case, a manufacturer sought approval for 40 varying sizes of stethoscopes, all with the same technology.³⁷ Yet in another case, a company only wanted to change the name of the equipment but not the equipment itself.³⁸ In all these cases, separate approvals were required. However, a foreign company said it had received approval for a family of products,³⁹ and many others said that only local, not foreign, manufacturers can receive approvals for families of products.

The process becomes very expensive and time-consuming when one considers equipment such as stethoscopes with a value per item less than the fee for approval. Most of those interviewed believe ANVISA will not change the procedures. Doing so would reduce revenues from licensing fees—a major source of funding for ANVISA’s operations.^{40, 41, 42}

Families of Products: Comments and Recommendations

Approval of families of equipment seems to depend on the individual inspector reviewing the application. Approval of more families of equipment would lower approval costs for manufacturers of equipment of similar design but not reduce ANVISA’s ability to evaluate its safety or efficacy. This might help make more equipment at more reasonable prices available to local buyers.

ANVISA’s motivation will be questioned to the extent that the equipment is essentially the same, but separate approvals, and therefore fees to be paid, are required. It appears that preference given to local companies results from more favorable treatment by the inspectors and not discrimination under the law.

³⁶ Telephone conversation, Washington, D.C., United States, 9 April 2001.

³⁷ Telephone conversation, Florida, United States, 12 December 2000.

³⁸ Telephone conversation, São Paulo, Brazil, 1 March 2001.

³⁹ Telephone conversation, São Paulo, Brazil, 16 April 2001.

⁴⁰ Telephone conversation, São Paulo, Brazil, 26 April 2001.

⁴¹ Telephone conversation, São Paulo, Brazil, 1 March 2001.

⁴² Telephone conversation, São Paulo, Brazil, 20 April 2001.

3. Consistency and Equality in the Process

Standards set by ANVISA should insure equipment used to treat patients is safe and effective. Standards should be the same for both imported and locally manufactured equipment. Regulations are, *de jure*, consistent,⁴³ although in practice they vary depending on the person reviewing the application.⁴⁴ There is a belief that only large, highly visible companies worry about registration of products with ANVISA but not small ones.⁴⁵

Only recently has permission been given for pre-used equipment to be imported, but only if the original manufacturer has reconditioned it and the original equipment has received ANVISA's approval.⁴⁶ By requesting the approval code, purchasers of pre-used medical equipment can help the process, yet they seldom request it, although a representative of a hospital interviewed said they consistently asked for the code.⁴⁷,⁴⁸ Many sources said such equipment is often imported without the required approval, and paid for in cash (illegally),⁴⁹ even though customs is considered quite strict in checking for the required approvals.⁵⁰

Brazilian manufacturers are required to meet ISO 9000 and GMP standards when bidding for government tenders.⁵¹,⁵² Only three or four appear to have done so to date.⁵³ It is not clear if manufacturers that have not met such standards may still gain ANVISA's approval for equipment they manufacture. At least one US medical equipment manufacturer agreed that their local competitor makes a good quality product. Local production is not necessarily inferior to imported equipment, although larger high-technology-equipment must usually be imported.⁵⁴

Persons interviewed suggested that foreign companies with local operations, such as Siemens, should consider expanding the range of products manufactured locally in order to benefit from the perceived advantage given to them by buyers.⁵⁵ They also cite the government's favorable reaction to IBM when the company maintained the level of technology in a facility after it was sold to local investors.⁵⁶ They claim it makes good business sense for local subsidiaries of foreign companies to locally manufacture medical equipment of higher technology.

Argentina, a member of Mercosur, requires that Brazilian manufacturers of medical equipment meet ISO 9000 and GMP standards in order for the equipment to be imported into Argentina.⁵⁷ There would be an advantage to exporting to Mercosur if higher technology equipment not currently available were to be manufactured in Brazil under ISO 9000 or GMP standards.

When a philanthropic hospital, usually exempt from import duties, wishes to import equipment, it must prove that no comparable equipment is produced within Brazil or pay the import duties on the imported equipment.⁵⁸,⁵⁹,⁶¹ Local manufacturers using ten-year old technology or that

⁴³ Telephone conversation, Washington, D.C., United States, 9 May 2001.

⁴⁴ Telephone conversation, São Paulo, Brazil, 27 April 2001.

⁴⁵ Telephone conversation, São Paulo, Brazil, 1 March 2001.

⁴⁶ Telephone conversation, São Paulo, Brazil, 16 April 2001.

⁴⁷ Telephone conversation, São Paulo, Brazil, 1 March 2001.

⁴⁸ Telephone conversation, São Paulo, Brazil, 23 May 2001.

⁴⁹ Telephone conversation, Florida, United States, 16 November 2000.

⁵⁰ Telephone conversation, São Paulo, Brazil, 26 April 2001.

⁵¹ Telephone conversation, São Paulo, Brazil, 16 April 2001.

⁵² Telephone conversation, São Paulo, Brazil, 26 April 2001.

⁵³ Telephone conversation, São Paulo, Brazil, 27 April 2001.

⁵⁴ Telephone conversation, Washington, D.C., United States, 9 April 2001.

⁵⁵ Telephone conversation, São Paulo, Brazil, 26 April 2001.

⁵⁶ Telephone conversation, Rio de Janeiro, Brazil, 26 April 2001.

⁵⁷ Telephone conversation, São Paulo, Brazil, 27 April 2001.

⁵⁸ Telephone conversation, São Paulo, Brazil, 26 April 2001.

⁵⁹ Telephone conversation, Washington, D.C., United States, 11 April 2001.

have not met ISO 9000 or GMP standards can claim to make comparable equipment even if it doesn't utilize the same level of technology and diagnostic capability. Consequently, the hospital pays the duties^{60,61}.

Approved reimbursement rates for medical treatment and diagnostic testing does not differentiate between levels of sophistication of equipment. Therefore, there is no economic incentive to utilize equipment that may be more effective in detecting illness. Reimbursement rates have not been updated in two and one-half years and should be brought up-to-date to reflect current costs.⁶²

A number of interviewees believed that ANVISA was established to protect the local medical equipment manufacturers and to help them grow.⁶³ This perception will continue to the extent that the law is applied differently to local and for foreign companies. There are some examples to substantiate this claim. A manufacturer of blood pressure measuring devices, with a reputation of being the most accurate worldwide, was told by INMETRO⁶⁴ that their devices did not meet standards. The approval came through only after a personal visit to INMETRO to prove product capabilities by a senior officer of the company.⁶⁵

Consistency and Equality of the Process: Comments and Recommendations

The application of standards for equipment to be used by the healthcare industry in Brazil must be consistent to achieve and maintain ANVISA's objective of ensuring quality healthcare services. It appears that standards are not as rigorously or equally applied to local and foreign equipment manufacturers nor are hospitals required to ensure that equipment purchased, whether new or used, has been certified by ANVISA.⁶⁶

Charging philanthropic hospitals duties on imported medical equipment if comparable equipment is produced locally is understandable. However, when locally produced equipment is not of the same technology level, it cannot provide the same quality of diagnostic testing or of early detection of disease as can more advanced equipment. Charging duties on imported equipment when comparable equipment is not produced locally is not only unfair, but it increases healthcare costs by not helping detect disease early in its development when it is less costly to treat and a more successful.

Approved reimbursement rates for diagnostic testing should be updated and provide a higher rate of reimbursement for the use of higher technology. Healthcare providers would have an incentive to utilize more advanced equipment to detect disease or illness at an earlier stage.

⁶⁰ Telephone conversation, São Paulo, Brazil, 26 April 2001.

⁶¹ Telephone conversation, Washington, D.C., United States, 11 April 2001.

⁶² Telephone conversation, São Paulo, Brazil, 23 May 2001.

⁶³ Telephone conversation, Washington, D.C., United States, 5 April 2001.

⁶⁴ National Institute of Metrology, Standardization and Industrial Quality - responsible for the accreditation process in Brazil.

⁶⁵ Telephone conversation, Florida, United States, 7 May 2001.

⁶⁶ Telephone conversation, São Paulo, Brazil, 1 March 2001.

4. Cost of Gaining Product Approval and Licensing

Current costs for approval is as follows:

- Approximately \$4,000 for less-sophisticated equipment (generally valued under \$30,000, such as monitors).
- Approximately \$9,000 for more-sophisticated equipment,^{67, 68}
- About \$16,000 for “families” of products.⁶⁹

This fee structure is applied for every piece of equipment but can be reduced by up to 90% for smaller companies or in cases where the volume of equipment to be exported to Brazil is small.^{70, 71} Costs are added to the product price tag, clearly affecting price competitiveness.⁷²

Originally, the fee structure for approvals was unrealistically high, but the government reacted very quickly to bring fees to more realistic levels.⁷³ Although most people interviewed were consistent on the fees, there were some reports of ANVISA employees insisting on payments of “urgency fees” to ensure speedy approval. These apparently are not official fees, therefore, ANVISA may never know about them.⁷⁴

For a company to sell in Brazil, it must meet “Good Manufacturing Practices” (GMP) and/or ISO 9000 standards requiring separate registration with ANVISA, for a fee of \$20,000 p.a. The registration has to be obtained by the importer.

Product Approval and Licensing: Comments and Recommendations

A fee structure in line with the amount of work required by ANVISA would be fairer than when it is based on the manufacturer’s ability to pay. As Brazilian healthcare providers eventually pay the added cost, fees should be reasonable.

⁶⁷ Telephone conversation, São Paulo, Brazil, 1 March 2001.

⁶⁸ Telephone conversation, Washington, D.C., United States, 9 April 2001.

⁶⁹ Telephone conversation, São Paulo, Brazil, 9 May 2001.

⁷⁰ Telephone conversation, São Paulo, Brazil, 9 May 2001.

⁷¹ ANVISA website, Resolução - RDC nº 6, de 2 de janeiro de 2001, Anexo I, Section 7.

⁷² Telephone conversation, Washington, D.C., United States, 5 April 2001.

⁷³ Telephone conversation, Washington, D.C., United States, 17 November 2000.

⁷⁴ Telephone conversation, Florida, United States, 12 Dec 2000.

5. Effects on Quality and Costs

Hospitals that focus on and are known for providing high level, quality care (essentially tertiary and quaternary care hospitals) feel locally manufactured equipment is inadequate, not of the same quality, and lacking comparable warranties, servicing, or financing.⁷⁵ Registered products can be imported but are clearly more expensive and may simply not be accessible.⁷⁶ Since top hospitals serve only 3% to 5% of the population, and the smaller hospitals are prepared to buy used and locally produced equipment, the overall impact of ANVISA's charges on healthcare costs may be marginal.⁷⁷

Some hospitals, mostly with 150 beds or less, will not be able to pay the additional cost for importing equipment. To the extent alternative equipment is available, either locally produced or imported refurbished equipment, their capital costs and cost of operations are reduced.⁷⁸ However, in many cases alternative equipment will be of a lesser technology⁷⁹ and will provide a reduced ability for early detection of disease or illness. A market appears to be developing for selling refurbished equipment to smaller hospitals with original manufacturers providing them with product training, warranties, and repair support.⁸⁰

There are many reports of equipment being purchased by hospitals, and presumably also by physicians groups, or illicitly imported or produced by companies without GMP or ISO 9000 certification. To the extent that healthcare providers use equipment without ANVISA's registration, the care offered may not be of the quality paid for by the provider. Hospitals are presumed to be sufficiently interested in their patients' health to ask medical equipment providers for the ANVISA registration number.⁸¹ However, there is no evidence to support this occurs regularly.⁸²

Warranties and after-sales service regularly provided by most foreign equipment manufacturers have benefits such as minimum downtime for the equipment, and leading to technology upgrades as the manufacturers developed them. Reportedly operators of used equipment have more difficulty obtaining equipment servicing so they often encounter longer equipment downtimes. On the other hand, product training by local manufacturers appears to be comparable to that provided by foreign companies.⁸³

Financing the import of medical equipment is often subsidized by the manufacturer.⁸⁴ Purchases of locally manufactured equipment can receive government financing at subsidized rates through the National Development Bank (BNDES) or FINAME. However, some buyers are having difficulty obtaining such financing because of their credit quality.⁸⁵ A finance company specializing in financing of imported medical equipment and two banks that also provide such financing are encountering a scarcity of quality buyers.⁸⁶

⁷⁵ Telephone conversation, São Paulo, Brazil, 16 April 2001.

⁷⁶ Telephone conversation, São Paulo, Brazil, 20 April 2001.

⁷⁷ Telephone conversation, São Paulo, Brazil, 20 April 2001.

⁷⁸ Telephone conversation, São Paulo, Brazil, 20 April 2001.

⁷⁹ E-mail message, São Paulo, Brazil, 19 April 2001.

⁸⁰ Telephone conversation, Florida, United States, 16 November 2000.

⁸¹ Telephone conversation, São Paulo, Brazil, 26 April 2001.

⁸² Telephone conversation, São Paulo, Brazil, 1 March 2001.

⁸³ E-mail message, São Paulo, Brazil, 19 April 2001.

⁸⁴ E-mail message, São Paulo, Brazil, 19 April 2001.

⁸⁵ Telephone conversation, São Paulo, Brazil, 16 April 2001.

⁸⁶ Telephone conversation, Florida, United States, 16 April 2001.

Foreign companies appear to have lost market share to local manufacturers,⁸⁷ helping improve Brazil's balance of trade and, therefore, balance of payments. If the equipment is of lesser quality or technology, these macroeconomic savings are counterbalanced by higher costs of treating patients when an illness is detected too late.

In certain cases, such as when diagnostic equipment is used to analyze tissue or blood samples, the samples can be sent to a foreign laboratory, or the patient can fly abroad for diagnosis and treatment. Either alternative raises the cost of care. The impact on diagnostic testing applies equally to the top diagnostic labs in Brazil. They too must ship samples abroad for testing.⁸⁸ The accuracy of testing by smaller labs, unable to send samples abroad or less concerned with diagnostic quality, will become increasingly suspect.

Effects on Quality and Costs: Comments and Recommendations

Apparently, ANVISA has increased the costs of medical equipment imports for providers of more sophisticated healthcare services by charging high approval fees and duties, while also delaying those imports. To the extent that this may only affect the top 5% to 10% of the population, it will not have a significant effect on healthcare costs on a nation-wide basis.

While perhaps ANVISA believes that costs associated with fees and time to gain approval are absorbed by manufacturers, they are, in fact, added to product prices and paid indirectly by Brazilian consumers. As a result, smaller or financially weaker providers might buy used or refurbished equipment of lesser technology or buy from local equipment manufacturers. While lowering the capital costs for the providers, this may lead to diseases or illnesses not being caught in their early stages and raise the overall cost of patient care nation-wide.

Where diagnostic testing labs do not have equipment using the most current technology and are not prepared to undergo the additional cost of shipping samples to foreign diagnostic labs for testing, that can also lead to increasing doubt about the accuracy of their testing. It may also result in potentially higher treatment costs in the future. If healthcare providers are to have incentives to use the most current technology to detect disease or illness early, there should be higher reimbursement rates for use of more advanced diagnostic equipment.

⁸⁷ Telephone conversation, São Paulo, Brazil, 26 April 2001.

⁸⁸ Telephone conversation, São Paulo, Brazil, 20 April 2001.

6. Expectations for the Future

Protecting the health of Brazilians was a powerful argument for the creation of ANVISA. However, it is widely believed that Brazil's balance of payments and balance of trade deficits in the late 1990s were the main reasons for the agency's establishment.^{89, 90, 91} By reducing imports and helping the local medical equipment manufacturing industry to grow, the law benefited Brazil economically. Increasing concern about escalating prices of pharmaceuticals forebodes even more rigid oversight by ANVISA in this area.⁹²

Arguably, fees paid by foreign companies benefit the growing government agency and help it gain expertise. Upgrading university laboratories to test equipment has the added benefit of improving technology levels and teaching quality of Brazilian institutions. It is not expected that ANVISA will ease regulations. Changes would not be supported by the Association of Brazilian Medical Equipment Manufacturers (ABIMO).^{93, 94, 95} Moreover, given his political aspirations, the current Minister of Health may be less motivated to improve ANVISA's flexibility in dealing with foreign medical equipment manufacturers.⁹⁶

In the 1980s, Brazil did not allow the import of computers in order to help the local development of the computer industry. The law was eventually changed and today Brazil has a much more flexible view on foreign trade issues.⁹⁷ Brazil's desire to learn from the EU, the US, Canada, and other governments about establishing common standards for equipment to lower production costs is commendable. While every Latin American country poses difficulties for importers, Brazil is not particularly more difficult than other countries (Chile currently is and has a history of being the least challenging country for importers).⁹⁸

In the future, importing medical equipment may be affected by pending regulation (currently under discussion) that would limit the number and kind of equipment based on availability and location. The purpose would be to prevent an undue concentration of equipment in one place (for example, there are four MRIs in Florianopolis).⁹⁹ Theoretically, and evidence in various countries seems to confirm it, too much medical equipment or too many hospital facilities result in over-prescription of diagnostic testing or hospitalization and higher healthcare costs. In France, a similar process, called the Carte Sanitaire, regulates the supply and availability of medical equipment.

⁸⁹ Telephone conversation, Washington, D.C., United States, 11 April 2001.

⁹⁰ Telephone conversation, Rio de Janeiro, Brazil, 26 April 2001.

⁹¹ Telephone conversation, Florida, United States, 12 December 2000.

⁹² Telephone conversation, Rio de Janeiro, Brazil, 26 April 2001.

⁹³ Telephone conversation, São Paulo, Brazil, 20 April 2001.

⁹⁴ Telephone conversation, São Paulo, Brazil, 26 April 2001.

⁹⁵ Telephone conversation, São Paulo, Brazil, 1 March 2001.

⁹⁶ Telephone conversation, Washington, D.C., United States, 5 April 2001.

⁹⁷ Telephone conversation, Washington, D.C., United States, 11 April 2001.

⁹⁸ Telephone conversation, Washington, D.C., United States, 11 April 2001.

⁹⁹ Telephone conversation, São Paulo, Brazil, 23 May 2001.

7. Conclusions

The creation of a regulatory agency such as the Agência Nacional de Vigilância Sanitária (ANVISA) makes perfect sense for a country wishing to ensure the protection of its citizens as to the quality of food, pharmaceuticals, and the healthcare services they consume. Some of the initial problems with implementing its establishment such as high fees, delays in approval, and lack of understanding of how to test equipment have been mostly resolved.

One can argue that, due to the import restrictions and costs imposed by ANVISA, much medical equipment will be purchased from local suppliers or imported used (i.e., reducing new equipment imports). The overall amount spent on medical equipment will not likely go up, and the impact on the cost of medical care will be minimal. This theory, however, underestimates the failure to diagnose disease/illness by equipment of lesser technology until the disease's later stages, when it becomes more expensive to treat. More people will be sicker or die prematurely—and those costs need to be considered.

It seems in Brazil's best interest, as measured by the overall cost to treat the population, that equipment with the latest technology be imported (if not locally available) and that the costs be kept as low as possible. Recommendations include:

- ANVISA should recognize that the cost of approvals is forcing smaller foreign companies to stop exporting to Brazil and accelerating the substitution by buyers of locally produced equipment of lower technology for that of higher technology imports.
- Approvals of equipment be granted for “families” of comparable equipment (i.e., equipment that is essentially comparable from a risk and efficacy perspective). If approvals continue to be made on an individual model basis, unnecessary costs are added.
- Recognition be given to the fact that the apparent move to physically test medical equipment in Brazil rather than relying on review of certifications by independent testing agencies in other parts of the world, will result in much higher costs for those wishing to sell to the Brazilian market. It will also lead to an agency of the government growing much larger than it needs to be and thus more expensive to operate.
- ANVISA's standards for equipment used in the Brazilian market, whether imported or produced locally, mirror multilaterally agreed-upon “harmonized” standards. This ensures that special models of equipment do not have to be designed exclusively for the Brazilian market at higher costs.
- Application of equipment standards and the approval process should be consistent for both foreign and local manufacturers. Preferences for local manufacturers tend to raise questions about ANVISA's credibility.
- The Law of Similar be applied consistently. If a philanthropic hospital wishes to import equipment duty free, it should only be permitted to do so if there is no local manufacturer of equipment of the same level of technology.
- Close scrutiny should be given to diagnostic testing facilities to ensure the quality of their diagnosis meets established standards. If it does not, they should be required to upgrade their equipment, procedures, and management. The costs of inaccurate testing are hidden but significant.

- Approved reimbursement rates for diagnostic testing should be updated and provide a higher rate of reimbursement for the use of higher technology equipment. Healthcare providers would have an incentive to utilize more advanced equipment to detect disease or illness at an earlier stage.
- All hospitals should be required to obtain equipment registration numbers to ensure that used and locally produced equipment that they purchase has been approved by ANVISA. The resulting costs from inaccurate equipment are too high.
- Costs incurred by manufacturers for exporting medical equipment to Brazil will ultimately be paid for by providers and thus the Brazilian population. ANVISA needs to evaluate whether its charges are appropriate from that perspective.

ANVISA has made remarkable progress since its creation in 1999. If the cost of imported equipment was essential for its growth, then its actions may be justified. ANVISA will be doing a disservice to Brazil and will not be accomplishing the purpose such an organization is meant to fulfill if it builds a bureaucracy without considering the impact of its costs on the Brazilian population.

Medical Equipment Import Costs

Comparison of Duties and Other Costs

Draft 4 June 01

The information below is calculated to compare the cost of importing an hypothetical piece of new medical equipment with a CIF value of USD100,000 into four Latin American countries.

	Argentina	Brazil	Chile	Mexico
CIF cost	\$ 100,000	\$ 100,000	\$ 100,000	\$ 100,000
VAT (10.5%)	10,500			
FDA tax	10			
II tax (Mammo or Xray only – 14%)		14,000		
IPI tax (2% or 4%)		2,000		
		or 4,000		
Brazilian ANVISA		13,000		
Add Valorem tax (8%)			8,000	
IVA (18% of CIF & ad valorem)			19,440	
Other (0.5% of CIF)			500	
Ad valorem (13%)				13,000
For ultrasound (18%)				or 18,000
VAT (15%)				15,000
Other (.008%)				8
Totals:	\$ 110,510	\$ 129,000	\$ 127,940	\$ 128,008
Or		131,000		133,008

Courtesy of GE Medical Systems

Medical Equipment Imports

Impact on the Cost and Quality of Brazilian Healthcare

Framing Paper

Agência Nacional de Vigilância Sanitária, ANVISA, is responsible, *inter alia*, for regulating the import of medical equipment. ANVISA has been criticized by US and European medical equipment manufacturers for making it difficult to export medical equipment to Brazil. This causes delays for healthcare providers wishing to import equipment, and makes the equipment more expensive – due to fees charged and time needed for product registration.

Issues for discussion:

1. What are the real reasons for the expected decrease in imports of new medical equipment? The increased costs of importing medical equipment because of devaluation of the *real*, or the import regulatory delays and costs imposed by registration of products with ANVISA?
2. Can Brazil afford the higher costs of treating diseases and illnesses that were not detected earlier because equipment of older technology was used?
 - a. Does the increased availability to providers of lower priced used or lower technology equipment offset the increased cost of not detecting disease or illness earlier? Must one opt for one or the other?
 - b. Is the Ministerio da Saude willing to set minimum technology standards for medical equipment?
 - c. Will the Ministerio da Saude permit a change in the schedule of reimbursements for diagnostic testing to provide for a higher fee when more advanced equipment is used? Will it be updated for the changes in costs in the past 2½ years?
 - d. When determining if comparable locally produced equipment is available when considering approval for the duty-free import of equipment by a philanthropic healthcare provider, should the level of technology also be considered?
3. Why are the results of medical equipment tested by agencies and others acceptable to the European Union approval authorities or to the US FDA not acceptable to ANVISA? Instead of using those test results as the basis for equipment approval, as is done in the EU and the US, why does ANVISA require testing in Brazil or having their employees certify tests in the production facilities of the manufacturer?
4. As the cost of registration of medical equipment with ANVISA translates directly to higher prices for the Brazilian purchasers, are ANVISA's charges and unique requirements appropriate from that perspective?
5. Should hospitals and other healthcare providers be required to obtain ANVISA registration numbers when purchasing used or locally produced medical equipment?