



HOW TO REGISTER LIFE SCIENCES PRODUCTS IN BRAZIL

BRAZILIAN FACTS AND STATS

- 187 million habitants.
- 7,564 hospitals (30% private; 70% public).
- 15,000 health clinics – 12,000 laboratories.
- US\$ 30 billion budget – overall expenditure, including public and private sectors.
- 240,000 medical doctors and 720,000 nurses and nursing personnel.
- Nearly 500,000 hospital beds (80% private; 20% public).
- Fertility rate 2,5 – life expectancy 67 years (male) and 72 (female).
- 7% GDP invested in Healthcare in 2006.
- Healthcare budget increase in 2006: 21%.

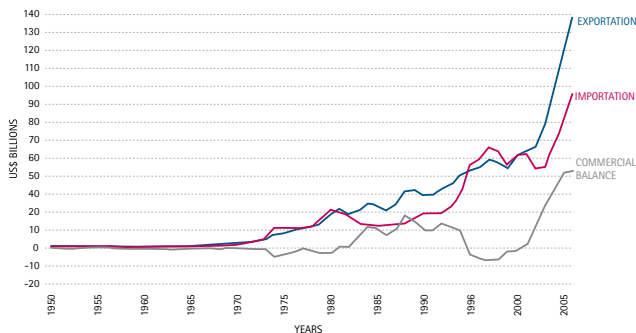
Source: Ministry of Health, 2006.

THE BRAZILIAN MARKET FOR LIFE SCIENCES PRODUCTS

Since 1990, Brazil has opened up its economy to international markets. Import taxes and import procedures have been reduced. Opportunities for foreign suppliers, including manufacturers of medical devices, have substantially increased. Japan, Germany and the USA have profited from this scenario and established themselves as the main suppliers of medical/hospital equipment in Brazil. Unfortunately, the UK market share in Brazil is still quite small: less than 2% of all medical devices imports.

Brazilian Commercial Balance (1950-2005)

Source: SECEX, 2006



There are nearly 550 local manufacturers in the medical sector in Brazil today. Approximately 20% are multinationals or have foreign participation in their capital structure. In size, the breakdown of the Brazilian medical industry is as follows: 3.3% (large); 68.7% (medium); 28% (small). About 90% of local production is destined for the domestic market. The remaining is exported, mainly to other South American countries, to Europe or the United States. In Brazil, 48% of medical equipment sales goes to the private sector, 44% goes to the public sector and 8% is exported.

There are about 3,000 importers and distributors of medical devices in Brazil. Most of them represent small and medium-sized companies that operate in well-defined niche markets. They are mostly based in the Southeastern (Minas Gerais, Rio de Janeiro and São Paulo) and Southern (Paraná and Rio Grande do Sul) regions. Excluding the direct sales network of individual multinational manufacturers, virtually, all distributors are regional, rather than national, though they normally work with a network of associated dealers.

ANVISA: THE BRAZILIAN REGULATORY AGENCY

The Brazilian government establishes specific regulations for the registration and licensing or exemption of Life Sciences products. The National Health Surveillance Agency - ANVISA - was established in 1999 to foster protection of the health of the population by exercising sanitary control over production and marketing of products and services subject to sanitary surveillance. The role of ANVISA is equivalent to the role of the MHRA in the UK. In order to export and distribute their products in Brazil, foreign companies must either establish a local manufacturing unit, a local office or appoint a Brazilian distributor to hold the registration with ANVISA.

GETTING INTO THE MARKET COST-EFFECTIVELY: APPOINT A LOCAL DISTRIBUTOR

The selection of the right distributor is essential in the process. A solid contract, including the ownership of its registration with ANVISA, should be agreed. It is also recommended to establish specific clauses in the contract which would allow the transfer of ownership of the registration from the local distributor to the manufacturer. In Brazil, this transfer can only occur if the company opens an office or plant in Brazil, since no registration can be transferred overseas. The transfer of ownership is an important clause because without it it would be difficult to transfer it from one agent to another. Besides selecting a distributor, the foreign company should also apply for registration of the trademark and patent at the INPI -

National Industrial Property Institute - through a local law firm (this service is usually provided by the distributor).

REGISTRATION OF YOUR PRODUCT

The product registration is valid for five years and can be renewed continuously for the same period. Although this process might be costly and time consuming, registering your products will guarantee several benefits including support by law and compliance with the Brazilian Health regulations; product reliability; access to new markets (public bids and exportation to Latin America) and the possibility to import and export without sanitary barriers.

PRODUCT CLASSIFICATIONS ACCORDING TO ANVISA

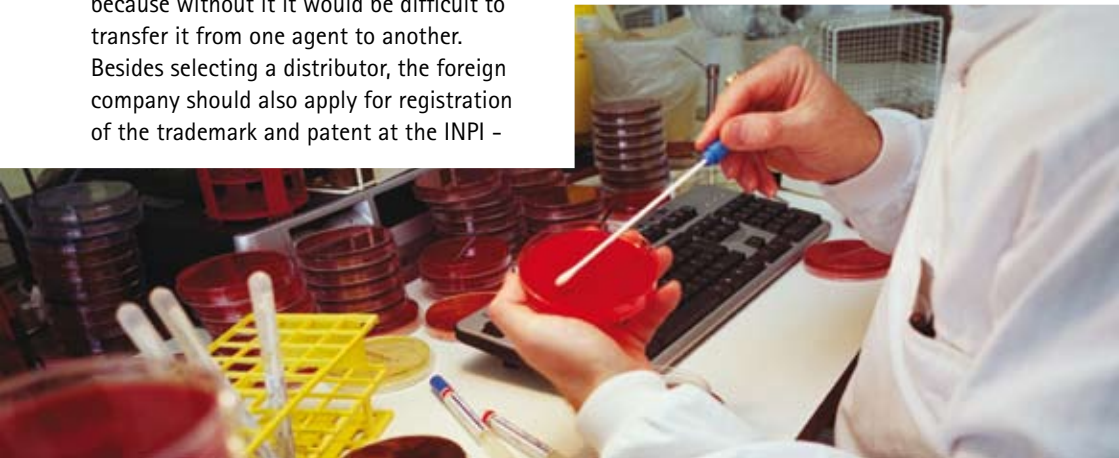
ANVISA classifies Life Sciences products in the following categories (Law 9.782/99):

1. Medications for human use.

The Medication category is divided into three distinct areas:

New Product: Innovative medication that has patent protection and whose efficacy, safety and quality have been scientifically proven and identified by its brand.

Similar Product: Medication that contains the same active principle, or principles, in the same concentration with the same pharmaceutical



form, manner of administration, posology and therapeutic, preventive or diagnostic indication as the reference medication registered with ANVISA. Permitted to differ from the original product only in terms of characteristics related to the size and shape of the product, expiry date, packaging, labelling, excipients and its contents, and should always be identified by its trade name or brand. Produced after expiry of patent protection.

Generic Product: Medication similar to a reference product or innovative product with which it is intended to be exchangeable, generally produced after the expiry or waiver of patent protection or other exclusive rights, with its efficacy, safety and quality having been scientifically proven, and named in accordance with the Common Brazilian Name Listing (DCB) or the Common International Name Listing (DCI).

2. Cosmetics, personal hygiene products and perfumes.

Classified according to the health risk they may present, hence the need to register (or exempt) certain products.

Cosmetic with "no-risks" or "risk 1" products:

Defined as products with minimal risk, such as soaps; shampoos, toothpastes and deodorants; beauty/facial lotions, grooming products.

These products no longer need registration, and do not incur administrative fees. However, companies must notify the Agency by using the appropriate form while the product can only be launched on the consumer market 30 days after this notification has been sent.

Cosmetic "risk 2" products: Defined as products that present potential risk, such as: hair colours; hair straighteners; products for hair and scalp treatment (anti-dandruff shampoos); chemical depilatories; insect repellents; and products for children. The company must register the product, pay the administrative fees and wait for the registration approval.



3. Pharmaceutical raw materials (drugs or raw materials to be used in the manufacturing of medications).

4. Food (including beverages, bottled waters, food additives).

5. Household products.

Registration is no longer needed for products ranked as "no-risk" or "risk 1", which are defined as products offering minimal risks to human health. The registration shall be processed on the basis of evaluation and management of the involved risks. The following aspects shall be taken into consideration when evaluating such risks: the toxicity of the substances and their concentration in the product; the purpose of use; the conditions under which they shall be used; the occurrence of previous problems; the population likely to be exposed to such products; the exposure frequency and its duration and the form of product presentation.

6. Sets, reagents and inputs intended for *In Vitro* diagnostics.

7. Medical equipment and devices.

Medical equipment and devices are grouped in "family products" and also classified in three risk classes (1, 2 and 3) according to the health risk they may present. The classification of the product is usually indicated by ANVISA according to risk lists.

8. Immunobiological materials and their active substances, blood and hemoderivates.

9. Human and veterinary organs and tissues.

10. Cigarettes, cigars, and smoking products.

11. Others. Any product that might cause health risks, that utilises genetic engineering or from any other procedure subject to sources of radiation.

Observations

The relevant classification criteria is defined on the basis of product usage purposes, affected body areas, directions for use and precautions to be taken when using such products.

Brazil does not yet have an OTC (Over the Counter Product). Thus, sometimes it is very hard to classify an OTC product with the Brazilian legislation. Most of them are considered by the Brazilian legislation as pharmaceutical or cosmetic products.

WHAT DOCUMENTS DO YOU NEED TO REGISTER YOUR PRODUCT?

- a) Application form obtained from the Brazilian Ministry of Health;
- b) Proof of payment of registration fee;
- c) Trade Permit issued by the State authority to the manufacturer's distributor;
- d) Trade Permit, issued by the Federal authority to the manufacturer's distributor;
- e) Document showing the technical responsibility of the distributor/manufacturer, issued by the certification entity;
- f) Technical Report on the product, detailing the components of the formula, instructions, directions, cautions, etc;
- g) Label sample, brochures, pertinent information about the products, all translated into Portuguese;
- h) For products not clearly mentioned in

the Brazilian law, it is mandatory to provide information about their utilisation in order to demonstrate their efficacy and safety;

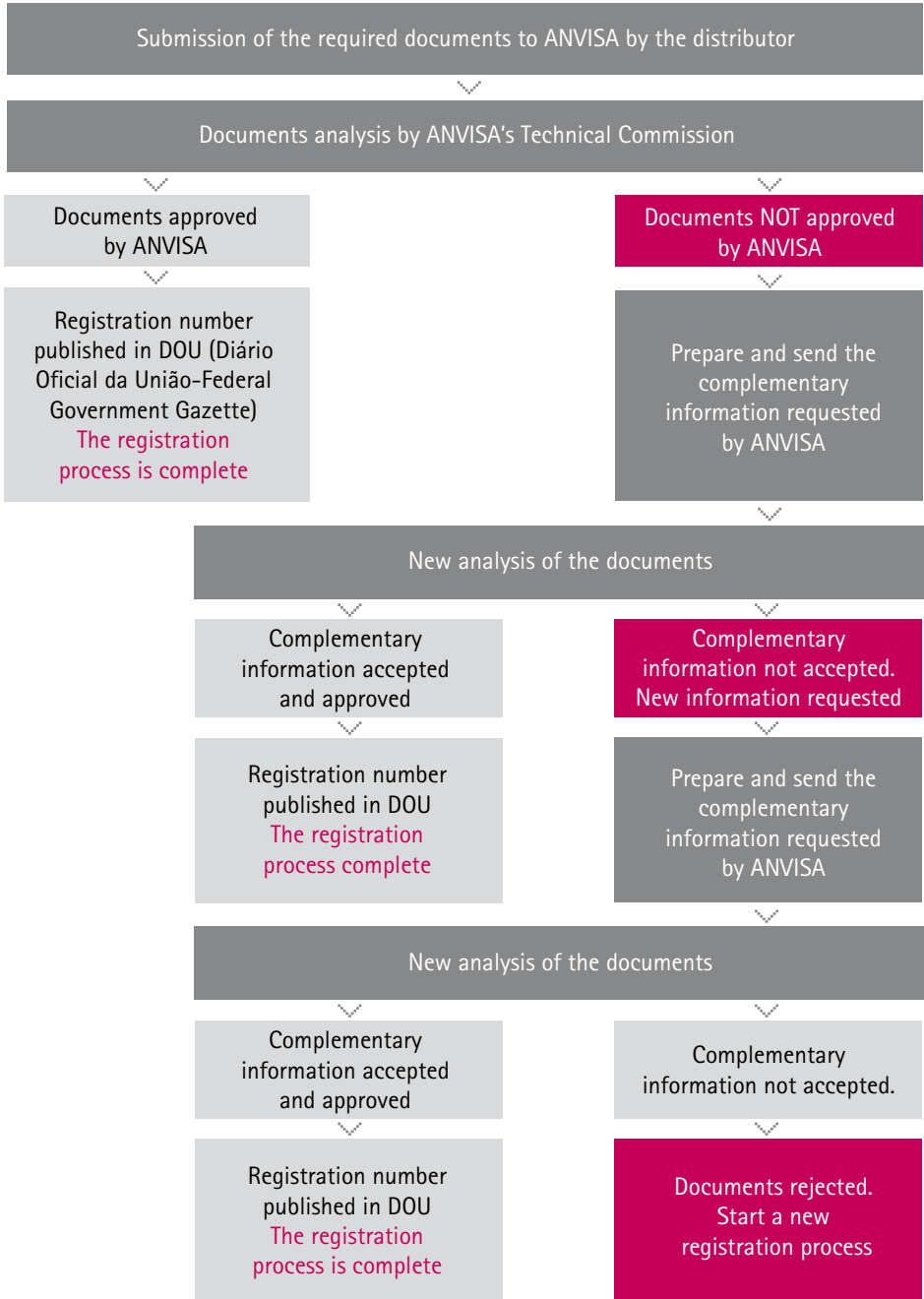
- i) Copy of the registration granted to the products at the country of origin (or copy of the Free Sale Certificate);
- j) Copy of the legal document, by which the manufacturer authorises its distributor to trade and distribute the products;
- k) GMP (Good Manufacturing Practice);
- l) For medical equipment, all documents showing product safety, country of origin, detailed (exploded view) of the equipment inner parts and user manual;
- m) Financial, pricing and market strategy reports (determined by Resolution - RDC nº 185/06).

With the requirements above, special attention should be paid to the TECHNICAL REPORT. This is mentioned in the Administrative Act, and it is required by the cosmetics, vitamins, and pharmaceutical manufacturers.

The documentation presented for registration, alteration or revalidation of the registration will be assessed by ANVISA, which will issue its decision through publication in the Federal Government Gazette (DOU - Diário Oficial da União).



REGISTRATION FLOWCHART





FREQUENTLY ASKED QUESTIONS

1) What are the administrative fees for product registration?

The Administrative fees levied on a medicine product are:

- £20,000 (for a new drug/large company)
- £2,000 (new drug/small company)
- £5,250 (similar medicine/large company)
- £525 (similar/small company)
- £1,500 (generic/large company)
- £150 (generic /small company)

The administrative fees levied on medical equipments and devices ranges between £500 (small company) and £5,000 (large company). The size of the company is stipulated according to its annual revenue and the fee values are based on an approximate exchange rate of £1 = 4 Brazilian Reais.

2) Does Brazil accept bio-equivalence tests done abroad?

Brazil accepts bio-equivalence tests done abroad. If the product is made in Brazil, the clinical tests should be done by a Brazilian Laboratory accredited by ANVISA.

3) Are there any common registration processes for the Mercosur countries?

It is not possible to use the registration issued in Brazil for other countries of Mercosur (Argentina, Uruguay and Paraguay). There is no common registration procedure for the Mercosur countries. The company must apply for registration in each country individually.

4) Is there a pre-market notification process?

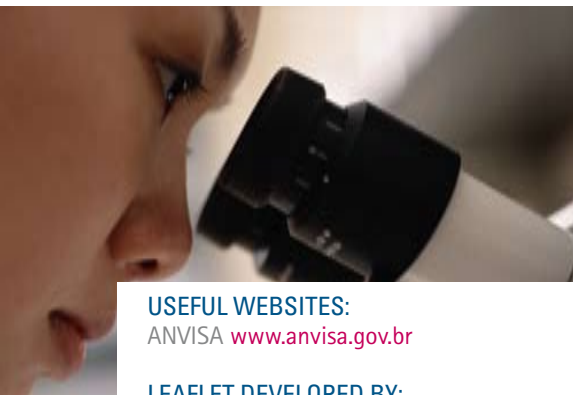
No. Brazil does not have any policy for pre-market notification process. The company must get the registration approval before launching its product in the market.

5) How many distributors can market a company product and register it in Brazil?

There is no limit. However, we recommend that the company elects just one main distributor to register its product at Anvisa and gives the authorisation for new distributors to sell the products under his registration number.

6) How long does the whole process of registration take?

The registration process takes about 8-12 months to be completed.



USEFUL WEBSITES:

ANVISA www.anvisa.gov.br

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**UK TRADE & INVESTMENT
OVERSEAS MARKET INTRODUCTION
SERVICE (OMIS)**

Accurate and up-to-date market information is crucial to the success of your product or service in Brazil. UK Trade & Investment's Overseas Market Introduction Service (OMIS) is a flexible tool enabling direct communication between you and more than 150 commercial teams located in the British global network of Embassies, High Commissions and Consulates.

An OMIS carried out by the Life Sciences team in Brazil can provide you with a market/sector overview; market and distributors analysis (feasibility of your product/service in the market); opportunities, prospects and evaluation of market-entry strategies; identification and in-depth assessment of potential business of contacts/partners who may be "warmed up" if required and local market introductions.

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