

Provisional Remedy n° 2.039-20, of August 25, 2000

Alters provisions of Law No. 9.782, of January 26, 1999, which Defines the National Sanitary Surveillance System, establishes the National Sanitary Surveillance Agency and sets out other provisions.

THE PRESIDENT OF THE REPUBLIC, in the use of the attributions vested in him under Article 62 of the Constitution, adopts the following Provisional Remedy:

Article 1 - The provisions of Law No. 9.782, of January 26, 1999, indicated below, shall henceforth be in force with the following changes:

"Article 7 -
.....

VII. to authorize the operation of companies that manufacture, distribute and import the products mentioned in Article 8 of this Law, and that market medicines;
.....

XXV. to monitor the evolution of prices of medicines, health equipment, components, inputs and services, with power to:
request, at its discretion, information about production, inputs, raw materials, sales and any other information held by private or public corporations which perform activities of production, distribution and marketing of goods and services provided for in this item, keeping legal secrecy whenever the case;
carry out examination of stock, papers and documents of any companies or private or public corporations which perform activities of production, distribution and marketing of goods and services provided for in this item, keeping legal secrecy whenever the case; when evidence of the existence of infractions provided for in items III or IV of Article 20 of Law No. 8.884, of June 11, 1994, is verified, by means of unjustified rise of prices or imposition of excessive prices of goods and services referred to in these items, summon those responsible in order for them to justify their respective conduct within ten working days;
apply the penalties provided for in Article 26 of Law No. 8.884, 1994;

XXVI - to control, inspect and supervise, in the light of sanitary legislation, the advertising and publicity of products subject to the sanitary surveillance regimen.
.....

Paragraph 4 - The Agency may devolve to an organization within the Ministry of Health the discharge of functions listed in this article and pertaining to medical, out-patient and hospital services, provided for in Paragraphs 2 and 3 of Article 8 of Law No. 9.782, of 1999, provided that interdictions defined in Paragraph 1 of this Article are obeyed.

Paragraph 5 - The Agency shall always act in compliance with guidelines set out by Law No. 8.080, of September 19, 1990, in order to continue the development of the process of decentralization of activities towards the States, the Federal District and the Municipalities, provided that interdictions defined in Paragraph 1 of this Article are obeyed.

Paragraph 6 - Decentralization referred to in the previous Paragraph shall be carried out only after favorable opinions by the respective State, District and Municipality Health Councils. (Re-edition)."

"Article 8 -

Paragraph 5 - The Agency may waive the registration of immune-biological products, insect killers, medicines and other strategic inputs whenever they are acquired through international multilateral organizations to be used in public health programs by the Ministry of Health and its related bodies.

Paragraph 6 - The Minister of Health may determine the development of activities under the competence of the National Sanitary Surveillance Agency, in specific cases that may jeopardize the health of the population.

Paragraph 7 - The deed mentioned in the previous paragraph must be published in the Official Journal of the Union." (Re-edition).

"Article 9 -

Only Paragraph - The Agency shall also count on an Advisory Council, that shall include, at least, representatives of the Union, of the States, of the Federal District, of the Municipalities, of producers, of traders, of the scientific community and of users, as provided for in regulation." (Re-edition).

"Article 15 - It is due to the Collegiate Board of Directors:

to establish the strategic guidelines of the Agency;

to propose to the Minister of Health governmental policies and guidelines meant to allow the Agency to fulfil its goals;

to enact norms on matters within the sphere of competence of the Agency;

to enforce and ensure enforcement of norms pertaining to sanitary surveillance;

to prepare and issue periodical reports on its activities;

to judge, at appeal level, upon decisions taken by the Agency, as per request by the parties concerned;

to refer the accounting statements of the Agency to the relevant bodies.

Paragraph 1 - The Board of Directors shall convene with the presence of at least three directors, amongst them the Chairperson or his or her lawful deputy, and shall decide by simple majority of votes.

Paragraph 2 - Deeds of the Agency shall be susceptible of appeal to the Collegiate Board of Directors, with suspending effect, as last administrative level." (Re-edition)

"Article 16 - It is due to the Chairperson:

to represent the Agency in and out of court;

to chair the meetings of the Collegiate Board of Directors;

to decide on urgent issues, *ad referendum* of the Collegiate Board of Directors;

to decide in cases of tie in the deliberations of the Collegiate Board of Directors;

to appoint and dismiss civil servants, filling effective commissioned grades and functions, and to exercise the disciplinary power, as provided for in the legislation in force;

to refer to the Advisory Council the periodical reports prepared by the Collegiate Board of Directors;

to sign contracts and agreements and to determine expenditure.

to elaborate, approve and promulgate the internal regulations, define the field of action of the organizational units and the executive structure of the Agency; to perform the operational management of the Agency." (Re-edition)

"Article 19 - The Agency's management shall be governed by a management contract, negotiated between its Chairperson and the Minister of Health, the Ministers of Finance and of Planning, Budget and Management having been previously heard, within one hundred and twenty days after the appointment of the agency's Chairperson.

....." (Re-edition)

"Article 22 -

.....

X - amounts obtained through investments in the financial market of revenues provided for in numerals I through IV and VI through IX of this Article.

....." (Re-edition)

"Article 23 -

.....

Paragraph 6 - Laboratories created or controlled by the Public Power, producing medicines and inputs subject to Law No. 6.360, of September 23, 1976, in the interest of Public Health, are exempt from payment of the Sanitary Surveillance Inspection Fee.

Paragraph 7 - Renewals of registrations, authorizations and certificates are subject to the periodical schedule and to the amounts stipulated for the initial deeds, as provided for in Annex II.

Paragraph 8 - The provisions of the previous Article apply to the contents of Paragraphs 1 through 8 of Article 12 and to the Only Paragraph of Article 50 of Law No. 6.360, of 1976, of Paragraph 2 of Article 3 of Decree-Law No. 986, of October 21, 1969 and of Paragraph 3 of Article 41 of this Law." (Re-edition).

"Article 30 - The moment the National Sanitary Surveillance Agency is created, with the publication of its internal regulation by the Collegiate Board of Directors, the Autonomous Agency shall be automatically vested in the exercise of its functions, and the Secretariat for Sanitary Surveillance shall become extinct". (Re-edition).

"Article 41 -

Paragraph 1 - The Agency may grant operation authorization to companies and registration to products applicable solely to producing factories and to merchandise geared to external markets, provided that they do not bring about risks for public health.

Paragraph 2 - The regulation referred to in the *Caput* of this Article includes within its coverage the exemption of registration.

Paragraph 3 - Companies subject to Decree-Law No. 986, of 1969, must also comply with Article 2 of Law No.6.360, of 1976, in what regards the authorization for operation by the Ministry of Health and the licensing by the sanitary bodies of the Units of the Federation where they are located". (Re-edition).

Article 2 - Law No. 9.782 shall henceforth be in force added of the following articles:

"Article 41-A - The registration of medicines with exclusively generic names shall have priority over that of the others, as provided for in a deed by the Collegiate Board of Directors of the National Sanitary Surveillance Agency". (Re-edition).

"Article 41-B - When the marketing of products subject to sanitary surveillance that are unfit for use is verified, the company responsible for them must issue advertisement containing a warning to the population, within the period of time and under the conditions indicated by the sanitary authority, and the company shall have to pay a fee corresponding to the examination and to the previous agreement on the informative contents by the National Sanitary Surveillance Agency". (Re-edition).

Article 3 - The National Institute for Quality Control in Health shall be technically subordinated to the National Sanitary Surveillance Agency, and administratively subordinated to the Oswaldo Cruz Foundation.

Only Paragraph - Appointments for commissioned grades and nominations for bonus-earning functions of the National Institute for Quality Control in Health shall be under the competence of the Minister of Health, as per nomination by the Chairperson of the National Sanitary Surveillance Agency, the President of Oswaldo Cruz Foundation having been heard.

Article 4 - Food imported in its original packing shall have as its dates of expiry, for the purposes of regularizing its registration situation vis-à-vis of the National Sanitary Surveillance Agency, March 1st, 2000.

Article 5 - Effective civil servants from the staff of the Ministry of Health who were in office on December 31, 1998, at the Secretariat for Sanitary Surveillance and in the Airport, Port and Border Stations are hereby redistributed to the National Sanitary Surveillance Agency.

Paragraph 1 - The civil servants from the National Health Foundation, redistributed according to the provisions in the *Caput*, shall be included in the same grade plan as the civil servants redistributed from the Ministry of Health.

Paragraph 2 - In the event that the result of the inclusion mentioned in the previous paragraph generates amounts inferior to those previously received, the difference shall be paid as a nominally identified advantage, the same percentages of general revision or anticipation of salary readjustment being applicable.

Article 6 - Annex I, regarding the Demonstrative Chart of Commissioned Functions of Sanitary Surveillance of the National Sanitary Surveillance Agency, and Annex II to Law 9.782, of 1999, shall respectively be henceforth in force in the form of the Annexes I and II to this Provisional Remedy.

Article 7 - Articles 2 and 3 of Law 9.294, of July 15th, 1996, shall be henceforth in force with the following language:

"Article 2 -

.....

Paragraph 2 - The use of products referred to in the *Caput* is for interdicted in aircraft and collective transport vehicles." (Re-edition)

Article 3 -

Paragraph 2 - Advertisement shall contain, in the media, and according to its characteristics, a warning, where possible oral and written, on the ill-effects of tobacco, alcoholic beverages, medicines, therapies and agricultural defensives, according to phrases established by the Ministry of Health, to be used sequentially, in simultaneous or rotational form". (Re-edition).

Paragraph 6 - The National Sanitary Surveillance Agency, in order to prevent the circulation of false advertising of products and services subject to its control, may demand prior presentation of copies of the advertisements referring to these products and services, in compliance with regulation approved by its Collegiate Board of Directors" (Re-edition)

Article 8 - Articles 3 and 57 of Law No. 6.360, of September 23, 1976, altered by article 1 of Law No. 9.787 of February 10, 1999, shall henceforth be in force with the following language:

"Article 3 -

XX - Similar Medicine - that which contains the same active principle(s), presents the same concentration, pharmaceutical form, means of administration, dosage and therapeutic indication, and which is equivalent to the reference medicine registered at the federal agency in charge of sanitary surveillance, being allowed to differ only in characteristics related to size and form of the product, expiry date, packaging, labeling, excipients and vehicles, always being identified by its trade mark;

Only Paragraph - In the case of imported generic medicines, whose bio-equivalence tests have been carried out outside the Country, the comparative dissolution tests between the test-medicine, the international reference medicine used in the bio-equivalence study and the national reference medicine must be presented" (Re-edition)

"Article 57 -

Only Paragraph - In addition to the trademark, medicines must display, in the pieces referred to in the *Caput* of this Article, in the packaging and in the advertising material, the Brazilian Common Denomination or, when appropriate, the International Nonproprietary Name, in lettering and characters in a size never under half that of the lettering and characters of the trademark." (Re-edition)

Article 9 - The *Caput* of Article 2 of Law No. 9.787, of February 10, 1999, shall henceforth be in force with the following language:

"Article 2 - The federal agency responsible for sanitary surveillance shall regulate, within one hundred and eighty days, counting as from February 11, 1999". (Re-edition).

Article 10 - Provisions of Article 15 of Law No. 5.991, of December 17, 1973, apply to medicine distributing companies.

Article 11 - Deeds performed based upon Provisional Remedy 2.039-19, of July 28, 2000 are hereby validated.

Article 12 - This Provisional Remedy enters into force on the date of its publication.

Article 13 - Article 4 of Decree-Law No. 986, of October 21, 1969, Article 82 of Law No. 6.360, of September 23, 1976, Article 3 of Law No. 9.005, of March 16, 1995, the Only Paragraph of Article 5, numerals XI, XII and XIII of Article 7, Articles 32 and 39 and their paragraphs, of Law No. 9.782, of January 26, 1999 are hereby revoked.

Brasilia, August 25th, 2000; 179th of the Independence and 112th of the Republic.

FERNANDO HENRIQUE CARDOSO

José Serra

Martus Tavares

ANNEX I

DEMONSTRATIVE CHART OF COMMISSIONED FUNCTIONS OF SANITARY SURVEILLANCE AT THE NATIONAL SANITARY SURVEILLANCE AGENCY

| CODE/FCVS | NUMBER | AMOUNT |
|-----------|--------|------------|
| FCVS/V | 42 | 1,170.00 |
| FCVS/IV | 58 | 855.00 |
| FCVS/III | 47 | 664.00 |
| FCVS/II | 58 | 585.00 |
| FCVS/I | 69 | 518.00 |
| TOTAL | 274 | 199,610.00 |

ANNEX II

SANITARY SURVEILLANCE INSPECTION FEE

| Item | Generating Facts | Amounts in R\$ | Period of Time for Renewal |
|--------|--|----------------|----------------------------|
| 1. | Authorization for operation of companies, per establishment or manufacturing unit, for each type of activity | | |
| 1.1. | On the medicine manufacturing sector | 20,000 | annual |
| 1.2. | On equipment and related matters | - | |
| 1.2.1. | Equipment (nuclear medicine, computerized tomography, magnetic resonance and cineangiography) | 10,000 | annual |
| 1.2.2. | Other equipment, instruments and sets for diagnoses | 5,000 | annual |
| 1.3. | Distributors of medicines | 15,000 | annual |
| 1.4. | Drugstores, pharmacies and the retail trade of | 5,000 | annual |

| | | | |
|----------|---|---------|---------------|
| | medical and hospital material | | |
| 1.5. | On the food and beverages industry | 6,000 | annual |
| 1.6. | On the cosmetic industry | 6,000 | annual |
| 1.7. | On the sanitizing products industry | 6,000 | annual |
| 1.8. | Others | 6,000 | annual |
| 2. | Change to the addition to the authorization (type of activity, registry data, business merger or incorporation) | 4,000 | indeterminate |
| 3. | Replacement of legal representative, technical representative or cancellation of authorization | exempt | |
| 4. | Certificate of good practices in terms of manufacturing and control for each establishment or manufacturing unit, type of activity and line of production/marketing | - | |
| 4.1. | In the country and in MERCOSUR | | |
| 4.1.1. | Medicines | 15,000 | annual |
| 4.1.2. | Related matters | - | annual |
| 4.1.2.1. | Equipment (nuclear medicine, computerized tomography, magnetic resonance and cineangiography) | 10,000 | annual |
| 4.1.2.2. | Other equipment, instruments and sets for diagnoses | 5,000 | annual |
| 4.1.3. | Food and beverages | 3,000 | annual |
| 4.1.4. | Cosmetics | 3,000 | annual |
| 4.1.5. | Sanitizing products | 3,000 | annual |
| 4.2. | Other countries | 37,000 | annual |
| 5. | Registration or Registration Renewal for Products or Group of Products | - | |
| 5.1. | Cosmetics | 2,500 | five years |
| 5.2.1. | Sanitizing products - Category 1 | 3,000 | five years |
| 5.2.2. | Sanitizing products - Category 2 | 3,000 | five years |
| 5.3. | Related products | - | |
| 5.3.1. | Equipment (nuclear medicine, computerized tomography, magnetic resonance and cineangiography) | 20,000 | five years |
| 5.3.2. | Other equipment (instruments and sets for diagnosis) | 8,000 | five years |
| 5.4. | Medicines | - | |
| 5.4.1 | New | 80,000 | five years |
| 5.4.2. | Similar | 21,000 | five years |
| 5.4.3. | Generic | 6,000 | five years |
| 5.6. | Tobacco and similar products | 100,000 | annual |
| 6. | Addition or change in registration | - | |

| | | | |
|-------|--|--------|---------------|
| 6.1. | Presentation | 1,800 | indeterminate |
| 6.2. | Concentration and pharmaceutical formula | 1,800 | indeterminate |
| 6.3. | Text of description, form for use and labeling | 1,800 | indeterminate |
| 6.4. | Period of time of validity or cancellation | exempt | indeterminate |
| 6.5. | Any other | 1,800 | indeterminate |
| 7. | Exemption of registration | 1,800 | indeterminate |
| 8. | Certificate, attestation, toxicological classification, extension of use, quota for marketing, per company, of controlled product, other declaratory deeds | 1,800 | indeterminate |
| 9. | Reopening of cases and second copy of documents | 1,800 | indeterminate |
| 10. | Agreement in the advertising notification of products for maximum use during six months, in cases of notification to the population | 8,800 | indeterminate |
| 11. | Agreement in cases of clinical research | 10,000 | indeterminate |
| 12. | Agreement for tax exemption and in cases of import or export of products subject to sanitary surveillance | exempt | |
| 13. | Agreement in cases of import and export for the purpose of marketing a product subject to sanitary surveillance | 100 | indeterminate |
| 14. | Collection and transportation of samples for control analysis of imported products | - | |
| | - within a municipality | 150 | indeterminate |
| | - another municipality of the same state | 300 | indeterminate |
| | - another state | 600 | indeterminate |
| 15. | Inspection for checking compliance with sanitary requirements | Exempt | |
| 16. | Activities of sanitary control of ports, airports and borders | - | |
| 16.1. | Issuance of certificates of rat and mice elimination and exemption of same for boats | 1,000 | indeterminate |
| 16.2. | Issuance of manifest of disembarking passengers and crew members of crafts, aircraft and land vehicles of international transit | 500 | indeterminate |
| 16.3. | Issuance of certificate of free practice | 600 | indeterminate |
| 16.4. | Issuance of manifest for transportation of corpse in crafts, aircraft and land vehicles in inter-state and international transit | Exempt | |

1. Amounts in the Chart shall be reduced by:

15% in cases of companies with an annual turnover of less than R\$ 50.000.000,00 (fifty million reais);

30%, in cases of average companies with a turnover above R\$ 6.000.000,00 (six million reais);
60%, in cases of medium companies with a turnover of R\$ 6.000.000,00 (six million reais) or less
90%, in case of small companies;
e) 95%, in cases of micro-companies, except for items 1.3 and 1.4, the amounts for which, in cases of micro-companies, are reduced by 90%.

2. Beverages and food shall be registered in cases within the competence of the Ministry of Health.

3. For small and micro-companies, the fee for the concession of Certificates of Good Practice of Manufacture and Control, item 4, shall be collected for each establishment or manufacturing unit.

4. Until December 31st, 1999, micro-companies shall be exempt from the fee for the concession of Certificates of Good Practice of Manufacture and Control, Registration or Renewal of Registration of Products or Group of Products, items 4 and 5. The exemption may be extended to December 31st, 2000, as per decision by the Collegiate Board of Directors of ANVISA.

5. The fee for Registration or Registration Renewal for medicines or group of physiotherapy medicines and homeopathic medicines, Large Volume Parenteral Solution and Small Volume Parenteral Solution shall be that of item 5.4.3, Generics.

6. For the purposes of Registration or Registration Renewal, medicines shall be deemed new if they contain new molecules and if they are covered by patents.

7. The amounts of the Chart for Registration Renewal of Products or Groups of Products shall be reduced by 10% at each renewal, up to the total limit of 50%.

8. The fitting of companies in the sizes provided for in letters "b" through "d" of item 1 shall be done starting from what is established by Laws 9.317, of December 5th, 1996 and 9.531, of December 10th, 1997.

9. The Collegiate Board of Directors of ANVISA shall fit the provisions of items 16.1, 16.2 and 16.3 and their discounts to the size of crafts, as per number of passengers, weight of cargoes or as per a mixed criterion.

10. In cases of exports, the collection of fees pertaining to generating facts listed in items 8 and 13 is exempted.

11. Special Authorizations for Operation for marketing controlled medicines shall have 50% discounts on the value of item 1.4, with further cumulative application of the reduction dealt with in note 1.

12. In cases where two or more authorizations for financing are necessary for the same company as per establishment or for authorizations for operation where only part of the activities are regulated by ANVISA, as listed in item 1 and its sub-items,

discounts shall be granted, as provided for in a deed by the Agency's Collegiate Board of Directors.

13. According to provisions by the Collegiate Board of Directors of ANVISA, the addition or change of registration pertaining to the text of medicine description, form for use and labelling, listed in item 6.3, are exempt from the collection of the relevant fees in cases of changes of telephone number, CGC/CNPJ or other legal information.

14. The reduction amounts provided for in this Table are not applicable to companies located in other countries, which are provided for in sub-item 4.2.