LAW NO. 6.360 OF 23 SEPTEMBER 1976

Provides for the Health Surveillance which medicinal products, drugs, pharmaceutical inputs and related products, cosmetics, sanitizing products, and other products are henceforth subject to, and gives other provisions.

The President of the Republic: I let be known that the National Congress decrees and I sanction the following Law:

TITLE I

Preliminary Provisions

Article 1. Medicinal products, drugs, pharmaceutical inputs and related products, as defined in Law no. 5,991 of 17 December 1973, as well as hygiene products, cosmetics, perfumes, household sanitizing products, products meant for aesthetic enhancement and others defined below, are henceforth subject to the health surveillance regulations instituted by this Law.

Article 2. Only companies duly authorized by the Ministry of Health and whose facilities have been licensed by the health authorities of the Federal Units where they are located may extract, produce, manufacture, transform, synthesize, purify, fraction, pack, re-pack, import, export, store, or dispatch the products referred to in Article 1.

Article 3. For the purposes of this Law, in addition to the definitions set forth in items I, II, III, IV, V, and VII of Article 4 of Law No. 5,991 of 17 December 1973, the following definitions are adopted:

I – Diet Products: products technically elaborated to meet the dietary needs of people with special physiological conditions;

II – Nutrients: substances constituting food with nutritional value, including proteins, fats, carbohydrates, water, mineral elements, and vitamins;

III – Hygiene Products: products for external use, either antiseptic or not, meant for body cleaning or disinfecting, encompassing toilet soaps, shampoos, toothpastes, mouth-washes, antiperspirants, deodorants, shaving and after-shave products, astringents, and others;

IV – Perfumes: products with aromatic composition obtained from natural or synthetic substances that, in the appropriate concentration levels and vehicles, may have as their main purpose the addition of pleasant odor to people or environments, including extracts, perfumed waters, cream perfumes, bath preparations, and room scenting products, presented

in liquid, gelatinous, paste or solid form;

V – Cosmetics: products for external use, meant to protect or embellish different parts of the body, such as face powders, talcums, beauty creams, hand-creams and similar products, face masks, beauty lotions, milky, creamy, and astringent solutions, hand lotions, foundation creams and cosmetic oils, rouges, blushes, lipsticks, lip crayons, sun protectors, tan products and artificial tan products, mascaras, eye-shadows, eyeliners, hair dyes, hair bleaching products, hair curling or straightening products, wave setting products, hair sprays, hair grease and similar products, hair lotions, hair removing products, nail products, and others;

VI – Colorants: substances additional to medicinal products, diet products, cosmetics, perfumes, hygiene products and similar products, household sanitizing products and similar products, having the effect of giving color to those products and, in the case of certain types of cosmetics, that of transferring such color to skin surface and to skin annexes;

VII – Household Sanitizing Products: substances or preparations meant for household hygiene, disinfection, or pest-control, in collective and/ or public environments, in places of shared use and in water treatment, including:

a) insecticides – meant to fight, prevent, and control insects in residences, enclosures, and places of public use and their neighborhood;

b) rodenticides – meant to fight rats, mice, and other rodents, in residences, vessels, enclosures, and places of public use, containing active substances, either isolated or associated, and not hazardous to human health or life or to health or life of useful warm-blooded animals when applied in compliance with the recommendations contained in their packaging;

c) disinfectants – meant to destroy micro-organisms, in a selective or indiscriminate manner, when applied to inanimate objects or to environments;

d) detergents – meant to dissolve fats and for the hygiene of canisters and containers, and for household applications.

VIII – Labels: printed or lithographed identification, as well as the wording painted or fire-engraved, pressure-engraved, pasted or directly applied on canisters and containers, packages or packaging, cartons, or any other packaging protector;

IX – Packaging: container, canister, jar, or any other type of packaging, either removable or not, meant to cover, pack, bottle, protect, or maintain, specifically or otherwise, the products referred to in this Law;

X – Marketing Authorization: registration, in the appropriate ledger, after the decision on licensing by the head of the relevant organization within the Ministry of Health, under a serial number, of the products referred to in this Law, indicating their name, manufacturer, origin, purpose, and other elements that characterize them;

XI – Manufacturing: all operations necessary for obtaining the products covered by this Law;

XII – Raw Materials: active or inactive substances used in the manufacture of medicinal products and other products covered by this Law, both those that remain unaltered and those susceptible of undergoing alterations;

XIII – Batch or Consignment: amount of a medicinal product or other product covered by this Law, produced within one manufacturing cycle and the essential characteristic of which is homogeneity;

XIV – Lot Number: designation printed on the label of a medicinal product or of another product covered by this Law allowing to identify the batch or consignment they belong to, and, if needed, to locate and review all manufacturing and inspection operations carried out during production;

XV – Quality Control: set of measures meant to guarantee, at any time, the production of batches of medicinal products and other products covered by this Law, satisfying the regulations related to purity, efficacy, and innocuity;

XVI – Semi-Elaborated Product: all substances or mixture of substances still under a manufacturing process;

XVII – Purity: degree at which a given pharmaceutical contains other foreign materials;

XVIII – Brazilian Common Denomination (DCB): denomination of the pharmaceutical or of the active pharmaceutical ingredient approved by the federal organization responsible for health surveillance; **(Item included by Law no. 9,787 of 10 February 1999)**

XIX – International Nonproprietary Name (INN): denomination of the pharmaceutical or of the active pharmaceutical ingredient recommended by the World Health Organization; **(Item included by Law no. 9,787 of 10 February 1999)**

~~XX – Similar Medicinal Product: the one that contains the same active ingredient or ingredients, presenting the same concentration, pharmaceutical form, administration route, dosage, and therapeutic, preventive, or diagnostic indications of the reference medicinal product approved by the federal organization responsible for health surveillance, and it may differ solely in terms of characteristics related to size and form the product, its shelf life, packaging, labeling, excipients, and vehicles, and it must always be identified by a brand name or trademark; (Item included by Law no. 9,787 of 10 February 1999)~~

~~XX – Similar Medicinal Product: the one that contains the same active ingredient or ingredients, presenting the same concentration, pharmaceutical form, administration route, dosage, and therapeutic indication, and is equivalent to the medicinal product authorized by the federal organization responsible for health surveillance, and it may differ solely in terms of characteristics related to size and form the product, its shelf life, packaging, labeling, excipients, and vehicles, and it must always be identified by a brand name or trademark; (Wording given by Provisional Measure no. 2,190-34 of 2001)~~

XX – Similar Medicinal Product: the one that contains the same active ingredient or ingredients, presenting the same concentration, pharmaceutical form, administration route, dosage, and therapeutic, preventive, or diagnostic indication, and is equivalent to the

medicinal product authorized by the federal organization responsible for health surveillance, and it may differ solely in terms of characteristics related to size and form the product, its shelf life, packaging, labeling, excipients, and vehicles, having its efficacy, safety, and quality confirmed, and it must always be identified by a brand name or trademark; **(Wording given by Law no. 13,235 of 2015)**

XXI – Generic Medicinal Product: a medicinal product similar to a reference product or to an innovative product intended to be interchangeable with the latter, normally produced after validity or waiver of patent protection or of other exclusivity rights, once its efficacy, safety, and quality are confirmed, and it is designated by DCB or, in its absence, by INN; **(Item included by Law no. 9,787 of 10 February 1999)**

XXII – Reference Medicinal Product: an innovative product, authorized by the federal organization responsible for health surveillance and commercialized in Brazil, the efficacy, safety, and quality of which have been scientifically confirmed with the competent federal organization, on the occasion of its marketing authorization; **(Item included by Law no. 9,787 of 10 February 1999)**

XXIII – Interchangeable Pharmaceutical Product: product therapeutically equivalent to a reference medicinal product, having the same effects in terms of efficacy and safety essentially confirmed; **(Item included by Law no. 9,787 of 10 February 1999)**

XXIV – Bioequivalence: the demonstration of pharmaceutical equivalence between products presented under the same pharmaceutical form, containing identical qualitative and quantitative composition in terms of active ingredient(s), with comparable bioavailability, when studied under the same experimental design; **(Item included by Law no. 9,787 of 10 February 1999)**

XXV – Bioavailability: it indicates the speed and the extent of absorption of an active ingredient in a form of dosage, starting from its time/ concentration curb in the systemic circulation or in its excretion in urine. **(Item included by Law no. 9,787 of 10 February 1999)**

~~Sole Paragraph. In the case of imported generic medicinal products, the bioequivalence trials of which were conducted outside Brazil, the company must present the comparative dissolution trials between the experimental medicinal product, the international reference medicinal product used in the bioequivalence study, and the Brazilian reference medicinal product.~~ **~~(Wording given by Provisional Measure no. 2,190-34 of 2001)~~**

Sole Paragraph. Up to 30 June 2003, in the case of imported generic medicinal products, the bioequivalence trials of which were conducted outside Brazil, the company must present the comparative dissolution trials between the experimental medicinal product, the international reference medicinal product used in the bioequivalence study, and the Brazilian reference medicinal product. **(Wording given by Law no. 10,669 of 14 May 2003)**

Article 4. Products meant for use in children may not contain caustic or irritating substances, they must have packaging exempt from blunt parts and may not be presented in aerosol form.

Sole Paragraph. The products referred to in the caption of this article must have labeling and packaging characteristics that enable its immediate and precise distinction from those

intended for use in adults. **(Included by Law no. 13,236 of 2015)**

~~Article 5. The products referred to in this Law may not have names or designations leading to error.~~ **~~(Wording given by Law no. 6,480 of 1 December 1977)~~**

Article 5. The products referred to in this Law may not have names, designations, labels, or packaging leading to error. **(Wording given by Law no. 13,236 of 2015)**

Paragraph 1. The adoption of a name equal or similar for products having different compositions is forbidden, even if they are from the same manufacturer, and the priority of marketing authorization is ensured with the chronological order of submission of petitions at the competent office of the Ministry of Health, when there is not a prior marketing authorization.

Paragraph 2. The name of a product having its petition for marketing authorization submitted later may be approved, provided that the previous petition for marketing authorization has been denied for technical or scientific reasons.

Paragraph 3. Once the collision of brands is confirmed, the alteration of the product's name or designation must be requested in up to 90 (ninety) days from the date of publication of the decision in the Federal Official Gazette, under the penalty of marketing authorization rejection.

Paragraph 4. Without damage to the provisions of this Article, and, at the Ministry of Health's discretion, medicinal products containing a single widely known active substance and the immune-therapy products, medicinal products, and pharmaceutical inputs must be identified by the denomination listed in the Brazilian Pharmacopoeia, and in no case may they bear fantasy names or designations. **(Included by Law no. 6,480 of 1 December)**

Paragraph 5. The errors referred to in the caption of this article include dispensation and administration of medicinal products, pharmaceuticals, and related products. **(Included by Law no. 13,236 of 2015)**

Article 6. The verification that a given product, so far deemed useful, is harmful to health or does not meet the requirements established by law means its immediate withdrawal from the market and the requirement that its composition formula and the text in its labels, package inserts, and packaging be altered, under the penalty of marketing authorization cancellation and of seizure of the product in the whole Brazilian territory.

Sole Paragraph. The marketing authorization and licensing for use of medicinal products, as well as the approval or the requirement of alteration in their components are exclusively attributed to the Ministry of Health.

Article 7. As a measure of health safety and in view of reasons duly justified by the competent organization, the Ministry of Health may suspend, at any time, the manufacturing and commercialization of any of the products referred to in this Law which, although authorized, becomes suspect of having harmful effects for human health.

Article 8. No establishment manufacturing or industrializing a product covered by this Law may

operate without the assistance and effective responsibility of a legally certified technician.

Article 9. Establishments covered by this Law integrating Public Administration or created by the latter do not need licenses for operating, although they are subject to the requirements pertaining to the appropriate facilities, equipment, and machinery, as well as to technical assistance and responsibility.

Sole Paragraph. For the purposes of health control, as provided for in the legislation in force, communication to the Ministry of Health, by the organizations referred to in this Article, of the existence or installation of establishments referred to in this Law is mandatory.

Article 10. Imports of medicinal products, pharmaceuticals, pharmaceutical inputs, and other products referred to in this Law, for industrial and commercial purposes, and without previous and express favorable opinion by the Ministry of Health, are forbidden.

Sole Paragraph. The requirements provided for in this Article include procurements or donations involving persons of public and private law, the quantity and quality of which may compromise the execution of Brazilian health programs.

Article 11. Pharmaceuticals, medicinal products, and any related pharmaceutical inputs, hygiene products, cosmetics, and household sanitizing products, either imported or not, shall only be delivered for consumption in their original packaging or in other ones previously authorized by the Ministry of Health.

Paragraph 1. In order to meet the development of Federal Government plans and programs for the production and distribution to impoverished population, the Ministry of Health may authorize the use of special packaging or re-packaging, which allows cost reduction without prejudice to the purity or efficacy of the product.

Paragraph 2. Imported products, the commercialization of which in the domestic market does not require medical prescription, shall have clarifying text in Portuguese on their composition, indications, and mode of use added to the labels.

TITLE II

Marketing Authorization

Article 12. No product referred to in this Law, including imported ones, may be industrialized, displayed for sale, or delivered for consumption before marketing authorization at the Ministry of Health.

~~Paragraph 1. The marketing authorization referred to in this Article shall be valid for 5 (five) years, and may be revalidated for equal and successive periods, the initial number of marketing authorization being maintained.~~

Paragraph 1. The Brazilian Health Regulatory Agency – Anvisa – shall define by means of its own act the period for re-validation of the marketing authorization for the products referred

to in this Law, not longer than 10 (ten) years, considering the nature of the product and the health risk involved in its use. **(Included by Law no. 13,097 of 2015)**

Paragraph 2. The validity of marketing authorization and marketing authorization re-validation of diet products, the period of which is of 2 (two) years, is an exception to the provisions of the previous paragraph.

~~Paragraph 3. Marketing authorization shall be granted within at most 90 (ninety) days, counting from the date the petition is submitted, except in cases of non compliance with this Law or with its regulations.~~

Paragraph 3. Except for the provisions in articles 17-A, 21, and 24-A, the marketing authorization shall be granted within at most 90 (ninety) days, counting from the date the petition is submitted, except in cases of non compliance with this Law or with its regulations by the petitioner. **(Wording given by Law no. 13,411 of 2017)**

Paragraph 4. Deeds pertaining to marketing authorization and marketing authorization re-validation shall be effective only from the date of publication in the Federal Official Gazette.

Paragraph 5. Granting of marketing authorization and its re-validation, and the previous and control analyses, if appropriate, are subject to the payment of public prices, referred to in Article 82.

Paragraph 6. Re-validation of marketing authorization must be requested in the first semester of the last year of the five-year period of validity, and re-validation of marketing authorization shall be deemed automatically granted, irrespective of decision, should there be no pronouncement up to the date of termination of the validity in force.

Paragraph 7. The marketing authorization of a product whose re-validation has not been requested within the period of time referred to in Paragraph 6 of this Article shall be declared expired.

~~Paragraph 8. The marketing authorization of a product that is not industrialized within its first period of validity shall not be re-validated.~~

Paragraph 8. The marketing authorization shall not be revalidated in the following cases: **(Wording given by Law no. 13,411 of 2017)**

I – of a product not classified as medicinal product, which has not been industrialized within the period of validity of the expired marketing authorization; **(Included by Law no. 13,411 of 2017)**

II – of a medicinal product that has not been industrialized during at least the period corresponding to the two final thirds of the period of validity of the expired marketing authorization. **(Included by Law no. 13,411 of 2017)**

Paragraph 9. The marketing authorization referred to in this Article must contain the formula of the product's composition, indicating the ingredients used and the respective dosage.

Paragraph 10. Anvisa shall define by means of its own act the mechanisms to publicize the processes of marketing authorization, post-marketing authorization alteration, and marketing authorization revalidation, and the presentation of the following information is mandatory: **(Included by Law no. 13,411 of 2017)**

I – status of the analysis; **(Included by Law no. 13,411 of 2017)**

II – period expected for the final decision on the process; **(Included by Law no. 13,411 of 2017)**

III – technical grounds of the decisions on the process. **(Included by Law no. 13,411 of 2017)**

Article 13. Any alteration in the formula, alteration in composition elements or their quantity, addition, subtraction, or innovation introduced in the elaboration of the product shall depend upon previous and express authorization by the Ministry of Health, and such alterations shall be immediately added to the marketing authorization.

Article 14. Fantasy names or designations of products licensed and industrialized prior to the effectiveness of this Law are excluded from the requirements provided for in this Law. **(Wording given by Decree no. 6,480 of 1 December 1977)**

Article 15. The marketing authorization of products referred to in this Law shall be denied whenever conditions, requirements, and procedures for such purpose provided for in legislation, regulation, or instruction issued by the competent organization are not complied with.

TITLE III

Marketing authorization of Pharmaceuticals, Medicinal Products and Pharmaceutical Inputs

~~Article 16. The marketing authorization of pharmaceuticals, medicinal products, and pharmaceutical inputs, given their health, medicinal characteristics, or prophylactic, curative, palliative, or even diagnostics characteristics, is subject to the following specific requirements, in addition to meeting the appropriate regulatory requirements:~~

Article 16. The marketing authorization of pharmaceuticals, medicinal products, pharmaceutical inputs, and related products, given their health, medicinal characteristics, or prophylactic, curative, palliative, or even diagnostics characteristics, is subject to the following specific requirements, in addition to meeting the appropriate regulatory requirements: **(Wording given by Law no. 10,742 of 6 October 2003)**

I – that the product complies with the provisions of Article 5 and its paragraphs; **(Wording given by Decree no. 6,480 of 1 December 1977)**

II – that the product, by means of scientific verification and analysis, be recognized as safe and effective for the intended use and has the necessary identity, activity, quality, purity, and innocuity;

III – in the case of a new product, that extensive information be provided on its composition and use, so that its nature be assessed and its necessary degree of safety and efficacy be determined;

IV – presentation, when requested, of samples for analysis and experimenting deemed necessary by the competent organizations of the Ministry of Health;

V – when there is a new substance in the composition of the medicinal product, the delivery of a sample accompanied by chemical and physicochemical data identifying it;

VI – when it is a pharmaceutical or a medicinal product whose elaboration requires technical and specific machinery, evidence as to the fact that the establishment is duly equipped and maintains people capable of handling such machinery or the outsourcing of such activities;

VII – the presentation of the following economic information: **(Included by Law no. 10,742 of 6 October 2003)**

a) the price of the product charged by the company in other countries; **(Included by Law no. 10,742 of 6 October 2003)**

b) the procurement value of the product's active substance; **(Included by Law no. 10,742 of 6 October 2003)**

c) the treatment cost per patient using the product; **(Included by Law no. 10,742 of 6 October 2003)**

d) the potential number of patients to be treated; **(Included by Law no. 10,742 of 6 October 2003)**

e) the price list intended for domestic market, discriminating its tax burden; **(Included by Law no. 10,742 of 6 October 2003)**

f) the discrimination of the product's commercialization proposal, including the expected expenses of sales effort, as well as marketing and advertising; **(Included by Law no. 10,742 of 6 October 2003)**

g) the price of the product that has been altered, in case of formula or form alteration; and **(Included by Law no. 10,742 of 6 October 2003)**

h) the list of all substitute products existing in the market, accompanied by their respective prices. **(Included by Law no. 10,742 of 6 October 2003)**

~~Sole Paragraph – The provisions in item I do not apply to sera and vaccines, nor to pharmaceutical products containing one single active substance widely known, at the Ministry of Health's discretion.~~ **(Revoked by Law no. 6,480 of 1 December 1977)**

Paragraph 1. **(Revoked as sole paragraph by Law no. 6,480 of 1 December 1977) (Included by Law no. 10,742 of 6 October 2003)**

Paragraph 2. Presenting the information in item VII may be partially or totally waived, in accordance with specific regulations. **(Included by Law no. 10,742 of 6 October 2003)**

Article 17. The marketing authorization of the products referred to in this Title shall be denied whenever conditions, requirements, and procedures for such purposes provided for in law, regulations, or instructions issued by competent organization are not complied with.

Article 17-A. The periods established for the final decision on processes of marketing authorization and post-marketing authorization alterations of medicinal products shall consider the following criteria: **(Included by Law no. 13,411 of 2017)**

I – technical complexity; **(Included by Law no. 13,411 of 2017)**

II – clinic, economic, and social benefits of using the medicinal product object of petition. **(Included by Law no. 13,411 of 2017)**

Paragraph 1. The application of the criteria provided for in the caption of this article, in accordance with the methodology provided for in an act by Anvisa, shall determine the classification of the medicinal product under assessment into the following precedence categories: **(Included by Law no. 13,411 of 2017)**

I – priority; **(Included by Law no. 13,411 of 2017)**

II – ordinary. **(Included by Law no. 13,411 of 2017)**

Paragraph 2. The maximum periods for the final decision on processes of marketing authorization and post-marketing authorization alterations of medicinal products shall be, respectively: **(Included by Law no. 13,411 of 2017)**

I – for the priority category, of one hundred and twenty days and of sixty days, counting from the date the respective priority protocol was submitted; **(Included by Law no. 13,411 of 2017)**

II – for the ordinary category, of three hundred and sixty-five days and of one hundred and eighty days, counting from the date the respective protocol of marketing authorization or post-marketing authorization alteration was submitted. **(Included by Law no. 13,411 of 2017)**

Paragraph 3. Except in cases where there is an appeal against a prior decision, the final decision on processes of post-marketing authorization alterations may be taken by means of conditional approval, provided that Anvisa does not manifest otherwise in the periods defined in Paragraph 2. **(Included by Law no. 13,411 of 2017)**

Paragraph 4. The conditional approval referred to in Paragraph 3 may only occur in the hypotheses of post-marketing authorization alterations defined in regulations, and it shall be automatically reversed, at any time, in case of rejection of the post-marketing authorization alteration by Anvisa. **(Included by Law no. 13,411 of 2017)**

Paragraph 5. The periods referred to in Paragraph 2 may be extended for up to one third of the original period, only once, by Anvisa's reasoned decision issued at least fifteen days before the end of the original period. **(Included by Law no. 13,411 of 2017)**

Paragraph 6. The requests for clarification or rectification by Anvisa shall be consolidated in a single petition, except if, for clarification or rectification, there is a need for information related to a request previously met by the petitioning company, and the count of the periods determined in this article shall be suspended until they are met. **(Included by Law no. 13,411 of 2017)**

Paragraph 7. The unjustified incompliance with the periods provided for in this article implies in an investigation into the functional responsibility of the officer or officers who caused it, in terms of Law no. 8,112 of 11 December 1990. **(Included by Law no. 13,411 of 2017)**

Paragraph 8. Anvisa shall regulate the provisions in this article, particularly the specification of the criteria referred to in the caption of this article, aiming at the classification into priority categories. **(Included by Law no. 13,411 of 2017)**

Paragraph 9. When the period of one hundred and eighty days is expired, counting from the date this article enters into force, without the publication of the regulations provided for in Paragraph 8, and whilst the matter remains unregulated, the maximum period for the final decision shall be three hundred and sixty-five days for marketing authorization processes and one hundred and eighty days for the processes of post-marketing authorization alterations. **(Included by Law no. 13,411 of 2017)**

Article 18. The marketing authorization for pharmaceuticals, medicinal products, and pharmaceutical inputs of foreign provenance shall depend on the verification that such products are already approved in their countries of origin, in addition to the conditions, requirements, and procedures provided for in this Law and in its regulation.

Paragraph 1. In case it is impossible to meet the provisions in the caption of this article, the company must present the proof of marketing authorization in force, issued by the health authority of the country where it is commercialized, or by an international health authority, and approved by the Ministry of Health's Brazilian Health Regulatory Agency. **(Included by Provisional Measure no. 2,190-34 of 2001)**

Paragraph 2. At the moment of marketing authorization for a medicinal product of foreign origin, the manufacturing company must present proof of compliance with the Good Manufacturing Practices, acknowledged at national level. **(Included by Provisional Measure no. 2,190-34 of 2001)**

Article 19. The marketing authorization for pharmaceuticals, medicinal products, and pharmaceutical inputs shall be canceled whenever non authorized alterations in their formula, dosage, manufacturing conditions, indications for use and specifications announced in package inserts, labels, and advertisement material are introduced.

Sole Paragraph. Should it become necessary to alter the composition, the dosage, or the therapeutic indications of a technically produced pharmaceutical product, the company shall request the appropriate permission to the Ministry of Health, as provided for in the regulation of this Law.

Article 20. Medicinal products whose preparation requires special care in terms of purification, dosage, sterilization, or conservation shall only be granted marketing authorization when:

I – its composition contains a new substance;

II – its composition contains a known substance to which a new or advantageous application in therapeutics is given;

III – they present improvements in their formulae or forms, from pharmaceutical and/ or therapeutic point of view.

~~Sole Paragraph. The right to marketing authorization for medicinal products similar to others already approved is guaranteed, provided that they meet the requirements established by this Law.~~

Sole Paragraph. Medicinal products whose composition does not contain a substance known to be beneficial from the clinical or therapeutic point of view shall not be granted marketing authorization. **(Wording given by Law no. 9,782 of 26 January 1999)**

Article 21. The right to marketing authorization for medicinal products similar to others already approved is guaranteed, provided that they meet the requirements established by this Law. **(Wording given by Law no. 9,782 of 26 January 1999)**

~~Paragraph 1. The similar medicinal products to be manufactured in Brazil shall be deemed granted marketing authorization after a period of one hundred and twenty days counted from the date the respective petition is submitted, if they have not been rejected by then. **(Included by Law no. 9,782 of 26 January 1999)**~~

Paragraph 1. The similar medicinal products to be manufactured in Brazil shall be deemed granted marketing authorization after a period of one hundred and twenty days counted from the date the respective petition is submitted, if they have not been rejected by then, and provided that the provisions in Paragraph 6 of this Article are met. **(Wording given by Law no. 13,235 of 2015)**

Paragraph 2. The counting of the period for marketing authorization shall be interrupted until the concerned company satisfies the requirement of the health authority, and such period must not exceed one hundred and eighty days. **(Included by Law no. 9,782 of 26 January 1999)**

Paragraph 3. The marketing authorization, when granted under the conditions set forth in the previous paragraphs, shall lose its validity, irrespective of notification or summons, if the product is not marketed within one year after the date the marketing authorization is granted. This period may be extended for six more months, at the health authority's discretion, by means of written justification at the initiative of the company concerned. **(Included by Law no. 9,782 of 26 January 1999)**

Paragraph 4. The petition for a new marketing authorization of a product may be done two years after verification of the fact that caused the loss of validity of the previously granted marketing authorization, except if the company concerned is not liable for it. **(Included by Law no. 9,782 of 26 January 1999)**

Paragraph 5. The provisions of this Article apply to products approved and manufactured in a

State-Party of the South Common Market – MERCOSUR, for the purposes of commercialization in Brazil, if they correspond to a Brazilian similar product already granted the marketing authorization. **(Included by Law no. 9,782 of 26 January 1999)**

Paragraph 6. The similar medicinal product, whether manufactured in Brazil or not, must have its efficacy, safety, and quality confirmed in an equivalent way as that adopted for the generic medicinal product. **(Included by Law no. 13,235 of 2015)**

~~Article 22. Pharmaceuticals, medicinal products, and pharmaceutical inputs containing narcotic substances or that determine physical or psychical dependence, being subject to the special control provided for in Decree-Law no. 753 of 11 August 1969, as well as other acts, regulations and other relevant norms, and medicinal products in general, shall only be granted marketing authorization if, in addition to meeting the conditions, requirements, and procedures set forth in this Law and in its regulation, their packaging and labeling meet the standards approved by the Ministry of Health.~~

Article 22. Pharmaceuticals, medicinal products, and pharmaceutical inputs containing narcotic substances or that determine physical or psychical dependence, being subject to the special control provided for in Decree-Law no. 753 of 11 August 1969, as well as other acts, regulations and other relevant norms, and medicinal products in general, shall only be granted marketing authorization or have their marketing authorization renewed if, in addition to meeting the conditions, requirements, and procedures set forth in this Law and in its regulation, their packaging and labeling meet the standards approved by the Ministry of Health. **(Wording given by Law no. 10,742 of 6 October 2003)**

~~Article 23. The following are exempt from marketing authorization:~~

~~I – products whose formulae are listed in the Brazilian Pharmacopoeia, in the Codex, or in forms accepted by the Ministry of Health;~~

~~II – homeopathic preparations made of simple associations of tinctures or by the incorporation to solid substances;~~

~~III – concentrated solutes used for the extemporaneous obtainment of pharmaceutical and industrial preparations deemed officinal products;~~

~~IV – products deemed equal to officinal ones, whose formulae are not listed in the Pharmacopoeia or in the forms, but are approved and authorized by the Ministry of Health.~~

~~Sole Paragraph. The provisions of this Article do not preclude the fact that the company must present the Ministry of Health with the information and clarifying data on injectable solutes, for the commercialization of the products referred to in this Article.~~ **(Revoked by Law no. 10,742 of 6 October 2003)**

~~Article 24. New medicinal products exclusively meant for experimental use, under medical control, are equally exempt from marketing authorization, and may even be imported, by means of an express authorization by the Ministry of Health.~~

Article 24. New medicinal products exclusively meant for experimental use, under medical

control, are exempt from marketing authorization, and may even be imported, by means of an express authorization by the Ministry of Health. **(Wording given by Law no. 10,742 of 6 October 2003)**

Sole Paragraph. The exemption provided for in this Article shall be valid solely for a period of up to 3 (three) years, after expiry of which products must be granted marketing authorization, under the penalty of seizure determined by the Ministry of Health.

Article 24-A. The Simplified Renewal of Marketing Authorization for Medicinal Products is hereby established for the medicinal products that have marketing authorization granted by the Brazilian health organization during a period equal to or longer than 10 (ten), which have not had reports of inefficacy and/ or significant adverse events, and that are adequate to the health requirements in force, regardless of their sales classification. **(Included by Law no. 13,097 of 2015)**

Sole Paragraph. Anvisa shall define the period referred to in the caption of this article based on criteria involving the therapeutic class of the product, alterations made to its formulation, indications and posology, and the productive process, as well as the administration route, pharmaceutical form, and the product's effective exposure to use. **(Included by Law no. 13,097 of 2015)**

Article 24-B. For the purposes of renovation of marketing authorization for the medicinal products referred to in Article 24-A, the requirements to be observed by the interested parties shall be defined by Anvisa in a regulation. **(Included by Law no. 13,097 of 2015)**

TITLE IV

Marketing Authorization for Related Products

Article 25. Appliances, instruments, and accessories used in medicine, dentistry, and related activities, as well as in the activities of physical education, embellishment of aesthetic correction, may only be manufactured, or imported, for delivery for consumption and display for sale after the Ministry of Health issues an opinion on the mandatory or non mandatory character of marketing authorization.

Paragraph 1. Instruments or accessories referred to in this Article and contained in lists prepared by the Ministry of Health for this purpose are exempt from registration. For the other purposes of this Law and of its regulation, however, they remain subject to the regime of health surveillance.

Paragraph 2. The regulations in this Law shall provide for the conditions, requirements, and procedures concerning the marketing authorization for machinery, instruments, or accessories referred to in this Article.

TITLE V

Marketing Authorization for Cosmetics, Hygiene Products, Perfumes, and Others

Article 26. Only products meant for external use in environments shall be granted marketing authorization as cosmetics, products for personal hygiene, perfumes, and others with similar nature and purpose, in consonance with their aesthetic, protecting, hygienic, or odor-related purposes, and provided that they do not bring about skin rashes or harm to health.

Article 27. In addition to being subject to its own regulatory requirements, the marketing authorization of cosmetics, products meant for personal hygiene, perfumes, and others having similar purposes shall depend upon meeting the following requirements:

I – to fit the list of substances declared innocuous, developed by the competent organization of the Ministry of Health and published in the Federal Official Gazette, which shall contain the specifications pertinent to each category, as well as for pharmaceuticals, inputs, raw materials, colorants, solvents, and other products allowed to be used in their manufacturing;

II – if they do not fit the list referred to in the previous item, the innocuity of their respective formulae must be recognized, by means of conclusive opinions issued by the Ministry of Health's competent technical organizations responsible for analysis.

Sole Paragraph. The list of substances referred to in item I of this Article may be altered in order to exclude substances that may be deemed harmful to health, or to include others that may be approved.

Article 28. The marketing authorization for cosmetics, products meant for personal hygiene, and others having identical purposes, containing medicinal substances, although in dosages below therapeutic level, shall follow the regulations contained in articles 16 and its items, 17, 18, and 19 and its Sole Paragraph, 20 and 21, and in the regulation of this Law.

Article 29. Products referred to in Article 26 shall only be granted marketing authorization if they contain in their composition raw materials, solvents, colorants, or pharmaceutical inputs contained in the list developed by the competent organization of the Ministry of Health, published in the Federal Official Gazette, provided that restrictions to their use be expressly highlighted on labels and packaging, when appropriate, according to the area of the body on which they are to be applied.

Sole Paragraph. When presented in the form of aerosol, products referred to in Article 26 shall only be granted marketing authorization if they follow the technical standards approved by the Ministry of Health and other specific requirements and regulations.

Article 30. Cosmetics, products for personal hygiene for adults and children, perfumes, and related products may have their composition formulae altered, provided that such alterations be approved by the Ministry of Health, based upon the relevant technical reports.

Article 31. Alterations in formulae shall be incorporated to the product's marketing authorization, as provided for in regulations.

Article 32. The Ministry of Health shall publish in the Federal Official Gazette the list of natural organic, artificial, and synthetic colorants, including their salts and lacquers, as allowed for use

in the manufacturing of the products referred to in articles 29, Sole Paragraph, and 30.

Paragraph 1. Any colorant presenting active or potential toxicity shall be excluded from the list referred to in this Article.

Paragraph 2. Inclusion and exclusion of colorants and of their derivations shall follow the provisions contained in regulations.

TITLE VI

Marketing Authorization for Household Sanitizing Products

Article 33. The marketing authorization for household sanitizing products, disinfectants, and detergents shall follow the provisions of regulations and of specific complementary norms.

Article 34. Insecticides may only be granted marketing authorization if:

I – they may be properly applied, in strict compliance with the instructions contained on labels and other explanatory elements;

II – they do not represent any possibility of hazard for human health and for the health of domestic warm-blood animals in the conditions of use provided for;

III – they are not corrosive or harmful for the surfaces on which they are applied.

Article 35. Insecticides shall be granted marketing authorization only if:

I – they are presented according to norms provided for in the regulation of this Law;

II – if in their composition the insecticide and the synergetic substances, either natural or synthetic, comply with the appropriate concentration levels as established by the Ministry of Health;

III – if their composition formulae observe the necessary caution, aimed at their handling and at the therapeutic measures in case of accident, in view of the indispensable preservation of human life, according to the instructions of the Ministry of Health.

Sole Paragraph. Regulation of this Law shall set forth the requirements, conditions, and procedures related to the marketing authorization of insecticides.

Article 36. For the purposes of insecticide marketing authorization, the substances composing the respective formulae shall be considered:

I – solvents and thinners, those used as vehicles in the preparation of insecticides;

II – propellants, the propulsion agents used in preparations under pressure.

Article 37. The Ministry of Health shall develop and publish on the Federal Official Gazette the

list of solvents, thinners, and propellants allowed, with the respective maximum concentration levels.

Article 38. Insecticide associations shall be allowed, and these must have the concentration levels of active elements proportionally reduced, when belonging to the same class.

Article 39. Insecticide associations must satisfy the requirements provided for in Article 35 and its Sole Paragraph, related to toxicity for animals subject to the efficiency test.

Article 40. The marketing authorization of insecticides shall be permitted only when meant for:

I – the prompt application by any person for domestic purposes;

II – application and handling by specialized person or organization for professional purposes.

Article 41. Preparations whose composition formulae include active substances, either isolated or in association, in different levels of concentration and under certain forms and types of presentation shall be granted marketing authorization as rodenticides.

Sole Paragraph. Associations of rodenticide substances of the same class must be reduced proportionally to the concentration levels of their active ingredients.

Article 42. The provisions of this Law apply to the marketing authorization of rodenticide preparations and substances, further specific requirements pertaining to this class of products remaining to be established in regulations and by the Ministry of Health.

Article 43. The marketing authorization of disinfectants shall be carried out according to the provisions in the regulation to this Law and to instructions issued by the Ministry of Health.

Article 44. For the purposes of this Law, detergents and disinfectants and their respective related products are deemed equal to household sanitizing products, when meant for application on inanimate objects and environments, remaining subject to the same requirements and conditions related to marketing authorization, industrialization, delivery for consumption, and inspection.

Article 45. Sales of rodenticides and their delivery for consumption shall remain restricted, exclusively, to products classified as having low and medium toxicity, and it belongs exclusively to specialized companies or to organizations or entities within the Direct and Indirect Public Administration to supply products classified as having high levels of toxicity and to control their application.

TITLE VII

Marketing Authorization of Diet Products

Article 46. Products meant for oral ingestion that, although not fitting the provisions in Decree-Law no. 986 of 21 October 21 1969 and its respective regulations, have their use or

sale subject to medical prescription, shall be granted marketing authorization as diet products, provided that they are meant for the purposes below:

I – to meet special dietary needs;

II – to supplement and enrich the usual nourishment with vitamins, amino-acids, minerals, and other elements;

III – to disguise sensations of hunger, appetite, and taste, replacing usual food in restriction diets.

Article 47. Only products constituted with the following substances shall be granted marketing authorization as diet products:

I – natural food altered in its composition or characteristics;

II – natural food, although not deemed usual food, containing nutrients or having nutrients added to it;

III – mineral or organic products, either pure or associated, able to contribute for the elaboration of special diets;

IV – isolated or associated substances, without nutritional value, meant for restriction diets;

V – food complements containing vitamins, minerals, or other nutrients;

VI – other products that, either isolated or in association, may be characterized as diet products by the Ministry of Health.

Article 48. Diet products referred to in this Law may be presented under the usual forms of pharmaceutical products, in compliance with their names and their own characteristics.

Article 49. In order to ensure the minimum dietary efficiency necessary and prevent confusion with therapeutic products, the content of components of diet products, justifying their indication for special diets, must meet the standards accepted internationally, in accordance with lists developed by the Ministry of Health.

Paragraph 1. If there are no established standards for the purposes of this Article, the rate of nutrients of diet products shall depend upon decision by the Ministry of Health.

Paragraph 2. The proportion of vitamins to be added to the products shall correspond to the standards established by the Ministry of Health.

TITLE VIII

Authorization of Companies and Licensing of Establishments

~~Article 50. Operation of companies referred to in this Law shall depend upon authorization by~~

~~the Ministry of Health, in view of indication of the respective industrial activity, of the nature and kind of products, and of the verification of technical, scientific, and operational capability, and of other requirements provided for in regulations and administrative acts issued by the same Ministry.~~

Article 50. Operation of companies referred to in this Law shall depend upon authorization by Anvisa, granted by means of request for registration of its activities, payment of the respective Health Surveillance Inspection Fee, and other requirements provided for in specific regulations issued by Anvisa. **(Wording given by Law no. 13,097 of 2015)**

~~Sole Paragraph. The authorization referred to in this Article shall be valid for the whole Brazilian territory, and must be renewed whenever there are alteration in or inclusion of activities, or change of partners or directors in charge of the legal representation of the company.~~

Sole Paragraph. The authorization referred to in this Article shall be valid for the whole Brazilian territory, and must be updated in accordance with specific regulation by Anvisa. **(Wording given by Law no. 13,097 of 2015)**

Article 51. Licensing, by the local authority, of industrial or commercial establishments carrying out the activities referred to in this Law, shall depend upon operation of the company having been authorized by the Ministry of Health and upon being met, by each establishment, the technical and sanitary requirements set forth in regulations and instructions issued by the Ministry of Health, including in what concerns the effective assistance of accredited technical responsible officials to the different sectors of activity.

Sole Paragraph. Each establishment shall have a specific and independent license, although there be more than one establishment in the same location, belonging to the same company.

Article 52. Supplementary local legislation shall set forth the requirements and conditions for licensing the establishments referred to in this Law, in compliance with the following provisions:

I – when a single establishment industrializes or commercializes products with different natures or purposes, it shall be mandatory to have separate facilities for manufacturing and storing materials, substances, and finished products;

II – appropriate location of facilities and the interdiction of residences or dwelling places in the buildings allocated to the above mentioned activities and in nearby areas;

III – previous approval, by the State health authority, of projects and blueprints of buildings and inspection of the compliance with them.

TITLE IX

Technical Responsibility

Article 53. The companies carrying out the activities provided for in this Law are obliged to maintain legally accredited technical responsible officials in an amount and with qualifications enough for the appropriate coverage of the different types of production, in each establishment.

Article 54. The technical responsible official shall be responsible for elaborating the report to be presented to the Ministry of Health, for the purposes of product marketing authorization, as well as to lend effective technical assistance to the sector under his or her professional responsibility.

Article 55. Although the delivery of technical assistance to the establishment may be discontinued, or should the latter cease operating, the responsibility of the technical professional for the activities carried out so far shall remain in force for a one-year period counted from termination of activities.

Article 56. Irrespective of other legal typification, including criminal ones, for which technical and administrative responsible officials may be made accountable, the company shall have administrative and civil liability for health infraction resulting from noncompliance with this Law and its regulations, as well as with other complementary norms.

TITLE IX

Labeling and Advertising

Article 57. The Executive Power shall decide, by means of regulation, on labeling, package leaflets, printed material, labels, and other information material pertaining to the products referred to in this Law.

~~Sole Paragraph. The medicinal products that display fantasy or brand name must also display, with the same highlight and in a legible way, on the parts referred to in the caption of this article, on packages and promotional materials, the Brazilian Common Name or, in its absence, the International Nonproprietary Name, with letters and characters the size of which shall not be smaller than one half the size of the letters and characters of the fantasy or brand name.~~ **~~(Included by Law no. 9,787 of 10 February 1999)~~**

Paragraph 1. In addition to the fantasy or brand name, the medicinal products must display, on the parts referred to in the caption of this Article, on packages and promotional materials, the Brazilian Common Name or, as appropriate, the International Nonproprietary Name, with letters and characters the size of which shall never be smaller than one half the size of the letters and characters of the fantasy or brand name. **(Wording given by Law no. 13,236 of 2015)**

Paragraph 2. The labels of medicinal products, pharmaceuticals, and related products must have characteristics that make them clearly different from each other and that inhibit dispensation and administration mistakes, unwanted exchanges, or wrong use. **(Included by Law no. 13,236 of 2015)**

Article 58. Advertisement, under any form of publicizing and means of communication, of products under the regime of this Law may only be carried out after authorization by the Ministry of Health, as to be provided for in regulation.

Paragraph 1. In cases of pharmaceuticals, medicinal products, or any other product under the requirement of sale on medical or dental prescription, advertisement shall be restricted to publications exclusively meant for distribution to physicians, dentists, and pharmacists.

Paragraph 2. Advertisement of over-the-counter medicinal products, diet products, household sanitizing products, cosmetics, and hygiene products shall be subject to specific norms to be provided for in regulations.

Article 59. Designations, geographical names, symbols, images, drawings, or any indication leading to false interpretation, error, or confusion as to origin, provenance, nature, composition, or quality, attributing to the product purposes or characteristics other than those it really possesses, must not appear either in labeling or in advertising of the products referred to in this Law.

TITLE XI

Packaging

Article 60. Approval by the Ministry of Health, as shall be provided for in regulations, of packaging, equipment, and utensils elaborated or internally coated with substances that, in contact with the product, may alter its effects or bring about harm to health, is mandatory.

Paragraph 1. Packaging meant for containing pharmaceuticals, medicinal products, pharmaceutical inputs, hygiene products, cosmetics, perfumes, and related products that do not internally contain substances capable of altering the purity and efficacy conditions of the product shall not depend on approval.

Paragraph 2. The use of packaging meant for containing or packaging pharmaceuticals, medicinal products, or pharmaceutical inputs shall not be authorized if apt to bring about direct or indirect hazard to health.

Paragraph 3. Approval of types of packaging shall be preceded by previous analysis, when appropriate.

Article 60-A. In order to contain or package pharmaceuticals, medicinal products, or related products, the use of packaging that may induce unwanted exchanges or errors in dispensation, use, or administration of such products.

TITLE XII

Means of Transportation

Article 61. In case of products requiring special storage and safekeeping conditions, the vehicles used for their transportation must count on equipment allowing storage and preservation conditions apt to ensure the purity, safety, and efficacy conditions of the products.

Sole Paragraph. Vehicles used in the transportation of pharmaceuticals, medicinal products, pharmaceutical inputs and related products, diet products, hygiene products, perfumes, and similar products must be ensured the necessary disinfection and hygiene conditions necessary for the preservation of human health.

TITLE XIII

Infractions and Penalties

Article 62. A medicinal product, pharmaceutical, or pharmaceutical input is considered altered, adulterated, or unfit:

I – if it has been mixed or packed with substances that alter its therapeutic value or the purpose it is meant for,

II – when an integral element of its normal composition has been withdrawn or falsified, entirely or partly, or when such element has been replaced by another one of lower quality or when the dosage has been modified, or if a substance foreign to its composition has been added to it, so that it becomes different from the formula contained in the marketing authorization;

III – when its volume does not correspond to the approved quantity;

IV – when its purity, quality, and authenticity conditions do not meet the requirements of the Brazilian Pharmacopoeia or of another Code adopted by the Ministry of Health.

Sole Paragraph. In case of alterations due to the action of time or to causes beyond the responsibility of the technician or of the company, the latter would be obliged to withdraw the product immediately from the market, for correction or replacement, under the risk of incurring in health infraction.

Article 63. A hygiene product, cosmetic, perfume, or similar product is deemed counterfeit, falsified, or adulterated when:

I – it is presented with indications leading to error, mistake, or confusion regarding its provenance, origin, composition, or purpose;

II – it does not meet the standards and paradigms established in this Law and in regulations, or the specifications contained in the marketing authorization;

III – its nature, composition, properties, or characteristics instrumental for its marketing authorization are altered due to addition, reduction, or withdrawal of raw materials or components.

Sole Paragraph. The provisions of this Article include inputs constituted by active, additive, or complementary raw material, of a chemical, biochemical, or biological nature, of natural or synthetic origin, or any other material meant for manufacturing, handling, and processing hygiene products, cosmetics, perfumes, and similar products.

Article 64. It is forbidden to reutilize containers traditionally used for food, beverages, soft drinks, diet products, medicinal products, pharmaceuticals, chemicals, hygiene products, cosmetics, and perfumes for packaging sanitizing and similar products.

Article 65. It is forbidden to enter new dates or to re-pack in new packaging products whose shelf life has expired, except for therapeutic sera susceptible of being re-dosed and re-filtered.

Article 66. Failure to comply with the provisions contained in this Resolution shall be considered an infraction of health regulations, and the offender shall be subject to the process and penalties provided for in Decree-Law no. 785 of 25 August 1969 , without prejudice to the other applicable civil and criminal liabilities. **(Decree-Law no. 785 of 25 August 1969 was revoked by Law no. 6,437 of 20 August 1977)**

Sole Paragraph. The process referred to in this Article may be initiated and judged by the Ministry of Health or by the health authorities of the States, the Federal District, and the Territories, as appropriate.

Article 67. Regardless of the infractions provided for in Decree-Law no. 785 of 25 August 1969, in the terms of this Law, the following practices constitute serious or extremely serious infractions susceptible of punishment by sanctions established in that legal instrument: **(Decree-Law no. 785 of 25 August 1969 was revoked by Law no. 6,437 of 20 August 1977)**

I – to label the products under the regime of this Law or to advertise them without complying with the provisions of this Law and of its regulations, or in a manner contrary to the terms and conditions of the respective marketing authorization;

II – to alter the manufacturing process of products without previous consent by the Ministry of Health;

III – to sell or display for sale a product whose shelf life has expired;

IV – to enter new dates in products whose shelf life has expired or to re-pack them in new packaging, except for therapeutic sera that may be re-dosed and re-filtered;

V – to industrialize products without the assistance of a legally accredited technical responsible official;

VI – to use, in the preparation of hormones, organs of animals that are not sound, or presenting signs of decay the moment they are to be manipulated, or coming from ill or exhausted animals, or from animals having undergone loss of weight;

VII – to re-sell a biological product that has not been kept under refrigeration, in compliance with the indications determined by the manufacturer and approved by the Ministry of Health;

VIII – to use rodenticides, the action of which is performed through gas or steam, in galleries, drainpipes, basements, attics, or places having possible communication with residences or places frequented by human beings or useful animals.

TITLE XIV

Inspection

Article 68. Health surveillance activities shall encompass all and any product referred to in this Law, including those for which marketing authorization is waived, as well as related products, manufacturing, distribution, storage, and sale establishments, and the vehicles meant for the transportation of such products.

Sole Paragraph. The advertisement of products and brand names, through any means of communication, publicity, labeling, and labels are also subject to health surveillance activities.

Article 69. Inspection activities belong to:

I – the federal health organization;

a) when the product is in transit from one federal unit to another, by road, waterways, lakes, sea, or air, under the control of federal organizations;

b) when it is an imported or exported product;

c) when it is the case of sample collection for previous and fiscal control analysis.

II – the State, Territory or Federal District health organizations:

a) when it an industrialized product, or when it is delivered for consumption in the respective area of jurisdiction;

b) regarding industrial or commercial establishments, facilities, or equipment;

c) regarding transportation by road, waterways, and lakes within their jurisdictional areas;

d) when it is the case of sample collection for fiscal analysis.

Sole Paragraph. The competence referred to in this Article may be delegated, by means of agreement, in a reciprocal manner, by the Union, the States, and the Federal District, except for the hypotheses of non-transferable powers, as expressly provided for in legislation.

Article 70. Health surveillance activities shall be carried out on a permanent basis, being a routine activity of health organizations.

Article 71. The attributions and prerogatives of inspection agents shall be established in regulations to this Law.

Article 72. Assessment of infractions, under this Law, shall be done by means of seizure of samples and interdiction of the product or of the establishment, as provided for in regulation.

Paragraph 1. Confirmation of infraction shall give grounds, as appropriate, for seizure and destruction of the product, in the whole Brazilian territory, for cancellation of marketing authorization and termination of the establishment's license, steps that shall only become effective after publication of the condemning decision in the Federal Official Gazette.

Paragraph 2. Alterations due to natural or unpredictable causes, circumstances, or events, which determine damage, deterioration, or contamination of products, making them ineffective or harmful to health, shall also provide grounds for seizure, interdiction, and destruction.

~~Article 73. For the purposes of health surveillance, the trials meant for verifying the efficiency of formulae shall be conducted in compliance with the regulations established by the Ministry of Health.~~

Article 73. Fiscal and control analyses, for the purposes of inspection and monitoring of the products subject to the health surveillance regime, shall be conducted by an official laboratory, instituted by the Union, States, Federal District, or Municipalities, or by public or private laboratories accredited for such purposes. **(Wording given by Law no. 13,097 of 2015)**

Sole Paragraph. The accreditation referred to in the caption of this article shall be granted by Anvisa or by the official laboratories themselves, in the terms of specific regulations issued by Anvisa. **(Included by Law no. 13,097 of 2015)**

Article 74. Civil servants who are partners, shareholders of, or have an interest of any kind in companies carrying out activities subject to the regime of this Law, or who deliver services to such organizations, officially employed or not, shall not be allowed to work at health surveillance organizations and control laboratories.

TITLE XV

Quality Control of Medicinal Products

Article 75. The Ministry of Health shall enact norms and improve mechanisms meant to ensure consumers the quality of medicinal products, considering the identity, activity, purity, efficacy, and innocuity of products, as well as encompassing quality specifications and production inspection.

Sole Paragraph. The norms referred to in this Article shall determine the quality specifications of raw materials and semi-processed products used in the manufacture of medicinal products, as well as the quality specifications of the latter, and shall accurately describe the criteria for the respective acceptance.

Article 76. No raw material or semi-processed product may be used in the manufacture of medicinal products without the verification that they have acceptable quality, according to evidence that shall be object of norms issued by the Ministry of Health.

Article 77. The inspection of production of medicinal products shall consider, on a priority basis, the following aspects:

I – manufacturing, considering unfavorable intrinsic and extrinsic factors, including the possibility of contamination of raw materials, semi-processed products, and the finished product;

II – the finished product, in order to check whether it meets requirements pertaining to the technical officials in charge of manufacturing and inspection of products, to the sites and equipment, to the sanitation of the environment, to raw materials, and to inspection and self-inspection systems, as well as to the marketing authorization of medicinal products.

Article 78. Without prejudice to control and inspection carried out by the Public Powers, every establishment meant for the production of medicinal products shall have a technical department for quality inspection, operating in an autonomous manner within its sphere of competence, aimed at checking the quality of raw materials or substances, at surveying the qualitative aspects of manufacturing operations of the medicinal products manufactured, as well as at carrying out other necessary tests.

Sole Paragraph. Industrial pharmaceutical laboratories are allowed to carry out the controls provided for in this Article, in official institutes or laboratories, by means of agreements or contracts.

Article 79. All reports on accidents or harmful reactions caused by medicinal products shall be transmitted to the relevant health authority.

Sole Paragraph. Alterations in the quality of medicinal products and any alteration in their physical characteristics shall be investigated in all details, and once verified, shall be subject to the appropriate corrective measures.

TITLE XVI

Health Surveillance Organizations

Article 80. The health surveillance activities referred to in this Article shall be carried out:

I – at federal level, by the Ministry of Health, as provided for in legislation and regulations;

II – in the States, Territories, and in the Federal District, through their own organizations, in compliance with the relevant federal norms and with the local supplementary legislation.

TITLE XVII

Final and Transitional Provisions

Article 81. The companies that already carry out the activities referred to in this Law shall have a period of 12 (twelve) months to accomplish the alterations and adaptations necessary for compliance with its provisions.

~~Article 82. The services rendered by the Ministry of Health, related to this Law, shall be paid for through the regime of public prices, and the State Minister is responsible for determining the respective values and establishing the grounds for charging them.~~ **(Revoked by Provisional Measure no. 2,190 of 2001)**

Article 83. Pharmaceuticals, chemicals, and officinal products shall be sold in their original packaging and may only be fractionated for re-sale, in commercial establishments, under the direct responsibility of the respective technical official in charge.

Article 84. The provisions of this Law do not preclude the enforcement of other norms covering the activities referred to herein regarding aspects that are object of specific legislation.

Article 85. The provisions of this Law apply to the products referred to in Article 1, governed by special norms, as appropriate.

Article 86. Sanitizing phytosanitary and zoo-sanitary products, those of exclusive veterinarian use, and those meant for fighting rats and other rodents in agriculture are excluded from the regime of this Law, considering they are meant for purposes different from those established herein.

Article 87. The Executive Power shall enact the regulation and the acts necessary for the accurate compliance with this Law.

Sole Paragraph. While regulation and other acts provided for in this Article are not enacted, the current ones that do not conflict with the provisions of this Law shall remain in force.

Article 88. This Law enters into force 95 (ninety-five) days after its publication, and the provisions contrary to it are hereby revoked.

Brasilia, 23 September 1976; 155th day of the Independence and 88th day of the Republic.

Ernesto Geisel
Paulo de Almeida Machado