LAW No. 13,411 OF 28 DECEMBER 2016.

Alters Law no. 6,360 of 23 September 1976, which provides for the health surveillance actions medicinal products, drugs, pharmaceutical inputs and related products, cosmetics, sanitizers, and other products are subject to, and makes other provisions, and Law no. 9,782 of 26 January 1999, which defines the Brazilian Health Surveillance System, creates the Brazilian Health Regulatory Agency, and makes other provisions, in order to promote transparency and predictability to the process of grant and renewal of marketing authorization for medicinal products and post-marketing authorization alterations.

THE PRESIDENT OF THE REPUBLIC: I hereby make it public that the National Congress decrees and I sanction the following Law:

Article 1. Article 12 of Law no. 6,360 of 23 September 1976 is hereafter in force with the following amendments:

"Article 12 .....

.....

Paragraph 3. Except for the provisions in articles 17-A, 21, and 24-A, the marketing authorization shall be granted in up to ninety days from the date the request was registered, except when the requesting company does not comply with this Law or its regulations.

.....

Paragraph 8. The marketing authorization shall not be renewed for:

I – the product not classified as a medicinal product that has not been manufactured within the validity period of the expired marketing authorization;

II – the medicinal product that has not been commercialized during at least the period corresponding to the last two-thirds of the validity period of the expired marketing authorization.

.....

Paragraph 10. Anvisa shall define in its own regulations the mechanisms to publicize the processes of marketing authorization, post-marketing authorization alteration, and marketing authorization renewal, and the following information is required:

I – **status** of the analysis;

II – expected deadline for the final decision on the process;

III – technical basis for the decisions on the process.” (new wording)

Article 2. Law no. 6,360 of 23 September 1976 is hereafter in force with the addition of the following article 17-A:

“Article 17-A. The deadlines established for the final decision on marketing authorization and post-marketing authorization alteration processes shall consider the following criteria:

I – technical complexity;

II – clinical, economic, and social benefits from the use of the medicinal product object of the petition.

Paragraph 1. The application of the criteria provided for in the caption of this article, in accordance with the methodology established in Anvisa regulation, shall determine the classification of the medicinal product under assessment into the following precedence categories:

I – priority;

II – ordinary.

Paragraph 2. The maximum periods of time for the final decision on processes of medicinal product marketing authorization and post-marketing authorization alteration shall be, respectively:

I – for the priority category, one hundred and twenty days and sixty days, from the date of the respective prioritization submission;

II – for the ordinary category, three hundred and sixty-five days and one hundred and eighty days, from the date of the respective submission of marketing authorization or post-marketing authorization alteration.

Paragraph 3. Except when there is an appeal against a previous decision, the final decision on processes of post-marketing authorization alteration may be made through a conditional approval, presumed by the fact that Anvisa has not expressed otherwise within the periods defined in Paragraph 2.

Paragraph 4. The conditional approval provided for in Paragraph 3 may only occur in the cases of post-marketing authorization alteration defined in regulation, and shall be automatically reversed, at any time, if Anvisa rejects the post-marketing authorization alteration.

Paragraph 5. The periods of time provided for in Paragraph 2 may be extended for up to one-third of the original period, only once, through a well-founded decision by Anvisa issued at least fifteen working days before the end of the original period.

Paragraph 6. The requests for clarification or rectification by Anvisa must be consolidated into a single petition, except when necessary to clarify or rectify information related to a request previously responded to by the requesting company, and the calculation of the periods determined in this article shall be suspended until the requests are responded to.

Paragraph 7. The unjustified non-compliance with the periods of time provided for in this article implies an investigation into the working responsibility of the servant or servants who caused it, in accordance with Law no. 8,112 of 11 December 1990.

Paragraph 8. Anvisa shall regulate the provisions in this article, particularly the specification of the criteria mentioned in the **caption**, aiming at the classification into priority categories.

Paragraph 9. If the period of one hundred and eighty days from the date this article enters into force is expired before the regulation provided for in Paragraph 8 is published, and while the matter remains unregulated, the maximum period of time for the final decision shall be three hundred and sixty-five days for marketing authorization processes, and one hundred and eighty days for post-marketing authorization alteration processes."

Article 3. Articles 15, 19, and 20 of Law no. 9,782 of 26 January 1999 are hereafter in force with the following amendments:

"Article 15. .....

.....

III – editing regulations on matters of the Agency's competence, which must be accompanied by technical justifications and, whenever possible, by studies on the economic and technical impact on the regulated sector, as well as the impact on public health, but this requirement is waived in the cases of serious risk to public health;

.....

Paragraph 3. Unless provided for otherwise, the period of time to seek the administrative appeal provided for in Paragraph 2 shall be thirty days from the date the contested decision is officially published.

Paragraph 4. The final decision on the administrative appeal shall be published within ninety days, at the latest, counting from the date the appeal is lodged.

Paragraph 5. The period of time provided for in Paragraph 4 may be extended by a period equal to the original one, by means of publishing the respective justification.

Paragraph 6. The non-compliance with the periods established in paragraphs 4 and 5 implies an investigation into the working responsibility of the servant or servants in each specialized area responsible for process analysis." (new wording)

"Article 19. .....

Sole paragraph. The management contract is the instrument to assess Anvisa's administrative work and its performance, which establishes the parameters for the agency's internal management, as well as the indicators that allow to objectively quantify its regular assessment, and it must specify, at least:

I – goals and deadlines for management, operational, and monitoring performance;

II – budgetary forecast and payment planning for the resources necessary to comply with the goals agreed upon;

III – obligations and responsibilities of the parties regarding the goals agreed upon;

IV – a follow-up and assessment system;

V – measures to be taken in case of unjustified non-compliance with the goals and obligations agreed upon;

VI – period of validity;

VII – requirements and conditions for management contract review." (new wording)

"Article 20. The unjustified non-compliance with the goals and obligations agreed upon in the management contract during two consecutive fiscal periods shall imply the dismissal of the members of the Collegiate Board of Directors by the President of the Republic, by means of a request from the State Minister of Health." (new wording)

Article 4. The marketing authorization and post-marketing authorization alteration processes filed before the date this Law enters into force shall observe a timetable to be defined by the Brazilian Health Regulatory Agency – Anvisa, and the final decision on them shall be published in up to one year after the date this Law enters into force.

Article 5. This Law enters into force ninety days after its official publication.

Brasília, 28 December 2016; 195th year from the Independence and 128th year from the Proclamation of the Republic.

MICHEL TEMER

Ricardo José Magalhães Barros