



DRUG MARKET REGULATION CHAMBER COUNCIL OF MINISTERS

RESOLUTION CMED NO. 2, DATED 5 MARCH 2004*

(Altered by Resolution CMED no. 4, dated 15 June 2005, published on the Federal Official Gazette of 07 October 2005 and by Resolution CMED no. 4, dated 18 December 2006, published on the Federal Official Gazette of 12 March 2007)

*** CONSOLIDATED VERSION**

THE EXECUTIVE SECRETARIAT makes known that the COUNCIL OF MINISTERS of the DRUG MARKET REGULATION CHAMBER (CMED, in Portuguese), in the use of the attributions vested in it under items I, III, and VIII of Article 6, and considering Article 7, both of Law no. 10,742 dated 6 October 2003, decided to approve the following RESOLUTION:

Article 1. The criteria for defining the prices of new products and new pharmaceutical presentations referred to in Article 7 of Law no. 10,742 dated 6 October 2003 are approved, in the form of the Annex to this Resolution.

Article 2. Resolution CMED no. 1 dated 27 June 2003 is hereby revoked.

Article 3. This resolution enters into force on the date of its publication.

ANNEX

Article 1. Drug manufacturers should inform the Drug Market Regulation Chamber whenever they intend to market new products and new pharmaceutical presentations.

Paragraph 1. For the purpose of article 7 of Law no. 10,742 dated 6 October 2003, the drugs with a new molecule in the country are considered new products.

Paragraph 2. For the purpose of article 7 of Law no. 10,742 of 2003, all drugs that do not fit the definition provided for in the last paragraph are considered new pharmaceutical presentations.

Article 2. The new products should be classified into the following Categories:

I – Category I: new product with a molecule patented in the country that brings gain to the treatment in relation to the drugs already used for the same therapeutic indication, with the confirmation of one of the following requirements:

a) Greater efficacy in relation to the existing drugs for the same therapeutic indication;

- b) Same efficacy with a significant decrease in the adverse effects; or
- c) Same efficacy with a significant reduction in the global cost of treatment.

Sole paragraph. The Technical-Executive Committee may consider other added therapeutic advantages, as long as they are scientifically confirmed.

II – Category II: new products that do not fit the definition provided for in the last item.

Sole paragraph. The new presentations of products classified into Categories I, II, and V, which may be subsequently launched in the market, shall follow the same category classification originally determined, for the period of five years.

Article 3. The new pharmaceutical presentations should be classified as:

I – Category III: new pharmaceutical presentation of a drug already marketed by the company itself, in a same pharmaceutical form.

II – Category IV: new drug presentation that fits one of the following situations:

- a) drug considered new on the list of the ones marketed by the company, except the cases provided for in item III of this article;
- b) drug already marketed by the company, in a new pharmaceutical form.

III – Category V: drug fitting one of the following situations:

- a) new pharmaceutical form in the country;
- b) new association of active ingredients already existing in the country.

IV – Category VI: drug classified as generic, in accordance with Law no. 9,787 dated 10 February 1999, related to item XXI of article 3 of Law no. 6,360 dated 23 September 1976.

Sole paragraph. The new presentations provided for in items I and II of this article shall be classified into categories III or IV, as long as they do not fit Category VI.

Article 4. The drug manufacturers that intend to market new products and new presentations should register an Informative Document at the headquarters of the Drug Market Regulation Chamber Executive Secretariat, located at SEP 515, Bloco B, Edifício Omega, Protocolo, Térreo, CEP 70770-502, Brasília-DF, Brazil.

Paragraph 1. The front page of the Informative Document should include the Category which the company wants to see its product classified into, according to articles 2 and 3.

Paragraph 2. In case the product's classification option by the company was Category I, the Informative Document should include the following information:

I. brand name of drug in Brazil and the other brand names for the same drug, used in the countries mentioned in item VII of this paragraph and in the manufacturer's origin country;

II. drug approval number and EAN code, both comprised of thirteen digits;

III. substances from which the drug is formulated;

IV. copy of package leaflet;

V. presentation form in which the drug will be marketed;

VI. the price at which the company intends to market each presentation, with the discrimination of taxes and marketing margins;

VII. manufacturer's price, accompanied by the due source proof, traded in Australia, Canada, Spain, United States of America, France, Greece, Italy, New Zealand, Portugal, and the manufacturer's price in the product's country of origin, excluding taxes;

VIII. manufacturer's name and the manufacturing site of the active ingredient and the finished drug;

IX. potential number of patients to be treated with the drug, with the indication of the corresponding period;

X. cost-efficacy comparative analysis between the drug and the existing therapeutic alternatives;

XI. presentation of the following information on the product's patent:

- a) Number of the first international patent application, date of application, and the country where it was done;
- b) Number of patent application at INPI;
- c) Innovation presented by the product which the patent application was based on;

XII. when available, presentation of economic assessment studies published;

XIII. phase III clinical trials conducted, which are relevant for the comparison between the new drug and those existing in the country for the same therapeutic indication, if any; and

XIV. new therapeutic indications for the same drug – in trial, in phase of approval, or approved in other countries, if any.

Paragraph 3. If the classification option was Category II or Category V, the Informative Document should include the information referred to in items I to VIII, and XIII, as well as XIV of paragraph 2.

Paragraph 4. If the classification option was Category III, IV or VI, the Informative Document should include the information referred to in items I to VI of paragraph 2.

Paragraph 5. The Informative Document of the product classified into Category III should also include the list of all presentations of the drug in the market.

Paragraph 6. At the discretion of the Executive Secretariat, an official translation of the documents referred to in paragraph 2 may be required.

Article 5. For the new products classified into Category I, the Factory Price – FP proposed by the company shall not be higher than the lowest FP traded for the same product in the countries listed in item VII of paragraph 2 of article 4, taxes being added, as appropriate.

Paragraph 1. In order to check the FP authorized, the product should be marketed in at least three of the countries listed in item VII of paragraph 2 of article 4.

Paragraph 2. If the condition of the last paragraph is not met, the Technical-Executive Committee, considering the public interest, may establish a provisional price, observing the following conditions:

I – (REVOKED)

II – signature of a term of commitment, by which the company should commit to:

a) submit the approved provisional price to review every six months, until the provisions of the last paragraph and the caput of this article are met;

b) inform on the launch of the product, with its respective price, in the countries listed in item VII of article 4.

Paragraph 3. For the conversion of the price expressed in foreign currency into the Brazilian currency Real, the average exchange rate divulged by the Brazilian Central Bank (BACEN, in Portuguese) will be applied, calculated for the period of sixty work days previous to the date of approval of the Report by the Executive Secretariat, referred to in Article 14 of this Resolution.

I – The company may request, until the report's approval by the Executive Secretariat, the update of the price proposed in case of significant exchange appreciation or depreciation.

II – In case of appeal, the average exchange rate divulged by the Brazilian Central Bank (BACEN, in Portuguese) will be applied, calculated for the period of sixty work days previous to the date of the decision, with the purpose of conversion of the expressed price from foreign currency to Real.

Paragraph 4. The Price Adequacy Coefficient – PAC may be applied to the Factory Price of categories I, II, and V, in accordance with what will be defined by the Council of Ministers in a specific Resolution. [new text]

I – (REVOKED)

II – (REVOKED)

III – (REVOKED)

Article 6. The Factory Price authorized for the product classified into Category II will be defined based on the cost of treatment with the drugs used for the same therapeutic indication, and it must not be, in any case, higher than the lowest price traded among the countries listed in item VII of paragraph 2 of Article 4.

Paragraph 1. The price of the new product must not incur to consumers a higher cost of treatment with the drug than the one chosen as a comparative.

Paragraph 2. The drug to be used as a comparative will be defined based on an analysis by CMED, which should consider the drugs used for the treatment at issue in the country, as well as the existing scientific evidences.

Paragraph 3. In case of companies that do not market the product in other countries, the price of products with the same active ingredient in the countries listed in item VII of paragraph 2 of Article 4 will be used as reference.

Article 7. The Factory Price authorized for the product classified into Category III must not be higher than the arithmetic average of the drug presentation prices, with the same strength and pharmaceutical form, already traded by the company itself.

Paragraph 1. If there are not presentations with the same strength, the average shall be calculated based on all presentations of the drug, in the same pharmaceutical form, following the criterion of direct proportion of the active ingredient strength.

Paragraph 2. When the active ingredient strength alteration generates gain to the treatment, the criterion of treatment cost with the drug defined as comparative shall be considered.

Article 8. For the drug that had its formula altered and its brand name kept, the company shall submit a new price application in accordance with which category defined in this Resolution the drug fits into.

Article 9. The Factory Price authorized for the product classified into Category IV must not be higher than the average price of the drug presentations with the same active ingredient and the same strength available in the market, in the same pharmaceutical form, considered according to the profits from each presentation, based on the following criteria:

I – The average should be calculated based on the presentations of equal strength existing in the market;

II – If there are no presentations with equal strength, the average should be calculated based on all presentations of the same formula and pharmaceutical form existing in the market, following the criterion of direct proportion of the active ingredient strength.

Article 10. The product classified into Categories III or IV must not have its Factory Price higher than the Factory Price of the reference drug, defined according Law no. 9,787 dated 10 February 1999, related to item XXII of article 3 of Law no. 6,360 dated 23 September 1976.

Article 11. For the drugs classified into Category V, the criteria for establishing the authorized Factory Prices should be the following:

I – in the case of new associations in the country, the provisions of items III and IV of Article 13 of this Resolution, and the prices must not be, in any case, higher than the lowest price traded among the countries listed in item VII of paragraph 2 of Article 4. [new text]

II – in the case of new pharmaceutical forms, the price will be defined based on the cost of treatment with the drugs existing in Brazil for the same therapeutic indication, and it must not be, in any case, higher than the lowest price traded among the countries listed in item VII of paragraph 2 of Article 4. [new text]

a) (REVOKED)

b) (REVOKED)

Article 11-A. For the drug with an active ingredient in a new pharmaceutical form in the country, and that has confirmed gains for the treatment in relation to drugs available in the Brazilian market, the average relative difference of prices traded in the same countries listed in Article 4 of this Resolution shall be used as reference for the price definition.

Article 11-B. If the gains referred to in item II of Article 11 result from technology developed exclusively in the country, the company may present a justification for the price proposed, the relevance of which shall be assessed by the Technical-Executive Committee.

Article 11-C. In the case of new pharmaceutical forms in the country, the drug to be used as a comparative shall be defined based on technical analysis by CMED, which shall consider the drugs used for the treatment at issue in the country, as well as the existing scientific evidences.

Article 12. The Factory Price authorized for the product classified into Category VI must not be higher than 65% of the price of the corresponding reference drug.

Sole paragraph. When there is a new presentation of a generic drug already marketed by the company, the Factory Price authorized for the product classified into Category VI must not be higher than the arithmetic average of the prices of the other generic drug presentations traded by the company itself, with the same strength and pharmaceutical form, and it must not be higher than 65% of the price of the corresponding reference drug.

Article 13. The definition of the Factory Price of associations shall meet the following criteria:

I – in the case of associations in which one of the active ingredients is a new molecule in the country, the provisions of Articles 5 or 6 of this Resolution shall be considered, as appropriate;

II – in the case of associations classified into Categories III or IV where there are other associations with the same active ingredients in the Brazilian market, the provisions of Articles 7 or 9 aforementioned shall be considered, as appropriate;

III – in the case of a new association in the country of monodrugs marketed separately, the association's price must not be higher than the sum of the monodrugs' prices, observing the strength proportion of active ingredients and the number of units, as long as the price at issue does not incur a higher cost of treatment than the one already existing.

IV – in the case of a new association in the country of monodrugs already marketed, which replaces, with confirmed advantages, the treatment with the monodrugs taken separately, the company may present a justification for the proposed price, the relevance of which shall be assessed by the Technical-Executive Committee.

V – in the case of a new association already existing in the country, in which the alteration of active ingredient strength is advantageous for the treatment, the company may present a justification for the proposed price, the relevance of which shall be assessed by the Technical-Executive Committee.

Article 14. The Executive Secretariat, based on an analysis by CMED, should decide if the prices presented by the companies for new products and new presentations are in accordance with the provisions of this Resolution.

Paragraph 1 (REVOKED)

Paragraph 2 (REVOKED)

Article 15. CMED should observe the following deadlines to inform the company of its decision:

I – up to 90 days for the products classified into Categories I and II;

II – up to 60 days for the products classified into Categories IV, V, and Category III, when applicable.

Paragraph 1. If the Executive Secretariat does not mention the initial price proposed by the company, within the periods of time referred to in items I and II, counting from the submission of all information required, in the terms of this Resolution, the products may be marketed at the proposed price.

Paragraph 2. The deadlines mentioned by the heading of this article shall be suspended until all explanations and documents essential to the process analysis are submitted, which are requested through formal letters.

Article 16. The products classified into Categories III or IV may be marketed as soon as the Informative Document is submitted, as long as their prices are in accordance with articles 7 and 12, respectively.

Paragraph 1. The company that confirmedly publishes or trades at a higher price than the one defined based on the provisions of the heading shall be subject to the sanctions provided for in Article 8 heading and sole paragraph of Law no. 10,742 of 2003.

Paragraph 2. The marketing ruling referred to in the heading does not apply to the associations with strength alteration classified into Category III.

Article 17. The company may request a review of the Executive Secretariat's decision from the Secretariat itself, within the period of 15 days counting from the date the company received the decision.

Sole paragraph. If, in case of review, the Executive Secretariat keeps its decision, the company may appeal to the Technical-Executive Committee, within the period of 15 days counting from the date the company received the decision at issue.

Article 18. If the provisions of this Resolution are not met, the infringer shall be subject to the sanctions provided for in Law no. 10,742 dated 6 October 2003.

Article 19. The Factory Price, obtained from the calculations provided for in this Resolution, shall be expressed in two decimal places, rounded from the third decimal place, in accordance with the provisions in item 7 ("Rounding of Numeric Data"), of the publication "Norms for Tabular Presentation" by the Foundation Brazilian Institute of Geography and Statistics (IBGE, in Portuguese).

Article 20. The cases not provided for shall be assessed by the Technical-Executive Committee, and the company may appeal to the Council of Ministers.

LUIZ MILTON VELOSO COSTA
Executive Secretary