



Ministry of Health

Special Advisory for Parliamentary and Federative Affairs

LETTER No. 915/2024/ASPAR/MS

Brasília, June 14, 2024.

To His Excellency the Lord

**Federal Deputy Luciano Bivar**

First Secretary of the Chamber of Deputies

**Reference: Information Request No. 852/2024 Subject:** Information regarding the

decision taken by the Medicines Market Regulation Chamber (CMED) to increase medicine prices by up to 4.5% throughout Brazil.

Mr First Secretary,

Cordially greeting you, in compliance with Official Letter No. 80/2024, 1. coming from the First Secretariat the Chamber of Deputies, regarding **Information Request No. 852/2024**, authored by Federal Deputy Gustavo Gayer PL/GO, through which requests the Minister of State for Health, Nísia Trindade Lima, information regarding the decision taken by the Medicines Market Regulation Chamber (CMED), to increase the prices of medicines by up to 4.5% throughout Brazil, I serve you. I am hereby to forward the information provided by ANVISA, through Technical Note 206 (0041117690) and the Executive Secretariat, through Order (0041387552).

Therefore, within the scope of the Ministry of Health, this was the 2. information provided by the technical staff on the subject.

Without further ado for the moment, this Ministry remains at your disposal for any 3. clarifications that may be necessary.

Yours sincerely,



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Ofício 915 (0041380153)

SEI 25000.051270/2024-95 / pg. 1

2438353

**NÍSIA TRINDADE LIMA**  
Minister of State for Health



Document signed electronically by **Nísia Verônica Trindade Lima, Minister of State for Health**, on 06/17/2024, at 7:10 pm, according to official Brasília time, based on § 3 of art. 4th, of [Decree No. 10,543, of November 13, 2020](#); and art. 8th, of [Ordinance No. 900 of March 31, 2017](#).



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Ofício 915 (0041360153)

SEI 25000.051270/2024-95 / pg. two

2438353

**TECHNICAL NOTE No. 206/2024/SEI/SCMED/GADIP/ANVISA**

SEI Administrative Process No. 25351.910470/2024-18

Interested: ASPAR

Reference: Information Request nº 852/2024, authored by Federal Deputy Gustavo Gayer (PL/GO) who, "Requests information from the Minister of Health, regarding the decision taken by the Medicines Market Regulation Chamber (CMED), to increase drug prices by up to 4.5% throughout Brazil."

**1. REPORT**

This is ORDER No. 311/2024/SEI/ASPAR/GADIP/ANVISA (2893187), which forwards for knowledge, analysis and manifestation, if applicable, Information Request No. 852/2024 (2893179), authored by the Federal Deputy Gustavo Gayer (PL/GO), who "Requests information from the Minister of Health, regarding the decision taken by the Medicines Market Regulation Chamber (CMED), to increase medicine prices by up to 4.5% in all over Brazil."

The parliamentarian's request requests that the following questions be answered:

- 1- How does the Ministry of Health assess the impact of this decision to increase drug prices on the population's access to necessary treatments?
- 2- Is there any forecast or study on the possible effect of this price increase on the demand for medicines and on the budget of health services?
- 3- The Ministry of Health has a plan or strategy to mitigate the possible negative impacts of this price increase, especially for the most vulnerable groups of the population, such as the elderly, people with chronic illnesses and low-income people?
- 4- What is the position of the Ministry of Health in relation to regulating the medicines market and guaranteeing universal access necessary treatments?
- 5- Does the Ministry of Health consider it necessary to review the current drug price regulation policy, especially given concerns about accessibility and equity in access to health treatments?

**2. ANALYSIS**

Although the questions above are not under the jurisdiction of the Medicines Market Regulation Chamber (CMED), for the purpose of better elucidating the content covered, it is necessary to report on the CMED's duties, with emphasis on medicine pricing.

**2.1. The responsibilities of the Medicines Market Regulation Chamber (Law No. 10,742/2003) and regulation economics of the medicines market.**

Created by Law No. 10,742, of October 6, 2003, the Medicines Market Regulation Chamber (CMED), of the Government Council, aims to adopt, implement and coordinate activities related to the economic regulation of the medicines market, aimed at promoting pharmaceutical assistance to the population, through mechanisms that encourage supply of medicines and the competitiveness of the sector.

CMED's competencies are defined in article 6 of Law No. 10,742, of October 6, 2003, as well as in art. 2nd of Decree No. 4,766, of June 26, 2003, with the Chamber being composed of a Council of State Ministers (Ministry of Health; Farm; Justice and Public Security; Development, Industry, Commerce and Services; and the Civil House of the Presidency of the Republic); by a Technical-Executive Committee, composed of Secretaries of State linked to the aforementioned portfolios; and by an Executive Secretariat, exercised by ANVISA, in accordance with art. 7th of the aforementioned decree and the provisions of CMED Resolution No. 3/2003, which provides for the CMED's Internal Regulations.

In carrying out its regulatory activity, CMED routinely defines guidelines and procedures relating to the exclusive economic regulation of the medicines market; establishes criteria for setting and adjusting drug prices; define criteria for setting prices for new products and new drug presentations; proposes the adoption of legislation and regulations relating to the economic regulation of the medicines market; ensures the protection of the interests of medicine consumers; decides on the application of penalties relating to the medicines market, provided for in Law no. 8,078/1990; among other duties provided for in art. 6th of Law No. 10,742, of October 6, 2003.

Therefore, the economic regulation of the Brazilian pharmaceutical market is based on a price cap model, in which specific criteria are established for setting and adjusting maximum prices for marketing of medicines, as established by Law 10,742/2003. Through this model, CMED defines the maximum prices that medicines can be sold on the national market, both the Factory Price (PF) and the Maximum Consumer Price (PMC), from which the commercialization of medicines would be considered a practical practice. abusive, subject to penalties.

The determination of maximum commercialization prices is carried out in accordance with CMED Resolution nº 2, of March 5, 2004, which takes into account the external reference pricing system, evaluation of health technologies (health technology assessment) and pharmacoeconomic analysis (pharmacoeconomics analysis), and the objective of this methodology is bring drug prices in Brazil to international standards where the medicine market is regulated and, at the same time, time, prevent medicines from having prices here in the country above the prices sold on the international market. As external reference, prices from a basket of countries are used, such as Australia, Canada, Spain, the United States of America, France, Greece, Italy, New Zealand, Portugal and the manufacturer price charged in the product's country of origin.

Thus, new medicines, when subject to patents and with benefits for treatment, proven based on a health technology assessment analysis, cannot have prices higher than those found in those countries.

However, the international price comparison tool is not the only tool that can be used in market price regulation. In this sense, CMED introduced good practices first adopted in northern European countries, which is the use of Health Technology Assessment (ATS) to be able to compare different technologies and the existence of gains therapeutics. This new tool was very important so that Brazil did not import new, expensive and inefficient therapies instead of old, cheap and efficient therapies.

It is in this sense that new medicines, which do not prove therapeutic gain for treatment, have a double pricing method. One is the external price reference and the other is the introduction of pharmaco-economic criteria arising from the ATS, when analyzing the treatment costs of equivalent medicines for the same therapeutic indication already available on the Brazilian market. Similarly, the prices of new presentations of medicines already marketed in the country cannot be higher than the average domestic market prices nor higher than the prices of the corresponding reference medicines, maximum of 65% of the reference price, in the case of generics.



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SEP25000.051270/2024-95 / pg. 3

It should be noted that this regulatory model is widely used in regulating the medicines market in most European countries and also in other countries such as Jordan, South Africa, Japan, Turkey, Canada and Australia, among others. In most of the countries that adopt it, this model is the main criterion for determining the prices of new products, while Belgium, Italy, Germany, Finland, Poland and Spain use it as a criterion to support price establishment.

Therefore, it is a regulatory model that encourages and recognizes the development of new technologies by national and multinational companies, and at the same time contrasts with the older regulatory regime, that of the fixed rate of return (rate of return regulation), also known as cost-of-service regulation, accounting cost or historical cost, a model that is no longer used in countries that regulate the medicines market. In Brazil, CMED, like the vast majority of countries, does not set drug prices based on costs.

## 2.2. Price adjustment rules in the economic regulation of the medicines market.

Regarding price ceiling regulation, the CMED, in full compliance with the rules that regulate the medicines market, establishes the maximum sales prices for medicines in Brazil when it defines the Factory Prices (PF), the Maximum Consumer Prices (PMC) and the Maximum Sales Prices to the Government (PMVG), and also when defining the maximum rates of annual price adjustments.

Pursuant to art. 4 of Law No. 10,742, of 2003, companies producing medicines must observe, in order to adjust and determine their prices, the rules defined in the aforementioned law, with any adjustment being prohibited in disagreement with the criteria established in Decree No. 4,937, of 29 December 2003, as well as the rules set out by the Medicines Market Regulation Chamber (CMED).

Let's look at the rule expressed in art. 4th of Law No. 10,742, of 2003:

Art. 4 Companies producing medicines must observe, in order to adjust and determine their prices, the rules defined in this Law, from its publication, any adjustment in disagreement with this Law is prohibited.

§ 1. Medicine price adjustments will be based on a price ceiling model calculated based on an index, a productivity factor and an intra-sector and inter-sector relative price adjustment factor.

§ 2 The index used, for the purposes of the adjustment provided for in § 1, is the Broad National Consumer Price Index - IPCA, calculated by the Brazilian Institute of Geography and Statistics - IBGE.

§ 3 The productivity factor, expressed as a percentage, is the mechanism that allows consumers to be passed on, through drug prices, projections of productivity gains for drug producing companies.

§ 4 The relative price adjustment factor, expressed as a percentage, is made up of two parts:

I - the portion of the intra-sector relative price adjustment factor, which will be calculated based on market power, which is determined, between others, due to monopoly or oligopoly power, information asymmetry and barriers to entry; It is

II - the portion of the relative price adjustment factor between sectors, which will be calculated based on the variation in input costs, provided that such costs are not recovered by calculating the index provided for in § 2 of this article.

§ 5 The Medicines Market Regulation Chamber - CMED, created by art. 5th of this Law, propose criteria for the composition of factors referred to in § 1, as well as the degree of disaggregation of such factors, whether by product, by relevant market or by groups of relevant markets, to be regulated by December 31, 2003, in accordance with art. 84 of the Federal Constitution.

§ 6 CMED will provide transparency and publicity to the criteria referred to in §§ 1 and 2 of this article.

§ 7 Price adjustments will occur annually.

§ 8 The first adjustment, based on the criteria established in this Law, will occur in March 2004, considering, for the purposes of this adjustment:

I - the manufacturer price of the medicine on August 31, 2003; It is

II - the IPCA accumulated from September 2003 onwards.

§ 9 Exceptionally, the CMED Council of Ministers may authorize a positive price adjustment or determine a negative adjustment on August 31, 2003, taking as reference the manufacturer price on March 31, 2003.

As a rule, annually, in the month of March, after the official publication of the IPCA accumulated over the twelve-month period, CMED issues a specific resolution providing for price adjustments for the corresponding period, the Manufacturer Price (PF) and the Maximum Consumer Price (PMC) of medicines, as well as the form of presentation of the Marketing Report by producing companies, in addition to all other measures inherent to enabling the adjustment of medicine prices, in compliance with the command established by Law No. 10,742/2003.

CMED Resolution nº 01, of February 27, 2004, which established the criteria for the composition of factors for the adjustment of medicine prices, authorized, initially for the year 2004, an adjustment of medicine prices having as reference the Manufacturer Price (PF) practiced in the previous year, becoming the rule for subsequent years to issue a specific resolution to establish the adjustment criteria.

Subsequently, CMED Resolution nº 01, of February 23, 2015, began to establish the criteria for composition of factors for the adjustment of drug prices, foreseeing that the adjustment of drug prices, to occur on March 31 of each year, will be based on a price ceiling model calculated using a price index, a productivity factor (Factor X), a portion of the relative price adjustment factor between sectors (Factor Y) and a portion of the intra-industry relative price adjustment (Z Factor), using the Broad National Consumer Price Index (IPCA), calculated by the Brazilian Institute of Geography and Statistics Foundation (IBGE), accumulated in the twelve-month period prior to the publication of the price adjustment.

Therefore, annually, the Medicines Market Regulation Chamber publishes a specific standard defining the productivity factor (Factor of drug prices, projections of productivity gains for drug producing companies, being established based on the estimate of prospective productivity gains for the pharmaceutical industry.

Thus, following the legal provisions, for the price adjustment to be carried out in March 2024, CMED published CMED Resolution nº 01, of March 28, 2024, accompanied by SEI Technical Note nº 2752/2023/MF, authored by the Secretariat of Economic Reforms, of the Ministry of Finance, which is part of CMED, in which the calculation of the productivity factor (Factor X, of February 23, 2015, and CMED nº 05, of November 12, 2015, which establish the criteria for the composition of factors for adjusting drug prices. Under the terms of the aforementioned resolution, the X Factor for the year 2024 must be equivalent to 0% (<https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/cmcd/ajuste-anual-de-precos-de-medicamentos/2024>).

The productivity factor (Factor X) This device creates incentives for companies to seek

achieve continuous gains in efficiency, since the entire difference between the maximum market price (Factory Price, in the case of medicines) and the production costs of the good can be appropriated by it. This means that a productivity gain greater than value projected by the regulator could be entirely retained by the company producing the medicine.

The Pharmaceutical Sector Labor Productivity Index is, therefore, the time series to be projected using an econometric model. The Index is the ratio between the physical production of the Pharmaceutical Industry in a given month and the total hours worked by the total number of workers employed by the industry in the respective month.

Applying the methodology provided for in item 2 of the Annex to the aforementioned resolution, the X Factor is calculated through an analysis of an extensive time series econometric model integrated with moving averages (ARIMA), with monthly historical series starting

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in January 2002, consisting of the following series:

I - forecast time series: labor productivity of the Brazilian pharmaceutical industry obtained by dividing, in each period, the quantum index of physical production of the pharmaceutical industry, published in the Monthly Industrial Survey of Physical Production (PIM-PF), by the total monthly hours worked by personnel employed in the pharmaceutical industry, provided by the Annual Report of Social Information (RAIS) and the General Register of Employed and Unemployed Persons (CAGED);

II - time series forecast components: a) monthly average of the purchase price of the free exchange rate of the United States dollar, adjusted by the IPCA and the Consumer Price Index - CPI of the US Bureau of Labor Statistics; b) interest rate real ex-post obtained by the adjusted average rate of daily financing calculated in the Special Settlement and Custody System - SELIC for federal public securities - Selic rate, adjusted by the IPCA; c) real growth rate obtained by the monthly variation of the Product Gross Domestic Product (GDP) in current values in national currency, adjusted by the IPCA; d) monthly variation of the IPCA.

Still regarding the Productivity Factor (Factor

(i) analyze and verify the stationarity of time series and/or make them stationary;

(ii) identify the order model of autocorrelation and partial autocorrelation using the Akaike and Schwarz criterion;

(iii) test the impact of exogenous variables – real exchange rate, variation in the growth of the Brazilian economy, exchange rate real interest and IPCA variation rate – on the Labor Productivity Index of the Pharmaceutical Sector through the T and Wald tests;

(iv) estimate the model and verify the identified model to obtain the minimum squared error prediction series.

In relation to the portion of the relative price adjustment factor between sectors (Factor Y), referred to in item II of § 4 of Law No. 10,742, of 2003, it is expressed as a percentage and calculated based on the variation in input costs not recovered by computing the index provided for in the sole paragraph of article 1 of CMED Resolution nº 01, of 2015.

Factor Y aims to adjust relative prices between the pharmaceutical sector and other sectors of the economy, to minimize the impact of non-recoverable costs due to the application of the IPCA, and must be calculated in accordance with the methodology contained in item 3 of the Annex to the aforementioned resolution, and the weights of the costs considered in the calculation of the Y Factor will be obtained through the latest Input-Output matrix made available by IBGE.

Still when calculating the Y Factor, the series of annual averages up to the year prior to the corresponding adjustment must be used, for the following variables:

I - real rate of change in the purchase price of the free exchange rate of the United States dollar, adjusted by the IPCA and CPI.

II - real variation rate of electrical energy obtained from the average energy tariff for industry, defined by the National Electric Energy Agency - ANEEL, adjusted by IPCA.

The Y Factor index is announced annually. For 2024, we cite the Technical Note SEI 228/2024/MF, authored by the Secretariat of Economic Reforms, of the Ministry of Finance, which is part of CMED, which published the Relative Price Adjustment Factor Between Sectors (Factor Y) referring to the adjustment of medicine prices for the year 2024. Under the terms of the aforementioned Technical Note, the Factor Y for the year 2024 must be equivalent to 0% (<https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/cmmed/ajuste-anual-de-precos-de-medicacoes/2024>).

As for the portion of the intra-sector relative price adjustment factor (Z Factor), referred to in item I of § 4 of Law No. 10,742, of 2003, it is expressed as a percentage and calculated based on market power, which is determined, among others, due to the asymmetry of information, due to barriers to entry and monopoly power, according to the methodology contained in item 4 of the Annex to CMED Resolution nº 01, of 2015.

The Z Factor aims to promote competition in the different medicine markets, adjusting relative prices between the markets with the least competition and the most competitive. To define the level of market concentration, the Anatomical Classification level 4 (AC4) system of the European Pharmaceutical Market Research Association (EPHMA) will be used.

To assess the degree of market concentration, the Herfindahl-Hirschman Index (IHH) is used, considering the most recent data from the Medicines Market Monitoring System (Sammed) database, according to medicine marketing information provided by companies.

Once the market concentration has been defined and the IHH has been calculated, three levels are established for the Z Factor, discriminating between concentrated and moderately concentrated and competitive markets, according to the methodology contained in item 4 of the Annex to CMED Resolution No. 01, of 2015. To the price adjustment to be carried out in March 2024, CMED published, through the [CMED ORDINANCE No. 1, OF FEBRUARY 6, 2024](#), therapeutic classes classified according to the Herfindahl-Hirschman index (IHH) of drug market concentration, to establish the three levels of the intra-sector relative price adjustment factor (Z Factor) (<https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/cmmed/ajuste-anual-de-precos-de-medicamentos/2024>).

It is worth noting that the listing of the therapeutic classes of medicines and their classification according to the Herfindahl-Hirschman Index (IHH) of medicine market concentration already signals to the market at which level the medicine will be reached by the annual adjustment, as, in the wake of the previously announced division, the methodology of CMED Resolution nº 01, of February 23, 2015, is constructed so that the highest adjustment index is directed to markets considered competitive (Level 1), the index adjustment intermediary be directed to moderately concentrated markets (Level 2) and, finally, the lowest adjustment index or consider fully concentrated markets (Level 3), in which there is a low level of competition.

It is important to reiterate that the economic regulation of the medicines market is based on broad regulations knowledge on the part of the sectors involved, including the standard that defines the mechanisms for annual adjustment of the price of medicines (CMED Resolution nº 01, of February 23, 2015), being the subject of broad social participation through the Consultation CMED Public No. 01, of December 8, 2014, conduct that was repeated in other situations in which new regulatory rules have been implemented.

Regarding the annual adjustment itself, CMED Resolution nº 01, of February 23, 2015, provides the following formula for the calculation:  $VPP = IPCA - \text{on the market by producing or importing companies}$ . That is why it is considered in economic literature as a

regulatory incentive model, as it allows greater adjustments for more efficient companies or segments, and establishes lower price adjustments for companies or segments that present less efficiency.

Regarding the annual adjustment of medicine prices for 2024, in addition to the regulations highlighted above in relation to Factors X, Y and Z, the last piece of data to make up the calculation formula was the publication of the Broad National Consumer Price Index (IPCA) by Brazilian Institute of Geography and Statistics (IBGE) in March 2024, accumulating a percentage of 4.50% (four integers and fifty hundredths of a percent) in the period between March 2023 and February 2024. Using these data, it was possible to prepare the **maximum levels allowed for adjusting drug prices for the year 2024**, thus defining:

I - **Level 1: 4.50%** (four integers and fifty hundredths of a percent);

II - **Level 2: 4.50%** (four integers and fifty hundredths of a percent); It is

III - **Level 3: 4.50%** (four whole and fifty hundredths of a percent).

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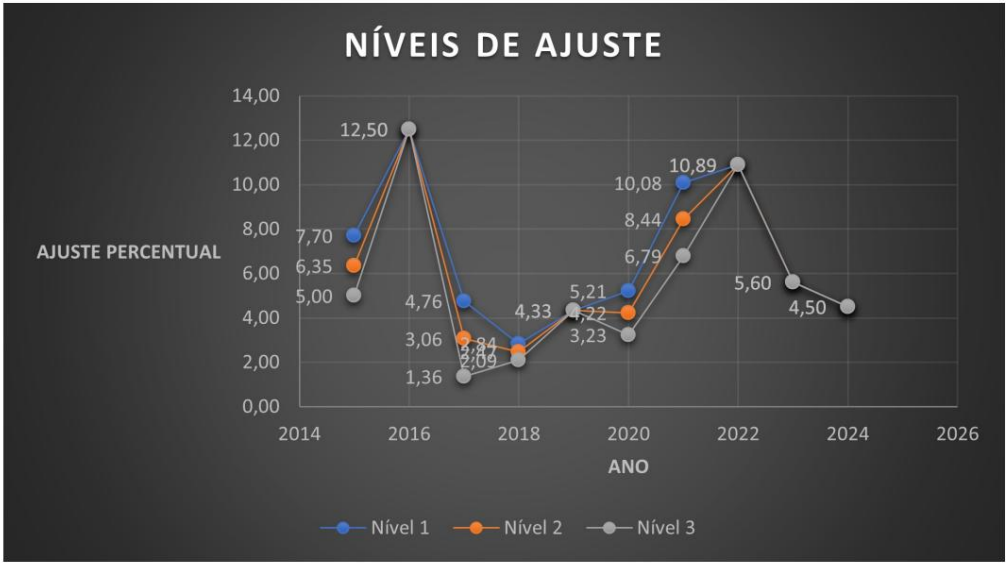
In possession of all the data, the Executive Secretariat of CMED forwarded the draft resolution, accompanied by the usual documentation, to the Ministries that make up CMED for analysis by the respective Legal Consultancies and consequent preparation of the Minutes of the Meeting of the CMED Council of Ministers to, in an individual deliberative circuit, approve the text of CM-CMED Resolution No. 01, of March 28, 2024, which provides for the maximum adjustment of medicine prices from 31 March 2024, the presentation of the Marketing Report to the Medicines Market Regulation Chamber - CMED and the advertising of pharmaceutical product prices.

It is worth noting that this is the lowest value practiced since 2020 and that the price adjustment for medicines is available to each company, which may decide to apply the total calculated index or a lower index, depending on its commercial strategy. However, the delivery of the relevant Marketing Reports is a necessary condition for applying the intended adjustment, until the maximum limit established.

Therefore, **the annual price adjustment arises from an express legal requirement contained in Law 10,742/2003, and it is up to the CMED will only operationalize it**, based on technical criteria and the methodology set out above. All documents that reference to the calculations of the annual adjustment of medicine prices are available at <https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/cmed/ajuste-anual-de-precos-de-medicamento>.

It is worth mentioning that it is the exclusive responsibility of the CMED Council of Ministers to approve criteria for readjustments of drug prices, in accordance with art. 6th, item II, of Law No. 10,742/2003, c/c art. 4th, item I, of Decree No. 4,766/2003.

Regarding adjustments applied in previous years, see the graph below, with data since the Resolution was issued CMED nº 01/2015, which defined the current rules for annual adjustment of medicine prices:



| Adjustments Year |  |  |  | Level 1 | Level 2 | Level 3 | CMED                                        | Source for consultation                                                                                                                                   |
|------------------|--|--|--|---------|---------|---------|---------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|
| Resolution 2024  |  |  |  | 4.50    | 4.50    | 4.50    | CM-CMED RESOLUTION No. 1, OF MARCH 28, 2024 | <a href="http://www.in.gov.br/web/dou/-/resolucao-cm-cmed-n-1-de-28-de-ma-2024">http://www.in.gov.br/web/dou/-/resolucao-cm-cmed-n-1-de-28-de-ma-2024</a> |
| 2023             |  |  |  | 5.60    | 5.60    | 5.60    | CM-CMED RESOLUTION No. 1, OF MARCH 30, 2023 | <a href="https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/cmed/legislaca">https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/cmed/legislaca</a>   |
| 2022             |  |  |  | 10.89   | 10.89   | 10.89   | CM-CMED RESOLUTION No. 2, OF MARCH 31, 2022 | <a href="https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/cmed/legislaca">https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/cmed/legislaca</a>   |
| 2021             |  |  |  | 10.08   | 8.44    | 6.79    | CM-CMED RESOLUTION No. 1, OF MARCH 31, 2021 | <a href="https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/cmed/legislaca">https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/cmed/legislaca</a>   |
| 2020             |  |  |  | 5.21    | 4.22    | 3.23    | RESOLUTION No. 1, OF JUNE 1, 2020           | <a href="https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/cmed/legislaca">https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/cmed/legislaca</a>   |
| 2019             |  |  |  | 4.33    | 4.33    | 4.33    | RESOLUTION No. 1, OF MARCH 26, 2019         | <a href="https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/cmed/legislaca">https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/cmed/legislaca</a>   |
| 2018             |  |  |  | 2.84    | 2.47    | 2.09    | RESOLUTION No. 01, OF MARCH 9, 2018         | <a href="https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/cmed/legislaca">https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/cmed/legislaca</a>   |
| 2017             |  |  |  | 4.76    | 3.06    | 1.36    | RESOLUTION No. 1, OF MARCH 10, 2017         | <a href="https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/cmed/legislaca">https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/cmed/legislaca</a>   |
| 2016             |  |  |  | 12.50   | 12.50   | 12.50   | Resolution nº 01, of March 14, 2016         | <a href="https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/cmed/legislaca">https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/cmed/legislaca</a>   |
| 2015             |  |  |  | 7.70    | 6.35    | 5.00    | Resolution nº 04, of March 12, 2015         | <a href="https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/cmed/legislaca">https://www.gov.br/anvisa/pt-br/assuntos/medicamentos/cmed/legislaca</a>   |

2.3. The possible effects of suspending the annual adjustment of medicine prices.

Regarding the merits of whether or not to suspend the annual adjustment of medicine prices, applied to the industry sector pharmaceutical, it should be noted that price regulation based on the price-cap model allows variations in the prices actually charged by agents, resulting from the impact of exogenous factors, such as exchange rate, supply or demand shocks. The market structure, whether competitive or concentrated, also influences the ability of companies to define the levels of discounts applied. Thus, the supply of medicines that operate with a lower level of margin or discount may potentially be committed in crisis scenarios.

In this sense, the annual price adjustment helps to mitigate the risk of shortages in classes of medicines in which an abrupt increase in costs has been observed. Furthermore, any suspension of the adjustment tends to be less effective at higher levels. competitive conditions, in which larger discounts are applied, given the greater flexibility in adapting prices in this specific situation.

In times of pandemic, for example, or health crises, there is the possibility of increases in the costs of pharmaceutical inputs, arising from the possibility of restricting access to inputs, in view of the restriction measures on the export of inputs and finished medicines established by several producing countries; the observed exchange rate devaluation; and the increase in demand to meet the national market.

In this sense, **any measure to freeze the ceiling price may increase the risk of shortages** for classes of medicines that have a price close to the established ceiling, or may have no effect on the prices actually charged in classes where there is a greater difference between the ceiling and the equilibrium price, given the margin that retail (pharmacies) has in its area of activity, meaning that the final price to the consumer, in certain drug segments, suffers little impact at the end of the line.



It is believed, therefore, that any proposal to suspend the adjustment, contrary to what it may seem, could contribute to Authenticated electronically, after checking the original.

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the increased risk of drug shortages, given possible increases in costs, being, from the point of view competitive, unfavorable to the medicine market and the consumer, and may cause a limitation of companies' ability to define prices for goods or services.

Furthermore, it is noteworthy that the medicines sector in Brazil is highly regulated, in line with the experiences of member countries of the Organization for Economic Co-operation and Development (OECD), such as most European countries, in addition to Canada, Japan and Australia, and based on a price ceiling model that aims to protect the interests of medicine consumers, avoiding adjustments well above inflation (measured by IPCA) and, at the same time, guaranteeing the viability of medicines in the market by producing or importing companies.

Thus, from an economic point of view, the price freeze could generate losses for companies operating in the sector and reflect on the production of medicines in aspects related to the quantity and quality of those offered at retail, directly impacting the consumer market, that is, directly at the end and the most vulnerable, that is, the people who need them. Furthermore, the reduction in the value of the pharmaceutical product may lead to a possible **reduction in investments in research and development** by the Brazilian industry operating in the area.

The indiscriminate price freeze could also affect all drug consumers in a widespread manner, both wholesale and retail, affecting both those who had their economic and financial condition shaken in as a result of the pandemic, such as those who did not have it and/or who have great economic capacity, such as companies that acquire medicines for resale.

2.4. From the strategic planning of CTE/CMED

It is important to highlight that the CMED Technical-Executive Committee (CTE/CMED) implemented, at its 7th Ordinary Meeting in 2023, held on 9/4/2023, its Strategic Planning, with the definition of priority Regulatory Projects, seeking to improve the work carried out by CMED, as well as updating pharmaceutical market regulation standards.

The priority projects include the themes highlighted in the table below (<https://www.gov.br/anvisa/pt-br/asuntos/medicamentos/cmmed/reunioes-CMED/cte/planejamento-strategico>).

| REGULATORY TOPICS                                                       |                                                                                                                                                                                                                                                    |
|-------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Name                                                                    | goal                                                                                                                                                                                                                                               |
| Update of CMED Resolution nº 2, of March 5, 2004                        | Technical discussions aimed at updating CMED Resolution No. 2/2004, which sets out the criteria for defining prices for new products and new drug presentations, following regulatory quality improvement guidelines and international references. |
| Internal Regulation CMED                                                | Technical discussions aimed at updating CMED's Internal Regulations, following quality improvement guidelines and greater regulatory legal security.                                                                                               |
| Incremental Innovation                                                  | Technical discussions with a view to developing a methodology for pricing medicines that present incremental innovation, following quality improvement guidelines and greater regulatory legal certainty.                                          |
| Update of criteria for applying the Coefficient of Price Adequacy (CAP) | Technical discussions aimed at updating the criteria for application of the Price Adequacy Coefficient - CAP.                                                                                                                                      |
| Advanced Therapies                                                      | Technical discussions with a view to developing a methodology for pricing advanced therapies, seeking balance the accessibility and sustainability of health.                                                                                      |
| Not new biological medicines                                            | Technical discussions with a view to developing a methodology for pricing non-new biological medicines, following quality improvement guidelines and greater regulatory legal security.                                                            |
| Update of CMED Resolution nº 2, of April 16, 2018.                      | Technical discussions aimed at updating CMED Resolution No. 2/2018, which regulates the administrative sanctioning process in within the scope of CMED, following quality improvement guidelines and greater regulatory legal certainty.           |

It is noteworthy that the aforementioned projects will be conducted in accordance with Good Regulatory Practices, under the terms of Decree No. 11,243, of October 21, 2022, enabling broad social participation and due analysis of regulatory impacts related to the topics under discussion.

3. CONCLUSION

In view of all of the above, based on the arguments contained in item 2 of this Technical Note, this Executive Secretariat understands that the annual adjustment of medicine prices established in **Resolution CM-CMED nº 01, of March 28, 2024**, published in Official Gazette of the Union in a session on 03/28/2024, covers medicines with a price ceiling established by the Medicines Market Regulation Chamber (CMED), which carries out regular monitoring of Factory Prices (PF), from Maximum Prices to Consumer Prices (PMC) practiced in the market and, in cases of sales destined to public bodies, the Maximum Sales Prices to the Government (PMVG), with a view to observing their evolution and identifying possible abusive practices in the behavior of companies.

Applied to the pharmaceutical industry sector, the annual price adjustment helps to mitigate the risk of shortages in classes of medicines in which an abrupt increase in costs was observed, among other consequences.

Finally, it should be noted that **the annual price adjustment arises from an express legal requirement contained in the Law 10,742/2003, and CMED is only responsible for operationalizing it**, based on technical criteria and the methodology set out above.

It is appropriate to inform that this Technical Note was approved by the Executive Technical Committee of CMED (CTE/CMED), within the scope of its 4th Ordinary Meeting, held on 04/25/2024 (1st part), without prejudice to possible analyzes and manifestations of merit and of a legal nature by the bodies that make up the CTE/CMED.



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This Secretariat remains available for any clarifications.



Document signed electronically by **Daniela Marreco Cerqueira, Executive Secretary of CMED**, on 04/26/2024, at 17:58, according to official Brasília time, based on § 3 of art. 4th of Decree No. 10,543, of November 13, 2020 [http://www.planalto.gov.br/ccivil\\_03/\\_ato2019-2022/2020/decreto/D10543.htm](http://www.planalto.gov.br/ccivil_03/_ato2019-2022/2020/decreto/D10543.htm).



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Ministry of Health  
Executive Secretary  
Cabinet

## DISPATCH

SE/GAB/SE/MS

Brasília, June 17, 2024.

**Subject: Information Request nº 852/2024.**

1. Aware and in agreement.

2. This is Information Request No. 852/2024 (0040061322), authored by Federal Deputy Gustavo Gayer - PL/GO, through which he requests the Minister of State for Health, Nísia Trindade Lima, information regarding the decision taken by the Medicines Market Regulation Chamber (CMED), to increase medicine prices by up to 4.5% throughout Brazil.

3. Below are the answers to the questions, item by item:

**1 – How does the Ministry of Health assess the impact of this decision to increase drug prices on the population's access to necessary treatments?**

We clarify that the annual price adjustment is a legal requirement provided for in Law 10,742/2003, and the CMED (Chamber of Medicines Market Regulation) is only responsible for operationalizing it, based on technical criteria and methodology established by law.

During pandemics or health crises, there may be an increase in the costs of pharmaceutical inputs due to export restrictions, currency devaluation and increased demand. In this context, freezing the ceiling price may increase the risk of shortages for medicines with prices close to the established ceiling, or not have a significant effect on prices charged in segments with a greater gap between the ceiling and the equilibrium price.

Therefore, annual price adjustment is necessary to maintain market balance and guarantee the supply of medicines.

**2 – Is there any forecast or study on the possible effect of this price increase on the demand for medicines and the budget of health services?**

CMED Resolution No. 01, of February 23, 2015, defines the formula for calculating price adjustments:  $VPP = IPCA - X + Y + Z$ . This model aims to protect consumers, avoiding increases far above inflation (measured by IPCA) and, at the same time, ensure the viability of medicines on the market for producers or importers.

In accordance with the legislation, CMED published CMED Resolution No. 01, of March 28, 2024, for the price adjustment that occurred in March 2024. This resolution was accompanied by SEI Technical Note No. 2752/2023/MF, prepared by the Secretariat of Economic Reforms of the Ministry of Finance, which is part of CMED.



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Order 004138/332

SEI 25000:051270/2024-95 / pg. 9

2438353

Annually, in March, after the official release of the IPCA accumulated over the last twelve months, CMED issues a specific resolution on price adjustments for the corresponding period, defining the Manufacturer Price (PF) and the Maximum Consumer Price (PMC) of medicines. , in addition to the guidelines for the presentation of the Commercialization Report by producing companies.

For 2024, in addition to the factors 2023 and February 2024. Based on this data, the maximum levels allowed for drug price adjustment for 2024 were defined as: - Level 1: 4.50% - Level 2: 4.50% - Level 3: 4, 50% In this sense, price regulation using the price-cap model allows variations in prices charged by agents, due to external factors such as exchange rate, supply or demand shocks. The structure of the market, whether competitive or concentrated, also affects the ability of companies to define the levels of discounts offered. In crisis scenarios, the supply of medicines with lower margins or discounts may be compromised.

In this way, the annual price adjustment helps to mitigate the risk of shortages, especially for medicines with abrupt increases in costs.

**3 – Does the Ministry of Health have any plan or strategy to mitigate the possible negative impacts of this price increase, especially for the most vulnerable groups of the population, such as the elderly, people with chronic illnesses and low-income people?**

The Ministry of Health understands the current regulation as necessary to mitigate the risk of shortages, especially for medicines with abrupt increases in costs. Furthermore, through the financing of public health actions and services, it seeks to guarantee the goals of the SUS, one of the largest public health systems in the world, ensuring full, universal and free access and health care.

**4 – What is the position of the Ministry of Health in relation to regulating the medicines market and guaranteeing universal access to necessary treatments?**

As already highlighted, the annual price adjustment is a legal requirement provided for in Law 10,742/2003, and the CMED (Chamber of Medicines Market Regulation) is only responsible for operationalizing it, based on technical criteria and methodology established by law.

CMED Resolution No. 01, of February 23, 2015, defines the formula for calculating the price adjustment. This model aims to protect consumers, avoiding increases far above inflation (measured by IPCA) and, at the same time, ensuring the viability of medicines on the market for producers or importers.

Therefore, price regulation using the price-cap model allows variations in prices charged by agents, due to external factors such as exchange rate, supply or demand shocks. The structure of the market, whether competitive or concentrated, also affects the ability of companies to define the levels of discounts offered. In crisis scenarios, the supply of medicines with lower margins or discounts may be compromised.

In this way, the annual price adjustment helps to mitigate the risk of shortages, especially for medicines with abrupt increases in costs.

During pandemics or health crises, there may be an increase in the costs of pharmaceutical inputs due to export restrictions, currency devaluation and increased demand. In this context, freezing the ceiling price can



increase the risk of shortages for medicines with prices close to the established ceiling, or have no significant effect on prices charged in segments with greater disparity between the ceiling and the equilibrium price.

Therefore, annual price adjustment is necessary to maintain market balance and guarantee the supply of medicines.

**5 – Does the Ministry of Health consider it necessary to review the current drug price regulation policy, especially given concerns about accessibility and equity in access to health treatments?**

The Ministry of Health understands that the current regulatory model meets the needs of not allowing shortages and ensuring market balance, mitigating possible risks, although improvements can always be evaluated to improve the current regulatory design.

4. To the Head of the Special Advisory for Parliamentary Affairs and Federatives - **ASPAR/MS**, in return.

#### Electronic signature



Document signed electronically by **Swedenberger do Nascimento Barbosa, Executive Secretary**, on 06/17/2024, at 4:47 pm, according to official Brasília time, based on § 3 of art. 4th, of [Decree No. 10,543, of November 13, 2020](#); and art. 8th, of [Ordinance No. 900 of March 31, 2017](#).



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Reference: Process nº 25000.051270/2024-95

SEI nº 0041387552



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Order 0041387552

SEI 25000.051270/2024-95 / pg. 11



CHAMBER OF DEPUTIES  
First Secretariat

Letter 1ªSec/RI/E/nº 80

Brasília, May 13, 2024.

Your Excellency Madam

**NÍSIA TRINADE**

Minister of State for Health

Subject: **Information Request**

Madam Minister,

In accordance with art. 50, § 2, of the Federal Constitution, I forward to Your Excellency copy(s) of the following Information Request(s):

| Information                                 | AUTHOR                                |
|---------------------------------------------|---------------------------------------|
| Request nº 319/2024 Information Request     | Deputy Chris Tonietto and others      |
| nº 322/2024 Information Request nº          | Deputy Marcos Pollon                  |
| 327/2024 Request for Information nº         | Deputy Clarissa Tércio and others     |
| 332/2024 Request for Information nº         | Deputy Silvia Waiãpi                  |
| 351/2024 Request for Information nº         | Deputy Helio Lopes                    |
| 474/2024 Request for Information nº         | Deputy Adriana Ventura and others     |
| 500/2024 Request for Information nº         | Deputy André Fernandes                |
| 546/2024 Request for Information nº         | Deputy Cabo Gilberto Silva and others |
| 575/2024 Request for Information nº         | Deputy Delegate Caveira               |
| 639/2024 Information Request nº 716/2024    | Deputy Dr. Zacharias Calil            |
| Information Request nº 720/2024 Information | Deputy Chris Tonietto                 |
| Request nº 721/2024 Information Request     | Deputy Ronaldo Nogueira               |
| nº 723/2024 Information Request nº          | Deputy Ronaldo Nogueira               |
| 726/2024 Information Request nº 727/2024    | Deputy Marcos Tavares                 |
| Information Request nº 728 /2024            | Deputy Saullo Vianna                  |
| Information Request nº 729/2024 Information | Deputy Saullo Vianna                  |
| Request nº 730/2024 Information Request     | Deputy Saullo Vianna                  |
| nº 731/2024 Information Request nº          | Deputy Saullo Vianna                  |
| 732/2024 Information Request nº 733/2024    | Deputy Saullo Vianna                  |
| Information Request nº 734/2024 Information | Deputy Saullo Vianna                  |
| Request nº 735/ 2024                        | Deputy Saullo Vianna                  |
|                                             | Deputy Saullo Vianna                  |
|                                             | Deputy Saullo Vianna                  |
|                                             | Deputy Saullo Vianna                  |

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Letter 1ªSec/RI/nº 80 (0040630353)

SEI 25000.051270/2024-95 / pg. 12

2438353



CHAMBER OF DEPUTIES  
First Secretariat

Letter 1ªSec/RI/E/nº 80

Brasília, May 13, 2024.

|                                  |                                           |
|----------------------------------|-------------------------------------------|
| Information Request No. 737/2024 | Deputy Saullo Vianna                      |
| Information Request No. 738/2024 | Deputy Messias Donato                     |
| Information Request No. 742/2024 | Deputy Saullo Vianna                      |
| Information Request No. 743/2024 | Deputy Saullo Vianna                      |
| Information Request No. 744/2024 | Deputy Saullo Vianna                      |
| Information Request No. 745/2024 | Deputy Saullo Vianna                      |
| Information Request No. 746/2024 | Deputy Saullo Vianna                      |
| Information Request No. 747/2024 | Deputy Saullo Vianna                      |
| Information Request No. 748/2024 | Deputy Saullo Vianna                      |
| Information Request No. 749/2024 | Deputy Saullo Vianna                      |
| Information Request No. 750/2024 | Deputy Saullo Vianna                      |
| Information Request No. 751/2024 | Deputy Saullo Vianna                      |
| Information Request No. 756/2024 | Deputy Dr. Frederico and                  |
| Information Request No. 768/2024 | others Deputy Captain                     |
| Information Request No. 776/2024 | Alberto Neto Deputy Captain               |
| Information Request No. 777/2024 | Alberto Neto Deputy Captain               |
| Information Request No. 779/2024 | Alberto Neto Deputy                       |
| Information Request No. 784/2024 | Fred Linhares Deputy                      |
| Information Request No. 789/2024 | Amália Barros Deputy                      |
| Information Request No. 790/2024 | Fred Linhares Deputy                      |
| Information Request No. 794/2024 | Delegate Caveira                          |
| Information Request No. 795/2024 | Deputy Aureo Ribeiro                      |
| Information Request No. 796/2024 | Deputy Saullo Vianna                      |
| Information Request No. 798/2024 | Deputy Saullo Vianna                      |
| Information Request No. 799/2024 | Deputy Saullo Vianna                      |
| Information Request No. 800/2024 | Deputy Saullo Vianna                      |
| Information Request No. 801/2024 | Deputy Saullo Vianna                      |
| Information Request No. 802/2024 | Deputy Saullo Vianna                      |
| Information Request No. 803/2024 | Deputy Saullo Vianna                      |
| Information Request No. 804/2024 | Deputy Saullo Vianna                      |
| Information Request No. 805/2024 | Deputy Saullo Vianna                      |
| Information Request No. 806/2024 | Deputy Saullo Vianna                      |
| Information Request No. 807/2024 | Deputy Saullo Vianna Deputy Saullo Vianna |

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Letter 1ªSec/RI/E/nº 80 (0040630353)

SEI 25000.051270/2024-95 / pg. 13

2438353



CHAMBER OF DEPUTIES  
First Secretariat

Letter 1ªSec/RI/E/nº 80

Brasília, May 13, 2024.

|                                  |                            |
|----------------------------------|----------------------------|
| Information Request No. 808/2024 | Deputy Saullo Vianna       |
| Information Request No. 809/2024 | Deputy Saullo Vianna       |
| Information Request No. 810/2024 | Deputy Saullo Vianna       |
| Information Request No. 811/2024 | Deputy Saullo Vianna       |
| Information Request No. 812/2024 | Deputy Saullo Vianna       |
| Information Request No. 814/2024 | Deputy Saullo Vianna       |
| Information Request No. 815/2024 | Deputy Saullo Vianna       |
| Information Request No. 816/2024 | Deputy Saullo Vianna       |
| Information Request No. 817/2024 | Deputy Saullo Vianna       |
| Information Request No. 824/2024 | Deputy Amom Mandel         |
| Information Request No. 825/2024 | Deputy Amom Mandel         |
| Information Request No. 828/2024 | Deputy Saullo Vianna       |
| Information Request No. 829/2024 | Deputy Saullo Vianna       |
| Information Request No. 830/2024 | Deputy Saullo Vianna       |
| Information Request No. 831/2024 | Deputy Saullo Vianna       |
| Information Request No. 832/2024 | Deputy Saullo Vianna       |
| Information Request No. 833/2024 | Deputy Saullo Vianna       |
| Information Request No. 834/2024 | Deputy Saullo Vianna       |
| Information Request No. 835/2024 | Deputy Saullo Vianna       |
| Information Request No. 836/2024 | Deputy Saullo Vianna       |
| Information Request No. 837/2024 | Deputy Saullo Vianna       |
| Information Request No. 838/2024 | Deputy Saullo Vianna       |
| Information Request No. 839/2024 | Deputy Saullo Vianna       |
| Information Request No. 840/2024 | Deputy Saullo Vianna       |
| Information Request No. 843/2024 | Deputy Saullo Vianna       |
| Information Request No. 844/2024 | Deputy Saullo Vianna       |
| Information Request No. 845/2024 | Deputy Saullo Vianna       |
| Information Request No. 846/2024 | Deputy Saullo Vianna       |
| Information Request No. 848/2024 | Deputy Saullo Vianna       |
| Information Request No. 852/2024 | Deputy Gustavo Gayer       |
| Information Request No. 854/2024 | Deputy Dr. Zacharias Calil |
| Information Request No. 866/2024 | Deputy Cabo Gilberto Silva |
| Information Request No. 871/2024 | Deputy Nikolas Ferreira    |

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Letter 1ªSec/RI/E/nº 80 (0040630353)

SEI 25000.051270/2024-95 / pg. 14

2438353



CHAMBER OF DEPUTIES  
First Secretariat

Letter 1ªSec/RI/E/nº 80

Brasília, May 13, 2024.

|                                                                     |
|---------------------------------------------------------------------|
| Request for Information nº 874/2024 Deputy Tabata Amaral and others |
| Request for Information nº 877/2024 Deputy Marcos Pollon            |
| Request for Information nº 889/2024 Deputy Saullo Vianna            |
| Request for Information nº 890/2024 Deputy Saullo Vianna            |
| Request for Information nº 891/2024 Deputy Marcos Pollon            |
| Information Request nº 892/2024 Deputy Marcos Pollon                |
| Information Request nº 893/2024 Deputy Captain Alberto Neto         |
| Information Request nº 894/2024 Deputy Captain Alberto Neto         |
| Information Request nº 896/2024 Deputy Amom Mandel                  |
| Information Request nº 897/ 2024 Deputy Amom Mandel                 |
| Request for Information No. 908/2024 Deputy Cabo Gilberto Silva     |
| Request for Information No. 911/2024 Deputy Captain Alberto Neto    |
| Request for Information No. 913/2024 Deputy Adriana Ventura         |
| Request for Information No. 923/2024 Deputy Dr. Zacharias Calil     |
| Request for Information nº 933/2024 Deputy Thiago Flores            |
| Request for Information nº 972/2024 Deputy Captain Alberto Neto     |
| Request for Information nº 973/2024 Deputy Amália Barros            |
| Request for Information nº 978/2024 Deputy Gustavo Gayer            |
| Request for Information nº 985/2024 Deputy Adriana Ventura          |
| Request of Information nº 1,015/2024 Deputy Mauricio Marcon         |
| Request for Information nº 1,032/2024 Deputy Adriana Ventura        |
| Request for Information nº 1,047/2024 Deputy Fernanda Pessoa        |
| Request for Information nº 1,063/2024 Deputy Helio Lopes            |
| Request for Information nº 1,064/2024 Deputy General Girão          |
| Request of Information nº 1,069/2024 Deputy Marcos Tavares          |
| Request for Information nº 1,070/2024 Deputy Kim Kataguirí          |
| Request for Information nº 1,074/2024 Deputy Chris Tonietto         |
| Request for Information nº 1,075/2024 Deputy Professor Goreth       |
| Request for Information nº 1,097/2024 Deputy Delegate Fabio Costa   |
| Request for Information nº 1,123/2024 Deputy Captain Alberto Neto   |
| Request for Information nº 1,124/2024 Deputy Helio Lopes            |
| Request for Information nº 1,126/2024 Deputy Marcelo Queiroz        |
| Request for Information nº 1,129/2024 Deputy Marcos Tavares         |

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Letter 1ªSec/RI/nº 80 (0040630353)

SEP25000.051270/2024-95 / pg. 15

2438353



CHAMBER OF DEPUTIES  
First Secretariat

Letter 1ªSec/RI/E/nº 80

Brasília, May 13, 2024.

|                                                                    |                           |
|--------------------------------------------------------------------|---------------------------|
| Request for Information No. 1,139/2024 Deputy                      | Maria Rosas Request for   |
| Information No. 1,142/2024 Deputy Dr. Frederico                    | Request for Information   |
| No. 1,143/2024 Deputy Dr. Frederico Request for                    | Information No.           |
| 1,145/2024 Commission for the Defense of Human Rights              | Disabled people           |
| Request for Information nº 1,148/2024 Deputy Cabo Gilberto Silva   | Request for               |
| Information nº 1,149/2024 Deputy Cabo Gilberto Silva               | Request for Information   |
| nº 1,152/2024 Deputy Fred Linhares Request for                     | Information nº 1,165/2024 |
| Deputy Marcos Tavares Request for Information nº 1,170/2024 Deputy |                           |
| Marcos Tavares Request for Information nº 1,171/2024 Deputy Marcos |                           |
| Tavares Request for Information nº 1,176/2024 Deputy Duda Ramos    | Request                   |
| for Information nº 1,178/2024 Deputy Chris Tonietto Request for    |                           |
| Information nº 1,203/2024 Deputy Laura Carneiro                    |                           |
|                                                                    |                           |

In the event that the requested information is of a confidential nature, I request that a copy of the classification decision issued by the competent authority, or equivalent term, be sent as well, containing all the elements listed in art. 28 of Law No. 12,527/2011 (Access to Information Law), or, in the case of other legal hypotheses of secrecy, the legal provision that underlies the secrecy must be expressly mentioned. In any case, I also request that confidential documents be packaged in a sealed and initialed envelope, with an obvious indication of the degree or type of secrecy.

Yours sincerely,

Deputy LUCIANO BIVAR  
First Secretary

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Office of Federal Deputy **GUSTAVO GAYER** – PL/GO

**, FROM 2024.**

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REG-2/2024

Mr. President,

In order to provide information relating to this request for information and also based on information published by the press, I request that the following be answered questions:

- 1- How does the Ministry of Health assess the impact of this decision to increase drug prices on the population's access to necessary treatments?
- 2- Is there any forecast or study on the possible effect of this price increase on the demand for medicines and the budget of health services?
- 3- The Ministry of Health has a plan or strategy to mitigate the possible negative impacts of this price increase, especially for the most vulnerable groups of the population, such as





CHAMBER OF DEPUTIES

Office of Federal Deputy **GUSTAVO GAYER** – PL/GO

elderly, people with chronic illnesses and low income?

4- What is the position of the Ministry of Health in relation to regulating the medicines market and guaranteeing universal access to necessary treatments?

5- The Ministry of Health considers it necessary to review the current drug price regulation policy, especially concerns about accessibility and equity in access to health treatments against

Finally, you are asked to provide information additional information that the Minister of Health understands as relevant, bearing in mind that this increase represents a significant measure that can have serious consequences for public health and citizens' access to essential treatments.

### JUSTIFICATION

We express our concern with the decision made by the Medicines Market Regulation Chamber (CMED) of increase drug prices by up to 4.5% throughout Brazil.

This increase represents an alarming measure, especially at a time when many families are already facing financial difficulties due to the current economic situation in our country.

According to information published in the media<sup>1</sup>, the federal government authorized an increase of up to 4.5% in medicine prices from the month of April. Companies will be able to adjust values within 15 days, according to the resolution published in the Official Gazette of the Union (DOU), on the day 03/28/2024. According to CMED, the price ceiling was calculated based on the

<sup>1</sup> <https://www.gazetadopovo.com.br/economia/com-aval-do-governo-preco-dos-medicamentos-subira-45-a-partir-de-abril/>

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Electronically signed by Representante Gustavo Gayer

SEI 25000.051270/2024-95 / pg. 19