AGREEMENT BETWEEN THE PORTUGUESE STATE, REPRESENTED BY THE MINISTERS OF STATE AND FINANCE, ECONOMY AND HEALTH, AND THE PHARMACEUTICAL INDUSTRY

The Portuguese State, represented by the Ministers of State and of Finance, Economy and Health, and the Pharmaceutical Industry, through APIFARMA - Associação Portuguesa da Indústria Farmacêutica, represented by its Chairman and Vice-Chairman of the Board of Directors, hereinafter jointly referred to as the Parties, agree to implement the measures provided for in this Agreement with a view to contributing to the sustainability of the National Health Service ('SNS'), guaranteeing access to medicines and strengthening the structural conditions favourable to economic development, in particular by reinforcing the attractiveness factors for investment in Portugal.

Considering:

The framework of the XXIV Government Programme in the area of Health, geared towards creating a favourable environment among all agents in the sector to promote and defend health, in order to increase the efficiency of the NHS in relation to the resources available and, in the area of medicines, to promote a sustainable policy in order to reconcile budgetary rigour with access to therapeutic innovation;

The importance of realising in the medium term, for the years 2025 to 2028, a benchmark for public spending on medicines that is closer to the average values in the European Union, taking into account the income levels, in order to create sustainable conditions that generate a sharing of gains between the state and the sector's agents;

The importance of promoting the country's economic development, namely through the pharmaceutical industry and in vitro diagnostic devices, by implementing measures to attract foreign investment, increase the number of clinical trials carried out in Portugal, set up research centres and make the most of scientific knowledge, strengthen production, scientific and commercial capacities based in Portugal, and set up structuring partnerships between companies with an international scale and those already operating in the national economy;

The need to respond to the trade deficit in health products, particularly medicines, by promoting production capacities in Portugal and export flows;

The need to strengthen the efficiency of the market, both in terms of ease of access for citizens to prescribed therapies and access to innovative medicines, under the terms of the rules established in the National Health Technology Assessment System

- SiNATS

Increasing national value in the financing of new health technologies, taking into account, in particular, their economic and social value, as well as reinforcing investment in Research and Development ('R&D'), hubs and manufacturing investment and reinforcing production capacity

The importance of continuing to ensure a convergence of endeavours between public institutions and economic agents, so that the national effort to control public spending allows the maintenance of high standards of accessibility for patients to the best therapies, as well as the provision of healthcare to citizens, which tends to be free of charge;

The importance of carrying out a balanced and sustained review of the instruments for access to medicines, including the reimbursement system and the policies for public funding of medicines, especially through the contracts for funding medicines subject to prior evaluation and the risk-sharing system;

The willingness of the pharmaceutical industry, represented by APIFARMA, to maintain its collaboration with the Portuguese state through a financial contribution aimed at guaranteeing the sustainability of the National Health Service, allowing control over the evolution of public spending on medicines and patient access to new innovative therapies, at prices resulting from existing legal mechanisms and within timeframes for market entry that respect the legislation in force;

The need to guarantee a framework of predictability for all players in the medicines sector in order to create an institutional environment favourable to investment, R&D and innovation.

This Agreement is signed and governed by the following clauses:

Clause One

Object

1. This Agreement ('Agreement') governs the terms and conditions under which the Portuguese State, represented by the Ministers of State and Finance, Economy and Health, on the one hand, and the Pharmaceutical Industry, represented by APIFARMA, on the other hand (hereinafter, the 'Parties'), through the voluntary adhesion of the Pharmaceutical Industry companies ('adhering companies'), under the terms set out in Clause Four, undertake to co-operate in order to achieve the budgetary goals for the years 2025 to 2028 for public expenditure on outpatient and inpatient medicines in the NHS.
2. O The Agreement provides for a medium-term understanding, covering the period 2025-2028.
3. Notwithstanding the provisions of the previous paragraph, the terms and conditions of this Agreement, in particular the provisions of Clause Twelve, shall, for 2026 and subsequent years, be reviewed annually between the Parties by signing an addendum which shall establish the maintenance or amendment of the current terms and conditions of this Agreement.

Clause Two

Expenditure on medicines and the pharmaceutical industry's financial contribution

1. In the year 2025, the financial contribution of the companies adhering to the Agreement corresponds to the amount resulting from the application of the rates provided for in the Extraordinary Contribution Scheme applicable to the Pharmaceutical Industry under the terms of the scheme approved by article 168 of Law no. 82-B/2014, of 31 December, kept in force by the State Budget Law currently in force, with the exception of that provided for in paragraph 2 of this Clause and the percentages provided for in paragraph 1 of Clause Three, on public expenditure on medicines in the SNS supplied by INFARMED.
2. The credit notes issued to NHS bodies by companies adhering to the Agreement under contracts for reimbursement or prior assessment, the amount relating to vaccines included in the National Vaccination Plan and the amount relating to contraceptive drugs shall be deducted from NHS public expenditure on medicines.

3. The deduction referred to in the previous paragraph shall be made in the period in which the payment was made and under the terms set out in Clause Three.
4. Under terms to be regulated by decision of the members of the government responsible for the areas of economy and health, the following amounts can be deducted, up to a limit corresponding to 100 per cent of the individual contribution of the companies adhering to the Agreement:
    a. R&D expenses in accordance with the provisions of the Investment Tax Code, approved by Decree-Law no. 162/2014, of 31 October;
    b. Investments made in hubs;
    c. Relevant industrial investments to strengthen the production base, in terms to be set by the members of the government responsible for the economy and health.
    d. The increase in purchases made from the local Pharmaceutical Industry compared to the average of the previous 5 years.
5. Notwithstanding the provisions of the previous paragraph, when the investment made by the company adhering to the Agreement exceeds its individual contribution, the amount invested may be deducted from the excess of the maximum amounts of charges provided for in the respective contracts for reimbursement or prior evaluation of medicines.

Clause Three

Deadlines for settlement of the Pharmaceutical Industry's contribution for the year 2025

1. Companies adhering to the Agreement undertake, in proportion to their market share in 2025, to pay:
    a. 30% of the amount resulting from the application of Clause Two, no. 1, in credit notes to hospitals and/or in payment to the Central Administration of the Health System, I.P., (hereinafter ACSS, I.P.) until 15 April 2025, the contribution to be made being the result of the invoicing amounts of each adhering company within the scope of the NHS recorded in 2024.
    b. 20% of the amount resulting from the application of Clause Two, no. 1, in credit notes to hospitals and/or in payment to ACSS, I.P., until 30 June 2025, the contribution to be made resulting from the proportion of each adhering company's invoicing within the scope of the NHS recorded from 1 January to 31 March 2025.

c. 30% of the amount resulting from the application of Clause Two, no. 1, in credit notes to hospitals and/or in payment to ACSS, I.P., until 30 September 2025, the contribution to be made resulting from the invoicing of each adhering company within the scope of the NHS recorded from 1 April to 30 June 2025.

d. 20% of the amount resulting from the application of Clause Two, no. 1, in credit notes to hospitals and/or in payment to ACSS, I.P., until 31 December 2025, the contribution to be made resulting from the invoicing amounts of each adhering company within the scope of the NHS recorded from 1 July to 30 September 2025.

2. The Parties shall share the information necessary for the validation of the final expenditure amounts, as well as the relevant information regarding the application of the respective contribution formulae.
3. Notwithstanding the provisions of Clause Eleven, INFARMED, I.P. is responsible for calculating the contributions referred to in the previous paragraphs and subject to payment by the companies adhering to the Agreement, on the basis of the market share data available to it, after consulting the Monitoring Committee.
4. Under the terms of the previous paragraph, the ACSS, I.P. is responsible for monitoring the entire process related to the payment of these contributions by the companies adhering to the Agreement.
5. If a company has legal relationships with several NHS organisations, credit notes must be issued in proportion to the weight that each NHS organisation represents in the company's invoicing, in a timely and transparent manner.
6. If the NHS organisation has no outstanding invoices that can be deducted on a credit note, the company must settle the amount of the contribution by direct payment to that organisation or to ACSS, I.P.
7. The companies adhering to the Agreement are obliged to share information on the issue of credit notes on a quarterly basis, by communicating it to INFARMED, I.P., ACSS, I.P., the Tax and Customs Authority and the members of the government responsible for the areas of health and finance.
8. The contracting parties undertake, through SPMS, E.P.E., ACSS, I.P. and INFARMED, I.P., to create and adapt the information systems needed to monitor expenditure on medicines and manage the credit notes issued under this Agreement.

Clause Four

Voluntary adhesion by companies of the pharmaceutical industry

1. Voluntary adhesion to the Agreement by each company holding a marketing authorisation for marketed medicinal products, local representative or marketing manager shall be formalised by a written and unequivocal declaration to that effect.
2. The declaration provided for in the previous paragraph shall be signed by the individual with powers of representation of the adhering company or by whoever has powers of representation of the legal person that owns the adhering company, in which case the agreement shall be formalised with acknowledgement of the signatures and mention of this capacity and powers for the act.
3. APIFARMA is obliged to deliver to INFARMED, I.P. and to the Agreement Monitoring Committee the declarations of voluntary adhesion of its member companies under the terms of the previous paragraphs.
4. Companies that are not members of APIFARMA must send the declaration of voluntary membership to INFARMED, I.P. by electronic means.
5. For the purposes of the previous paragraphs, the information provided to join the Agreement must include what is necessary to identify the company before the Portuguese state, namely the legal person identification number.
6. This Agreement shall only take effect once a number of companies, members of APIFARMA, representing a minimum of 75 per cent of the share of total charges - including outpatient and inpatient - of the SNS have voluntarily signed up to it.
7. The deadline for voluntary adhesion is 30 days after the date on which the Agreement is signed.
8. INFARMED, I.P. must send the identification and information on the companies adhering to the Agreement to the members of the government responsible for the areas of health and finance, as well as to the Tax and Customs Authority.

Clause Five

Marketing innovative medicines

1. The Ministry of Health must create the necessary conditions for patients to access innovative medicines, namely by complying with the evaluation and decision deadlines set out in the law, and by recognising the specificity of certain medicines, namely orphan drugs and those intended for specific populations, as set out in Decree-Law no. 97/2015, of 1 June, in its current wording.
2. The Ministry of Health undertakes, by the end of the first quarter of 2025, to review Decree-Law no. 97/2015, of 1 June, in its current wording.
3. The Government undertakes, in the course of 2025, to review the organic structure of INFARMED, I.P., including its specialised technical committees, in order to reinforce its capacity through the effective allocation of the financial resources generated by its activity.

Clause Six

Availability of the medicines

1. The companies adhering to this Agreement, in conjunction with APIFARMA, undertake to implement the necessary measures to guarantee the availability of medicines on the market, and must monitor the supply of their medicines on the national market and develop strategies for appropriate stock management, in order to prevent and minimise shortages in supply to the national market.
2. In the event that there are no stock shortages or supply difficulties, expressed by the placement of packages in the distribution and dispensing circuit below the prescription, under the terms of the previous paragraph, the excess of the maximum amounts of charges to be paid by each company adhering to this Agreement, in compliance with the provisions of the contracts for the co-payment or prior evaluation of medicines, will only be paid by 50% of the amount calculated.

Clause Seven

Clinical research

1. The Ministry of Finance, the Ministry of the Economy and the Ministry of Health undertake to guarantee the conditions for increasing clinical research in NHS institutions, in particular by building the capacity of centres specialising in clinical trials, which will allow for the reduction of approval times for clinical trials, financial contracts and patient recruitment.
2. The Ministry of Health undertakes to support the creation of a single clinical trials portal by the end of 2025.

Clause Eight

Deductibility of Pharmaceutical Industry contributions

The Ministry of Finance recognises the deductibility of financial contributions made by Pharmaceutical Industry companies under this Agreement for the purposes of corporate income tax.

Clause Nine

Payment to suppliers by NHS units

1. The Ministry of Finance and the Ministry of Health undertake to carry out the necessary actions to make payments to suppliers within 30 days.
2. They also undertake to carry out the necessary actions to settle the payments owed by National Health Service entities to companies in the pharmaceutical industry.
3. The ACSS undertakes to present the evolution of hospital debts to the Monitoring Committee.

Clause Ten

Legislative and administrative stability

The Ministry of Health will promote the maintenance of a stable legislative and regulatory framework during the term of this Agreement, particularly in relation to the regulation of medicine's prices, notwithstanding the legislative and regulatory changes and adjustments that are deemed necessary and appropriate for the sustainability of the NHS or to ensure compliance with the Portuguese State's international commitments, and that are in line with the goals and provisions of the terms of the Agreement, within a framework of appropriate institutional dialogue with APIFARMA. Legislative and regulatory initiatives must be the subject of appropriate impact assessment studies.

Clause Eleven

Monitoring the implementation of the agreement

1. The implementation of the Agreement shall be monitored by a committee made up of representatives of the Ministry of Finance, the Ministry of Economy and the Ministry of Health and APIFARMA, under terms to be defined by joint order of the members of the Government responsible for the areas of finance, health and economy.
2. When so requested by the Parties, the Monitoring Committee is responsible for commenting on technical issues arising from the implementation of the Agreement and proposing initiatives leading to the proper development of the goals set out in the Agreement.
3. The Monitoring Committee shall meet on a monthly basis to assess the adequacy of the Agreement to market developments, particularly in terms of pursuing the budgetary targets for expenditure on medicines and monitoring the economic environment of the medicines value chain, and shall submit bimonthly reports on the results obtained, which shall be sent to the Parties.
4. The Monitoring Committee shall draw up an annual implementation report so that the Parties can assess the results achieved and the adjustments to the terms of the Agreement that may result from it.

Clause Twelve

Expenditure Control

1. For the purpose of controlling public spending on medicines, and recognising the important role of the industry in this area, the Parties agree as follows:
    a. The annual growth rate of total public spending on medicines must not exceed 7 per cent (seven per cent) per year, and this figure, hereinafter referred to as the 'Base', is calculated using the formula: Base = Last Year's Expenditure * (1+ 0,07).

    b. The Last Year's Expenditure indicator refers to net public expenditure on medicines in the NHS.

    c. Based on the figures measured at the end of each year by INFARMED, I.P., and confirmed with the Monitoring Committee, a penalty will be applied, where appropriate, to the positive deviation from the Base.

    d. In the situations referred to in the previous paragraph, the amount corresponding to 50 per cent of the deviation from the Base will be added to the Contribution.

    e. The figures for expenditure on medicines to be considered are net figures, obtained according to the following formula: Net Expenditure on Medicines = Total Expenditure on Medicines NHS - Amounts paid within the scope of the Extraordinary Pharmaceutical Industry Contribution - Amounts paid within the scope of co-payment contracts or prior evaluation of medicines (price differential, excess amount of charges or other financing conditions).
2. In all other cases, no discount or penalty will be applied.
3. These amounts are applied to all companies globally, thus recognising the need for the industry to cooperate in order to control spending on medicines.
4. The amount of the deviation to be added to the overall value of the Gross Contribution of the companies adhering to the Agreement, will be distributed among them in proportion to the difference that each one registers between the registered turnover amount and the one which it would register at the base amount.

Clause Thirteen

Force majeure and change in circumstances

If abnormal and/or unforeseeable facts or events occur, as a result of which there is an exceptional increase in the prescription and sale of reimbursed medicines and hospital medicines within the scope of the NHS (in particular, exceptional circumstances regarding the prevalence or incidence of pathologies, such as epidemic outbreaks), the resulting increase in the NHS's costs with the reimbursement or purchase of medicines will not be taken into account for the purposes of determining the increase in State expenditure and determining the Pharmaceutical Industry's contributions, under the terms of this Agreement.

Clause Fourteen

Termination

1. Absolute and definitive non-fulfilment by either Party of its commitments under the Agreement, including the adoption of measures that contradict the terms of the Agreement, shall entitle the non-defaulting Party to terminate the Agreement.
2. Non-fulfilment shall be deemed to be absolute and definitive if it continues after two written reminders from the non-defaulting party.

Lisboa 20 March 2025,

The Minister of State and Finance	The Minister of Economy	The Minister of Health
(Joaquim José Miranda Sarmento)	*(Pedro Trigo de Morais de Albuquerque Reis)*	*(Ana Paula Mecheiro de Almeida Martins Silvestre Correia)*

On behalf of APIFARMA – Associação Portuguesa da Indústria Farmacêutica,

The Chairman of the Board

(João Pedro Mendes de Almeida Lopes)

The Vice-Chairman of the Board

(Paulo Alexandre Lourinho Ferreira Teixeira)